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



Volume 15 / Issue 2 | February 2020

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**NEONATOLOGY TODAY**  
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Published monthly. All rights reserved.  
ISSN: 1932-7137 (Online), 1932-7129 (Print)  
All editions of the Journal and associated  
manuscripts are available on-line:  
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# Clinical Pearls from Management of RSV Bronchiolitis Using High-Frequency Jet Ventilation in a Preterm Infant

Stefani Doucette MD, FRCPC, Lynda Duval, RRT, Lisa Ramnarine, BSc, RRT, Emanuela Ferretti MD, MSc, FRCPC

## Abstract

*In a 22-day old preterm infant with severe nosocomial respiratory syncytial virus (RSV) bronchiolitis, we have achieved effective respiratory management with the use of high-frequency jet ventilation (HFJV) combined with optimal sedation, adequate alveolar recruitment, and efficient pulmonary toileting. Other therapies including surfactant, antiviral medication, and inhaled prostacyclin were not used. HFJV might be useful for cases of hypoxemic respiratory failure due to nosocomial bronchiolitis pneumonia in the preterm population, as described in this report.*

**Keywords:** premature infants, high-frequency jet ventilation, Respiratory Syncytial Virus Infections, pneumonia, respiratory failure, nosocomial infection.

## Introduction

Respiratory syncytial virus (RSV) bronchiolitis in infants is the most common lower respiratory tract infection with a high disease burden worldwide (1). The majority of infants who experience RSV bronchiolitis will do so in the first two years of life (2). A great deal of literature in the past has explored the severity of RSV disease in the population of ex-preterm infants. Our case report differs in that we describe acute management of nosocomial RSV bronchiolitis pneumonia with high-frequency jet ventilation (HFJV), in a preterm infant of 30+2 weeks' gestational age prior to discharge home from the NICU.

## Case Report

An ex 30+2 weeks' gestation female infant, was transferred to our NICU at 22-days of life for management of apneic episodes. Her initial neonatal course was uneventful. Her mother received a complete course of betamethasone and erythromycin because of prolonged rupture of membranes prior to delivery. The baby was born vigorous; her birth weight was 1220 g, and Apgar 91-95. She was placed on nasal CPAP (nCPAP) for one day but required intubation with surfactant administration on the second day of life, followed by rapid extubation to nCPAP. She completed a 7-day course of ampicillin and tobramycin. She was started on caffeine for apnea of prematurity. The baby was weaned from nCPAP to room air for two weeks and tolerated full feeds. A head ultrasound on the tenth day of life showed a unilateral caudothalamic cyst and no intraventricular hemorrhage. On day of life 18 (corrected gestational age of 32+6 weeks), she began having apneic spells, and nCPAP was again initiated. She continued to have worsening apneic spells requiring intubation and mechanical ventilation on day of life 21. The patient was orally intubated with a size 2.5 endotracheal tube (ETT). Prior to the transfer, she received a 10cc/kg transfusion of packed red blood cells for hemoglobin of 84 g/L. Chest (CXR) and abdominal x-rays showed normal lung parenchyma and a questionable area of potential bowel wall thickening on the left hemi colon. Biliary aspirates were noted, feeds were held, and she underwent a full septic workup, including blood, urine, and cerebrospinal fluid cultures. Ampicillin, cefotaxime, cloxacillin, and acyclovir were started empirically for presumed sepsis.

Upon arrival to our neonatal unit, the patient was ventilated on conventional assist-control volume guarantee (AC VG) with the following settings: tidal volume of 4ml/kg, respiratory rate (RR) of

45 bpm, PEEP 6 cm H<sub>2</sub>O, PIP (measured) 14 cm H<sub>2</sub>O, FiO<sub>2</sub> 0.21. Initial arterial blood gas (ABG): 7.35/44/63/24/-1.1. When urine, blood, and CSF cultures were negative, antibiotics, and antiviral therapies were discontinued. Nasopharyngeal aspirates were positive for RSV, presumed to be nosocomial, and the baby was isolated.

Due to progressive airway instability, including excessive secretions and high airway pressure, possibly contributing to inadequate ventilation and excessive intrathoracic pressure with potential hemodynamic consequences, the small size oral ETT was electively changed to a nasally placed size 3.0 uncuffed, which optimized pulmonary toileting. There was additionally asynchrony with mechanical ventilation, and poor chest compliance felt to be due to patient agitation; therefore, a fentanyl infusion of 1mcg/kg/hour was initiated.

***“Due to progressive airway instability, including excessive secretions and high airway pressure, possibly contributing to inadequate ventilation and excessive intrathoracic pressure with potential hemodynamic consequences, the small size oral ETT was electively changed to a nasally placed size 3.0 uncuffed, which optimized pulmonary toileting.”***

Over the next 36 hours, conventional ventilation settings were gradually escalated due to increased oxygen requirements and sustained respiratory acidosis (ABG: 7.21/68/49/27/-1.3) with an OI = 12.9. Additionally, there were challenges as the patient's oxygen requirements increased significantly, requiring frequent endotracheal suctioning. Ventilation parameter settings were optimized. At this time, the fentanyl infusion was adjusted to allow the patient to remain comfortable. Follow-up capillary blood gas results showed no significant improvement (7.23/65/33/27/-1.8). A decision was made to trial high-frequency oscillatory ventilation (HFOV) using the VN500 Dräger ventilator (Drägerwerk AG & Co. Lübeck, Germany).

Initial parameters on HFOV were: frequency 12 Hz, amplitude (AMP) 26 cm H<sub>2</sub>O, measured tidal volume 2.2 ml/kg, MAP 16 cm H<sub>2</sub>O, FiO<sub>2</sub> 0.45. Chest x-ray findings one hour after initiation of HFOV are shown in Figure 1. Over the next several hours, the patient displayed episodes of “poor chest wiggle” with handling.

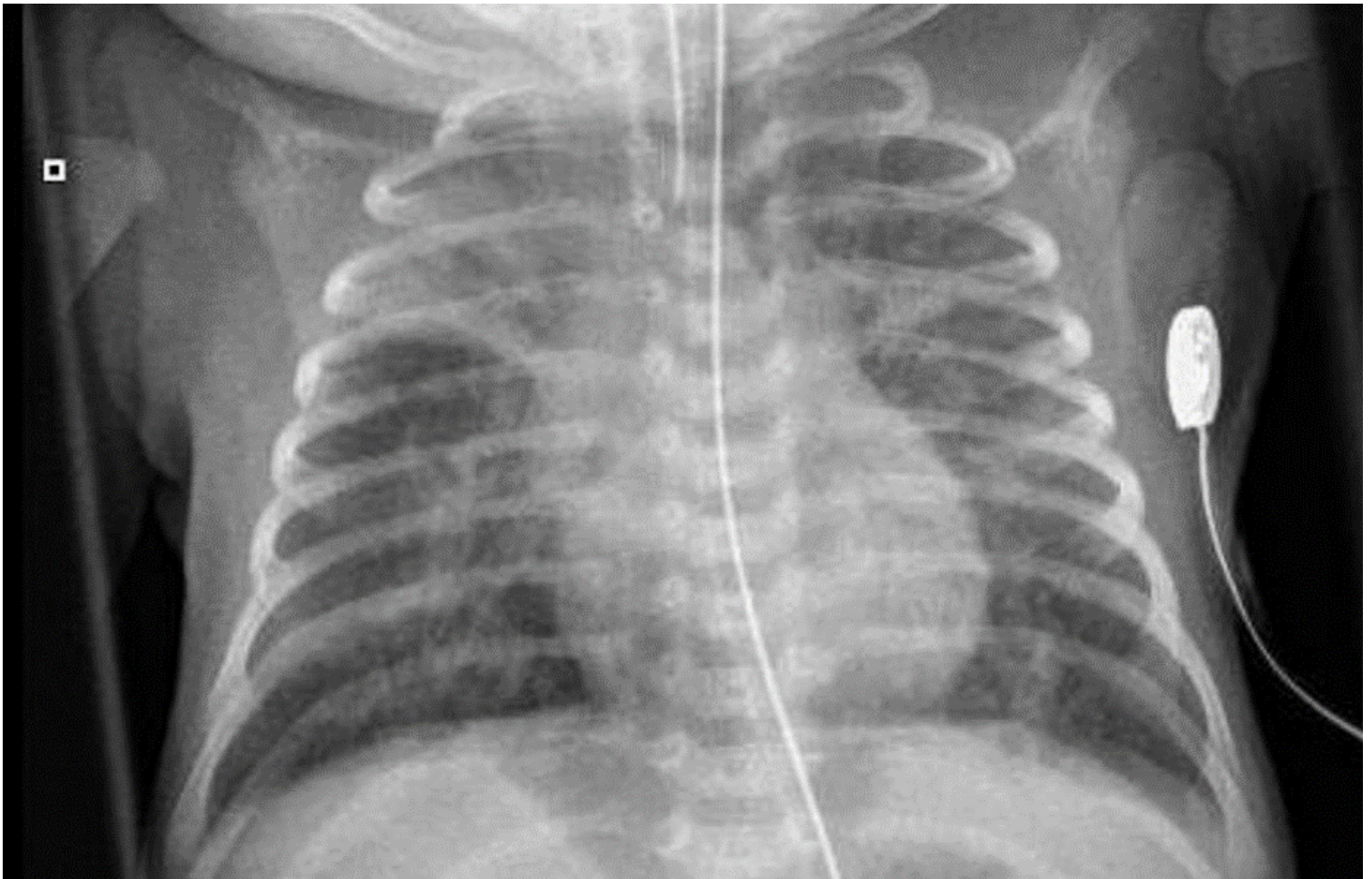
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*Figure 1. Endotracheal tube located at the T2 vertebra position, patchy opacities in the right lower lobe improved, denser opacities in the right upper lobe with volume lost, increased markings in the left perihilar and left lower lobe region, remainder of the lungs are clear.*

The amplitude was increased to 30 cm H<sub>2</sub>O with little benefit. The team recognized the need for a longer expiratory time, the urgency of enhancing secretion removal, and the need to reach an effective gas exchange at lower MAP due to lung hyperinflation. HFJV was indicated. The patient was switched to Life Pulse HFJV (Bunnell Inc, Salt Lake City, Utah) in tandem with Babylog 8000 plus (Drägerwerk AG & Co. Lübeck, Germany) with FiO<sub>2</sub> 1.0. Initial parameters on HFJV: RR 240 /min, PIP 40 cm H<sub>2</sub>O, PEEP (set/measured) 9/11.4 cm H<sub>2</sub>O, MAP 14 cm H<sub>2</sub>O, Ti 0.020, FiO<sub>2</sub> 0.50, and no sigh breaths were initially used. Sedation needs were reevaluated, hydration readjusted, and frequent ETT suctioning continued. Within an hour of HFJV and effective sedation, the ABG showed: 7.34/46/58/25/-1.0, with a calculated OI value of 12.1.

After 15 hours of ventilation using HFJV, a CXR was done (Figure 2), which showed findings of hyperinflation and concurrent subsegmental atelectasis. Another CXR was repeated on the third day of therapy with HFJV and showed improvement in overall aeration with no obvious areas of consolidation, uneven residual hyperinflation, or persistent bilateral perihilar peribronchial thickening in keeping with RSV bronchiolitis.

Throughout the 6-day period of HFJV support, minimal changes were made to the original ventilation parameters and the patient remained hemodynamically stable with no need for inotropic support. During her hospitalization, we noticed that her heart rate was persistently greater than 180 bpm. Caffeine had been discontinued at the time of her transfer, and her heart rate did not decrease

with adequate sedation. An electrocardiogram and echocardiogram excluded RSV myocarditis. Furthermore, her volume status was not consistent with dehydration as her total fluid intake and urinary output remained appropriate for gestational age. A repeat CBC showed anemia, therefore she received a second transfusion of packed red blood cells but her tachycardia persisted. Recurrent transient hypoxemia episodes lead to fluctuations in the patient's oxygen requirements (FiO<sub>2</sub> 0.31-1.0). The PaO<sub>2</sub> ranged from 35 to 84 mmHg.

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***“Another CXR was repeated on the third day of therapy with HFJV and showed improvement in overall aeration with no obvious areas of consolidation, uneven residual hyperinflation, or persistent bilateral perihilar peribronchial thickening in keeping with RSV bronchiolitis.”***

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Calculated OI ranged from 1.8 to 15.7, and there were no significant improvements associated with changing modes of ventilation or ventilator settings. Rather a gradual improvement with time was noted, which is in keeping with the natural history of RSV bronchi-





*Figure 2. Reported CXR findings after 15 hours on HFJV: persistent bilateral peri-hilar bronchial thickening with uneven hyperinflation were seen in both lungs and are in keeping with known RSV bronchiolitis. There are persistent streaky linear opacities representing sub-segmental atelectasis, and a new area of atelectasis seen in the right upper lobe. Endotracheal tube position was unchanged.*

olitis pneumonia. The measured PEEP values on the HFJV were always 2-3 cm H<sub>2</sub>O higher than the set PEEP displayed on the Babylog 8000 plus, which was suggestive of air trapping.

By day 3 of HFJV, sedation was transitioned from fentanyl to morphine infusion, as it was felt the patient had developed tolerance to fentanyl. The intent was to improve patient comfort and relaxation on the ventilator. By day 6 of HFJV, the patient was successfully transitioned to conventional ventilation settings: AC VG (4.5 ml/kg), RR 55, Peep 8 cm H<sub>2</sub>O, PIP 18 cm H<sub>2</sub>O, FiO<sub>2</sub> 0.25, ETCO<sub>2</sub> 51 mmHg. Conventional ventilation parameters were further weaned over the next 3 days as was sedation, and she was successfully extubated to nCPAP, followed by low flow oxygen and finally room air.

The baby was transferred to the Pediatric ward for convalescence

at 43 days of life.

### **Discussion**

A review of the literature at the time of this admission to our NICU revealed a significant gap in addressing the needs of premature infants in the context of nosocomial RSV. The majority of previously published literature addressed different management of RSV in ex-premature populations following discharge home from the NICU rather than during the initial course of admission (3). Although there have been a few case reports of surfactant, inhaled nitric oxide, and ribavirin as possible therapeutic avenues, none of these were part of the standard of recommended care, therefore inapplicable to our patient (4).

RSV bronchiolitis is characterized by obstruction and collapse of

small airways during expiration (4). The airway narrowing is due to virus-induced necrosis of the bronchiolar epithelium, mucus hypersecretion, and submucosal edema (4). Preterm infants due to the small size of their bronchioles are at a greater disadvantage compared to term infants. In addition, preterm infants are more susceptible to RSV disease from an immunological perspective (1). The majority of protective IgG is transferred across the placenta in the last four weeks of pregnancy prior to delivery, and as such preterm infants do not receive these antibodies prior to their birth (5).

The natural history of RSV is that the illness tends to peak in severity sometime between day 3 to day 6. In our patient, we appreciated the same pattern in that she seemed to be the most ill, requiring maximal ventilator support, oxygen needs, increased levels of sedation, and frequent pulmonary toileting, on day six of illness. Subsequently, illness resolution took much longer than anticipated, likely due in part to prematurity and complications associated with impaired immune function and smaller airways prone to mucus plugging. Previous work (6) found that children with atelectasis on days 1 and 2 following intubation for RSV bronchiolitis were more likely to have a protracted clinical course and intubation for greater than eight days' duration; this was in keeping with our case.

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***“The natural history of RSV is that the illness tends to peak in severity sometime between day 3 to day 6. In our patient, we appreciated the same pattern in that she seemed to be the most ill, requiring maximal ventilator support, oxygen needs, increased levels of sedation, and frequent pulmonary toileting.”***

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At the time of arrival to our NICU, the patient was not comfortable, and during the course of her admission, it became evident that optimal sedation was key to effective ventilation. Secretions were overwhelmingly excessive as we observed that despite frequent suctioning, the continuous overproduction of mucous, secondary to necrotizing bronchiolitis, contributed to the baby struggling. What proved to be a relevant factor for managing our patient, more so than changing modes of ventilation, was changing to a nasal ETT of the appropriate calculated size to weight ratio. This elective change allowed for optimal airway stability and improved pulmonary toileting.

Retrospectively, the respiratory therapy team felt that while on HFOV, optimal sedation had not yet been achieved. Nevertheless, the care team deemed necessary to sedate our patient until the problematic issue of overabundant secretions was under control. HFJV was chosen primarily to facilitate secretion clearance, and acknowledging that the performance of the HFJV is not influenced by the airway resistance nor lung compliance. Another unique feature of jet ventilation compared to HFOV is that HFJV has the ability to indicate the presence of air-trapping by showing that the measured PEEP on HFJV is greater than the set PEEP on the conventional ventilator. The passive exhalation phase on HFJV allowed for a greater I:E ratio of 1:12. This was beneficial in the context of air trapping compared to the I:E ratio of 1:2 delivered with HFOV. In fact, we know from experience that sick prematures with only 1:2 or 1:3 ratios are prone to gas trapping. While on

HFJV, the respiratory therapy team utilized manual lung volume recruitment techniques to improve secretion clearance. Although not supported by strong evidence, this maneuver is empirically associated with benefit in ventilated pediatric patients with RSV.

Possible explanations for lability in the oxygen requirement include challenges in maintaining adequate sedation and airway obstruction. Needing frequent pulmonary toileting, we repositioned our patient every 12 hours and trialed neuromuscular blockade (Rocuronium), with no substantial change in oxygen requirements.

Despite the escalation of ventilation support and periods of 100% oxygen requirements, episodes of hypoxemia were still noted. An echocardiogram was done to rule out a potential intracardiac shunt contributing to persistent hypoxemia. This echocardiogram revealed a structurally normal heart with no evidence of a PDA, PFO, or elevated pulmonary pressures. The hypoxemia was presumed to be likely due to intrapulmonary shunting with  $\dot{V}/\dot{Q}$  mismatch, secondary to RSV disease that resolved with the resolution of the patient's bronchiolitis pneumonia.

Persistent sinus tachycardia was a prominent feature of our patient's disease. In our NICU, tachycardia has also been clinically observed with other preterm infants on HFJV with non-compliant lung issues. Ultimately tachycardia did not resolve until our patient was extubated and had recovered from the worst phase of her RSV illness by day 11 of her admission.

#### **Conclusion**

- More research is needed to guide the supportive management of nosocomial RSV bronchiolitis in the preterm NICU population while these infants are still hospitalized prior to discharge home.
- Switching to an appropriately sized and more secure airway is indispensable to achieve effective pulmonary toileting as secretions can be abundant and present early in the course of the disease in premature lungs and airways.
- Adequate sedation remains a critical element of management to help optimize chest compliance and, therefore, efficient ventilation and oxygenation.
- In the clinical context of RSV in premature lungs, HFJV should be used with the understanding and the caution that measured PEEP and chest expansion, without hemodynamic instability, does not necessarily need to be matched.
- The main variable of treating premature with RSV is gas trapping, which leads to hyperinflated lungs. HFJV with passive exhalation enabled us to deliver longer i:e ratios of 1:12 compared to 1:1 to 1:3 provided by HFO with an active exhalation phase.
- In our experience, HFJV was able to support the management of hypercapnia and hypoxemia during the worst period of the disease in a premature infant.
- The duration of the disease was much more prolonged than what we would usually see in term babies or ex-preterm infants at a later age affected by RSV bronchiolitis: 11 days compared to the described average of 6 days.
- During RSV season, nosocomial bronchiolitis should be part of the differential for any baby presenting with a 'rule out sepsis' picture, and appropriate viral studies should be ordered.



- NICU personnel must be accountable for staying home when feeling unwell, and NICU visitation policies must be reinforced to exclude ill persons, including parents and siblings, especially during the viral season.

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**Disclosure:** The authors have no disclosures.

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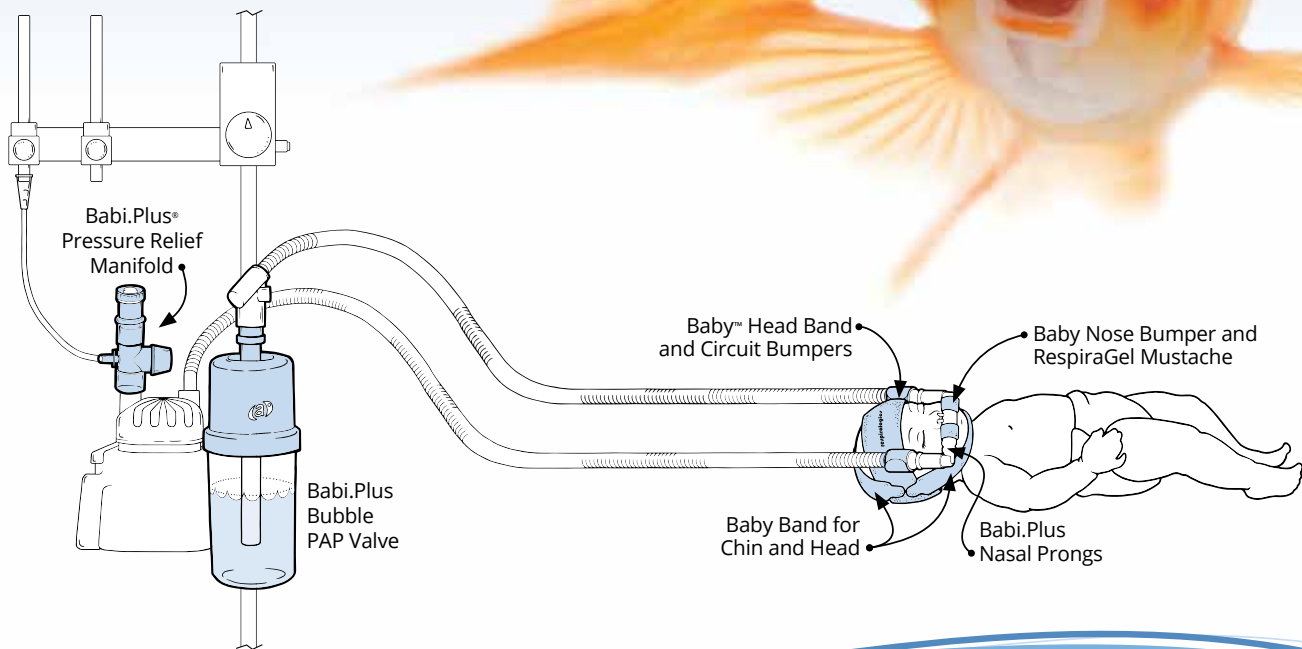
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# Fellow Column: Overview of Syphilis with a Discussion of Four Cases of Congenital Syphilis

James Morgan MS

## Introduction

Syphilis, caused by the spirochete *Treponema pallidum*, has a long history of human involvement, with recorded outbreaks dating back to the 1400s. (1) The majority of syphilis cases are sexually acquired, but any contact with spirochetes may lead to infection (2). Because syphilis has been recorded for so long, including the pre-antibiotic era, the disease course with and without treatment is well understood. Additionally, the infamous Tuskegee trial followed 431 black men with untreated syphilis, even though there was a known cure.(3)

Treponemal infection elicits both an adaptive and humoral immune response. The duration and progression of infection depend on the immune response mounted. (4) Stronger delayed-type hypersensitivity (DTH) reactions are associated with a better outcome, with total eradication of spirochetes in some cases; however, the majority of untreated cases proceed to prolonged latency. Individuals that respond initially with antibody production or a cytotoxic CD8 response are more likely to progress to secondary and tertiary disease. In primary syphilis, a delayed-type hypersensitivity reaction (DTH) is responsible for a painless well-circumscribed chancre. An initial cytotoxic t-cell response is associated with prolonged infection and progression to tertiary disease.

***“ In primary syphilis, a delayed-type hypersensitivity reaction (DTH) is responsible for a painless well-circumscribed chancre. An initial cytotoxic t-cell response is associated with prolonged infection and progression to tertiary disease.”***

## Progression of syphilis in adults

Primary syphilis occurs when spirochetes access subcutaneous tissues via microscopic abrasions. (2) The adaptive response consists of an infiltration of neutrophils and antigen-presenting cells that recruit T-Lymphocytes. Often the dendritic cells express the CCR5 receptor, which may explain the link between HIV and syphilis. The humoral response results in the development of antibodies, which are detected early in the disease, thus antibody testing may result in a false positive. This immune response is sufficient to resolve the chancre, but most often cannot prevent the spread of spirochetes. Inflammatory cells are very effective in clearing organisms in primary lesions; however they are much less effective in clearing secondary lesions. Progression to primary systemic syphilis occurs when the spirochetal load is too high to clear when an immune effector blunts the efficiency of the response (e.g., shift toward humoral response with plasma cell infiltration, or if the immune response is dampened before total elimination. In primary systemic syphilis, organisms are disseminated from the site of infection to the lymphatics in a few hours,

causing marked lymphadenopathy and splenomegaly. In some cases, mononuclear proliferative vasculitis may occur in various organs resembling a chronic allograft rejection.

Secondary syphilis usually occurs eight weeks after the initial appearance of the chancre. The majority of patients are asymptomatic, though nonspecific systemic symptoms may be seen. In secondary syphilis, the serologic markers are almost always present. Clinical manifestation of secondary syphilis is most commonly cutaneous (81%), but involvement may be seen in the oral mucosa (36%), genitals (20%), and in the CNS (10%). Cutaneous lesions may be urticarial, macular, maculopapular, papular, pustular, or nodular.(5) Patients may also present with alopecia syphilitica, which is a moth-eaten pattern of hair loss commonly seen in syphilis.

Sir William Osler was credited as describing syphilis as the great masquerader because the morphology of secondary syphilis is so broad. (6) conditions secondary syphilis may be mistaken for include alopecia areata, bullous pemphigoid, pemphigus vulgaris, pseudolymphoma, erythema multiforme, leprosy, lichen planus, SLE, mycosis fungoides, psoriasis, and eczema. The mucous patch seen in secondary syphilis is a slightly raised moderately indurated lesion with smooth borders and central necrosis. It is the homologue of the chancre of primary syphilis, and when present on the skin it is termed condylooma latum.

The immune response in primary syphilis is primarily CD4 dominated; however the immune response in secondary syphilis is CD8 dominated and not sufficient for clearing the infection. In response to *T. Pallidum*, vascular adhesion molecules (ICAM-1, VCAM-1, E-selectin) are upregulated, resulting in fibrin deposition and vascular inflammation. This vasculitis contributes to the varied clinical presentation of syphilis.





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***“Tertiary syphilis only occurs in 1/3 of untreated infected individuals. The onset of tertiary syphilis usually occurs 3-7 years following infection in immunocompetent patients, but may be more rapid in HIV coinfection. (7)”***

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Tertiary syphilis only occurs in 1/3 of untreated infected individuals. The onset of tertiary syphilis usually occurs 3-7 years following infection in immunocompetent patients, but may be more rapid in HIV coinfection. (7) The formation of a gumma results from an ineffective DTH reaction that results in chronic granulomatous inflammation due to persistent infection. This granuloma has broad irregular acellular zones with central necrosis. Syphilitic granulomas can be differentiated from the granulomas of tuberculosis by the irregular borders and lower cellularity, and from the granulomas of sarcoidosis by the presence of necrosis and plasma cells. Gummas will scar over if the organism is eradicated but may persist for years if treatment is insufficient or immune response is inadequate. Progression to tertiary syphilis can also affect the CNS, as well as any internal organ through vascular damage. (8) Most notable is cardiac involvement in which inflammation of the vasa vasorum of small blood vessels, increases the risk for aneurysm and rupture. “Tree barking” of the vasa vasorum occurs due to heaping up and thickening of endothelium and may speed up ASCVD. Neurovascular involvement leads to meningo-vascular inflammation, inflammation of cerebral vessels, and general paresis. (9) This neurosyphilis has many manifestations, including meningitis, cortical inflammation, and tabes dorsalis due to the demyelination of the posterior column. Renovascular involvement presents a challenge in treatment as increased circulating immune complexes cause nephritis in 10% of patients with neurosyphilis.



Figure 1 - Primary syphilitic chancre; CDC

### **Syphilis in pregnancy(10)**

The course of syphilis is not significantly changed by pregnancy; however the risk of vertical transmission is increased proportionately to spirochetal load. From 2014 - 2018, primary and secondary syphilis has more than doubled in pregnant women. The highest rates of infection are seen in women age 20-24 (10/100k) and 25-29 (9.4/100k) years old. In 2018 there were 1306 cases of congenital syphilis reported. Of those cases, there were 78

stillbirths and 16 infants died shortly after birth. The incidence of syphilis in 2018 was reported to be 33.1/100k live births, which is a 185% increase since 2014. Syphilis is most common among poor, young (<29), African American women, and those lacking health insurance and prenatal care. (11) Risk factors include drug use, other STDs, living in area w/ high syphilis prevalence, being a sex worker, and having more than one sexual partner in the past year. (12) However, 50% of pregnant women with syphilis do not have any risk factors.



Figure 2- Rash of secondary syphilis; CDC

Because syphilis is so easily treated and screening is so inexpensive, universal antepartum screening is recommended at the 1st prenatal encounter. If the patient has risk factors, screening should be repeated at 28-32 weeks and delivery. Additionally, screening is recommended in all women who have a stillbirth child after 20 weeks. Because HIV is so closely associated with syphilis, all pregnant women should be offered HIV counseling and screening using an opt-out approach.

In order for the diagnosis to be confirmed, spirochetes must be visualized on darkfield microscopy, or two serologic tests (treponemal and non-treponemal) must be positive. Nontreponemal tests include RPR, VDRL, and TRUST, and treponemal tests include FTA-ABS, MHA-TP, TPPA, TP-EIA, and CIA. FT-ABS and RPR must both be positive since RPR may be positive in certain underlying conditions despite no treponemal infection. (13) Causes of false-positive include febrile illness, advanced age, tumor, di-



Figure 3- Snuffles; CDC/Dr. Norman Cole

alysis, and autoimmunity. False-positive must be followed up 4-6 weeks following delivery.

The preferred treatment for pregnant women is penicillin.(14) All *T. Pallidum* is sensitive to penicillin, and treatment is effective for maternal disease, preventing vertical transmission, and treating fetal disease. If the mother has penicillin sensitivity, inpatient treatment is recommended with desensitization and subsequent penicillin treatment. In situations where an actual anaphylactic reaction is suspected, consultation of an allergist for skin testing is advised. Mothers should also be monitored for Jarisch-Herxheimer (JH) reaction. (15) JH reactions typically occur within 1-2 hours, peak at 8 hours, and resolves in 24-48 hours. Because of the increased inflammatory response, JH reaction may precipitate uterine contractions, preterm labor, and/or variable heart fetal heart rates. JH may be prevented or blunted by the administration of oral prednisolone(16).

Because penicillin is relatively inexpensive, very efficacious against *T. Pallidum*, and has high beneficence for patients, treatment of syphilis need not be conservative. Penicillin dosing for primary, secondary, or early latent infection is a single dose of 2.4M units Pen G IM, with an optional second dose one week later. For latent or tertiary syphilis, three doses of Pen G 2.4 should be given intramuscular weekly. For both regimens, these doses must be given sequentially and must be restarted if greater than two weeks pass from the last dose. Patients in which verification of treatment cannot be made should receive treatment regardless of symptoms. Presumptive treatment should be administered to all women who have had sexual contact with partners with known syphilis. In order to ensure adequate treatment, titers should be drawn prior to treatment, and treatment should result in at least a fourfold reduction (e.g., 1:16 -> 1:4, 1:32 -> 1:8).

### Congenital Syphilis (17)

Congenital syphilis incidence peaked in 1991 at 100/100k births, had a nadir at 8.4 in 2012, and increased to 23.3/100 in 2017. Vertical transmission of syphilis occurs after *T. Pallidum* has infected the placenta, with transplacental transmission occurring as early as 9-10 weeks gestation. The manifestation of congenital infection depends on the state of maternal syphilis, maternal treatment, and fetal immunological response. The highest risk for transmission occurs if the mother has contracted syphilis in the last four years. However, if the mother contracts syphilis late in pregnancy, the risk of transmission increases. Failure to identify and treat is a significant risk factor for transmission. Adequate treatment reduces fetal deaths or stillbirths by 82%, preterm low birth weight by 65%, and clinical disease in infants by 97%.

Fetal abnormalities result from a robust fetal immune response to *T. Pallidum*, which causes damage to the developing fetus. Because the fetal immune system is not well developed until after 20 weeks, signs of fetal infection are not seen until the second trimester. The first sign of fetal infection is hepatic infection/dysfunction, followed by amniotic fluid infection, fetal hematologic abnormalities (anemia, thrombocytopenia), ascites, hydrops, and fetal IgM production. (18)

Ultrasound findings in fetal infection are nonspecific and include early findings of hepatomegaly (liver length >95th percentile), placentomegaly (thickness >2 SD above mean), and late findings of anemia, polyhydramnios, and Ascites or hydrops.

Management of pregnancy includes ultrasound after 20w to look for congenital signs. If signs are present, ultrasound should be repeated weekly to monitor fetal health. Late preterm delivery is warranted if there is a high risk of fetal treatment failure. After delivery, the placenta should be evaluated histopathologically to determine the stage and inform treatment. An untreated placenta is large and edematous and may lead to a negatively impacted fetoplacental exchange of oxygen and nutrients (11).

After birth, congenital syphilis is divided into early congenital syphilis with symptoms occurring before two years, and late syphilis with symptoms manifesting thereafter.

### Early Congenital syphilis

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Figure 4 - Tertiary Syphilis; National Museum of Health and Medicine

Clinical manifestations occur before two years of age but are most commonly seen within five weeks – 3 months. 60-90% of infants are asymptomatic at birth, with symptoms depending on the timing of intrauterine infection and treatment.

Only severe cases are clinically apparent at birth. Clinical manifestations of early congenital syphilis include hepatomegaly, jaundice, nasal discharge, rash, generalized LAD, and skeletal abnormalities. The placenta may exhibit necrotizing funisitis, which presents as a large thick and pale, “barber’s pole” w/o spiral red and light blue discoloration alternating with steaks of chalky white. (Figure 8) Hepatomegaly and splenomegaly occur in almost all infants, presenting as jaundice and cholestasis with elevated AST, ALT, ALP, Direct Bilirubin, prolonged PT. Snuffles, or rhinitis, usually develops in the first week of life and often heralds the onset of congenital syphilis. The nasal discharge is white and may be bloody if mucosal erosion has occurred.



Figure 5 - Primary syphilitic chancre acquired from mother during birth; CDC/Susan Lindsley

Snuffles is more severe and persistent than viral rhinitis. Care must be taken to not spread infection due to contact with discharge. A rash usually appears within a few weeks, which is most prominent on the back, buttocks, posterior thighs, and soles. The rash progresses for three weeks, followed by desquamation and crusting. The rash may also occur at birth with wide dissemination



Figure 6 - Necrotizing Funisitis; Obstetrical Pathology

and bullous lesions (pemphigus syphiliticus).(19)(20) In addition to hepatosplenomegaly and rash, palpable epitrochlear lymphadenopathy is characteristic of syphilis; however, Generalized lymphadenopathy is commonly seen. Occasionally CNS involvement may be seen but has become less common due to treatment. Acute syphilitic leptomenigitis occurs during the first year of life, most commonly within 3-6months, and resembles bacterial meningitis with vomiting, bulging fontanelle, increased head circumference, and splitting of cranial sutures. However, CSF analysis is more reflective of aseptic meningitis. Chronic meningovascular syphilis occurs toward the end of the first year and presents as progressive hydrocephalus, CN palsies, papilledema, optic atrophy, neurodevelopmental regression, and seizure.

Long bone abnormalities are the most specific finding for syphilis, occurring in 60-80% of infants. They are usually the only findings present at birth but may appear in the first few weeks of life. Congenital syphilis may be associated with pathological fractures and pseudoparalysis. Radiographic findings are usually bilateral, symmetric, and polyostotic (femur, humerus, tibia). Lucent bands, symmetric demineralization, destruction of the medial proximal tibia (Wimberger sign), Metaphyseal serration (Wegener sign), Periostitis, and/or moth-eaten appearance may be seen.

Radiographs are warranted in 1) neonates who have VDRL or RPR titers less than fourfold the maternal titer, a normal physical exam, and a mother who was not treated, treated  $\leq 4$ weeks, or

had evidence of infection relapse or 2) infants and children with reactive VDRL or RPR with abnormal skeletal findings on physical exam (pain, decreased ROM)



Figure 7 - papular perioral rash and plantar rash; CDC/Susan Lindsley

A radiograph may also reveal a diffuse infiltrative fluffy appearance in all lung areas.

Lab abnormalities include coombs negative hemolytic anemia neonatally, nonhemolytic anemia after neonatal period, thrombocytopenia, and leukopenia. CSF findings include reactive VDRL (54% & 90%), pleocytosis (38% & 88%), and elevated CSF protein (56% & 78%).(19) (sensitivity and specificity respectively)

### Late congenital syphilis

Late congenital syphilis is related to scarring or persistent inflammation from early infection, with gumma formation in various tissues. It develops in 40% of infants born to women w/ untreated syphilis during pregnancy and as a wide variety of symptoms.

Late congenital syphilis may also present as neurological abnormalities, which include intellectual disability, arrested hydrocephalus, cranial nerve palsies, and sensorineural hearing loss.

### Evaluation and management of congenital syphilis (20)

Because maternal nontreponemal and treponemal IgG antibodies can be transferred through the placenta, serologic tests may not be sufficient to prove the diagnosis if clinical signs are absent. [21] Therefore, treatment decisions must be made on the basis of identification of syphilis in the mother, adequacy of maternal treatment, presence of clinical, laboratory, or radiographic evidence of syphilis in the neonate, and comparison of maternal and neonatal non-treponemal tests. For infants less than one month of age born to mothers with reactive nontreponemal and treponemal tests, the initial evaluation should include Quantitative tests, physical examination with darkfield microscopy of suspicious discharge/lesions, and pathologic examination of the umbilical cord with FT-ABS. Quantitative tests should include treponemal tests (VDRL or RPR) of the infant's serum. Nontreponemal tests of infant serum should be done according to which test the mother received so a direct comparison can be made. All serological tests should be performed on neonatal serum, because umbilical cord blood can become contaminated with maternal blood and yield a false-positive result. Subsequent evaluation should be done based on likelihood as follows:

- If congenital syphilis is proven or highly probable syphilis, evaluate with CSF VDRL, cell count, and protein, CBC w/ diff, and any additional warranted tests. , including long bone radiographs, chest radiograph, liver-function tests, neuroimaging, ophthalmologic examination, and auditory brain stem response. CSF tests results obtained during the neonatal period can be difficult to interpret, as normal neonatal CSF may show elevated WBCs or protein. All other possible causes of elevated CSF values must be considered when an infant is being evaluated. Treat with ten days of parenteral penicillin if:
  - o Physical exam findings are compatible with congenital

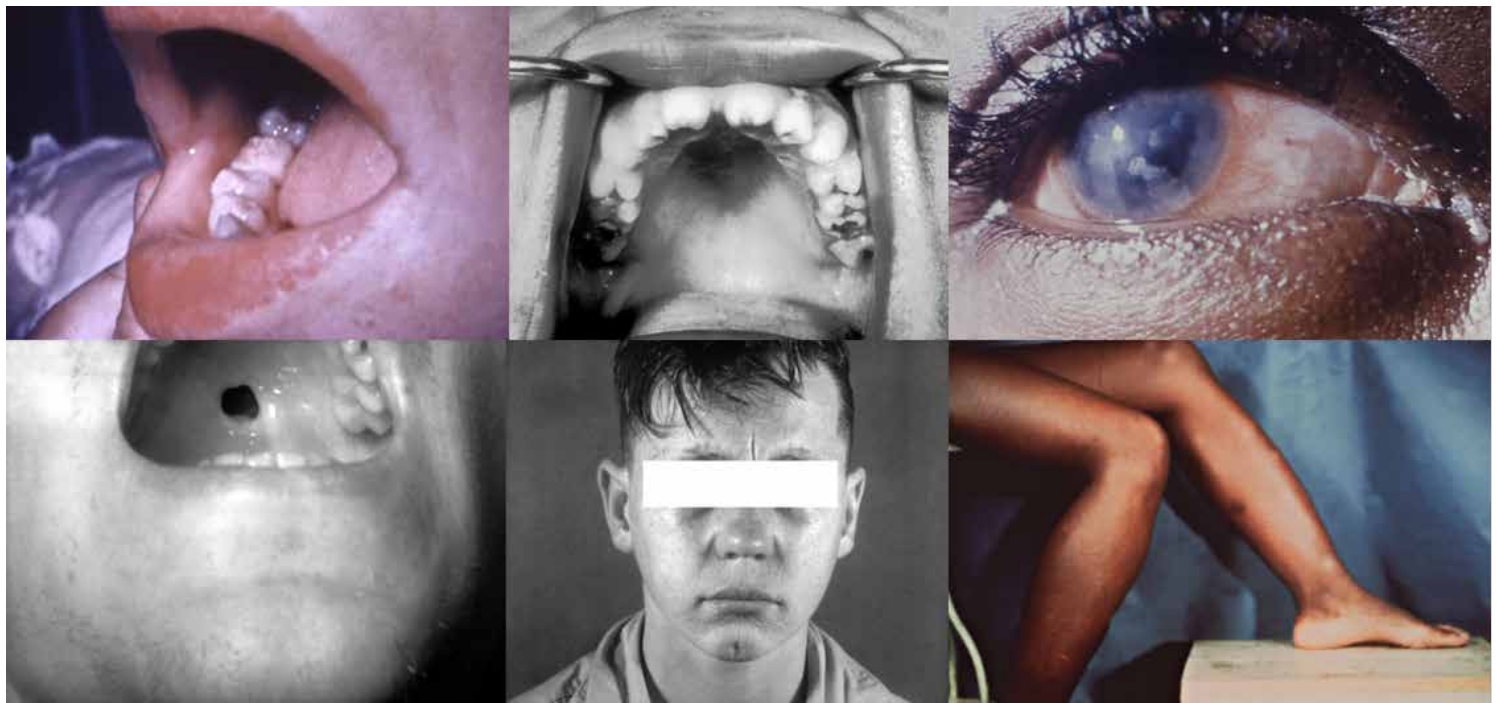


Figure 8 - Left to right top to bottom: Mulberry molars; Hutchinson Teeth; Keratomalacia; Perforated soft palate; Rhagades; Saber shins; CDC/Susan Lindsley and Robert Sumpter

syphilis, regardless of lab results or maternal treatment

- o Baby's titer is fourfold higher than mom's titer
- o Baby has reactive titer (<4x), and mom received inadequate treatment during pregnancy
- o Baby has reactive titer (<4x), and mom showed evidence of relapse (single dose if the neonatal exam is normal, ten days if abnormal)
- If congenital syphilis is possible, evaluate with CSF analysis for VDRL, cell count, and protein. A complete evaluation is not necessary if 10 days of parenteral therapy is administered, but evaluation may be useful. Treat with a single-dose IM benzathine penicillin, procaine penicillin G IM for 10 days, or aqueous crystalline penicillin if:
  - o Baby has reactive titer < fourfold mom and Mom was inadequately treated before or during pregnancy
  - o Baby has a nonreactive titer, but mom was inadequately treated.
  - o Mother received recommended treatment < 4 weeks before delivery
- If congenital syphilis is unlikely, no evaluation or treatment is necessary if:
  - o Baby has nonreactive or less than 4x titer, and mom was adequately treated.

In infants greater than one month of age with serological tests that remain reactive, it is more difficult to know if syphilis is congenital or acquired. Evaluation should include CSF for VDRL, cell count, and protein, CBC w/ diff, HIV screening, and any other tests as clinically indicated. Long bone abnormalities may be helpful in determining whether syphilis is acquired or congenital. The possibility of sexual abuse should be considered as the cause of acquired syphilis

### Treatment of congenital syphilis (22)

Effective treatment requires maintaining a minimum inhibitory concentration (MIC) of 0.03 units/mL for ten days. MIC for treponemal treatment with penicillin is approximately 0.004 units. There are multiple options to maintain the specified MIC:

#### Single-dose regimen

##### Penicillin G benzathine

Given as 50,000 units/kg intramuscular injection. The benzathine component causes a slow release of penicillin, allowing for extended action. This administration is ideal for patients that may have difficulty following up. This option, however, is contraindicated in asymptomatic infants born to women with inadequate/suboptimal treatment unless labs and imaging are entirely normal. If there are any lab abnormalities, the patient must be treated with the ten-day regimen.

#### 10-day regimens

##### Aqueous Penicillin G

Given as 50,000 units/kg IV twice daily if under days old, or three times daily if over seven days old. This is the treatment of choice for children >1 month of age or chil-

dren with acquired syphilis.

##### Procaine penicillin G

Given as 50,000 units/kg IM QD 10 days. This treatment has been shown to have lower levels of penicillin than IV aqueous penicillin, but this finding has not proven to be clinically significant.

If any signs of neurosyphilis are present, patients must complete a 10-day course to be followed with a single IM dose of 50,000 unit/kg penicillin G benzathine

Adverse effects to infants include a JH reaction that is usually self-limited but may lead to cardiovascular collapse, seizure, or death. If more than one day of therapy is missed in the ten-day regimen, the course must be restarted. As in adults, if the infant is sensitive to penicillin, desensitization should occur.

### Follow-up evaluations

During well-child visits, serologically reactive children should be evaluated for signs of congenital syphilis for the first year of life and beyond. Specific attention should be paid to hearing, vision, and neurodevelopmental abnormalities. If diagnosed after infancy, non-treponemal tests (VDRL or RPR) should be performed every 2-3 months. Serology should be repeated until the test becomes non-reactive, or titer has decreased fourfold. If VDRL or RPR fail to decrease or increase within 6-12 months, a lumbar puncture should be obtained and evaluated for VDRL, cell count, and protein, and be treated with ten days parenteral penicillin regardless of previous treatment. Treponemal tests (FTA-ABS, T. pallidum agglutination (TP-PA), microhemagglutination test for T. Pallidum (MHA-TP)) should not be used to evaluate treatment, as they may remain positive despite adequate treatment. Treponemal tests can, however, be used for confirmation of diagnosis if tests at 12-15 months and 18-24 months are positive

### Outcomes

Case fatality rates range from 6-8%, with 90% of cases associated with a lack of prenatal care. Certain clinical manifestations, including Interstitial keratitis and saber shins, may occur despite appropriate therapy. Infection may persist for life if spirochetes persist in extracellular loci with no inflammatory response elicited. It is important that patients are instructed that prior infection with syphilis is NOT protective against future infection.

### Patient cases

#### Patient 1

The first patient treated was born at a gestational age of 27 weeks and five days at a weight of 1090g. The infant was admitted to the NICU for prematurity as well as respiratory failure. Throughout the first month of life, the infant repeatedly decompensated, requiring intubation and ventilation. At the time of delivery, the mother presented with a reactive titer of 1:64, and the infant's RPR titer was measured to be 1:128. FT-ABS was reactive in both patients. Radiography showed osteochondropathy of the long bones consistent with congenital syphilis. The infant completed a ten-day course of Penicillin G 50,000 units/kg twice daily. When the infant reached seven days of age, the dose was increased from twice daily to three times daily. Throughout the hospital stay, the patient never exhibited any neurological deficits.

#### Patient 2

This patient was born at 32 weeks and five days weighing 2060 grams with weight and length between 76-90th percentile, and



head circumference between 51-75th percentile. The mother stated she had received treatment in another country, though her RPR titer was 1:4, and FT-ABS was reactive. The infant's titer was measured to be 1:1. The infant received ten days of penicillin G, while the mother was not re-treated. Because the infant's RPR titer was fourfold less than the mother's RPR titer, imaging was not ordered. This infant did not show any signs of syphilis, including rash or snuffles. The baby did present with jaundice and was borderline LIRZ/HIRZ, which responded well to phototherapy.

### Patient 3

Patient three was born at 26 weeks and six days with a birth weight of 990 grams via C-section due to transverse lie and premature rupture of membranes. Following birth, the infant was intubated and given surfactant in the delivery room. The patient was transferred to the NICU and remained intubated for the three weeks of life, and was then slowly weaned to Nasal intermittent mandatory ventilation. Upon screening mother had a urine drug screen positive for amphetamines, a positive GBS and E. Coli blood culture (gentamicin sensitive), and reactive RPR with a titer of 1:8. The infant's RPR was positive with a titer of 1:1 negating the need for long bone imaging. The mother was treated with a 10-day course of penicillin G, and titers improved. The infant's hospitalization was complicated with sepsis, for which the patient was treated with seven days of vancomycin and cefepime. Following treatment for sepsis, a 10-day regimen of penicillin G was started three times daily. The patient did not exhibit any signs of syphilis, including rash, rhinitis, or neurological dysfunction.

### Patient 4

Patient 4 was born at 39 weeks gestation with a birth weight of 2105g. Weight, length and head circumference were below the third percentile, consistent with intrauterine growth restriction. The infant was noted to have down facies on delivery, confirmed by karyotype 47 XY + 21. The denied any prenatal care and screened positive for RPR with a titer that was pending at the time of the report. The infant's VDRL titer was nonreactive, RPR titer was also pending, and a survey of the long bones showed no abnormalities. The infant received ten days of penicillin G.

### Discussion and Conclusion

Although syphilis is highly infective and has poor outcomes if left untreated, the disease is easily treated with inexpensive and widely available medications. However, despite the treatment being so simple, barriers to care, including lack of insurance, lower socioeconomic status, and lack of health education, prevent pregnant mothers from being treated and syphilis from being eradicated. By ensuring each pregnant woman is screened for syphilis and treated if positive, many of the complications of syphilis can be avoided, thus providing better health and quality of life to both the mother and child.

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Disclosure: The author has no disclosures

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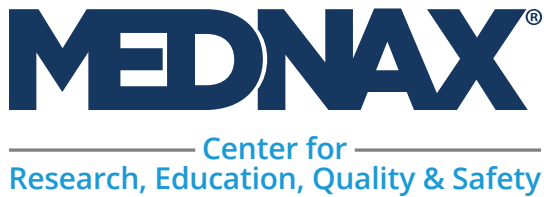


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Perinatal detection of congenital anomalies leads to the identification of infants who are affected by life-limiting conditions with a short life expectancy. Moreover, a significant number of newborns admitted to the neonatal ICU in critical condition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

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

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

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

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

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

*See site for full instructor list.*

### Continuing Medical Education (CME) and Continuing Nursing Education (CNE):

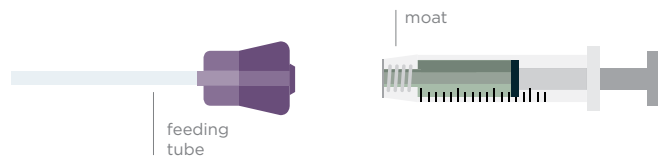
This course has been approved for CME credits. CNE credits pending.

**Accreditation Statement:** The Columbia University Vagelos College of Physicians and Surgeons is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. **AMA Credit Designation Statement:** The Columbia University Vagelos College of Physicians and Surgeons designates this live activity for a maximum of 20.75 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

More details and registration: [mailman.columbia.edu/comfort-care](http://mailman.columbia.edu/comfort-care)



**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.



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#### 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*

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# Reducing Disparities in Maternal Mortality

Alison Jacobson

## first candle

Saving babies. Supporting families.

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

The statistic is staggering. According to the Centers for Disease Control and Prevention, Black mothers in the United States are dying at a rate three to four times higher than their white counterparts. While 13 white women die for every 100,000 live births, for black women, the statistic is 42.8 for every 100,000 live births. Even more disturbing, the rate of maternal mortality is actually rising in the U.S.

***“Black mothers in the United States are dying at a rate three to four times higher than their white counterparts. While 13 white women die for every 100,000 live births, for black women, the statistic is 42.8 for every 100,000 live births.”***

For Black babies, the statistics are equally as sad; twice as many Black babies die before their first birthday than white babies. The racial disparity in infant mortality is wider than in 1850. Think about that for a moment.

In looking at the reasons for this, it would be easy to simply conclude this is an issue of socio-economic status and, to a great degree, this is indeed the case. The CDC has concluded that sixty percent of all pregnancy-related deaths can be prevented, in part through better health care, communication and support, and access to stable housing and transportation.

To be sure, ensuring access to comprehensive, affordable, high-quality health care is vital in the effort to eliminate racial disparities in maternal and infant mortality. A priority must be placed on underserved populations, including women and infants of color, low-income communities, and those living in rural and medically underserved areas.

But far greater is the issue of systemic racism and how it impacts a mother's care before, during, and after pregnancy. Black women are more likely to die in childbirth than white women regardless of education, income, or any other socio-economic factors. Tennis superstar Serena Williams, who has access to the best doctors and undeniably knows her body incredibly well, was ignored when she knew something was wrong after giving birth and nearly died.

As the New York Times reported in 2018, "For black women in America, an inescapable atmosphere of societal and systemic racism can create a kind of toxic physiological stress, resulting in conditions — including hypertension and pre-eclampsia — that leads directly to higher rates of infant and maternal death. And that societal racism is further expressed in a pervasive, long-standing racial bias in health care — including the dismissal of legitimate concerns and symptoms — that can help explain poor birth outcomes even in the case of black women with the most advantages."

The solution to the high rates of black maternal and infant mortality lies in providing care that is patient-centered, unbiased, and high quality.

Bias can take many forms and can be related to education level, income, sexual orientation, disability, and immigration status, which can also negatively affect patients' experiences in health care settings as well as their health outcomes. Implicit bias training cannot merely be a box to check off for health care providers. At First Candle, our Straight Talk for Infant Safe Sleep Training explores unconscious bias and works with care providers to improve communication with patients to understand better their obstacles



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

**At First Candle we're educating parents, grandparents and caregivers about safer sleep to make sure all babies reach their first birthday. Learn more at [firstcandle.org](http://firstcandle.org)**



and objections to adopting safe sleep guidelines and breastfeeding, which can significantly reduce the rates of infant mortality.

Patient-centered, high-quality care can be enhanced by including a doula in a woman's birthing team. Doulas are more extensive to empowering women to take control of their birthing choices, while also providing a continuum of care from pregnancy through the first year of a baby's life.

According to a report from the American Congress of Obstetricians and Gynecologists, doula-assisted mothers were less likely to deliver babies with low birth weights or with birth complications than were mothers who opted not to receive such support, and they were more likely to breast-feed their infants. Another study found that mothers attended by female caregivers during labor were less likely than others to have Caesarean births, require painkillers, or deliver babies in poor health.

---

***“According to a report from the American Congress of Obstetricians and Gynecologists, doula-assisted mothers were less likely to deliver babies with low birth weights or with birth complications than were mothers who opted not to receive such support, and they were more likely to breast-feed their infants.”***

---

Black women have a long history of supporting each other through childbirth. “Granny midwives,” as they were known, delivered babies of all races throughout the rural South in the 1800s, but at the beginning of the 1900s, doctors sought to diminish their role and discount this form of care.

It is indeed ironic that in the late 90s, doulas became in demand by wealthy white women who could afford their services. Doulas are not usually covered under Medicaid and therefore become inaccessible to the very women who need their services most. But recently, there has been a growing movement for Medicaid expansion to cover doulas. A few states have pilot programs in place to cover doulas and private groups around the country offer free or discounted services to women of color

As awareness of the importance of doulas grows, First Candle supports all efforts to provide access to all women.

References:

1. *CDC Vital Signs, May 2019*
2. *Why America's Black Mothers and Babies Are in a Life-or-Death Crisis, April 11, 2018*
3. *ACOG Committee Opinion 766*

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

**NT**

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[alison@firstcandle.org](mailto:alison@firstcandle.org)  
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March 5-7, 2020

*Through the darkness of my grief  
I light a candle to show the world  
my love for you.*

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provide bereavement  
support to the over  
27,000 families who  
will experience the loss  
of a baby every year.**

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# Keeping Nurses in Their Comfort Zone

A NICU nurse's devotion to patient care makes a difference in at least one baby's life every single day. It's that same dedication to care that inspired the development of Embrace®, the world's first FDA-cleared, CE marked compact neonatal MRI system designed for use *inside* the NICU.

Compared to standard MRI scanning, the Embrace® system saves time and reduces patient risk with bedside to bedside scans in under an hour. Now, neuro scans can be performed within minutes of an order, and the long preparation and transit times can become a thing of the past.



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Discover more at [embracemri.com](http://embracemri.com)

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# The Survey says RSV



What you need to know about RSV

**RSV** stands for **Respiratory Syncytial Virus**

RSV is a **Really Serious Virus**

**WHEN IS RSV SEASON?**

Typically RSV season runs from November - March. But it can begin as early as July in Florida and end as late as April in the West.

Protect babies and families this RSV season  
**Educate. Advocate. Integrate.**

National Perinatal Association

Consult the CDC's RSV Census Regional Trends to learn more [www.cdc.gov/rsv/census/regional-trends-surveillance.html](http://www.cdc.gov/rsv/census/regional-trends-surveillance.html)

[www.nationalperinatal.org](http://www.nationalperinatal.org)

## 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](http://nicuawareness.org) and [nationalperinatal.org/NICU\\_Awareness](http://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](http://www.nicuawareness.org)

[www.nationalperinatal.org/NICU\\_Awareness](http://www.nationalperinatal.org/NICU_Awareness)





*In January, heaven gained a new angel - Laura Renc.*

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

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

*Laura will be greatly missed.*

**first candle**

Saving babies. Supporting families

Babies are just tiny adults, right? So ... half?

Infants need drugs tested and approved just for them.

Coalition for Clinical Trials in Pediatrics **NCJFH** National Coalition for Infant Health  
Protective Access for Premature Infants through Age Two

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# Still a Premie?

Some premies are born months early, at extremely low birthweights. They fight for each breath and face nearly insurmountable health obstacles.

But that's not every premie's story.

**Born between 34 and 36 weeks' gestation?** **STILL A PREMIE**

Just like premies born much earlier, these "late preterm" infants can face:

- Jaundice
- Feeding issues
- Respiratory problems

And their parents, like all parents of premies, are at **risk for** postpartum depression and PTSD.

**Born preterm at a "normal" weight?** **STILL A PREMIE**

Though these babies look healthy, they can still have complications and require NICU care.

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

**Born preterm but not admitted to the NICU?** **STILL A PREMIE**

Even if preterm babies don't require NICU care, they can still face health challenges.

Those challenges can extend through childhood, adolescence and even into adulthood.

Some Premies	All Premies
<ul style="list-style-type: none"> <li>Will spend weeks in the hospital</li> <li>Will have lifelong health problems</li> <li>Are disadvantaged from birth</li> </ul>	<ul style="list-style-type: none"> <li>Face health risks</li> <li>Deserve appropriate health coverage</li> <li>Need access to proper health care</li> </ul>

**NCJFH** National Coalition for Infant Health  
Protective Access for Premature Infants through Age Two  
[www.infanthealth.org](http://www.infanthealth.org)

# 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 5<sup>th</sup> 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](http://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.





Save the Date: March 4-7, 2020

Call for Abstracts: Due Monday, October 28, 2019



# The 33<sup>rd</sup> Annual Gravens Conference

*on the Environment of Care for High Risk Newborns*

*Biophysiology of  
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Sheraton Sand Key  
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March 4-7, 2020

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March 24-28, 2020; Snowbird, UT

<http://paclac.org/advances-in-care-conference/>



# Innovative Care of the Newborn Brain

## March 16 to 18, 2020

Join us for a 2-day course and bonus half-day skills workshop. In addition to our local experts in nursing, neonatology, neurology, and neuroradiology, we have several international experts in neuro-monitoring and neuro-protection joining us to share their knowledge and passion.

### Location:

Li Ka Shing Conference Center  
Stanford University, Palo Alto, CA

## Our Invited Guest Faculty



### Donna Ferriero, MD, MS

*Distinguished Professor of Neurology & Pediatrics  
Director, Neonatal Brain Disorders Laboratories  
UCSF Weill Institute for Neurosciences  
San Francisco, USA*

Dr Donna Ferriero is the recently retired Chair of Pediatrics at UC San Francisco and Director of the Neonatal Brain Disorder Laboratories. Her laboratory has been critical in defining the relationship of selectively vulnerable populations of neural cells during maturation-dependent injury.



### Lena Hellström-Westas, MD, PhD

*Professor of Perinatal Medicine  
Senior Consulting Neonatologist  
Uppsala University Hospital  
Uppsala, Sweden*

Dr. Lena Hellström-Westas is one of the pioneering clinical researchers on amplitude-integrated EEG monitoring with a focus on early prediction of outcome in asphyxiated infants and preterm infants, seizure detection, sleep and neonatal pain assessments.



### Gabriel Variane, MD

*Founder of PBSF  
Protecting Brains & Saving Futures  
Medical Director, NeuroNICU  
Santa Casa de Sao Paulo, Brazil*

Dr. Variane is the founder of PBSF – a company dedicated to education and implementation of neuro-protective strategies in different NICU's across Brazil. He is the Medical Director of the NeuroNICU of Santa Casa de Sao Paulo and a Neuro NICU program consultant and neonatologist at Grupo Santa Joana Hospitals.

## CONFERENCE AGENDA

**Monday, March 16**  
8 am to 5 pm

### 4 Pillars of NeuroNICU Care

*Kathi Salley Randall, MSN, NNP-BC*

### Why the Global NeuroNICU Trend ?

*Looking back over 10 years  
Donna Ferriero, MD MS*

### Fetal and neonatal brain development:

*Timing, significance, and outcomes  
Courtney Wusthoff, MD MS*

### Neurological Examination of the Newborn

*Courtney Wusthoff, MD, MS*

### IVH and white matter injuries: Understanding the pathophysiology, and risks for the small and big baby

*Valerie Chock, MD MSEpi*

### HIE – Insult, impact, & interventions

*Krisa Van Meurs, MD*

### Systemic Implications of Hypothermia:

*Bedside Management Pearls  
Shannon Tinkler, BSN, RNC-NIC*

### LUNCH—PROVIDED

### The Mild HIE Dilemma

*Sonia Bonifacio, MD*

### The past, present and future of neonatal neuroprotection

*Donna Ferriero, MD MS*

### Psychological support in the NICU to effect short and long-term neonatal outcomes—Dr. Richard Shaw

**Tuesday, March 17**  
8 am to 5 pm

### Short-Term and Early Neurodevelopmental Outcomes of Extremely Preterm Infants

*Susan R. Hintz, MD MS*

### aEEG in Every Day Practice

*Lena Hellström-Westas, MD, PhD*

### NIRS in the NICU—Gabriel Variane, MD

### Diagnosis and management of neonatal seizures—Courtney Wusthoff, MD, MSEpi

### Comfort Care vs Critical Care

*Sonia Bonifacio, MD*

### Neuro-Imaging 101:

*What the NICU Clinician needs to know  
Drs. Carolina Guimaraes & Sonia Bonifacio*

### Telemedicine to improve care and outcomes for infants with HIE

*Gabriel Variane, MD*

### 5 Ways to Offer Neuro-Protective Care in the NICU—Kathi Salley Randall

### Controversies of Pain and Sedation Medication Management

*Lena Hellström-Westas, MD, PhD*

### Looking back to look forward: The parent's perspective of life in the NICU and beyond LPCH Family-Centered Care Department

## WORKSHOP SCHEDULE

**Wednesday, March 18**  
10am to 2 pm

10 am to 12 pm—Session 1 & 2

12 noon  
**Networking Lunch Presentation:  
"How to Create a Neuro NICU" &  
Panel Discussion**

1 pm to 2 pm—Session 3

*Reserve a seat in your favorite track during registration.*

## Track A

### Topics to include:

- aEEG + NIRS sensor application, protocols, monitor set up & case studies

### Facilitated by:

*Valerie Chock, Lena Hellström-Westas, Kathi Randall, Shannon Tinkler*

## Track B

### Topics to include:

- Neuroimaging, Cooling Cases and Clinical QI Measures for Neuroprotection

### Facilitated by:

*Sonia Bonifacio, Celia Glennon, Carolina Guimaraes, Krisa Van Meurs,*

## Track C

### Topics to include:

- Multi-Modal Brain Monitoring Cases, Writing reports on brain monitoring and using AI to improve seizure detection

### Facilitated by:

*Valerie Chock, Lena Hellström-Westas, and Gabriel Variane*

## Register Online

<https://tinyurl.com/neuronicu-march>



# Retinopathy of Prematurity (ROP) Can We Do Better?

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

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

Perhaps the most famous victim of ROP is Stevie Wonder. Born 6 weeks prematurely in 1950, he was one of many babies who had their incubators flooded with oxygen. (1) While Mr. Wonder may be one of the earliest and most recognisable cases of ROP, by the time he came along the use of supplemental oxygen in the management of infants had been a therapeutic intervention in the "first world" since the 1930s and 1940's. (2)

***"While Mr. Wonder may be one of the earliest and most recognisable cases of ROP, by the time he came along the use of supplemental oxygen in the management of infants had been a therapeutic intervention in the "first world" since the 1930s and 1940's. (2)"***

Perhaps not surprisingly, the first case of what is now referred to as ROP was discovered in 1941. Between 1942 and 1945, a further 117 cases were discovered. The link between the new condition (then referred to as Retrolental Fibroplasia) and oxygen therapy was established in the early 1950s but by 1953 10,000 cases of blindness due to ROP had been diagnosed. (2)

***"Without fully understanding the positive role of oxygen therapy, clinicians in the 1950s and 1960s restricted oxygen use during the first 2 to 6 days of life. This practice virtually eliminated ROP; however the incidence of spastic diplegia increased to about 25%."***

Without fully understanding the positive role of oxygen therapy, clinicians in the 1950s and 1960s restricted oxygen use during the first 2 to 6 days of life. This practice virtually eliminated ROP;

however the incidence of spastic diplegia increased to about 25%. Furthermore, it was later estimated that for every case of blindness prevented by this practice, 16 babies died. Conversely, when oxygen was administered over 17 to 25 days or more, the rate of ROP increased to over 25% while spastic diplegia was seen in only 2-5% of infants. (2) This observation is similar to later studies on the use of higher or lower oxygen levels in infants.

Recent data suggests that we are not winning the war against ROP. A 2018 study found that 41.3% of premature infants developed ROP, and 12.5% of these infants are expected to develop severe ROP, almost exclusively in the sub-1251 gram cohort. (3) In the U.S. alone this represents over 2000 cases of blindness per year. (2) On the surface this is bad enough, considering the fact that blindness is associated with severely abnormal neurodevelopmental outcomes. Over half of those with unfavourable vision have a severe disability: 77% are unable to provide self-care; 50% have continence issues; 43% have motor disabilities, and 66% have altered personal-social skills. This represents a 3 to 10-fold increase compared to those with good vision. (2)

Technology in the NICU has exploded since the first cases of ROP were discovered. Nevertheless, this morbidity clearly remains one of the most significant sequelae of NICU patients, more than chronic lung disease, (4) one of the main foci of NICU quality improvement.

The advent of oxygen blenders and oxygen analyzers have allowed accurate FiO<sub>2</sub> delivery and measurement, and pulse oximetry (SpO<sub>2</sub>) helps monitor blood oxygen levels in almost real-time. Still, while we know oxygen poses a substantial risk for the development of ROP, just how much oxygen to give (or not give as the case may be) remains a topic of hot debate.

Just as in the 1950s and 1960s, more recent studies have demonstrated the conundrum faced by NICU clinicians: give more oxygen and get more ROP or give less oxygen and face higher mortality; a perfect "catch 22". Or is it?

It is likely, not surprising to most clinicians that maintaining low serum oxygen levels (PaO<sub>2</sub>) may have deleterious consequences and that maintaining high SpO<sub>2</sub> levels has different, although still dire consequences. Aside from higher rates of ROP, higher oxygen levels have been associated with CLD, periventricular leukomalacia (PVL), and may be a factor in white matter injury and carcinogenesis. In the STOPROP trial, there were more respiratory-related deaths in the higher SpO<sub>2</sub> group. (2)

While we are confident high SpO<sub>2</sub> is bad, the question is how low those levels can be and still be considered safe. While related studies consistently indicate that low SpO<sub>2</sub> is associated with higher mortality, this may not translate to higher mortality in clinical practice. Unlike in a study situation, bedside caregivers are not likely to allow their patients to have low SpO<sub>2</sub> for an extended length of time.

Consider the example of the unit in which I work. Concerned about possible increased mortality led to a shift in targeted SpO<sub>2</sub> and related alarms upward from 88-92% with the "hard" alarm set at 80% and the high alarm at 96% to a target of 90-94% and an increase in the "hard" alarm to 85%. Some were surprised at the resulting significant increase in the incidence of ROP, an increase



significant enough to result in a resumption of previous parameters except for the low “hard” alarm being raised to 82%. Why did this happen?

Alarm fatigue is a continuing problem in intensive care units, NICU's included. The higher SpO<sub>2</sub> targets and related alarm parameters resulted in more alarms, which, in turn, led bedside caregivers to increase FiO<sub>2</sub> to achieve higher SpO<sub>2</sub> values since a high SpO<sub>2</sub> alarm is typically quieter and less annoying than a low alarm. While this happens with lower targeted SpO<sub>2</sub> as well, when targets were increased, the resulting SpO<sub>2</sub> increased further. The end result was nothing if not predictable.

---

*“The visualisation of the vocal cords with the nasal CPAP apparatus in place is perhaps the most challenging aspect of MIST.”*

---

Speaking of alarm fatigue, in my opinion, the design of saturation monitors contributes to the practice of keeping babies' SpO<sub>2</sub> higher than ideal. A high SpO<sub>2</sub> alarm is generally a gentle “bing... bing... bing...” while a low SpO<sub>2</sub> sounds roughly like the sky is falling. While a delay function or longer averaging time is available, there seems to be a reluctance to use them. As well, the algorithms used may not allow enough time for a baby to self-recover. The monitors I am accustomed to using also send an alarm to the staff communication devices even if the alarm is silenced on the monitor immediately. Bedside caregivers are nothing if not human, and human nature leads to infants being maintained in enough oxygen to minimise annoying low SpO<sub>2</sub> alarms. A common lament is “you're not sitting here all day” when FiO<sub>2</sub> is weaned. While I am sympathetic, one's purpose at the bedside is not one's own appeasement.

All saturation monitors are not created equal. If the monitor dutiful-

ly displays a SpO<sub>2</sub> of 89% when lying in the bed its reliability must be called into question. The best monitors resist motion artifact and extraneous light interference fairly well; others, not so much. Servo-controlled combined blender/saturation monitor systems hold much promise; however, they are inevitably only as good as the signal received. Given a baby's movement, low perfusion, and use of bilirubin lights, any monitor used to servo-control a blender must be up to the task. Even without servo-control, I have often witnessed FiO<sub>2</sub> being increased for a “desaturation” when the signal display on the monitor is clearly showing artifact or a poor signal. There is evidence that the use of Masimo™ signal extraction technology may significantly reduce the incidence of ROP. (2)

I was told many years ago that oxygen desaturation in isolation and not associated with bradycardia was likely clinically insignificant. Although I am unaware of any evidence to support this statement, it may make sense from a physiological standpoint. I recall viewing a poster at a Pediatric Academic Societies conference several years ago that looked at hypoxia in rats. One group was exposed to 100% nitrogen for 10 minutes, another group was exposed to 100% nitrogen first for 5 minutes and then later for 10 minutes. While all in the former group died, surprisingly all those in the latter group survived. This raised two questions in my mind: 1) if desaturations are normal in the premature infant in utero and 2) if they serve to condition the brain for the relative hypoxemia of birth. After all, as humans, we experience the lowest SpO<sub>2</sub> levels at the hour of our birth and that of our death.

With judicious bedside monitoring, I believe it is safe to target SpO<sub>2</sub> of 88-92% in premature infants, with a “hard” low alarm of 80%. Babies should be given a minute or so to recover on their

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own without increasing FiO<sub>2</sub>, and the bedside caregiver should not allow SpO<sub>2</sub> to remain low for long. Adding a time-weighted factor to low alarms would make this even safer.

It can be easy to be discouraged to see the lack of improvement in ROP rates and evidence that does not support low SpO<sub>2</sub>: “truly effective care based on systematic reviews of the evidence obtained from randomized controlled trials is still not possible in relation to prevention of ROP, clearly not for O<sub>2</sub> therapy, PaO<sub>2</sub> and SpO<sub>2</sub> levels”. (2) Be that as it may, there are practices that respiratory clinicians and bedside caregivers should emulate, and those that should be avoided.

There is no debate about the deleterious effect of hyperoxia on the developing eye; rather, the debate is over what SpO<sub>2</sub> levels constitute hyperoxia in the premature infant. Knowing that oxygen also wreaks havoc on the developing lung, it behooves clinicians to use as little as possible to safely meet the needs of the patient.

It is all too common for a responder to a low SpO<sub>2</sub> alarm to increase FiO<sub>2</sub> and then leave the room to attend to another patient or task. Too often, the FiO<sub>2</sub> is left increased, and if the FiO<sub>2</sub> is normally 0.21, the high alarm is set at 100% and will give no warning of resulting hyperoxia. As a standard design feature, ventilators, including equipment providing non-invasive support (NIV), should incorporate a temporary FiO<sub>2</sub> increase function available in all modes. This would reduce inadvertent sustained increases in FiO<sub>2</sub>.

It is also common practice in the NICU to pre-oxygenate babies when handling. This is sometimes done several minutes in advance, and the degree of increase is often not uniform, despite whatever policy may dictate. Pre-oxygenation should be done for as little time as possible, and certainly not minutes prior to handling. This increase should be limited as a matter of policy to 5-10% above baseline unless the need for more is demonstrated. As well, any infant whose SpO<sub>2</sub> is >96% with a FiO<sub>2</sub> of 0.21 should not be pre-oxygenated at all, rather FiO<sub>2</sub> should be increased as required. SpO<sub>2</sub> level cannot be reliably estimated when PaO<sub>2</sub> is high, and a SpO<sub>2</sub> of 100% may represent a PaO<sub>2</sub> of 60 mmHg or 400 mmHg. (2)

When FiO<sub>2</sub> is increased, it should be to the lowest level to provide adequate SpO<sub>2</sub> and then returned to baseline judiciously as tolerated so as not to result in rebound desaturation. Rapid swings in PaO<sub>2</sub> lead to repeated vasoconstriction and dilation, which results in reperfusion injury.

The increasingly common use of NIV raises another important point. Avoidance of high SpO<sub>2</sub>, as well as widely fluctuating SpO<sub>2</sub> from birth and during the first weeks, thereafter reduces the rate of severe ROP without increased mortality and results in lower rates of CLD. Given the frequency of bradycardia and desaturation episodes in very premature infants receiving NIV, we should be monitoring ROP rates in this group of patients very carefully. Some believe that proper, lung-protective ventilation with an endotracheal tube is preferable to NIV in the micro-premature infant. The truth will no doubt reveal itself, provided we are looking for it.

Permissive hypercapnia has become an accepted practice to reduce CLD, although CO<sub>2</sub> should be controlled as carefully as possible in the first few days of life. While CO<sub>2</sub> has the opposite effect on cerebral and ocular vasculature, it makes sense that large, rapid swings in CO<sub>2</sub> levels would have the same deleterious effect as oxygen and may be a risk factor for ROP. A British study did not find an association with PaCO<sub>2</sub>/TcPCO<sub>2</sub> fluctuations and ROP, although it does not indicate how rapidly these fluctuations occurred.<sup>5</sup> Another article lists high PaCO<sub>2</sub> and low pH as possible risk factors,<sup>6</sup> and within search results for “CO<sub>2</sub> and ROP” one will

find a law firm linking CO<sub>2</sub> “Neonatal Breathing Mismanagement” and adverse outcomes including ROP. (7) Given the risk of litigation that raises it is likely a good idea to monitor CO<sub>2</sub> carefully and adjust ventilation accordingly.

As with all things medical, best practice is a moving target. Evidence drives practice, and evidence has been known to change. In the here and now, clinicians must work with the evidence we have. That evidence suggests that, yes, we can do better.

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

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## Cultural Humility in the NICU

Alison R. Hartman, BA, Pamela A. Geller, Ph.D., Chavis Patterson, 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.*

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Educate. Advocate. Integrate.

The scope of NICU care was once focused solely on the medical needs of the neonate. Today, compelled by an international movement towards family-centered care, many NICU environments now prioritize attending to the psychosocial needs of the patient's family. As society has grown increasingly attuned to the unique experiences and needs of diverse populations, so too is healthcare adopting the idea of cultural humility. Cultural humility goes above and beyond cultural sensitivity or competency; rather, practicing cultural humility in healthcare "incorporates a lifelong commitment to self-evaluation and self-critique, to redressing the power imbalances in the patient-physician dynamic, and to developing mutually beneficial and non-paternalistic clinical and advocacy partnerships" (Tervalon & Murray-Garcia,

1998). Each person who comes through the NICU, be they patient, provider, or family member, brings with them a unique experience of healthcare and the medical environment. As such, practicing cultural humility when serving NICU family members is paramount. After all, the provision of good psychosocial care is not, and should not be; one size fits all.

***"The First 1,000 Days was initiated in 2010 by Secretary of State Hillary Clinton in response to ground-breaking scientific evidence that identified a powerful window of opportunity from a woman's pregnancy to a child's 2nd birthday when nutrition has a long-term impact on the future health and development of both children and societies."***

What space, if any, should religion and spirituality occupy in a modern NICU? Research suggests that patients and providers may hold incongruent attitudes towards the role and relative importance of religion, spirituality, and folk medicine in the NICU; one study found that 45% of professionals reported that they prefer parents not express their religious or spiritual beliefs (i.e., engage in religious or spiritual practices) in the NICU setting (Lloreda-Garcia, 2017). Delivering care that acknowledges and accepts parental religious and spiritual practices can and should be a priority in the NICU, particularly surrounding difficult end-of-life decisions.

Religion and spirituality can be an important means to help parents cope with life in the NICU.

While some parents with a strong religious background may experience a deepening of their faith as a result of the NICU experience (Brelsford & Doheny, 2016), others may demonstrate a more questioning or negative religious coping style (i.e., questioning "why me?" or feeling abandoned by or angry at God). Negative religious coping has been associated with poor family cohesion and the use of denial (Brelsford et al., 2016). A growing body of literature has revealed that religion and spirituality, particularly spiritual coping skills, may protect against poor mental health and grief outcomes in NICU parents following the death of a child (Hawthorne, 2013). In response to such findings, a subset of NICUs around the world has begun to implement spiritual care interventions for families. Two recent randomized controlled trials reveal that spiritual care interventions may increase the quality of life (Sekhvatpour et al., 2018) and decrease stress (Küçük Alemdar et al., 2018) in NICU parents. While some culture- or belief system-specific guidelines do exist in the literature – for example, culturally competent guidelines for withdrawal of life-sustaining treatment from a Hindu perspective (Das, 2012) – there currently are no written guidelines for standard of care in the NICU. One strategy that providers might use is to ask parents for their input while remaining curious and open to their feedback. For example, providers might ask questions such as: How does your culture or religion view the end of life? How might we best support your religious practices surrounding these decisions?

Within the United States, the ethnic-racial background has been associated with differential experiences. People of color may experience unique stressors in the NICU setting, putting them at increased risk for negative psychosocial outcomes. A recent study found that Black parents were less satisfied than their White peers with the nursing care they received in the NICU, wanting compassionate and respectful



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communication but feeling dissatisfied by the level of support from nurses (Martin et al., 2016). Chinese American parents similarly have reported limited support from healthcare providers in the NICU. Parents from an Asian cultural background may be particularly distressed by uncertainty surrounding the impact of their infant's current illness on the infant's future (Lee et al., 2005).

Mother's own milk (MOM) feeding is associated with significant health benefits in preterm infants (Schanler, 2007). One recent study revealed that, although initiation rates of mother's own milk (MOM) feedings were similar across racial/ethnic groups, Black infants were significantly less likely to receive MOM at NICU discharge (Patel et al., 2019). This relationship was, in part, mediated by daily pumping frequency in the first 14 days postpartum, a factor that is potentially modifiable with support from NICU staff and the provision of free breast pumps to socioeconomically disadvantaged mothers.

Perinatal/postpartum depression (PPD) is a debilitating condition that can have a lasting impact on the mother and baby. PPD has been associated with impaired maternal-infant interactions (Reck et al., 2004), decreased parenting quality and effectiveness (Paulson et al., 2006), and negative infant health and cognitive outcomes (O'Hara & McCabe, 2013). A study by Barroso and colleagues (2015) revealed that, amongst a sample of mostly Black and Latina mothers, preterm birth was associated with a significant increase in PPD symptoms. This is particularly notable due to the fact that, compared to their non-Hispanic White peers, 1) African American, Hispanic, and Asian/Pacific Islander women may be at an increased risk for postpartum depression (Liu & Tronick, 2013) and 2) non-White women, particularly non-Hispanic Black women, are at a dramatically increased risk for preterm birth (Martin, Osterman, & Sutton, 2010). For an overview of empirically supported interventions to reduce PPD in NICU mothers, practice guidelines, and information about the increased risk for PPD amongst "ethnic minority status and low socioeconomic status" women, please see Hall et al., 2019.

In light of these pervasive disparities, the promotion of cultural literacy, and the practice of cultural humility in the provision of NICU care is crucial. One of the first intervention studies to mention cultural sensitivity in the NICU aimed to match NICU mothers with language, culture, and ethnically congruent peer-support partners (Preyde, 2007). This type of matched, peer-to-peer support model has been shown to increase parent satisfaction and access to support services (Ardal et al., 2011). One study reported that increased levels of nursing support were linked to increased parenting efficacy amongst parents of color in the NICU (Denney, 2004).

Communication barriers, such as parental lack of fluency in the primary language of NICU staff (i.e., parents in the United States whose preferred language is not English) and low literacy, have been identified as major stressors and sources of anxiety for NICU parents (Denney et al., 2001; Fabiyi et al., 2012). Facilitating clear communication between staff and parents is a cornerstone of family-centered care. Parents are able to play an active role in their infant's care when their needs, questions, and opinions can be conveyed clearly to the medical team. Many modern NICUs utilize language interpretive services in an attempt to bridge the communication gap. This may come in the form of in-person interpretation or telephonic. While this approach is preferred by professionals, it is important to note that some parents may wish to be independent and speak for themselves, or to translate through a trusted friend or healthcare professional (Patriksson et al., 2019). Low-literate parents and family members may benefit from additional interventions to increase communication of important information, such as web-based education utilizing visual aids, audio

recordings, and simplified text (Choi & Bakken, 2010).

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***“Mindfully delivering culturally humility-consistent, individually tailored care to each family that enters the NICU may seem like a formidable task.”***

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Mindfully delivering culturally humility-consistent, individually tailored care to each family that enters the NICU may seem like a formidable task. In an attempt to make the provision of this type of care actionable in the NICU setting, Wiebe and Young (2011) proposed the following four tenets, which “are infused with the sociopolitical history and dynamics of culture, ethnicity, immigration, and colonization that patients bring to their experience of health and health care.” Beneath each tenet, we offer recommendations for implementation in the NICU.

1. Building a provider-patient relationship of caring and trust
  - a. Take time to get to know your patients' families. Ask them questions about their past experiences of healthcare, hospitals, or the NICU.
  - b. Ask parents for their opinions or preferences whenever possible, and take steps to make sure that the family's wishes are honored.
  - c. When in doubt, “strive to understand rather than inform” (Perryman et al., 2019).
2. Engaging in respectful and appropriate communication
  - a. Ask parents, especially parents whose primary language does not match yours, how they would prefer to communicate (e.g., directly with the provider themselves, through an interpreter, through a language-matched trusted healthcare provider). If interpreter services are utilized to facilitate communication, efforts should be made to foster a relationship of trust between the interpreter and the family.
  - b. Mirror word and language choices that parents make when communicating with you. For example, family members may express their distress as “anxiety,” “stress,” “fear,” “feeling overwhelmed.” Utilize the individual's own words in your communications.
3. Making available culturally responsive and accessible social and spiritual supports
  - a. Do your research. If a family comes in with a cultural or religious background with which you are unfamiliar, educate yourself. In addition, ask the individuals themselves to describe their beliefs and preferences. Serve as a liaison to work with the family and hospital system to carry out parental preferences when possible (particularly with cultural practices surrounding death/dying and treatment of remains).
  - b. Support efforts to expand social and spiritual supports within your hospital, department, unit, clinic, and team. Make it a priority.



- c. Be an ally to families. Help to connect families with social and spiritual supports within the NICU and hospital, as well as in the larger community.
  - d. Involve NICU graduate families as cultural humility consultants, as well as providers of additional support for current families who share faiths/backgrounds.
4. Fostering a welcoming and flexible organizational environment
- a. Be an advocate for diversity and inclusivity. This includes staffing and hiring decisions to create a diverse NICU staff that reflects the patient population served by the NICU.
  - b. Do not fear what you do not know. Be open to welcoming new practices, programming, and supports into your NICU environment.
  - c. Seek out and promote educational opportunities (e.g., workshops, trainings, webinars) to expand your knowledge and that of your fellow NICU providers.
  - d. Be introspective. Be aware of your own personal and cultural biases (both implicit and explicit), reflect on how your cultural context has shaped your perception of your role as a provider, and consider how your unique perspective differs from that of your patients and other NICU staff members.
  - i. To aid in your understanding of your biases, consider taking an Implicit Association Test from Project Implicit®: <https://implicit.harvard.edu/implicit/takeatest.html>.

Just as life-saving medical interventions are tailored to fit each neonate's unique medical needs, psychosocial care and support for families must also be tailored to address the social, emotional, cultural, and spiritual needs of the family. Prioritizing culturally informed, humility-based family-centered care has the potential to positively impact a NICU family long after they leave the hospital.

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## National Perinatal Association PERINATAL SUBSTANCE USE

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Perinatal providers promote better practices when they adopt language, attitudes, and behaviors that reduce stigma and promote honest and open communication about perinatal substance use.



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

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

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#### Who Can Help

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- cardiologists
- nutritionists
- CSHCN - Programs for Children with Special Health Care Needs

### Special Developmental Needs

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

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

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

#### Who Can Help

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

### Special Educational Needs

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

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

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

#### Who Can Help

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





My NICU Network



National Perinatal  
Association



Patient+Family  
Care



NICU Parent  
Network

# Online NICU Staff Education Program

## Caring for Babies and their Families: Providing Psychosocial Support in the NICU

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Looking to improve  
NICU staff skills in  
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This conference provides education and networking opportunities to healthcare professionals who provide care for pediatric patients with a focus on advances in therapeutics and technologies including telemedicine and information technologies. Along with featured speakers, the conference includes abstract presentations on research on advances in these areas. Registration open mid June, 2019!

<http://paclac.org/advances-in-care-conference/>

*Physician, Nursing, and Respiratory Care Continuing education hours will be provided.*

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Call for Abstracts – Deadline December 15, 2019

Abstract submission: As are currently being accepted. Download the Abstract Guidelines from the website.

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Glendale, CA 91202

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## THE BRETT TASHMAN FOUNDATION

The Brett Tashman Foundation is a 501(c)(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](http://TheBrettTashmanFoundation.org) or phone (909) 981-1530.

Newly-Validated Online  
NICU Staff Education

## Caring for Babies and their Families: Providing Psychosocial Support to NICU Parents

based on the "Interdisciplinary Recommendations for Psychosocial Support for NICU Parents."

Contact [sara@myNICUnetwork.com](mailto:sara@myNICUnetwork.com) for more information.

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- National Perinatal Association
- Patient + Family Care
- Premie Parent Alliance



[www.myNICUnetwork.com](http://www.myNICUnetwork.com)



Transform Your NICU

# The Gap Baby: An RSV Story



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



## The National Coalition for Infant Health advocates for:

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

[www.infanthealth.org](http://www.infanthealth.org)



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# Federal Spending and Policy Priorities take Center Stage Ahead of FY2021 Budget Proposal

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

*The Alliance for Patient Access ([allianceforpatientaccess.org](http://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.*



February is an important month for advocates to hear from the federal government about their 2020 - 2021 priorities. This being a Presidential election year, messaging on policy priorities from the Executive Branch, Congress and candidates can impact federal, state, and local races, but also what actually gets funded.

On February 4th, President Donald Trump stood before a joint session of Congress and delivered his annual State of the Union Address. Although no laws or regulations were directly created from the address, it gave the American people a glimpse into the priorities of the Administration for the coming year. As expected, access to healthcare and drug costs were featured.

A highlight of the speech for maternal and infant health advocates was President Trump's call for an additional \$50 million to fund neonatal research. The \$50 million request would help ensure that premature babies are given the opportunity to thrive despite their many challenges and extensive, treatment needs at birth.

In the second week of February, the President will submit the Administration's Fiscal Year 2021 budget proposal. Although it is not yet known what will be included in the President's FY 2021 budget proposal, new and continuing programs to support maternal and

infant health are likely to be included. These programs include:

- Funding for Maternal, Infant, and Early Childhood Home Visiting Services

The MIECHV Program funds support communities to provide voluntary, evidence-based home visiting services to women during pregnancy, and to parents with young children up to kindergarten entry. The MIECHV Program supports pregnant women and families, particularly those considered at-risk, as they raise children who are physically, socially, and emotionally healthy and ready to succeed.

***“The MIECHV Program funds support communities to provide voluntary, evidence-based home visiting services to women during pregnancy, and to parents with young children up to kindergarten entry. ”***

Of note, “over the past seven years, the MIECHV Program has provided over [five] million home visits. Almost three-fourths of families participating in the program had household incomes at or below 100 percent of the Federal Poverty Level, and 76 percent of adults and children relied on Medicaid or the Children's Health Insurance Program.” (1)

- Funding for Maternal Health

Through the State Maternal Health Innovation (State MHI) Program, the Health Resources & Services Administration (HRSA) awards funding (approximately \$18.7 million in new funding was released in September 2019) through nine cooperative agreements to assist states in addressing disparities in maternal health and improving maternal health outcomes, with an emphasis on preventing and reducing maternal mortality and severe maternal morbidity. (2)

Also, the Supporting Maternal Health Innovation (Supporting MHI) Program that serves as both a national resource center and provides “capacity-building assistance to HRSA's maternal health grantees and other stakeholders as they engage in efforts to reduce maternal mortality and [severe maternal morbidity] (SMM)

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through innovative and evidence-informed strategies.” Last year the program was implemented through \$2.6 million in HRSA awards to grantees.

Finally, the Alliance for Innovation on Maternal Health (AIM) – Community Care Initiative, a nearly \$2 million HRSA program in 2019, to increase the reach of an existing AIM program, by focusing on maternal safety in outpatient/ non-hospital settings and addressing preventable maternal mortality among pregnant and postpartum women in a community-based setting.

**“Finally, the Alliance for Innovation on Maternal Health (AIM) – Community Care Initiative, a nearly \$2 million HRSA program in 2019, to increase the reach of an existing AIM program, by focusing on maternal safety in outpatient/ non-hospital settings and addressing preventable maternal mortality among pregnant and postpartum women in a community-based setting.”**

• **Gabriella Miller Kids First Act**

Launched in 2015, the Gabriella Miller Kids First Pediatric Research Program focuses on the relationships between birth defects and childhood cancer. Since its enactment, 26 patient cohorts have been chosen for the program, and more will be chosen in the near future. The program revolves around whole-genome sequencing in children's birth defects and childhood cancer. The goal is to discover new clinical pathways through whole-genome sequencing. (3)

• **Maternal, Infant and Early Childhood Home Visiting Program (MCHB)**

The MCHB, in conjunction with the Administration for Children and Families, funds states to create volunteer-based programs aimed at increasing health and awareness in the community. These programs create the opportunity for health, social service, and child development professionals to plan regular visits to homes and al-

Babies are just tiny adults, right? So ... half?

Infants need drugs tested and approved just for them.

Centers for Clinical Trials Administration | NCJFH National Coalition for Infant Health

# Still a Premie?

*Some preemies are born months early, at extremely low birthweights. They fight for each breath and face nearly insurmountable health obstacles.*

**But that's not every preemie's story.**

**Born between 34 and 36 weeks' gestation?** **STILL A PREMIE**

*Just like preemies born much earlier, these "late preterm" infants can face:*

- Jaundice
- Feeding issues
- Respiratory problems

And their parents, like all parents of preemies, are at **risk for postpartum depression and PTSD.**

**Born preterm at a "normal" weight?** **STILL A PREMIE**

*Though these babies look healthy, they can still have complications and require NICU care.*

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

**Born preterm but not admitted to the NICU?** **STILL A PREMIE**

*Even if preterm babies don't require NICU care, they can still face health challenges.*

Those challenges can extend through childhood, adolescence and even into adulthood.

<p><b>Some Premies</b></p> <ul style="list-style-type: none"> <li>Will spend weeks in the hospital</li> <li>Will have lifelong health problems</li> <li>Are disadvantaged from birth</li> </ul>	<p><b>All Premies</b></p> <ul style="list-style-type: none"> <li>Face health risks</li> <li>Deserve appropriate health coverage</li> <li>Need access to proper health care</li> </ul>
---	---

**NCJFH** National Coalition for Infant Health  
 Protecting Access for Premature Infants through Age Two  
[www.infanthealth.org](http://www.infanthealth.org)

low parents to create a better environment for their children, while also improving their family's overall health. (4)

## Looking into Fiscal Year 2021

Taking a dive into what has been appropriated previously can give insight into what to expect from the upcoming appropriations cycle. However, while the process begins in February, final funding and priorities will not be known until November or December 2020.

As mentioned above, the President's proposed FY 2021 budget is expected to be submitted to Congress shortly. At that point, advocates will have more clarity on the Administration's intent to fund and support programs that support maternal and infant health needs.

Congress will thereafter have its role in using the budget as a blueprint, determining their roadmap on funding the programs mentioned above, and/or creating new programs to serve the health outcomes of mothers and children.

### References:

1. <https://www.hhs.gov/about/news/2019/09/12/hhs-awards-374-million-programs-supporting-maternal-child-health.html>
2. <https://www.hhs.gov/about/news/2019/09/12/hhs-awards-374-million-programs-supporting-maternal-child-health.html>
3. <https://commonfund.nih.gov/kidsfirst>
4. <https://mchb.hrsa.gov/maternal-child-health-initiatives/home-visiting-overview>

The author has not indicated any disclosures.

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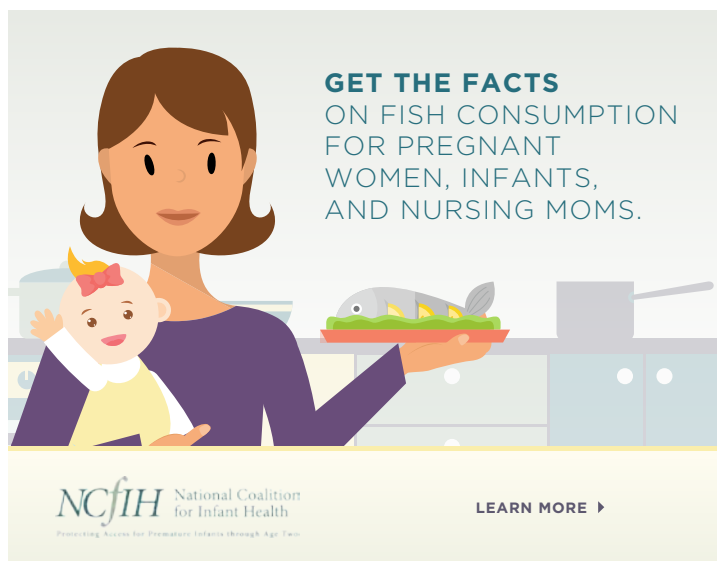
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# ADVANCE REGISTRATION FORM

ADVANCES IN PEDIATRICS | MARCH 28, 2020

Los Angeles, California

Sponsored by AAP California Chapter 2

## CONTACT INFORMATION (PLEASE PRINT)

Name \_\_\_\_\_  
FIRST MI LAST DATE

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City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_ ABP ID \_\_\_\_\_

Email \_\_\_\_\_

## ATTENDEE PROFILE (PLEASE MARK)

MD  DO  RV  NP  PA-C  OTHER \_\_\_\_\_

## SYMPOSIUM REGISTRATION SATURDAY, MARCH 28 (PLEASE CIRCLE TUITION AMOUNT)

TUITION FEE	EARLY BIRD (by February 29 at midnight)	By March 27	At-The-Door
Physician Member (AAP CA Chapter 2 only)	\$169. <sup>00</sup>	\$230. <sup>00</sup>	\$290. <sup>00</sup>
Physician Non-Member (See Join option below)	\$225. <sup>00</sup>	\$300. <sup>00</sup>	\$350. <sup>00</sup>
Pediatric Residents (by circling the tuition amount to the right, "I attest that I am currently a Resident")	\$75. <sup>00</sup>	\$100. <sup>00</sup>	\$150. <sup>00</sup>
Medical Students	\$50. <sup>00</sup>	\$99. <sup>00</sup>	\$150. <sup>00</sup>
Allied Health Professionals	\$169. <sup>00</sup>	\$190. <sup>00</sup>	\$225. <sup>00</sup>
Physician Emeritus & Retired	\$169. <sup>00</sup>	\$190. <sup>00</sup>	\$225. <sup>00</sup>

\*Join the Chapter option: Pay Member Rate plus \$99 to Join AAP-CA2

## TRACK SELECTION

- Track #1: General Pediatrics     Track #2: Hospital Pediatrics     Track #3: Pediatric Policy
- I am seeking MOC Part 2 credit. Please provide your ABP ID \_\_\_\_\_
- Special dietary requests \_\_\_\_\_

## MINDFULNESS SESSION (COMPLIMENTARY, pre-registration required to attend. Offers CME)

- I plan on attending.

## THREE WAYS TO REGISTER (PLEASE SELECT ONE)

1. **ONLINE** Visit our website at [www.aapca2.org](http://www.aapca2.org)
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Time is precious, just like your patients.





# Respiratory Syncytial Virus:

## How you can advocate for babies this RSV season

Track national data and trends at the CDC's website [www.cdc.gov/rsv](http://www.cdc.gov/rsv)



Identify babies at greatest risk



including those with CLD, BPD, CF, and heart conditions

Teach families how to protect



their babies from respiratory infections

Advocate for insurance coverage for palivizumab prophylaxis so more babies can be protected \*



Use your best clinical judgement



when prescribing RSV prophylaxis

Tell insurers what families need



and provide the supporting evidence



\*See the NPA's evidence-based guidelines at [www.nationalperinatal.org/rsv](http://www.nationalperinatal.org/rsv)

## Survey Says: RSV

RESPIRATORY SYNCYTIAL VIRUS, or RSV, is a dangerous virus that can lead to:

- Hospitalization
- Lifelong health complications
- Death

for infants and young children



ACCORDING TO A NATIONAL SURVEY, Specialty Health Care Providers say:

- 80% They treat RSV as a priority, "often" or "always" evaluating their patients
- 77% RSV is the "most serious and dangerous" illness for children under four
- 77% Barriers to access and denials from insurance companies limit patients' ability to get preventive RSV treatment



But Parents are Unprepared.

- 18% Only 18% know "a lot" about RSV
- 22% Only 22% consider themselves "very well" prepared to prevent RSV



RSV EDUCATION & AWARENESS CAN HELP

After parents learned more about RSV, they were:

- 65% "More concerned" about their child contracting the disease
- 67% Likely to ask their doctor about RSV



NCJIH National Coalition for Infant Health  
Preventing RSV in Preterm Infants through Age Five

Learn More about RSV at [www.infanthealth.org/rsv](http://www.infanthealth.org/rsv)

# Postpartum Revolution

@ANGELINASPICER



## OPIOIDS and NAS

When reporting on mothers, babies, and substance use

## LANGUAGE MATTERS



### I am not an addict.

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



### I was exposed to opioids.

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



### NAS is a temporary and treatable condition.

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



### My mother may have a SUD.

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



### My potential is limitless.

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

Learn more about  
Neonatal Abstinence Syndrome  
at [www.nationalperinatal.org](http://www.nationalperinatal.org)



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# Nurses: parents trust you.

You can help reduce the risk of Sudden Infant Death Syndrome (SIDS), the leading cause of death among infants between 1 month and 1 year of age. Take our **free continuing education (CE) activity** to stay up to date on the latest safe infant sleep recommendations. Approved for 1.5 contact hours.

Learn more about the free online activity at <https://nichd.nih.gov/SafeSleepCE>.

The CE activity explains safe infant sleep recommendations from the American Academy of Pediatrics and is approved by the Maryland Nurses Association, an accredited approver of the American Nurses Credentialing Center's Commission on Accreditation.



Eunice Kennedy Shriver National Institute  
of Child Health and Human Development





# Medical News, Products & Information

Compiled and Reviewed by Mitchell Goldstein, MD Editor in Chief

## FDA approves first drug for treatment of peanut allergy for children

*Treatment of this common allergy early can have life changing implications.*

For Immediate Release:  
January 31, 2020

Today the U.S. Food and Drug Administration approved Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] to mitigate allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanuts. Treatment with Palforzia may be initiated in individuals ages 4 through 17 years with a confirmed diagnosis of peanut allergy and may be continued in individuals 4 years of age and older. Those who take Palforzia must continue to avoid peanuts in their diets.

“Peanut allergy affects approximately 1 million children in the U.S. and only 1 out of 5 of these children will outgrow their allergy. Because there is no cure, allergic individuals must strictly avoid exposure to prevent severe and potentially life-threatening reactions,” said Peter Marks, M.D., Ph.D., director of the FDA’s Center for Biologics Evaluation and Research. “Even with strict avoidance, inadvertent exposures can and do occur. When used in conjunction with peanut avoidance, Palforzia provides an FDA-approved treatment option to help reduce the risk of these allergic reactions in children with peanut allergy.”

Peanut allergy is a condition in which the body’s immune system mistakenly identifies even small amounts of peanut as harmful. Allergic reactions to peanut are unpredictable in occurrence and in how they present, with some individuals experiencing severe reactions from even trace amounts. Physical symptoms can develop within seconds of exposure and may include skin reactions (e.g., hives, redness or swelling), digestive discomfort, or more dangerous reactions, such as constriction of the throat and airways, and loss of adequate blood flow to vital organs of the body. Antihistamines and epinephrine can be used to treat allergic reactions, but severe reactions can be fatal even with appropriate, prompt treatment. Palforzia cannot be used for the emergency treatment of allergic reactions, including anaphylaxis.

Treatment with Palforzia consists of three phases: Initial Dose

Escalation, Up-Dosing, and Maintenance. The Initial Dose Escalation phase is given on a single day. The Up-Dosing phase consists of 11 increasing dose levels and occurs over several months. Initial Dose Escalation, and the first dose of each Up-Dosing level, are administered under supervision of a healthcare professional in a healthcare setting with the ability to manage potentially severe allergic reactions, including anaphylaxis. While anaphylaxis can occur at any time during Palforzia therapy, patients are at highest risk during and after the Initial Dose Escalation and the first dose of each Up-Dosing level. During Up-Dosing, if the patient tolerates the first dose of an increased dose level, the patient may continue that dose level daily at home. After a patient completes all Up-Dosing levels, they may begin the daily maintenance dose. Patients who experience certain allergic reactions due to Palforzia may need to discontinue treatment or have their dosing

# neo



## The conference for neonatology

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## The National Urea Cycle Disorders Foundation



The NUCDF is a non-profit organization dedicated to the identification, treatment and cure of urea cycle disorders. NUCDF is a nationally-recognized resource of information and education for families and healthcare professionals.

[www.nucdf.org](http://www.nucdf.org) | Phone: (626) 578-0833

schedule modified.

Palforzia is a powder that is manufactured from peanuts and packaged in pull-apart color-coded capsules for Dose Escalation and Up-Dosing, and in a sachet for maintenance treatment. The powder is emptied from the capsules or sachet and mixed with a small amount of semisolid food - such as applesauce, yogurt, or pudding - that the patient then consumes.

The effectiveness of Palforzia is supported by a randomized, double-blind, placebo-controlled study conducted in the U.S., Canada and Europe in approximately 500 peanut-allergic individuals. Effectiveness was assessed by evaluating the percentage of study participants tolerating an oral challenge with a single 600 mg dose of peanut protein (twice the daily maintenance dose of Palforzia) with no more than mild allergic symptoms after 6 months of maintenance treatment. The results showed that 67.2% of Palforzia recipients tolerated a 600 mg dose of peanut protein in the challenge, compared to 4.0% of placebo recipients.

The safety of Palforzia was assessed in two double-blind, placebo-controlled studies in approximately 700 peanut-allergic individuals. The most commonly reported side effects of Palforzia were abdominal pain, vomiting, nausea, tingling in the mouth, itching (including in the mouth and ears), cough, runny nose, throat irritation and tightness, hives, wheezing and shortness of breath and anaphylaxis. Palforzia should not be administered to those with uncontrolled asthma.

To mitigate the risk of anaphylaxis asso-

ciated with Palforzia, the FDA is requiring a Risk Evaluation and Mitigation Strategy (REMS) with this approval, which includes elements to assure safe use. Palforzia will only be available through specially certified healthcare providers, health care settings, and pharmacies to patients who are enrolled in the REMS program. The FDA is requiring that healthcare providers who prescribe Palforzia - and healthcare settings that dispense and administer Palforzia - are educated on the risk of anaphylaxis associated with its use. In addition, the Initial Dose Escalation phase and first dose of each Up-Dosing level must only be administered to patients in a certified healthcare setting equipped to monitor patients and to identify and manage anaphylaxis. Patients or their parents or caregivers must also be counseled on the need for the patients to have injectable epinephrine available for immediate use at all times, the need for continued dietary peanut avoidance, and how to recognize the signs and symptoms of anaphylaxis. The FDA granted approval of Palforzia to Aimmune Therapeutics.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

Inquiries  
Media:  
Stephanie Caccamo  
301-348-1956  
Consumer:  
888-INFO-FDA

NT

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

Released: Thursday 12/13/2018 12:32 PM, updated Saturday 3/16/2019 08:38, and Sunday 11/17/2019 1020

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

- Connect with other AAP members who share your interests in improving effective drug therapies and devices in children.
- Receive the SOATT newsletter containing AAP and Section news.

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NT

## FDA Continues Strong Support of Innovation in Development of Gene Therapy Products

*Guidances issued today provide regulatory clarity for product developers*

For Immediate Release:  
January 28, 2020

This is a pivotal time in the field of gene therapy as the FDA continues its efforts to support innovators developing new medical products for Americans and others around the world. To date, the FDA has approved four gene therapy products, which insert new genetic material into a patient's cells. The agency anticipates many more approvals in the coming years, as evidenced by the more than 900 investigational new drug (IND) appli-

cations for ongoing clinical studies in this area. The FDA believes this will provide patients and providers with increased therapeutic choices.

In that spirit, today, the FDA is announcing the release of a number of important policies: six final guidances on gene therapy manufacturing and clinical development of products and a draft guidance, Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations.

"The growth of innovative research and product development in the field of gene therapy is exciting to us as physicians, scientists and regulators," said FDA Commissioner Stephen M. Hahn, M.D. "We understand and appreciate the tremendous impact that gene therapies can have on patients by potentially reversing the debilitating trajectory of diseases. These therapies, once only conceptual, are rapidly becoming a therapeutic reality for an increasing number of patients with a wide range of diseases, including rare genetic disorders and autoimmune diseases."

"As the regulators of these novel therapies, we know that the framework we construct for product development and review will set the stage for continued advancement of this cutting-edge field and further enable innovators to safely develop effective therapies for many diseases with unmet medical needs," said



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Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research. "Scientific development in this area is fast-paced, complex, and poses many unique questions during a product review; including how these products work, how to administer them safely, and whether they will continue to achieve a therapeutic effect in the body without causing adverse side effects over a long period of time."

One of the most important steps the FDA can take to support safe innovation in this field is to create policies that provide product developers with meaningful guidance to answer critical questions as they research and design their gene therapy products.

The six final guidances issued today provide the agency's recommendations for product developers on manufacturing issues and recommendations for those focusing on gene therapy products to address specific disease areas. The six guidance documents incorporate input from many stakeholders and take a significant step toward helping to shape the modern structure for the development and manufacture of gene therapies. The agency is issuing this suite of documents to help advance the field of gene therapy while providing recommendations to help ensure that these innovative products meet the FDA's standards for safety and effectiveness.

The scientific review of gene therapies includes the need to evaluate highly complex information on product manufacturing and quality. In addition, the clinical review of these products frequently poses more challenging questions to regulators than reviews of more conventional drugs, such as questions about the durability of response, and these questions often can't be fully answered in pre-market trials of reasonable size and duration. For some gene therapy products, therefore, although they have met the FDA's standards for approval, we may need to accept some level of uncertainty around questions of the duration of the response at the time of marketing authorization. Effective tools for reliable post-market follow up, such as post-market clinical trials,



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are going to be key to advancing this field and helping to ensure that our approach fosters safe and innovative treatments.

The draft guidance on interpreting sameness of gene therapy products under the orphan drug regulations provides the FDA's proposed current thinking on an interpretation of sameness between gene therapy products for the purposes of obtaining orphan-drug designation and eligibility for orphan-drug exclusivity. The draft guidance focuses on how the FDA will evaluate differences between gene therapy products when they are intended to treat the same disease. As laid out in the draft guidance and our regulations, the agency's determination will consider the principal molecular structural features of the gene therapy products, which includes transgenes (the transferred gene) and vectors (the vehicle for delivering the transgene to a cell).

With the large volume of products currently being studied, gene therapy product developers have asked the agency important questions about orphan-drug designation incentives to develop products for rare diseases with very small patient pop-

ulations. The draft guidance has potential positive implications both for product developers and patients by providing insight into the agency's most current thinking on the sameness of products, and thus, not discourage the development of multiple gene therapy products to treat the same disease or condition. For patients, this policy could help lead to the development and approval of multiple treatments, creating a more competitive market with choices. We encourage stakeholders to provide their comments.

In sum, these policy documents are representative of efforts to help advance product development in the field of gene therapy. We will continue to work with product innovators, sponsors, researchers, patients, and other stakeholders to help make the development and review of these products more efficient, while putting in place the regulatory controls needed to ensure that the resulting therapies are both safe and effective. We also encourage developers of new gene therapy products to make full use of our expedited programs available for products intended to address unmet medical





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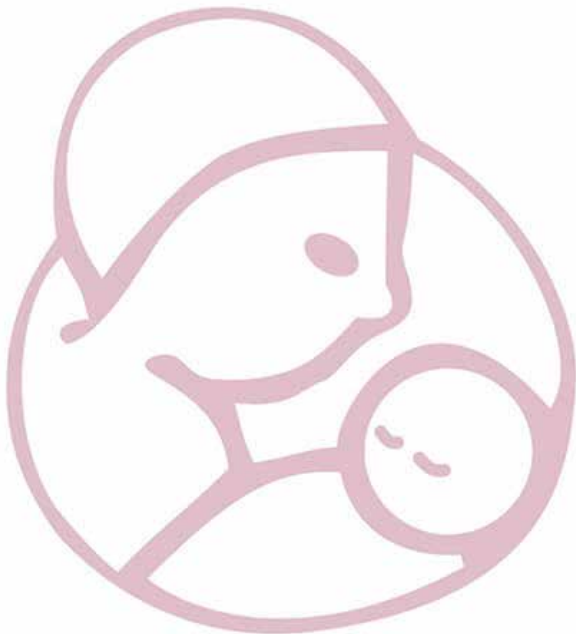
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needs in the treatment of serious or life-threatening conditions. These programs include breakthrough therapy designation, regenerative medicine advanced therapy designation, and fast track designation, as well as priority review and accelerated approval. Developers should pursue these programs whenever possible to help bring the benefits of important advances to patients as soon as possible. We believe our work will help advance innovations in a way that assures their safety and effectiveness, provides new therapeutic choices to patients and providers and continues to build confidence in this novel and emerging area of medicine.

The FDA is an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

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## Adults Unintentionally Make It Easy for Young Children to Eat Dangerous Pills

*Over half of kids poisoned by prescription*

*pills got them after an adult removed safety packaging*

Press Release

For Immediate Release: Wednesday, February 12, 2020

Contact: Media Relations  
(404) 639-3286

Each year there are about 400,000 poison center calls and 50,000 ER visits as a result of young children ingesting medications when adults weren't paying attention. A new study finds that more than half of the time when children get into prescription pills, the medication had already been removed from the child-resistant container by an adult.

The findings come from a study of calls to five U.S. poison control centers by researchers from the U.S. Centers for Disease Control and Prevention (CDC), Emory University School of Medicine, and the Georgia Poison Center. The study appears this week in *The Journal of Pediatrics* external icon

"These data suggest it may be time to place greater emphasis on encouraging adults to keep medicines in containers with child-resistant features," says the study's senior author, Daniel Budnitz, M.D., MPH, of CDC's Division of Healthcare Quality Promotion. "There is an opportunity here for innovative medication container options that promote adult adherence and provide portability and convenience, while maintaining child safety." Child-resistant packaging keeps kids safe – but only when pills are inside

The current study found four common scenarios in which young children get into prescription pills after the pills are out of their original containers:

1. Removed to remember to take as prescribed: Adults put pills into pill organizers that are not child-resistant.
2. Removed for ease of travel or transport: Adults put pills into baggies or other small containers that are not child-resistant to carry with them.
3. Removed for convenience: Adults leave

pills out on countertops or on a bedside table for someone to take later.

4. Removed unintentionally: Adults sometimes spill or drop pills and may miss some when picking them up.

The most common scenarios varied by type of medication. Attention-deficit/hyperactivity disorder (ADHD) medications (49%) and opioids (43%) were more often not in any container when found by young children. Diabetes drugs (34%) and cardiac medications (31%) were more often transferred to alternate containers such as pill organizers or baggies. Nonprescription medications were most often accessed from the original containers, but for many of these medications, child-resistant packaging is not required because of low potential for toxicity.

Grandparents' pill organizers often involved. Investigators also asked whose pills the children were getting into. Most of the time, the children got into their parents' pills. However, for some prescription medications that can be very harmful to young children in small amounts (e.g., diabetes or cardiac medications), over half belonged to grandparents. Therefore, it will be important to remind grandparents, as well as parents, about the importance of keeping medications up and away and out of the reach and sight of children.

CDC recommends keeping medications in the original child-resistant packaging. If one must remove pills from their original containers, a few precautions can help keep children safe:

- Use a container that is child resistant.
- Securely re-close the container after every use.
- Put the container up and away and out of a child's reach and sight immediately after every use.
- Keep purses, other bags, or pockets with medicines in them up and away from young children.
- If pills are spilled when taking or transferring medications, double-check to make sure that all pills are picked up.
- Save the Poison Help number in your



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phone – (800) 222-1222 – and call right away if you think your child might have gotten into a medicine or a vitamin, even if you are not sure.

For more information on what parents and grandparents can do to safely store their medications, visit: <https://www.cdc.gov/features/medicationstorage/index.html> and [UpandAway.org](http://UpandAway.org)

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

NT

## Study shows how a

## tiny and strange marine animal produces unlimited eggs and sperm over its lifetime

Thursday, February 13, 2020

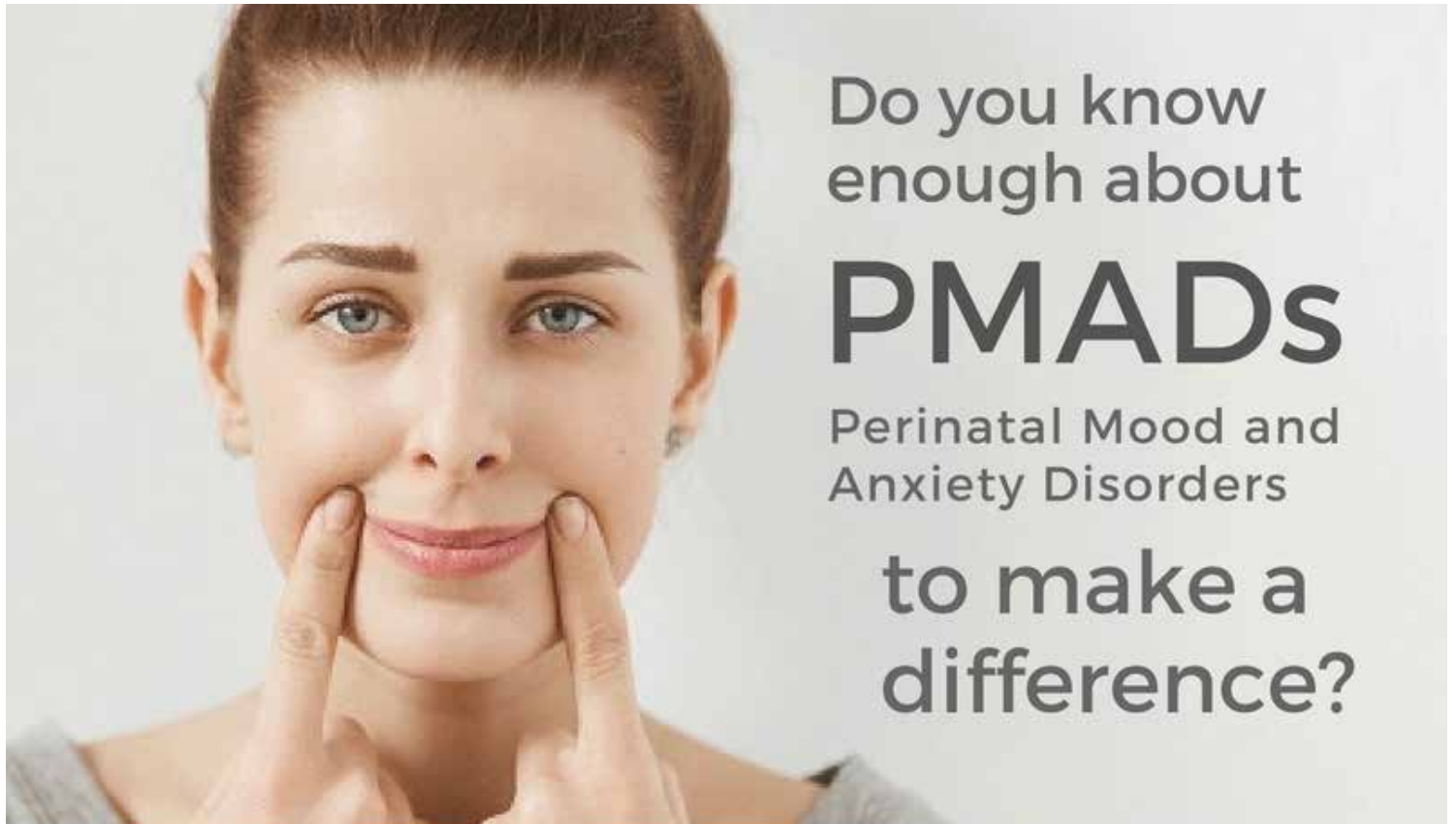
*NIH-supported research of Hydractinia could provide clues to human reproductive conditions.*

A little-known ocean-dwelling creature most commonly found growing on dead hermit crab shells may sound like an unlikely study subject for researchers, but this animal has a rare ability – it can make eggs and sperm for the duration of its lifetime. This animal, called Hydractinia, does so because it produces germ cells, which are precursors to eggs and sperm, nonstop throughout its life. Studying this unique ability could provide insight into the development of human reproductive system and the formation of reproductive-based conditions and diseases in humans.

“By sequencing and studying the genomes of simpler organisms that are easier to manipulate in the lab, we have been able to tease out important insights regarding the biology underlying germ cell fate determination – knowledge that may ultimately help us better understand the processes underlying reproductive disorders in humans,” Dr. Andy Baxevanis, director of the National Human Genome Research Institute’s (NHGRI) Computational Genomics Unit and co-author of the paper. NHGRI is part of the National Institutes of Health.

In a study published in the journal *Science*, collaborators at NHGRI, the National University of Ireland, Galway, and the Whitney Laboratory for Marine Bioscience at the University of Florida, Augustine, reported that activation of the gene *Tfap2* in adult stem cells in Hydractinia can turn those cells into germ cells in a cycle that can repeat endlessly.

In comparison, humans and most other mammals generate a specific number of germ cells only once in their lifetime. Therefore, for such species, eggs and



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sperm from the predetermined number of germ cells may be formed over a long period of time, but their amount is restricted. An international team of researchers have been studying *Hydractinia*'s genome to understand how it comes by this special reproductive ability.

*Hydractinia* lives in colonies and is closely related to jellyfish and corals. Although *Hydractinia* is dissimilar to humans physiologically, its genome contains a surprisingly large number of genes that are like human disease genes, making it a useful animal model for studying questions related to human biology and health.

*Hydractinia* colonies possess feeding polyps and sexual polyps as a part of their anatomy. The specialized sexual polyps produce eggs and sperm, making them functionally similar to gonads in species like humans.

During human embryonic development, a small pool of germ cells that will eventually become gametes is set aside, and all sperm or eggs that humans produce during their lives are the descendants of those original few germ cells. Loss of these germ cells for any reason results in sterility, as humans do not have the ability to replenish their original pool of germ cells.

In a separate study, Dr. Baxeavanis at NHGRI and Dr. Christine Schnitzler at the Whitney Lab have completed the first-ever sequencing of the *Hydractinia* genome. In this study, researchers used this information to scrutinize the organism's genome for clues as to why there are such marked differences in reproductive capacity between one of our most distant animal relatives and ourselves.

"Having this kind of high-quality, whole-genome sequence data in hand allowed

us to quickly narrow down the search for the specific gene or genes that tell *Hydractinia*'s stem cells to become germ cells," said Dr. Baxeavanis.

The researchers compared the behavior of genes in the feeding and sexual structures of *Hydractinia*. They found that the *Tfap2* gene was much more active in the sexual polyps than in the feeding polyps in both males and females. This was a clue that the gene might be important in generating germ cells.

The scientists next confirmed that *Tfap2* was indeed the switch that controls the process of perpetual germ cell production. The researchers used the CRISPR-Cas9 gene-editing technique to remove *Tfap2* from *Hydractinia* and measured the resulting effects on germ cell production. They found that removing *Tfap2* from *Hydractinia* stops germ cells from forming, bolstering the theory that *Tfap2* controls the process.

The researchers also wanted to know if *Tfap2* was influencing specific cells to turn into germ cells. Their analysis revealed that *Tfap2* only causes adult stem cells in *Hydractinia* to turn into germ cells.

Interestingly, the *Tfap2* gene also regulates germ cell production in humans, in addition to its involvement in myriad other processes. However, in humans, the germ cells are separated from non-germ cells early in development. Still, despite the vast evolutionary distance between *Hydractinia* and humans, both share a key gene that changes stem cells into germ cells.

This press release describes a basic research finding. Basic research increases our understanding of human behavior and biology, which is foundational to advancing new and better ways to prevent, di-

agnose and treat disease. Science is an unpredictable and incremental process — each research advance builds on past discoveries, often in unexpected ways. Most clinical advances would not be possible without the knowledge of fundamental basic research.

The National Human Genome Research Institute (NHGRI) is one of the 27 institutes and centers at the NIH, an agency of the Department of Health and Human Services. The NHGRI Division of Intramural Research develops and implements technology to understand, diagnose and treat genomic and genetic diseases. Additional information about NHGRI can be found at: <https://www.genome.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](http://www.nih.gov).*

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## Genetic profile may predict chance of type 2 diabetes among women with gesta-

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## tional diabetes

*Enhanced screening may have broad implications for better management.*

Thursday, February 13, 2020

Women who go on to develop type 2 diabetes after having gestational, or pregnancy-related, diabetes are more likely to have particular genetic profiles, suggests an analysis by researchers at the National Institutes of Health and other institutions. The findings provide insight into the genetic factors underlying the risk of type 2 diabetes and may inform strategies for reducing this risk among women who had gestational diabetes.

The study was conducted by Mengying Li, Ph.D., of the Division of Intramural Population Health Research at NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), and colleagues. It appears in *BMJ Open Diabetes Research & Care*.

"Our study suggests that a healthful diet may reduce risk among women who have had gestational diabetes and are genetically susceptible to type 2 diabetes," said the study's senior author Culin Zhang, M.D., Ph.D., of NICHD's Division of Intramural Population Health Research. "However, larger studies are needed to validate these findings."

Gestational diabetes (high blood sugar that first occurs during pregnancy) increases the risk of complications for mothers and their infants. In most cases, the condition resolves soon after the baby is born, but nearly half of women with gestational diabetes go on to develop type 2 diabetes later in life. Type 2 diabetes increases the risk of heart disease, kidney disease and other health problems. However, little research has been done on the genetic factors influencing a woman's risk for progressing to type 2 diabetes after gestational diabetes.

In the current study, researchers analyzed data from 2,434 women with gestational diabetes who participated in the Diabetes & Women's Health Study. The study followed women before, during and after pregnancy and captured data on their health later in life. Of the original group, 601 women with gestational diabe-

tes went on to develop type 2 diabetes.

Previous research has linked variations in certain genes (called single nucleotide polymorphisms) to a higher risk of type 2 diabetes. In the current study, researchers checked genetic scans of the 2,434 women for the presence of 59 gene variants thought to be more common in people who have type 2 diabetes. The researchers found that women who had the largest proportion of these gene variants were 19% more likely to develop type 2 diabetes, compared to those who had the lowest proportion of these variants.

The researchers also ranked the women's diets according to the proportion of healthy foods. Among women who adhered to a healthier diet, the risk associated with the gene variants was lower than that of the other women, but the differences between the two groups were not statistically significant.

The authors believe their study is among the largest to date that looks at genetic factors underlying development of type 2 diabetes among women with prior gestational diabetes. However, the number of women participating in the study may not be large enough to find a significant interaction between healthy diet and genetic susceptibility in relation to this risk, explained Dr. Zhang.

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](http://www.nih.gov).*

Contact  
Robert Bock or Meredith Daly

301-496-5133

NT

## NIH-Funded Clinical Trial to Test PrEP, Dapivirine Ring for Safety in Pregnant Women

*Study Also to Examine Whether Pregnant Women Accept, Use These HIV Prevention Tools.*

Monday, February 10, 2020

The first clinical trial specifically designed to test the safety of the monthly dapivirine vaginal ring in pregnant women has begun in southern and eastern Africa. The National Institutes of Health-funded study also will test the safety of a daily oral antiretroviral tablet for HIV pre-exposure prophylaxis (PrEP) in pregnant women and will assess how much they accept and use these two HIV prevention tools. The study will complement an ongoing NIH-funded trial of PrEP in adolescents and young women during pregnancy and the first six months after birth. PrEP is available in some countries and is being rolled out in others, while the dapivirine ring is under regulatory review by the European Medicines Agency for potential use in sub-Saharan Africa.

"Women need reliable HIV prevention methods that they know are safe during pregnancy for themselves and their babies," said Anthony S. Fauci, M.D., director of the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH. "This new clinical trial will provide important data on the safety of PrEP and the dapivirine ring during pregnancy and will help expectant parents make well-informed HIV prevention choices."

Studies have found that for women of reproductive age, the risk of acquiring HIV is two to four times greater during pregnancy and the first six months after childbirth than at other times. In sub-Saharan Africa, women tend to be pregnant for a substantial portion of their reproductive years, with an estimated 5.1 births per woman.

Limited evidence from earlier clinical trials and reports suggests that PrEP and the dapivirine ring are safe for pregnant women and their fetuses, but the safety of these tools during pregnancy has not yet been proven in a clinical trial designed specifically to address this question.

The new trial is called DELIVER: A Phase 3b Safety Study of the Dapivirine Ring and PrEP in Pregnant Women.

Using PrEP to prevent HIV involves taking an oral tablet containing two anti-HIV drugs, emtricitabine and usually tenofovir, once a day. Numerous studies have shown that PrEP is about 99% effective at protecting people from sexually acquiring HIV when taken daily.

The dapivirine vaginal ring slowly releases the anti-HIV drug dapivirine in the vagina and is replaced once a month. Two large, Phase 3 clinical trials demonstrated that the dapivirine ring is well-tolerated and roughly 30% effective overall at protecting women from acquiring HIV through vaginal sex.

Another NIH-funded trial that began in early 2019 has been studying whether PrEP drug concentrations in adolescents and young women aged 16–24 years are different during pregnancy than at other times. The trial, called IMPAACT 2009, soon will begin testing the safety, acceptability and feasibility of PrEP drugs during pregnancy and the first six months after birth in this population and their infants in southern and eastern Africa. Results are expected in 2022.

NIAID is sponsoring the DELIVER trial and co-funding it with the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Mental Health, both part of NIH. The study, also known as MTN-042, is being conducted by the NIH-funded Microbicide Trials Network (MTN) at four sites in Malawi, South Africa, Uganda and Zimbabwe. Gilead Sciences, Inc., and the International Partnership for Microbicides, which developed the dapivirine ring, are donating PrEP medication and rings for the study, respectively.

The design of the DELIVER trial has been carefully reviewed and approved by the communities, national health authorities, ethicists and other key stakeholders where the study will take place. Data from DELIVER may help some countries decide whether and how to roll out PrEP among pregnant women. If the ring receives regulatory approval, the study may inform its rollout in that population as well. Katherine Bunge, M.D., M.P.H., and Bonus Makanani, M.B.B.S., F.C.O.G.(SA) are leading the DELIVER study with Lee Fairlie, M.B.Ch.B., F.C.Paed. Dr. Bunge is an assistant professor in the department of obstetrics, gynecology and reproductive sciences at the University of Pittsburgh School of Medicine, and Dr. Makanani is an associate professor of obstetrics and gynecology at the University of Malawi College of Medicine in Blantyre. Dr. Fairlie is the director of child & adolescent health in the Wits Reproductive Health and HIV Institute at the University of the Witwatersrand in Johannesburg.

The DELIVER study team plans to enroll

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750 healthy, HIV-negative women aged 18–40 years who have an uncomplicated singleton pregnancy. The women will be assigned at random to receive either the dapivirine vaginal ring or PrEP in a 2-to-1 ratio and will be asked to use their assigned product until the end of their pregnancy or 42 weeks gestation, whichever comes first. The study team subsequently will enroll the mothers' newborn infants.

Out of an abundance of caution, the study team will enroll participants in four stages, beginning with women latest in pregnancy, and will pause to conduct a safety analysis before enrolling the next group. The first enrollment group, consisting of 150 women, will begin using their assigned product at 36 to 37 weeks gestation. The study team will follow these women through the end of their pregnancy and enroll their newborns for additional safety assessments. Then a panel of international experts unaffiliated with the trial will conduct an independent, interim safety analysis to determine if the next group of women can be enrolled or the study needs to stop early. If it is safe to proceed, this process will be repeated with a group of 150 women at 30 to 35 weeks gestation, 150 women at 20 to 29 weeks gestation, and 300 women at 12 to 19 weeks gestation. The participating women will be followed until approximately six weeks after their pregnancy ends, and the infants will be followed until they are approximately 1 year old.

The study team will record any medical problems and deaths among the women and infants, as well as birth defects in the infants. In addition, the team will track the frequency of full-term live births, premature live births and pregnancy losses. Investigators also will record pregnancy complications associated with exposure to PrEP or the dapivirine ring, measure levels of study drugs in the infants, and determine the extent to which women accept and use their assigned study product. Questionnaires will be used to assess the acceptability of the study products. Finally, the team will evaluate changes in women's genital microenvironment associated with the use of PrEP or the dapivirine ring during pregnancy.

A related NIH-funded clinical trial that is expected to begin in the coming months will test the safety of PrEP and the dapivirine ring in HIV-negative breastfeeding women and their infants. The trial, called B-PROTECTED or MTN-043, will enroll 200 women and their infants aged 6 to 12 weeks in Malawi, South Africa, Uganda and Zimbabwe. As in DELIVER, the data gathered during the B-PROTECTED study will help countries decide whether and how to roll out PrEP and the dapivirine ring, if approved, among breastfeeding women and will help these women make informed

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

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*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](http://www.nih.gov).*

Contact  
Laura Leifman  
301-402-1663

**NT**

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## NIH scientists link higher maternal blood pressure to placental gene changes

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*Gene modifications correspond to blood pressure increases at distinct pregnancy intervals.*

Monday, February 10, 2020

What

Higher maternal blood pressure in pregnancy is associated with chemical modifications to placental genes, according to a study by researchers from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), part of the National Institutes of Health (NIH). The changes involve DNA methylation, the binding of compounds known as methyl groups to DNA, which can alter a gene's activity. Exposure to high blood pressure in the womb increases the risk for impaired fetal growth and the risk for cardiovascular disease in adult life. Ultimately, the findings could yield information on the earliest origins of cardiovascular disease and how to prevent it from occurring.

The researchers conducted a comprehensive genetic analysis, called an epigenome-wide association study (EWAS), on biopsies of placentas delivered from 301 pregnant women in the

NICHD Fetal Growth Study. EWAS detects DNA methylation and other changes to gene functioning. The authors believe their study is the first EWAS to compare placental DNA methylation to maternal blood pressure across trimesters. The study team found distinct patterns of DNA methylation in the placental tissue, which corresponded with the timing of blood pressure elevations in pregnancy. Many of the methylated genes were found in earlier studies to be involved in cardiovascular functioning.

The researchers hope to study patterns of DNA methylation in larger groups of pregnant women, including those with pregnancy-associated blood pressure disorders such as preeclampsia. Funding for the work was provided by NICHD, the National Institute on Minority Health and Health Disparities and the National Institute of Diabetes and Digestive and Kidney Diseases, all part of NIH.

Who

The study's senior author, Fasil Tekola-Ayele, Ph.D., of NICHD's Epidemiology Branch, is available for interviews.

Reference

Workalemahu T, Ouidir M, Shrestha D, Wu J, Grantz KL, and Tekola-Ayele F. Differential DNA methylation in placenta associated with maternal blood pressure during pregnancy. Hypertension DOI: 10.1161/HYPERTENSIONAHA.119.14509 (2020).

*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>.*

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Contact  
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**NT**



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## Neonatology Solutions NICU Directory: 6 month anniversary, over 2000 active users!

Scott Snyder, MD



As we approach our 6 month anniversary, Neonatology Solutions is excited to announce that we've reached over 2000 active users! The Directory now contains data for more than 900 NICUs and 27 State Summary pages. There are currently links to 82 Neonatology job requisitions on the site for job seekers.

As the data on the site continues to expand, we are hard at work enhancing the backstage infrastructure to ensure a speedy and responsive user experience. You should see improved page downloads and search query response times in the coming

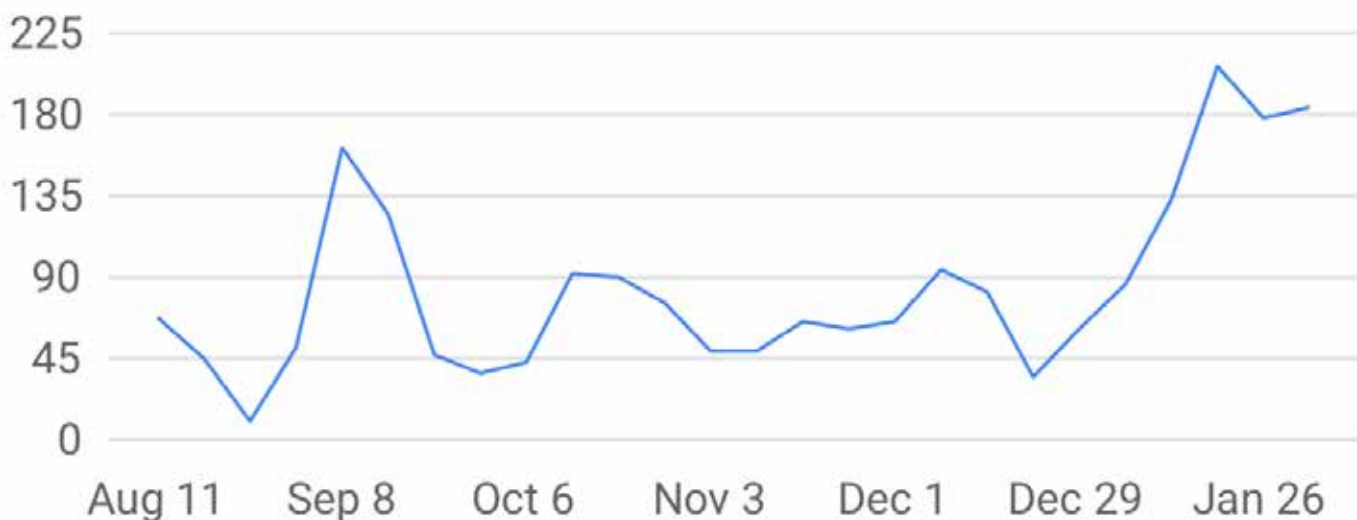
### Audience overview

Users	Sessions	New users
2.0K	2.9K	2.0K

— Users over time



# 2,014





weeks.

While this may seem difficult to believe, we know of absolutely NO source of information that details the exact number of NICUs in the United States. As we approach completion of the final few states, we anticipate being the first source to be able to provide the most accurate estimate of this information. Our goal is for completion of the Directory and State Summaries in the next three months. The positive feedback and encouragement we have received from colleagues around the country keeps us motivated to forge ahead with our endeavors. Thank you for your contributions!"

---

***"Your assistance is most appreciated. Please click the link to the Directory, search for your program, and update any missing or incorrect information. There's a convenient data submission link right on the Directory, or feel free to reach out directly to Scott Snyder, MD via email at [scott@neonatalogysolutions.com](mailto:scott@neonatalogysolutions.com)."***

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Your assistance is most appreciated. Please click the link to the Directory, search for your program, and update any missing or incorrect information. There's a convenient data submission link right on the Directory, or feel free to reach out directly to Scott Snyder, MD via email at [scott@neonatalogysolutions.com](mailto:scott@neonatalogysolutions.com).

Thank you to everyone who has submitted their NICU information! As always, we welcome comments and feedback on how to make the resource more useful and relevant.

**References:**

1. <https://neonatalogysolutions.com/explore-nicus-and-programs/>

The author is a principal of Neonatology Solutions, LLC.

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1%	12%

of Exclusive Human Milk Diet vs. Non-Human Milk Products

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**NCfIH** National Coalition for Infant Health

# Genetics Corner: Alveolar Simplification and Down Syndrome

Robin Clark, MD

## A Case History:

A 7 month-old Hispanic male with translocation Down syndrome was referred to the genetics clinic for an initial evaluation. His prenatal history was complicated by an abnormal maternal serum screening test that revealed an increased risk for Down syndrome, and there was pylectasis on fetal ultrasound. He was born at 39 1/7 weeks to a 35-year old G3P2->3 mother by C-section at a community hospital. Birth weight was appropriate at 3.880 kg. He was transferred to a tertiary care facility 2 hours away for a higher level of care because of bilateral hydronephrosis, microphalus, and right undescended testis. Chromosome analysis there revealed Down syndrome with a translocation between two chromosomes 21: 46,XY,+21,der(21;21)(q10;q10). Parental testing has not been completed.

He remained in the NICU for two months due to respiratory distress attributed to alveolar simplification. An initial echocardiogram demonstrated a patent foramen ovale (PFO) and tiny patent ductus arteriosus (PDA) with no pulmonary hypertension. Since discharge, he has been followed by multiple specialists at the tertiary facility. He is followed by Pulmonology for hypoxemia. He was treated with supplemental oxygen, day and night, during his first six months, but for the last month, he has only been using oxygen at night when his oxygen levels drop to lower than 80%. Both PFO and PDA have resolved, and his cardiologist at the tertiary care facility plans on discharging from further follow up once he is completely off oxygen.

***“Both PFO and PDA have resolved, and his cardiologist at the tertiary care facility plans on discharging from further follow up once he is completely off oxygen.”***

He was breastfed until he was six months and is now on formula. His mother is concerned that he is not interested in feeding, but his growth is adequate according to growth charts for Down syndrome. His phallus was of adequate size but appeared small because it was buried in perineal fat. The right testicle was undescended. He was seen by a nutritionist and a urologist at the tertiary care facility.

## Developmental History:

He was able to lift his head at two months and started babbling at 4-5 months. He was rolling over at seven months. He is not receiving early infant intervention services because the mother has not initiated the referral.

## Discussion:

In the 1980s, early in my genetics fellowship, my mentor, Dr. Michael Kaback, sat all of us trainees around a table and asked us

to recite a fact about Down syndrome (DS) that had not yet been mentioned. We were confident for the first few turns around the table, but soon, our answers did not come as quickly, and then, embarrassed, we collectively ran out of facts. Instead of dwelling on our ignorance, he suggested that we try to learn something new about DS each time we saw a patient with the condition. I thought it was good advice then, and I still do. Responding to Dr. Kaback these many years later, I tasked myself to learn more about DS from this patient. I have more questions than I can address here (including why would such devoted parents decide to stop breastfeeding and why would they fail to initiate early intervention services and could all that driving and all those appointments so far from home have contributed to those decisions?). I will not discuss the nature of translocation Down syndrome now either (although I recommended chromosome analysis for both parents). This discussion will focus on only 2 of the many questions that could be asked: 1. How often are full-term babies with DS who do not have congenital anomalies admitted to the NICU, and why? And 2. How common is alveolar simplification in newborns with DS, and what are its effects?

***“This discussion will focus on only 2 of the many questions that could be asked: 1. How often are full-term babies with DS who do not have congenital anomalies admitted to the NICU, and why? And 2. How common is alveolar simplification in newborns with DS, and what are its effects?”***

A study from Dublin, Ireland, by Martin et al. (2018) addressed my first question. These authors found that 87% of all infants with DS in their sample required NICU admission prior to discharge. Among their cohort of 121 infants with DS, 54 (45%) were initially admitted to the well newborn nursery, but 38 of these (70%) were later admitted to the NICU. A low oxygen saturation profile was the most common cause for the initial and subsequent admission to the NICU.

McAndrew et al. (2018) reviewed the databases of 277 Pediatric NICUs from 2005-2012 to identify 4623 infants with DS and 606,770 infants without DS. They found that 36% of infants with DS who were admitted to the NICU were full-term and without a major anomaly, surprisingly similar to the proportion in the euploid group (37%). The term infants with DS were admitted for reasons that could not be anticipated prior to delivery. Many diagnoses were only slightly, but still significantly, more common among the term DS group compared to the term group without DS: rule out sepsis (80% vs. 77%), hyperbilirubinemia (65% vs. 42%) and respiratory distress (58% vs. 50%). However, term infants with DS had strikingly and significantly more frequent diagnoses of throm-



bocytopenia (38% vs. 5%), PDA (37% vs. 3%), feeding problems (34% vs. 15%), persistent pulmonary hypertension of the newborn (27% vs. 3%), polycythemia (12% vs. 0.8%), VSD (25% vs. 1.4%) and ASD (15% vs. 0.8%). There was no difference in the need for mechanical ventilation between the two groups, but significantly only 28% of the term infants with DS remained in room air, compared to 56% of the term infants without DS. Term infants with DS had significantly longer stays in the NICU compared to term infants without DS: 10 days vs. five days. At discharge, term infants with DS had significantly higher needs for home oxygen (8.3% vs. 0.7%) and tube feeding at home (5.2% vs. 0.4%). (All significant differences had p values < 0.001).

***“Moving to the second question, alveolar simplification (fewer and larger alveoli), which is probably better known as the predominant pathologic finding associated with prematurity, is also a common and even typical feature of DS.”***

Moving to the second question, alveolar simplification (fewer and larger alveoli), which is probably better known as the predominant pathologic finding associated with prematurity, is also a common and even typical feature of DS. The lung architecture of DS, enlarged airspaces, and fewer and more dilated alveoli, appears to reflect poor postnatal alveolarization rather than primary lung hypoplasia. Bush et al. (2017) reported abnormal lung histology in a retrospective review of autopsies in 13 children with Down syndrome, ages 0-8 years, most of whom died of cardiac-related deaths, and four age-matched controls with congenital heart defects but without DS. They found alveolar simplification, a persistent double capillary network, and intrapulmonary bronchopulmonary anastomoses in all cases of DS, implicating impaired alveolar and pulmonary vascular development in Down syndrome. Several anti-angiogenic peptides, such as endostatin, are encoded on chromosome 21 and may contribute to the reduced total arterial surface area in DS. Both the reduced alveolar surface area and the diminished vascular bed are likely to contribute to the increased requirements for supplemental oxygen in infants with DS, who lack other reasons for an increased oxygen requirement, such as prematurity, congenital heart defects or pulmonary hypertension.

These differences may help explain why DS infants are at increased risk for lower respiratory tract infections in general and the respiratory syncytial virus (RSV) in particular. This relationship was supported by the meta-analysis performed by Mitra et al. (2018), who found that children with DS have a significantly increased risk for RSV infection, RSV-related hospitalization (RR 6.06; 95% CI, 4.93-7.45), hospital length of stay (mean difference 2.11 days) and need for assisted ventilation (RR 5.82; 95% CI, 1.81-18.69). Children with DS without congenital heart disease

also had a significantly increased risk of RSV-related hospitalization (RR 6.31; 95% CI, 4.83-8.23).

***“Their results suggest that palivizumab is associated with a 3.6-fold reduction in the incidence rate ratio for RSV-related hospitalization in children with DS during the first two years of life (95% CI, 1.52–8.67).”***

Infants with prematurity and those with DS share common lung histology and an increased risk for RSV infection, but current AAP guidelines do not yet recommend prophylactic palivizumab for children with DS as they do for premature infants. However, data from Japan and elsewhere have demonstrated a beneficial effect for prophylactic palivizumab in infants with DS. Yi and colleagues (2014) compared hospitalization rates for RSV infection among 532 Canadian children with DS who prospectively received palivizumab and an untreated group of 233 Dutch children with DS. In total, 31 RSV-related hospitalizations were documented: 23 untreated and eight treated. Their results suggest that palivizumab is associated with a 3.6-fold reduction in the incidence rate ratio for RSV-related hospitalization in children with DS during the first two years of life (95% CI, 1.52–8.67). A randomized prospective trial may be needed to eventually settle the question.

#### **Practical applications:**

1. Expect that term infants with Down syndrome who lack major congenital anomalies may require NICU admission.
2. Anticipate that infants with DS have alveolar simplification and be ready for the pulmonary sequelae. Be prepared to offer more respiratory support than might be expected for an infant of similar gestational age or cardiac status but without DS.
3. Consider infants with Down syndrome at increased risk for RSV infection and advise parents about risk reduction strategies. Expect evolving recommendations regarding palivizumab prophylaxis in DS infants.
4. Encourage parents to prioritize breastfeeding and early infant stimulation programs to optimize outcome in infants with DS.
5. Make recommendations that support the health of the child. Recognize the unintended consequences (opportunity costs) associated with referrals to distant health care facilities (especially when they bypass closer facilities) including time away from home and work, cost and stress of traffic, separation, and stress to other family members, early termination of breastfeeding, lack of time for other supportive



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The authors have no relevant disclosures.

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



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- Use less often
- Learn how to use safer

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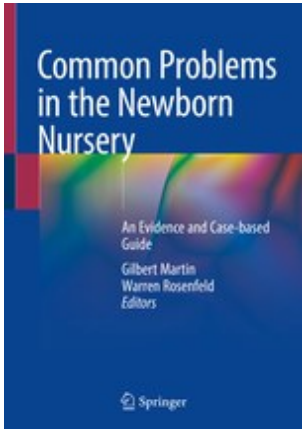
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Editors: **Martin**, Gilbert, **Rosenfeld**, Warren (Eds.)



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## FCC Suicide Hotline Comment Letter NCfIH

Mitchell Goldstein, MD and Susan Hepworth



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

The National Coalition for infant health recently sent a letter to the Federal Communications Commission in support of the implementation of the National Suicide Hotline Improvement Act of 2018. The letter in its entirety follows.

February 10, 2020

Marlene H. Dortch, Secretary  
Federal Communications Commission  
Office of the Secretary  
236 Massachusetts Ave., NE  
Washington, DC 20002

Re: WC Docket No. 18-336: Implementation of the National Suicide Hotline Improvement Act of 2018

Dear Secretary Dortch:

On behalf of the National Coalition for Infant Health, I am writing to express support for the Federal Communications Commission's recommendation to implement a three-digit dialing code, 988, for a national suicide prevention and mental health crisis hotline. This would serve as an important step in increasing access to life-saving resources for those in crisis.

The National Coalition for Infant Health (NCfIH) is a collaborative of over 200 professional, clinical, community health, and family support organizations focused on improving the lives of premature infants and their families. The coalition's mission is to promote lifelong clinical, health, education, and support services needed by premature infants and their families. One area of NCfIH's focus is



on access to diagnosis and treatment for postpartum depression and post-traumatic stress disorder. Many of NCfIH's members know first-hand how childbirth, especially traumatic births, can affect the mental health of mom and dad.

Postpartum depression is a mood disorder that affects approximately 600,000 women each year and is most likely caused by a combination of physical and emotional factors. It can also af-

***“Postpartum depression is a mood disorder that affects approximately 600,000 women each year and is most likely caused by a combination of physical and emotional factors. It can also affect men.”***

fect men. Common symptoms like extreme sadness, irritability, exhaustion, and withdrawal are often dismissed as just the “baby blues.” While the “baby blues” and postpartum depression have some commonalities, they are not the same.

Postpartum depression symptoms typically develop within a week or two after the baby is born. But for some new parents, it may not emerge for months, or even up to one year later. This is especially true for parents of babies admitted to the neonatal intensive care unit. Left untreated, postpartum depression can have dire consequences for new moms, dads, and their babies.

NCfIH applauds the efforts of the FCC to improve access to critical mental health resources with the implementation of a three-digit emergency number. This number is an important step in recognizing that mental health is as important as physical health. NCfIH urges the FCC to ensure callers are protected from any financial burden associated with the implementation of this proposal.

Thank you for the opportunity to provide comments, and we ap-



preciate your attention to this matter. If NCfIH can provide further details or be of assistance, please contact us at [info@infanthealth.org](mailto:info@infanthealth.org).

Sincerely,

Mitchell Goldstein, MD

Medical Director, National Coalition for Infant Health

*Disclosures: The authors do not have any relevant disclosures.*

**NT**

**National Coalition for Infant Health Values (SANE)**

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

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

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

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



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# National Perinatal Association PERINATAL SUBSTANCE USE

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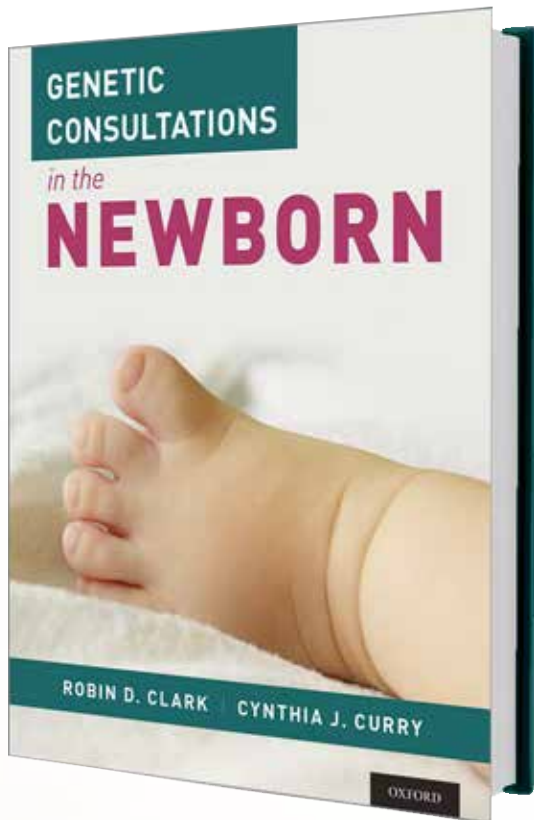


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OXFORD

# RSV AWARENESS:

## *A National Poll of Parents & Health Care Providers*

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

Yet a national poll of parents and specialty health care providers reveals a startling divide in attitudes toward the virus. While both groups acknowledge RSV as a significant concern, the two populations vary widely in their reported ability to meet RSV's threat head-on. Health care providers vigilantly

monitor for the virus, which they report seeing regularly in their practices. Parents, however, feel unequipped to protect their young children.

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

## KEY FINDINGS

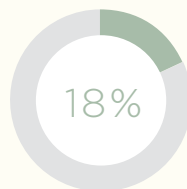
### *Preparedness*

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

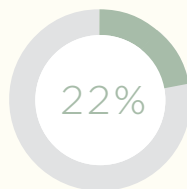
Specialty health care providers reiterated these concerns; 70% agreed that parents of their patients have a low awareness of RSV. Meanwhile, specialty health care providers themselves actively monitor for RSV. They reported that:

#### PARENTS

**Only 18% said parents know “a lot” about RSV,** reflecting an awareness level that’s roughly half that of the flu

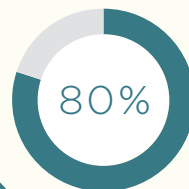


**Only 22% of parents consider themselves “very well prepared” to prevent RSV.**

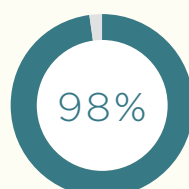


#### SPECIALTY HEALTH CARE PROVIDERS

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



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



# Clinical Pearl:

## Periviability: Old Perspective and New Insights

Joseph R. Hageman, MD

I was at an insightful talk on February 5, 2020, about new aspects of the discussions we have as clinicians with our colleagues and families when we are called about pregnancies from 22-25 weeks gestation. The talk was for the residents and was given by Drs. Kelly Nelson Kelly and Marin Arnolds, two of our former residents and neonatal fellows, who are now attending neonatologists. Marin is at NorthShore University HealthSystem, Evanston Hospital, a level III neonatal intensive care unit (NICU), and Kelly is at Comer Children's Hospital Level IV NICU and is now the Associate Medical Director of the NICU.

First, Marin discussed aspects of the historical perspective beginning with the death of Patrick Kennedy, the son of President John and Jackie Kennedy, who was a premature infant born at 34 weeks in August of 1963 and died of respiratory distress syndrome. His passing stimulated a lot of interest in advancing the care of premature newborn infants. She then discussed Baby Doe, the laws that were passed to protect premature newborn infants including the Child Abuse and Prevention Act (CAPTA), Emergency Medical Treatment and Labor Act (EMTALA- 1986), and the recommendations from American College of Obstetrics and Gynecology (ACOG) and the American Academy of Pediatrics (AAP) re the care of extremely premature infants at 21-25 weeks gestation that have influenced the clinical decision making of these infants and the discussion with parents. CAPTA was passed in 1974 and was most recently reauthorized in January 2019.

---

***“CAPTA was passed in 1974 and was most recently reauthorized in January 2019.”***

---

I began my pediatric residency in 1977 and finished my neonatal fellowship in 1982. I practiced clinical neonatology from 1982-1989. As I listened to Marin review this valuable and thoughtful information, I began to relive the effects of these laws and guidelines during this critical time. We were very thoughtful about our discussions, management, and care of our infants in the NICU as providers were being reported for not providing the basic care of babies in the NICU and were investigated by the government watchdog investigators during this time. Fortunately, I did not have the experience of being investigated. When we had discussions with families who were 23-24 weeks gestation, at that time, after we talked with our maternal-fetal medicine colleagues, we talked with the family on a case-by-case basis. I had situations when parents talked about how this was their last chance as they had been trying to have a baby without success. We individualized our delivery room management each time. We were prepared to instill surfactant as per our research protocol at 24 weeks gestation, and I did for a 500-gram infant born at 24 weeks gestation in around 1983 with excellent results. With

each baby, we spent time keeping their parents up to date with the clinical course of their infant as soon as we had new information. This was a time when we began to have bedside cranial ultrasound and used the Papile classification for periventricular-intraventricular hemorrhage (4). This was all new for us at that time, and we continued to reassess each infant and family and make decisions on a case-by-case basis.

In listening to Kelly and Marin, there is the additional clinical experience over the years and additional tools like the Tyson calculator and data from the NICHD neonatal research network with outcome data re survival and neurodevelopmental outcomes to refer to in discussions with the family prior to delivery of the infant (references). The discussion of the approach to the periviable infant begins at 21 weeks gestation with MFM re corticosteroid therapy for lung maturation and monitoring of the fetus. Periviability and potential delivery room resuscitation begins at 22 weeks with the “gray area” being 22-24 weeks gestation. (5,6). The parents are provided survival and neurodevelopmental outcome data from national references and from the individual NICUs as well. Some NICUs will also present these data from other NICUs, for example, the University of Iowa or international data (references). Each case is individualized with the parents, MFM, and neonatal providers. The parents are given a tour of the NICU, and further counseling about what they can expect re care of their infant is provided.

In the delivery room, once it is decided to provide basic resuscitation, some general principles include (1) gentle initiation of lung expansion to supplement the infant's own efforts, (2) provision of supplemental oxygen beginning with around 30% FiO<sub>2</sub> and adjusting with oxygen saturation values measured by pulse oximetry postductally to maintain appropriate oxygen saturation values as per the first 5 minutes post-delivery, (3) instillation of surfactant as an appropriate time post-delivery if it is suspected the infant has clinical and/or radiographic evidence of respiratory distress syndrome (RDS).

More of the NICUs have adopted and set up “small baby or micro-preemie units” to provide specialized care with decreased stimulation, the optimal range for oxygen saturation of the infants, optimal nutrition with maternal breast milk, midline positioning, kangaroo care, and gentle ventilation if necessary (references).

Once the baby is born and stabilized, there are also ongoing discussions and counseling with parents and providers about the clinical course of the infant with input from everyone involved. The parents are given daily updates and, with significant changes in clinical status, the family is notified and things are explained.

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Acknowledgment: Kelly Nelson Kelly, MD and Marin Arnolds, MD.

The author has no conflicts to disclose

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- Please send your submissions to:

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Babies are just tiny adults, right? So ... half?

Infants need drugs tested and approved just for them.

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

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## Which Infants are More Vulnerable to Respiratory Syncytial Virus?

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

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

\*Source: Respirator Syncytial Virus and African Americans

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

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



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

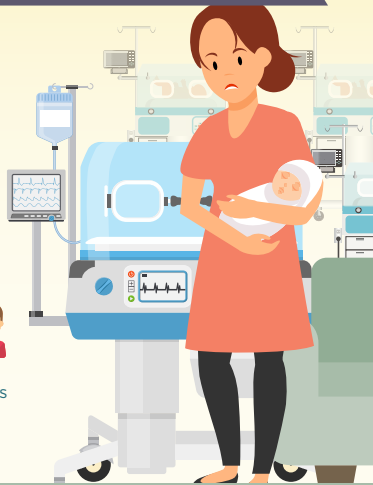
Preterm infants are:

**2x** more likely to have developmental delays

**5x** more likely to have learning challenges



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



Early intervention can help preterm infants:



Enhance language and communication skills



Build more effective learning techniques



Process social and emotional situations



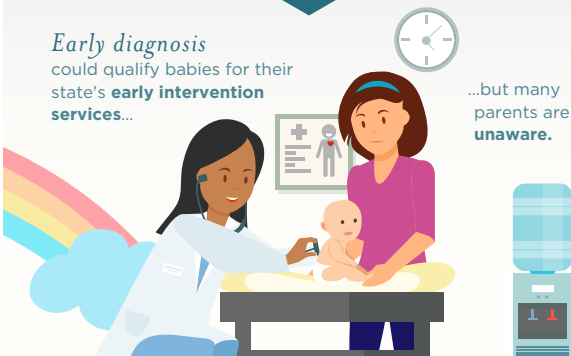
Address physical challenges



Prevent mild difficulties from developing into major problems

Early diagnosis could qualify babies for their state's **early intervention services**...

...but many parents are **unaware**.



*NICU staff, nurses, pediatricians and social workers should talk* with NICU families about the challenges their baby may face.

Awareness, referral & timely enrollment in early intervention programs can help **infants thrive** and grow.



**NCfIH** National Coalition for Infant Health  
Protecting Access for Premature Infants through Age Two  
[www.infanthealth.org](http://www.infanthealth.org)

Visit [CDC.gov](http://CDC.gov) to find contact information for your state's early intervention program.

Survey Says: **RSV**

**RESPIRATORY SYNCYTIAL VIRUS, or RSV,** is a dangerous virus that can lead to:

- Hospitalization
- Lifelong health complications
- Death

for infants and young children.



ACCORDING TO A NATIONAL SURVEY, *Specialty Health Care Providers say:*

**80%** They treat RSV as a priority, "often" or "always" evaluating their patients

**77%** RSV is the "most serious and dangerous" illness for children under four

**77%** Barriers to access and denials from insurance companies **limit** patients' ability to get preventive RSV treatment



*But Parents are Unprepared.*

**18%** Only 18% know "a lot" about RSV

**22%** Only 22% consider themselves "very well" prepared to prevent RSV



**RSV EDUCATION & AWARENESS CAN HELP**

*After parents learned more about RSV, they were:*

- 65%** "More concerned" about their child contracting the disease
- 67%** Likely to ask their doctor about RSV



**NCfIH** National Coalition for Infant Health  
Protecting Access for Premature Infants through Age Two

Learn More about RSV at [www.infanthealth.org/RSV](http://www.infanthealth.org/RSV)



# Medical Legal Forum –Residency for Sale? The Closure of Hahnemann University Hospital

Jonathan Fanaroff MD, JD and Gilbert Martin, MD

Medical residency has been around for approximately 130 years, taking the place of the traditional apprenticeship. Since then, of course, there have been and continue to be a number of changes in the trajectory from newly graduated medical students to attending physicians. The Accreditation Council of Graduate Medical Education (ACGME) is the organization that has a tremendous impact on this trajectory. According to the organization's website, there are "11,700 ACGME-accredited residency and fellowship programs in 181 specialties and subspecialties at approximately 850 Sponsoring Institutions. There were approximately 140,500 active full- and part-time residents and fellows." Many hospitals require board certification in order to obtain privileges, and in turn, the boards require training at an ACGME-accredited program to qualify for certification. Thus it is significant to understand the mission of the ACGME, which is "to improve health care and population health by assessing and advancing the quality of resident physicians' education through accreditation." (1) Nothing in there about commerce.

***"Thus it is significant to understand the mission of the ACGME, which is "to improve health care and population health by assessing and advancing the quality of resident physicians' education through accreditation." (1)***

Thus it was jarring to read about the efforts of Hahnemann University Hospital to auction off its residency programs to the highest bidder. Even more amazing was the result of the auction – Thomas Jefferson University agreed to pay \$55 million for 550 Medicare-funded residency slots. The notion of a residency position as an asset on a balance sheet and a source of revenue that can be auctioned off upon the closing of a hospital is troubling and has led to a legal battle that is still playing out. Let us examine more closely the details of this important legal case.

Hahnemann University Hospital, a 495-bed safety-net hospital in Philadelphia that had been in operation for 170 years, was the main teaching hospital for Drexel University College of Medicine. On June 30, 2019, the parent company of Hahnemann filed for Chapter 11 bankruptcy. Shortly thereafter, the residency and fellowship slots were put up for sale with the noted results. While the bankruptcy court judge was prepared to

split the \$55 million among the creditors, The Centers for Medicare and Medicaid Services (CMS) objected to the sale, and in response, a federal judge temporarily halted the sale. CMS cares because, while ACGME accredits training programs, it is CMS that funds the residency slots, and in their view, residency programs are a contract between them and the hospital as opposed to an asset of the hospital that can be sold. (2) CMS has a process in place for this situation in which priority for the slots is given to local hospitals but without any charges involved. Additionally, there are significant concerns about the precedent of allowing such a sale. Many hospitals with large residency programs are financially troubled and could potentially 'sell-off' some residency slots as a 'quick fix' way to improve their balance sheet. (3)

CMS was not the only party concerned with the sale. The State of Pennsylvania objected to the manner in which hospital licensing regulations were handled and the ACGME, along with the Association of American Medical Colleges (AAMC) and the Educational Commission for Foreign Medical Graduates (ECFMG) advocated for insurance coverage for residents. (4) Congress got involved as well, with Energy and Commerce Chairman Frank Pallone, Jr. (D-NJ) and Ways and Means Chairman Richard Neal (D-MA) releasing a statement objecting to the "dangerous precedent" set by the sale including the concern it "sends a signal to Wall Street that there is money to be made off the downfall of community hospitals." (5)

***"Congress got involved as well, with Energy and Commerce Chairman Frank Pallone, Jr. (D-NJ) and Ways and Means Chairman Richard Neal (D-MA) releasing a statement objecting to the 'dangerous precedent' set by the sale including the concern it 'sends a signal to Wall Street that there is money to be made off the downfall of community hospitals.'"***

Perhaps the most invested party to this tragedy are the residents themselves, many of whom had started residency days earlier. Reading from a prepared statement, third-year Hahnemann Radiology resident Raluca McCallum spoke to the judge on behalf of Hahnemann trainees and noted the group's anger at "the perception that residents are viewed as nothing more than assets, the sale of which might offset the debt." (6) As we were all trainees once, let us hope that as this bankruptcy case drags on, the residents and fellows all find appropriate positions to continue their training with proper malpractice coverage for their care at the now-shuttered hospital.

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The authors have no conflicts of interests to disclose.

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**Disclaimer:**

This column does not give specific legal advice, but rather is intended to provide general information on medicolegal issues. As always, it is important to recognize that laws vary state-to-state and legal decisions are dependent on the particular facts at hand. It is important to consult a qualified attorney for legal issues affecting your practice.

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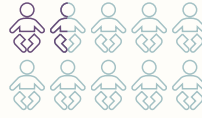


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## Why PREMATURE INFANTS Need Access to an EXCLUSIVE HUMAN MILK DIET



In the United States, more than **1 IN 10** BABIES ARE BORN PREMATURE. Micro preemies are born severely premature, weighing less than 1,250 grams.

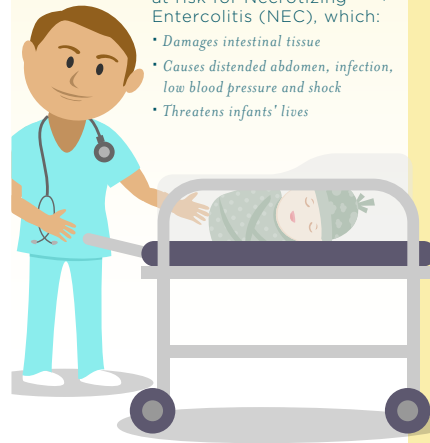
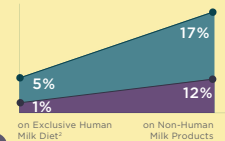


**MICRO PREMIES** are at risk for Necrotizing Enterocolitis (NEC), which:

- Damages intestinal tissue
- Causes distended abdomen, infection, low blood pressure and shock
- Threatens infants' lives

NEC occurrence increases when a preemie consumes non-human milk products.

When that happens:



30% of micro preemies needing surgery will die from NEC\*

### HOW TO HELP PREVENT NEC: EXCLUSIVE HUMAN MILK DIET

What is an Exclusive Human Milk Diet?



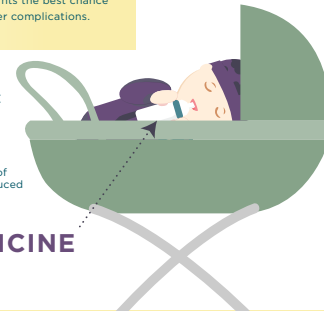
#### Why Is An Exclusive Human Milk Diet Important?

An Exclusive Human Milk Diet gives vulnerable infants the best chance to be healthy and reduces the risk of NEC and other complications.

- ✓ mother's milk
- ✓ human donor milk
- ✓ human milk-based fortifier

#### When a micro preemie can access an EXCLUSIVE HUMAN MILK DIET:

- Mortality is reduced by **75%\***
- Feeding intolerance decreases\*
- Chances of NEC are reduced by **77%\***



**HUMAN MILK = MEDICINE**

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OPIOIDS and NAS  
When reporting on mothers, babies, and substance use  
**LANGUAGE MATTERS**



**I am not an addict.**

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



**I was exposed to opioids.**

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



**NAS is a temporary and treatable condition.**

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



**My mother may have a SUD.**

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

**My potential is limitless.**



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

Learn more about Neonatal Abstinence Syndrome at [www.nationalperinatal.org](http://www.nationalperinatal.org)



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# From The National Perinatal Information Center: Taking Care of a Sick Newborn in the NICU... And Taking Care of a Mother's Heart, Too

Elizabeth Rochin, PhD, RN, NE-BC

The National Perinatal Information Center (NPIC) is driven by data, collaboration and research to strengthen, connect and empower our shared purpose of improving patient care.

For over 30 years, NPIC has worked with hospitals, public and private entities, patient safety organizations, insurers and researchers to collect and interpret the data that drives better outcomes for mothers and newborns.



National Perinatal Information Center

This month, the American Heart Association will recognize American Heart Month for the 56th consecutive year. Heart health continues to be a discussion, no matter the age of your patient. Much of that discussion over the past year has focused on maternal health and heart disease. There is a great deal of discussion in the United States currently that is focused on maternal mortality. And for a good reason. The United States is currently the only developed nation in the world in which the maternal mortality rate is increasing rather than decreasing. The reasons for that are clear in the literature: 1) Racial disparities, which have highlighted the rates of maternal death in the black community, in which black women are dying during or after childbirth at 3-4 times the rate of white women, regardless of education or socioeconomic status. The most recent data from the CDC National Center for Health Statistics (NCHS) described the latest statistics from 2018, which revealed racial and ethnic gaps exist between non-Hispanic black (37.1 deaths per 100,000 live births), non-Hispanic white (14.7), and Hispanic (11.8) women (Centers for Disease Control, 2020). 2) Women are older when they are entering pregnancy. One of the most significant findings from the NCHS report revealed that maternal mortality rates also increased substantially by age, with rates for women aged 40 and over roughly eight times the rate for women under 25 (81.9 and 10.6, respectively) (Centers for Disease Control, 2020).

However, there is one area that is increasingly and unintentionally overlooked, and that is the focus on maternal morbidity. And what confounds this is that at present, there are three (3) definitions of

Severe Maternal Morbidity (SMM) that exist in the literature:

#### CDC definition of SMM:

Severe maternal morbidity is defined by the Centers for Disease Control (CDC) as the “unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman’s health” (Centers for Disease Control, 2020). Severe Maternal Morbidity is identified using administrative hospital discharge data and the International Classification of Diseases (ICD) diagnosis codes and procedures (ICD-10). There are currently twenty-one (21) indicators of severe maternal morbidity:

Acute Myocardial Infarction	Aneurysm	Acute Renal Failure
Adult Respiratory Distress Syndrome	Amniotic Fluid Embolism	Cardiac Arrest/Ventricular Fibrillation
Conversion of Cardiac Rhythm	Disseminated Intravascular Coagulation	Eclampsia
Heart Failure/Arrest during Procedure or Surgery	Puerperal Cerebrovascular Disorders	Pulmonary Edema/Acute Heart Failure
Severe Anesthesia Complication	Sepsis	Shock
Sickle Cell Disease with Crisis	Air and Thrombotic Embolism	Blood Products Transfusion
Hysterectomy	Temporary Tracheostomy	Ventilation

Table 1. Severe Maternal Mortality (SMM). Adapted from Centers for Disease Control, 2020

#### AIM Definition of SMM Event:

The Alliance for the Innovation of Maternal Health (AIM) lists many of these as diagnosis codes and includes five procedure codes (blood transfusion, conversion of cardiac rhythm, hysterectomy, temporary tracheostomy, and ventilation). ([www.safehealthcareforeverywoman.org](http://www.safehealthcareforeverywoman.org)).

- Pregnant, peripartum or postpartum women receiving four or more units of blood products
- Pregnant, peripartum or postpartum women who are admitted to an ICU as defined by the birth facility
- Other pregnant, peripartum or postpartum women who have an unexpected and severe medical event – at the discretion of the birth facility
- Review form includes guiding questions for OB hemorrhage, hypertensive disease, cardiac disease (including cardiomyopathy), thrombotic disease, and infectious disease (including sepsis).

#### Joint Commission Definition of SMM:

**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](mailto:LomaLindaPublishingCompany@gmail.com)

The Joint Commission has defined severe, temporary harm focused on severe maternal mortality (SMM) as a patient safety event that occurs from the intrapartum through the immediate postpartum period (24 hours), requiring the transfusion of 4 or more units of packed red blood cells (PRBC) and/or admission to the intensive care unit (ICU) per the American College of Obstetricians and Gynecologists (ACOG), Centers for Disease Control and Society of Maternal-Fetal Medicine (SMFM) (Joint Commission, 2020).

Admission to the ICU is defined as admission to a unit that provides 24-hour medical supervision and is able to provide mechanical ventilation or continuous vasoactive drug support.

### National Perinatal Information Center and Maternal Hypertension

The National Perinatal Information Center (NPIC) has been a national leader in perinatal and neonatal data analytics for over thirty-five years. On any given year, NPIC has an average of 325,000 linked mother/baby discharge records per year (for example, 07/2018 – 06/2019 discharges, there were a total of 311,377 obstetrical records and 299,651 newborn charts linked, for a total of 611,028 perinatal discharges). One of the linked diagnosis codes tracked is that of hypertension and subsequent admission to the NICU at birth.

Over time, it becomes clear that discharge data with a maternal diagnosis of hypertension during hospitalization for childbirth has been a factor in neonatal admission to the NICU, and in fact, has been rising in the NPIC Database from 2012-2018. While there could be a number of variables and factors within the decision to admit a baby to the NICU, it also warrants attention to ensure the mother is receiving the care needed and necessary to assure her stabilization and continued recovery after childbirth. When the mother of your NICU patient diagnosed with hypertension is sitting at the bedside with her sick newborn, does she appear well? Or ill-appearing? What education is she receiving to ensure she is ready for discharge herself? While the focus of care naturally flows to the sick newborn, it is important to ensure that the mother is cared for as well, and is recognizing warning signs of what to report to her own provider. As the mother will be caring for her baby (or babies), ensuring she is getting the care and resources she needs is essential to the optimal outcomes of the baby. AWHONN (Association of Women's Health, Obstetric, and Neonatal Nurses) has developed a POST-BIRTH Save Your Life discharge education program that can be used for postpartum education and empowering women to seek out medical attention for signs of complications after childbirth. This flyer is available at [www.AWHONN.org](http://www.AWHONN.org) and may be ordered free of charge for hospitals to use in their postpartum discharge education programs.

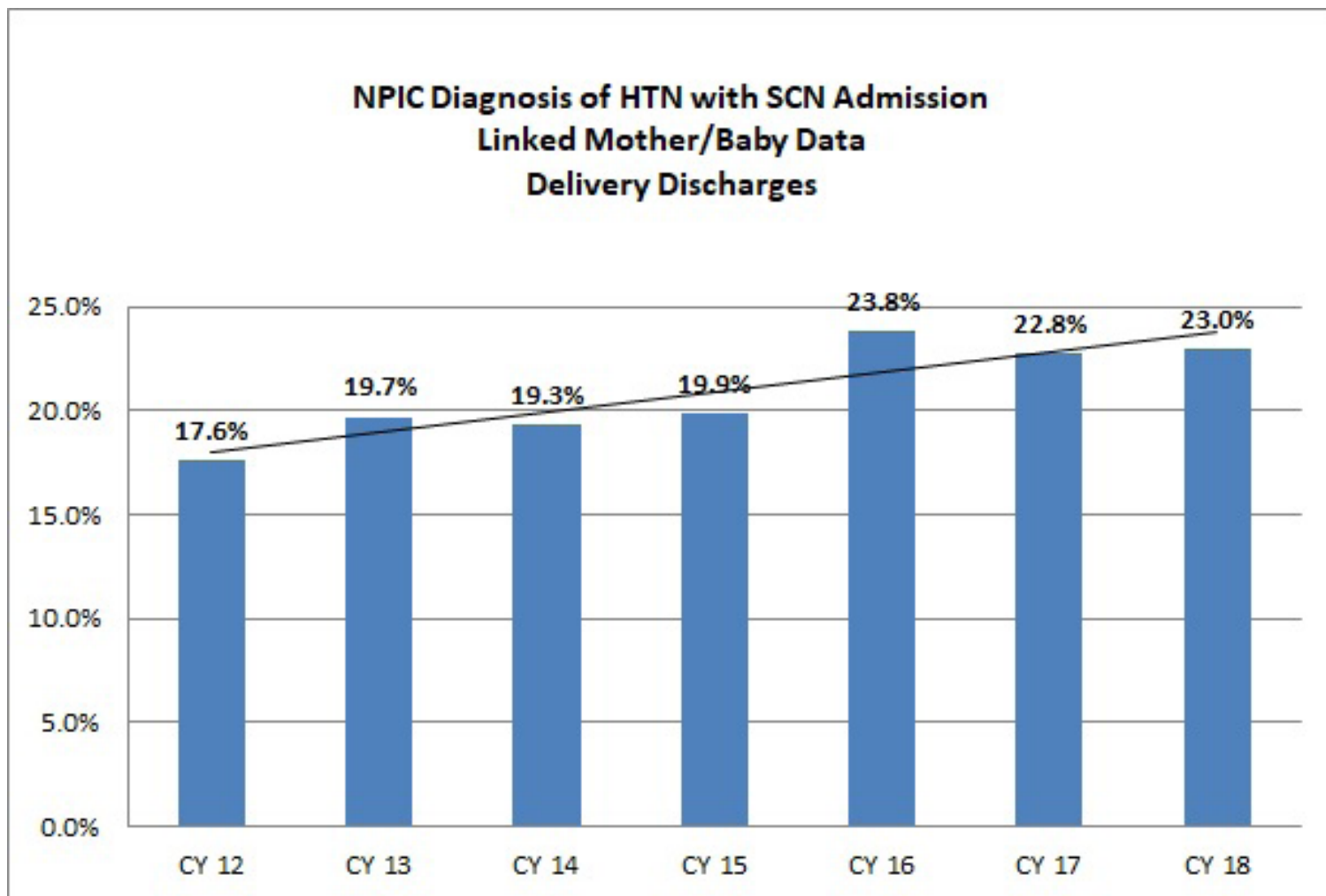


Figure 1. NPIC Maternal Diagnosis of Hypertension with Special Care Admission, 2012-2018

# SAVE YOUR LIFE:

## Get Care for These POST-BIRTH Warning Signs

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



<p><b>Call 911</b> if you have:</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> <b>Pain in chest</b></li> <li><input type="checkbox"/> <b>Obstructed breathing or shortness of breath</b></li> <li><input type="checkbox"/> <b>Seizures</b></li> <li><input type="checkbox"/> <b>Thoughts of hurting yourself or your baby</b></li> </ul>
<p><b>Call your healthcare provider</b> if you have:</p> <p>(If you can't reach your healthcare provider, call 911 or go to an emergency room)</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> <b>Bleeding, soaking through one pad/hour, or blood clots, the size of an egg or bigger</b></li> <li><input type="checkbox"/> <b>Incision that is not healing</b></li> <li><input type="checkbox"/> <b>Red or swollen leg, that is painful or warm to touch</b></li> <li><input type="checkbox"/> <b>Temperature of 100.4°F or higher</b></li> <li><input type="checkbox"/> <b>Headache that does not get better, even after taking medicine, or bad headache with vision changes</b></li> </ul>



**Tell 911 or your healthcare provider:**

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

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

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

**GET HELP** My Healthcare Provider/Clinic: \_\_\_\_\_ Phone Number: \_\_\_\_\_  
Hospital Closest To Me: \_\_\_\_\_



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

16003  
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Figure 2 Association of Women's Health, Obstetric, and Neonatal Nurses POST-BIRTH Save Your Life Postpartum Discharge Flyer



February is American Heart Month and a month that brings attention to heart disease, the number one killer of Americans. During this American Heart Month, it is important to recognize that pregnancy can take a toll on a mother's heart. And that toll can be felt much more profoundly when she finds her newborn is in NICU.

The author has no conflicts of interests to disclose.

**NT**




Corresponding Author:

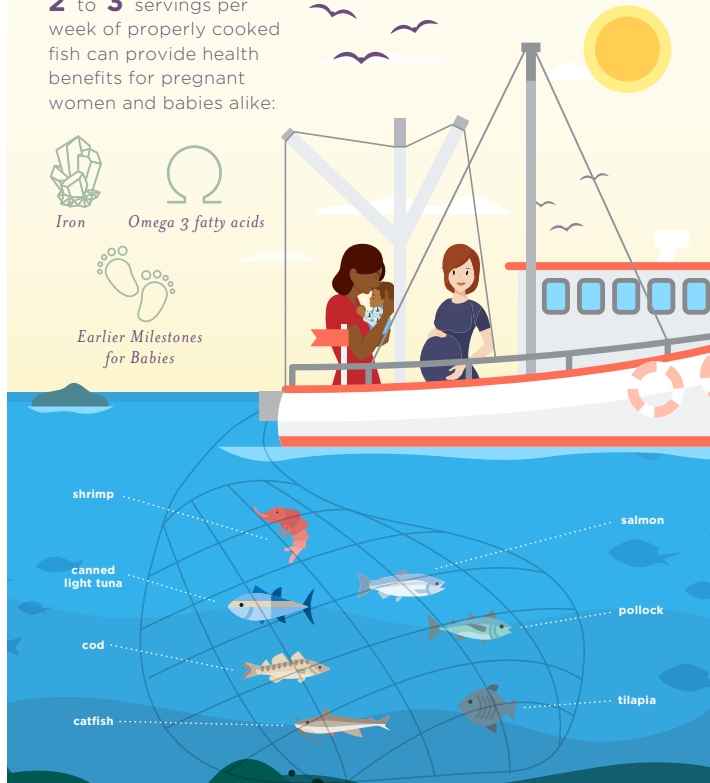


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## Why Pregnant and Nursing Women Need Clear Guidance on THE NET BENEFITS OF EATING FISH

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


-  Iron
-  Omega 3 fatty acids
-  Earlier Milestones for Babies



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?

Join  **NPA** [nationalperinatal.org/mental\\_health](http://nationalperinatal.org/mental_health)

**Support the  
 Open Letter**



**Breastfeeding  
 Innovations  
 Team**



**GET THE FACTS**  
 ON FISH CONSUMPTION  
 FOR PREGNANT  
 WOMEN, INFANTS,  
 AND NURSING MOMS.

 National Coalition for Infant Health  
Protecting Access for Premature Infants through Age Two

**LEARN MORE** ▶

## Planning the Type of Article

Gilbert Martin, MD

On January 5, 1665, the first scientific journal, "The Journal Des Scavans," published its first issue. The mandate offered by the editor was that this Journal was a "means of satisfying curiosity and becoming learned with little effort for those either too indolent or too occupied to read whole books."

There are now over 20,000 different biomedical journals published today. The journal article is still the "gold standard," and professionals are always referring to these original sources.

*" I am sure that there have been many times in your career that you observed a unique case or used a treatment plan which you believed would be interesting to others in your field. The fear of actually sitting down to collect your thoughts, organize them, and finally put the information down on paper is not easy."*

I am sure that there have been many times in your career that you observed a unique case or used a treatment plan which you believed would be interesting to others in your field. The fear of actually sitting down to collect your thoughts, organize them, and finally put the information down on paper is not easy. With a few guidelines and some encouragement, the task is really not difficult....and can even be fun. The feeling of accomplishment after the manuscript is sent to the editor is terrific (note I am not using carefully chosen medicaleaze type jargon, but writing as I would speak). A returned acceptance weeks later is even more gratifying.

SOYOUWANTTOWRITE:WHATNEXT????????????????????

### 1) PLANNING:

1. State an Idea
2. Develop the idea by researching the subject and obtaining information
3. State the thesis or hypothesis.
4. Decide on the type of article which will accurately express your thoughts:
  - Editorial
  - Letter to the Editor
  - Original Article
  - Case Report
  - State of the Art Review
5. Choose the Journal which publishes information on your topic.

6. Read and review the "instructions for the author's" section.

### 2) ORGANIZATION

- a) Format
- b) Order of presentation
  1. Abstract

**NCfIH** National Coalition  
for Infant Health  
Protecting Access for Premature Infants through Age Two

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



### The National Coalition for Infant Health advocates for:

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

[www.infanthealth.org](http://www.infanthealth.org)

2. Introduction
3. Material and methods
4. Results
5. Discussion
6. Conclusions
7. Bibliography

• *Each journal has its own specific order of presentation, and it is important to review this order before continuing with the organization of material.*

c) Illustrations

d) First draft

e) Questions to ask after first draft:

1. Is the topic stated clearly?
2. Are the methods simple and precise?
3. Is there a structure to the article?
4. Is the material divided and balanced well? (a two-page material and methods section followed by ten lines of results is not balanced)
5. Is the writing clear without:
  - a) grammatical mistakes
  - b) too much passive voice
  - c) jargon
  - d) excessive abbreviations
  - e) confusing pronouns
  - f) circumlocution (see definition under #6)
  - g) tautology (see definition under #7)
  - h) difficult words
6. Are the statistics accurate? It may be prudent to incorporate a statistician to review the data as the field of statistics has expanded greatly.
7. Is the bibliography current?

f) Second draft

g) Final review

h) Submit article

Now that I have outlined the steps involved in planning, organizing, and writing an article, let us deal with specifics.

### 3) THE TYPE OF ARTICLE TO WRITE

a) Letter to the Editor:

This column is usually the best read section of general medical journals. The letter should encourage peer review and demonstrates that the reader has read and thought about the material.

The letter to the editor should:

1. Be short (less than 500 words)
2. Use clear style
3. Focus on one point
4. Use correct references

The letter should not:

1. Become a mini-article
2. Be damning or overzealous

The editor:

1. Should correct spelling mistakes or edit material in bad taste
2. Should publish the material as soon as possible
3. Should send the letter to the author of record if his/her work is criticized. The letter and the reply should appear in the same issue.

b) Editorial

The editorials are “point of view” statements. The material can be about a new research advance, a political statement on a “position point,” or a review of an existing problem. The editorial should be signed, although sometimes anonymous editorials have been published. Editorial comment on issues appearing in the journal itself is particularly helpful. Editorials are hard to write because they must be brief, state a point of view quickly and concisely, often without the possibility of using data or statistics. The editorial should not be taken lightly for its role is that of “ultimate peer review.”

c) Case Report

Often placed in the least distinguished section of the journal, the case report is valuable and can be used to review the literature in the discussion section. The knowledge of the disease process is increased. The author should report the uncommon features of the case, the new associations between this case and others, and the importance of this new information. The case report echoes the bedside case presentation and is a valuable teaching tool.

d) State of the Art – Review Article

This type of article is written to organize the literature and present the information so that the practitioner can use it. If done correctly, the review article requires careful planning and extensive research. If too long, the author will lose the audience. If too short or not inclusive, the audience will look elsewhere for the information.

e) Original Article: Refer to the guidelines under “reading the biomedical literature.”

Once the format is chosen and the data presented, the results and statistical evaluation should be stated simply. There is a list provided by the journal concerning number, type, and clarity of illustration.



tions. The references to figures, tables, and graphs should simplify the work rather than falsely embellish the material.

The writing should be clear without:

- 1) Grammatical mistakes: spelling, punctuation, proper use of verbs, adverbs, and adjectives should be of primary importance. Have the material read by another individual who is knowledgeable in this field.
- 2) Overusing the passive voice:
  - Passive: This theory is supported by observations on the gravid rhinoceros.
  - Active: Observations on the gravid rhinoceros support this theory.
- 3) Jargon:
  - Don't say: After sequential interfacing, the therapeutic modality chosen was a surgical intervention.
  - Do say: After several meetings, surgery was the therapy chosen.
- 4) Excessive Abbreviations:

This LBW infant spent four weeks in the NICU and needed IMV, ECMO, and CPAP in addition to the closure of his PDA. He developed A&B and a PG before discharge.

ENOUGH SAID!!!!!!!!!!!!!!!!!!!!!!!!!!!!

- 5) Confusing pronouns:

Example: Indomethacin is used to close a patent ductus arteriosus. What *is* important? The "is" refers to the indomethacin, not the dutus arteriosus.
- 6) Circumlocution:

This is a roundabout way of saying something which should be said concisely, simply, and directly.

Don't say: On an experimental basis, a large number of patients at this point in time need a great deal of support.

Do say: By experiment, more patients now need support.
- 7) Tautology: saying the same things in different words.

Example: Vaguely Obscure

Recline Back

Still Continue
- 8) Overweight words:

Don't say: The requirements of the system forced modifications, which called for the assistance of the Director before a change was effectuated.

Do say: The need of the system forced changes, and help from the Director was necessary before an effect occurred.

The above examples demonstrate the need to write simply and use a heavy hand and pen to delete words and phrases if they

are cumbersome and not clear!!!!!!!

1. Are the statistics accurate?

If the statistics are not presented in an easy, clear manner, the reader will give up and skip the section entirely. The editor and referee reviewing the paper will do the same.

Use few words and concrete examples. Make sure the correct test is used.
2. Is the bibliography current?

Unless a review or historical manuscript is used, the current literature should be used.

Choose an initial reference that was the first article written in this particular field if necessary, but current up to date references are a must. Conform to the style of the journal!!!
3. Second Draft:

The second draft should focus on structure and balance. One section should not be too large or small compared to another. The abstract must state the purpose of the article, indicate the methods used, and summarize the results and conclusions. The abstract should be 200 words or less, convey the scope of the paper, and provide information. The abstract must stand on its own, and it should enable the reader to decide whether or not to proceed to a formal reading of the paper.

The date, references, style, and flow of the writing should be checked.
4. Final Draft:

After the second draft, put the paper on the shelf for a few days to recharge your batteries. Reread the material from a fresh perspective and try to cut and shorten words and phrases which are unnecessary. Ask another colleague to read the material from several viewpoints. First, are the questions answered clearly? Second, is the reading simple? Third, is the style simple?

If all of the above is true...You are ready to submit the manuscript

Disclosure: Dr. Martin indicates no relevant disclosure.

**NT**

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# Letters to the Editor

February 9, 2020

Mitchell Goldstein, MD

Editor-in-Chief, Neonatology Today

Dear Dr. Goldstein:

Neonatologists in the Netherlands (1) have published a multi-center, randomized, non inferiority trial involving 689 otherwise healthy newborns of 35 weeks or more at risk for hypoglycemia in the first 48 hours after birth. They sought to determine whether using a lower threshold for treatment of 36 mg/dL would be non-inferior to a traditional threshold of treatment at a glucose concentration of <47 mg/dL with respect to psychomotor developmental scores using the Dutch version of the Bayley Scales of Infant Development III at 18 months. Developmental scores were available for 82.5% of infants in the lower threshold and 86.5% of those randomized to the routine or higher threshold. In their population of asymptomatic moderately hypoglycemic newborns using the lower threshold (36 mg/dL) was found to be non-inferior to the routine and higher threshold for treatment. This well-executed trial offers additional support to previously published guidelines (2-3) regarding the lower threshold of treatment that might reduce more intensive interventions for hypoglycemia. The authors appropriately caution that 18 month psychomotor scores at 18 months are too early to draw conclusions regarding the longer-term developmental and cognitive performance of these children.

As many units have opted to use glucose gels for initial treatment of neonatal hypoglycemia, a practice the authors contend is unsupported by sufficient evidence; it is important to consider the number of asymptomatic infants 35 weeks or more might be spared any treatment and continued breastfeeding being uninterrupted. How should neonatologists interpret the results of this important trial in their approach to the management of infants 35 weeks or more with asymptomatic hypoglycemia with glucose values 36 or more during their first two days after birth?

T. Allen Merritt, MD MHA

## References

1. van Kempen, AAMW, Eskes, DHGM, Nuyteman JH, van der Lee, LM et al. *New Engl J Med* 2020, 382:6: 534-44
2. Neonatal glycaemia and neurodevelopmental outcomes: a systematic review and meta-analysis. *Neonatology* 2019; 115:116-126.



3. Caksen, j, Guven, AS, Yilmaz C, et al. *Clinical outcome and magnetic resonance imaging in infants with hypoglycemia. J. Child Neurol.* 2011; 26:25-30

Dear Dr. Merritt:

The issue of hypoglycemia in the newborn has long perplexed neonatologists. Normal is an elusive term. It is very difficult to identify a threshold beyond which there is a definitive effect. Healthy neonates are certainly different than sick neonates, and sick neonates may have significantly increased metabolic needs. Moreover, because of impaired glucose mobilization and varying degrees of insulin resistance, even a normal or high glucose can be associated with impaired glucose utilization.

Indeed, it is the well newborn where we may hope to find an answer as to what that appropriate lower limit is, but is it worth the effort? Although strong data do not exist for the use of glucose gels, the cost of this therapy is miniscule compared to the placement of an IV and administration of parenteral glucose.

Moreover, if the precise threshold were identified, how much more monitoring would be indicated, and what treatment would be sufficient to prevent the defined morbidity?

Still, it may be too early to define an effect. Although the study showed non-inferiority at 18 months, what longer term issues may be demonstrated when these infants reach kindergarten or beyond? All considered, we may have to wait for the answer.

In terms of present practice, as with many things in our field, it may be better to curse the darkness, than light the wrong candle.

Sincerely,

A handwritten signature in black ink, appearing to read "Mitchell Goldstein".

Mitchell Goldstein, MD

Editor in Chief



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c/o Mitchell Goldstein, MD

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NT



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

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

NT



### Erratum (Neonatology Today January, 2020)

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

Corrections can be sent directly to [LomaLindaPublishingCompany@gmail.com](mailto:LomaLindaPublishingCompany@gmail.com). The most recent edition of Neonatology Today including any previously identified erratum may be downloaded from [www.neonatologytoday.net](http://www.neonatologytoday.net).

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## Postpartum Revolution

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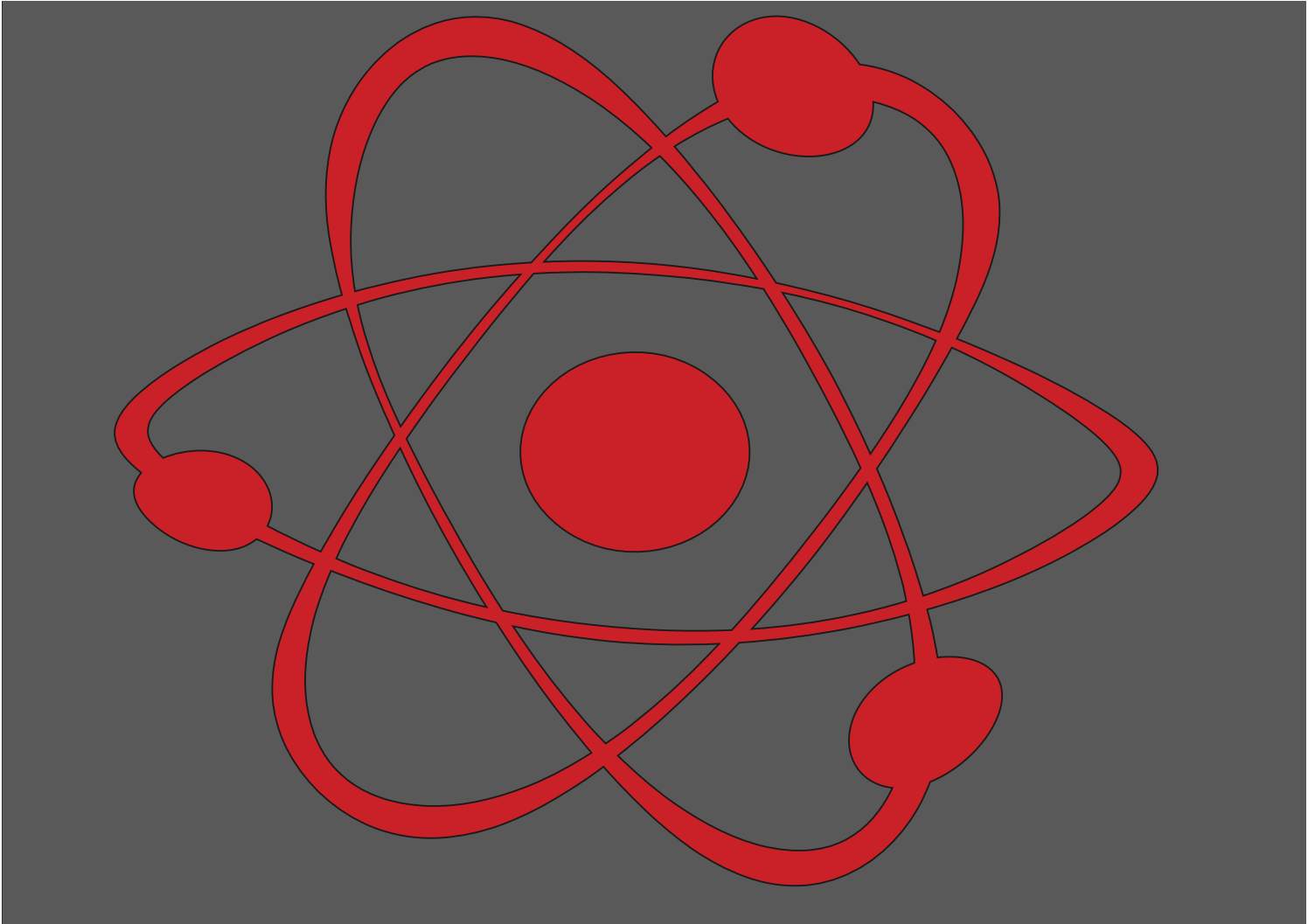
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11. A commitment to the ethical treatment of humans and animals in research.
12. Documentation of informed consent where indicated.

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ISSN: 1932-7137 (Online), 1932-7129 (Print)

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

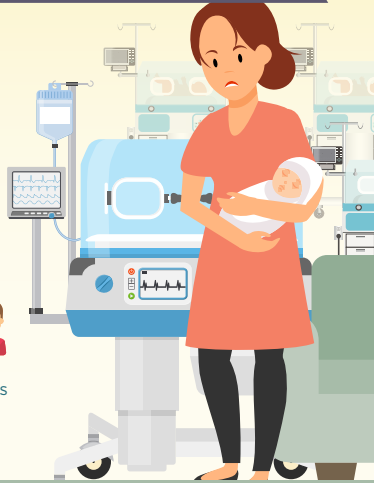
Preterm infants are:

**2x** more likely to have developmental delays

**5x** more likely to have learning challenges



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



Early intervention can help preterm infants:



Enhance language and communication skills



Build more effective learning techniques



Process social and emotional situations



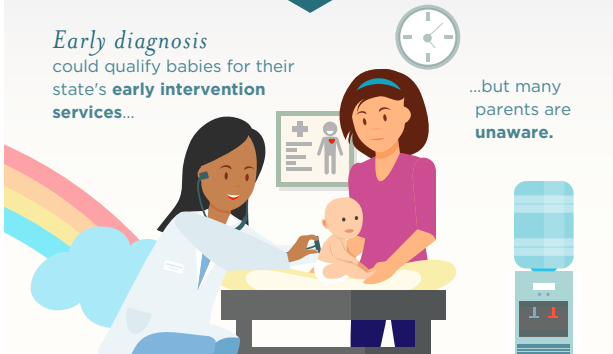
Address physical challenges



Prevent mild difficulties from developing into major problems

Early diagnosis could qualify babies for their state's **early intervention services**...

...but many parents are **unaware**.



**NICU staff, nurses, pediatricians and social workers should talk** with NICU families about the challenges their baby may face.

Awareness, referral & timely enrollment in early intervention programs can help **infants thrive** and grow.



**NCFIH** National Coalition for Infant Health  
Protecting Access for Premature Infants through Age Two  
[www.infanthealth.org](http://www.infanthealth.org)

Visit [CDC.gov](http://CDC.gov) to find contact information for your state's early intervention program.

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



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



Sin embargo, sólo el **15%** recibe tratamiento<sup>1</sup>

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

El sueño, la alimentación y el comportamiento del bebé a medida que crece<sup>2</sup>



La salud de la madre

La capacidad para cuidar de un bebé y sus hermanos

PARA AYUDAR A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSTPARTO



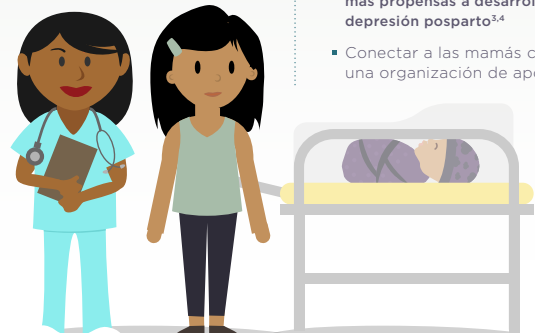
**LOS ENCARGADOS DE FORMULAR POLÍTICAS PUEDEN:**

- 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 postparto**<sup>3,4</sup>
- Conectar a las mamás con una organización de apoyo



**NCFIH** National Coalition for Infant Health  
Protecting Access for Premature Infants through Age Two  
[www.infanthealth.org](http://www.infanthealth.org)

<sup>1</sup> American Psychological Association. Accessed on: <http://www.apa.org/women/resources/reports/postpartum-depression.aspx>

<sup>2</sup> National Institute of Mental Health. Accessed on: <http://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml>

<sup>3</sup> Journal of Perinatology (2015) 35, 529–536. doi:10.1097/JP.0000000000000147

<sup>4</sup> Prevalence and risk factors for postpartum depression among women with problem and low-birth-weight infants: a systematic review. Vigod SN, Villiger L, Dennis CL, Ross LE BJOG. 2010 Apr; 117(5):540-50.

## Upcoming Medical Meetings

### NEO

The Conference for Neonatology  
February 19 – 21, 2020.  
San Diego, CA  
<http://www.neoconference.com/>

Specialty Review in Neonatology  
February 17-22, 2020  
<http://specialtyreview.com>

36<sup>th</sup> Annual Children's National  
Symposium ECMO and Advanced  
Therapies  
February 23 - 27, 2020  
Children's National  
Keystone, Colorado  
[https://web.cvent.com/event/  
a92c867d-d0d2-4eb5-888b-  
3b1672487c03/summary](https://web.cvent.com/event/a92c867d-d0d2-4eb5-888b-3b1672487c03/summary)

33<sup>rd</sup> Annual Gravens Conference on  
the EOC for High Risk Newborns  
March 4 - 7, 2020  
University of South Florida Health  
Clearwater Beach, Florida  
[https://health.usf.edu/publichealth/  
chiles/gravens-conference](https://health.usf.edu/publichealth/chiles/gravens-conference)

26<sup>th</sup> Annual Cool Topics in  
Neonatology  
March 6 - 8, 2020  
California Association of Neonatologists  
Coronado, California  
[https://caneo.groupsite.com/main/  
summary](https://caneo.groupsite.com/main/summary)

The 37<sup>th</sup> Annual Advances in  
Therapeutics and Technologies  
Conference  
March 24-28, 2020  
Snowbird, UT  
[http://paclac.org/advances-in-care-  
conference/](http://paclac.org/advances-in-care-conference/)

Perinatal Care and the 4th Trimester:  
Redefining Prenatal, Postpartum, and  
Neonatal Care for a New Generation  
March 25 - 27, 2020  
Aurora, Colorado  
[http://www.nationalperinatal.  
org/2020conference](http://www.nationalperinatal.org/2020conference)

4<sup>th</sup> Future of Neonatal Care  
Conference  
AKA the #99nicuMeetup!  
15-19 April 2020  
Vienna, Austria  
<https://99nicu.org/meetup/>

1<sup>st</sup> Annual Innovations in Maternal,  
Fetal, and Neonatal Medicine  
March 27 - 29, 2020  
Johns Hopkins All Children's  
Hospital  
St. Petersburg, Florida  
[http://www.cvent.com/events/the-  
annual-innovations-in-maternal-  
fetal-and-neonatal-medicine-the-  
continuum-of-care-conference/  
event-summary-772b578c0e5348d3b  
ba8a80915ffcac8.aspx](http://www.cvent.com/events/the-annual-innovations-in-maternal-fetal-and-neonatal-medicine-the-continuum-of-care-conference/event-summary-772b578c0e5348d3bba8a80915ffcac8.aspx)

Pediatric Academic Societies 2020  
Meeting  
April 29 – May 6, 2020  
Philadelphia, PA  
<https://2020.pas-meeting.org/>

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

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

*For up to date Meeting  
Information, visit  
[NeonatologyToday.net](http://www.NeonatologyToday.net) and click  
on the events tab.*

## NEONATOLOGY TODAY

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7129 (Print). Published monthly. All rights  
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## Academic Neonatologist Opportunity in Southern California

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

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

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

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

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

This opportunity is not eligible for a J1 Waiver.



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# Nursing Opportunities

*Many Strengths. One Mission.*



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GREAT  
MEDICINE.

## 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



EOE/AAE

## Who We Are

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

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

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

## Contact Us

Please visit our website <http://careers.llu.edu> or contact Jeannine Sharkey, Director of Advanced Practice Services at [jsharkey@llu.edu](mailto:jsharkey@llu.edu) or (909) 558-4486.

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Peer Reviewed Research, News and Information in Neonatal and Perinatal Medicine  
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<https://www.nc3rs.org.uk/arrive-guidelines>

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

NT

## Neonatology and the Arts

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

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

Logos and trademarks will usually not qualify for publication.

Dr. Mitchell Goldstein provides us with a "reflective" black swan this month from somewhere in Maui, Hawaii.



Herbert Vasquez, MD

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2. All material should be emailed to: [LomaLindaPublishingCompany@gmail.com](mailto:LomaLindaPublishingCompany@gmail.com) in a Microsoft Word, Open Office, or XML format for the textual material and separate files (tif, eps, jpg, gif, ai, psd, or pdf) for each figure. Preferred formats are ai, psd, or pdf. tif and jpg images should have sufficient resolution so as not to have visible pixilation for the intended dimension. In general, if acceptable for publication, submissions will be published within 3 months.

3. There is no charge for submission, publication (regardless of number of graphics and charts), use of color, or length. Published content will be freely available after publication (i.e., open access). There is no charge for your manuscript to be published under open access

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

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

6. An abstract may be submitted.

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

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

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

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