

NEONATOLOGY TODAY

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



Volume 14 / Issue 2 | February 2019

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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:
www.NeonatologyToday.net
www.Twitter.com/NeoToday



Loma Linda Publishing Company
A Delaware "not for profit" 501(c) 3 Corporation.
c/o Mitchell Goldstein, MD
11175 Campus Street, Suite #11121
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Nitric oxide combines with hemoglobin to form methemoglobin, which does not transport oxygen. Methemoglobin levels increase with the dose of INOmax; it can take 8 hours or more before steady-state methemoglobin levels are attained. Monitor methemoglobin and adjust the dose of INOmax to optimize oxygenation.

If methemoglobin levels do not resolve with decrease in dose or discontinuation of INOmax, additional therapy may be warranted to treat methemoglobinemia.

Airway Injury from Nitrogen Dioxide

Nitrogen dioxide (NO₂) forms in gas mixtures containing NO and O₂. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.

If there is an unexpected change in NO₂ concentration, or if the NO₂ concentration reaches 3 ppm when measured in the breathing circuit, then the delivery system should be assessed in accordance with the Nitric Oxide Delivery System O&M Manual troubleshooting section, and the NO₂ analyzer should be recalibrated. The dose of INOmax and/or FiO₂ should be adjusted as appropriate.

Worsening Heart Failure

Patients with left ventricular dysfunction treated with INOmax may experience pulmonary edema, increased pulmonary capillary wedge pressure, worsening of left ventricular dysfunction, systemic hypotension, bradycardia and cardiac arrest. Discontinue INOmax while providing symptomatic care.

ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse reaction information from the clinical studies does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

Controlled studies have included 325 patients on INOmax doses of 5 to 80 ppm and 251 patients on placebo. Total mortality in the pooled trials was 11% on placebo and 9% on INOmax, a result adequate to exclude INOmax mortality being more than 40% worse than placebo.

In both the NINOS and CINRGI studies, the duration of hospitalization was similar in INOmax and placebo-treated groups.

From all controlled studies, at least 6 months of follow-up is available for 278 patients who received INOmax and 212 patients who received placebo. Among these patients, there was no evidence of an adverse effect of treatment on the need for rehospitalization, special medical services, pulmonary disease, or neurological sequelae.

In the NINOS study, treatment groups were similar with respect to the incidence and severity of intracranial hemorrhage, Grade IV hemorrhage, periventricular leukomalacia, cerebral infarction, seizures requiring anticonvulsant therapy, pulmonary hemorrhage, or gastrointestinal hemorrhage.

In CINRGI, the only adverse reaction (>2% higher incidence on INOmax than on placebo) was hypotension (14% vs. 11%).

Based upon post-marketing experience, accidental exposure to nitric oxide for inhalation in hospital staff has been associated with chest discomfort, dizziness, dry throat, dyspnea, and headache.

DRUG INTERACTIONS

Nitric Oxide Donor Agents

Nitric oxide donor agents such as prilocaine, sodium nitroprusside and nitroglycerine may increase the risk of developing methemoglobinemia.

OVERDOSAGE

Overdosage with INOmax is manifest by elevations in methemoglobin and pulmonary toxicities associated with inspired NO₂. Elevated NO₂ may cause acute lung injury. Elevations in methemoglobin reduce the oxygen delivery capacity of the circulation. In clinical studies, NO₂ levels >3 ppm or methemoglobin levels >7% were treated by reducing the dose of, or discontinuing, INOmax.

Methemoglobinemia that does not resolve after reduction or discontinuation of therapy can be treated with intravenous vitamin C, intravenous methylene blue, or blood transfusion, based upon the clinical situation.

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Oropharyngeal Therapy with Mother's Own Milk (OPT-MOM) to Protect Extremely Premature Infants against Infectious Morbidities

Nancy A. Garofalo, PhD APN, NNP

Abstract

Background: Upon birth, the extremely low birth weight (ELBW) infant experiences an abrupt cessation of amniotic fluid exposure. The ELBW infant's oropharynx is no longer exposed to immunoprotective biofactors, which modulate the immune system and promote maturation of the gastrointestinal tract. Many immune and trophic biofactors are also contained in the mother's own milk, and are especially concentrated in the milk expressed by mothers of ELBW infants; particularly in colostrum. Unfortunately, clinical instability precludes enteral feeding for ELBW infants in the first days of life. Once started, enteral feeds are administered via a nasogastric tube; therefore oropharyngeal exposure to protective milk biofactors cannot occur until the infant begins per oral feeds, with mother's milk; typically at 32 weeks corrected gestational age. The delay, or lack of, oropharyngeal exposure to protective milk biofactors, during the critical first weeks of life for the ELBW infant, may be contributing substantially to prematurity-associated infectious morbidities. Oro-Pharyngeal Therapy with Mother's Own Milk (OPT-MOM)-placing drops of mother's milk onto the infant's oral mucosa to provide early postnatal modulation of the immune system- can serve as a potential substitute for amniotic-fluid (biofactor) exposure. Purpose: To describe how OPT-MOM may protect the ELBW infant against prematurity-associated infectious morbidities including Late-Onset Sepsis, necrotizing enterocolitis (NEC), and also Ventilator-Associated Pneumonia. This manuscript will provide neonatal clinicians with the latest evidence to guide clinical practice. Important implications, in terms of patient safety, will also be addressed.

Keywords: breastmilk, human milk, mother's milk, colostrum, oropharyngeal, oral immune, oral care, premature, extremely low birth weight, very low birth weight.

Introduction

Extremely low birth weight (ELBW) infants are born at the lower limits of viability, weighing less than 1000 grams, and experience an abrupt ending to amniotic fluid exposure. The oropharynx is no longer bathed with amniotic fluid biofactors which provide immunostimulatory effects, protect against infection, and promote gastrointestinal maturation. Protective biofactors are also contained in mother's own milk, with the highest concentrations present in the milk expressed by mothers of ELBW infants; especially in colostrum. However, with our current standard of care, the ELBW infant's oropharynx is not exposed to protective milk biofactors, for up to 10 weeks post-birth. Enteral feedings are administered via a nasogastric tube; which bypasses the oropharynx, until per oral feedings are introduced at >32 weeks corrected gestational age (CGA). It is possible that the lack of oropharyngeal exposure to protective biofactors, for a prolonged period post-birth, may be contributing to prematurity-associated infectious morbidities for the ELBW infant, including Late-Onset Sepsis (L-OS), Necrotizing Enterocolitis (NEC), and Ventilator-Associated Pneumonia (VAP). This deficit has never

been addressed in neonatal care. Oro-Pharyngeal Therapy with Mother's Own Milk (OPT-MOM)-placing drops of mother's milk onto the infant's oral mucosa- may serve as a natural substitute for amniotic fluid exposure; potentially correcting this deficit. This paper will present evidence that supports the concept that OPT-MOM may serve as a potential immunotherapy, to protect ELBW infants against infectious morbidities.

Prematurity-associated Infectious Morbidities

ELBW infants are at high risk for acquiring L-OS, NEC, and VAP; infections which are associated with significant mortality, costly morbidities, and the potential for adverse long-term neurodevelopmental outcomes. Late-onset sepsis (L-OS) is defined as the identification of pathogenic organisms from a blood culture (bacteremia) acquired after the third day of life. (1) LOS affects 32-53% of ELBW infants, with high mortality (30%) (2,3) and increases hospitalization costs by 31%. (4) Necrotizing Enterocolitis (NEC) is a gastrointestinal infectious and inflammatory disorder, which in severe cases can lead to bowel necrosis and death. (5-12) NEC affects 10-15% of ELBW infants, with 30% mortality and costs an estimated \$1 billion in healthcare dollars yearly. (8-10) Ventilator-associated pneumonia (VAP) accounts for up to 32.3% of NICU device-associated infections, is associated with secondary bacteremia and chronic lung disease, and prolongs hospitalization. (13,14) With the increased survival of ELBW infants, the incidence of prematurity-associated morbidities, and their associated costs, are on the rise. (15) The prevention of infectious morbidities, including L-OS, NEC, and VAP, is a clinical priority.

"With the increased survival of ELBW infants, the incidence of prematurity-associated morbidities, and their associated costs, are on the rise. The prevention of infectious morbidities, including L-OS, NEC, and VAP, is a clinical priority."

Infection Risk for ELBW Infants

ELBW infants are at high risk for acquiring L-OS, NEC, and VAP as a result of numerous factors. First, they have an abnormal host defense, with deficits in both innate and adaptive components of the immune system. The immature immune system is unable to mount an effective, appropriate response against pathogens encountered; often resulting in unbridled inflammation with subsequent tissue injury. (16-19)

Second, ELBW infants require multiple invasive catheters and

tubes for the provision of life-saving therapies. These devices become portals for pathogen entry. Bacterial colonization of the oropharynx and upper respiratory tract increases the risk for VAP, while bacterial colonization of the gastrointestinal tract increases the risk for both L-OS and NEC. Third, ELBW infants have an immature gastrointestinal tract which increases infection risk. Clinical instability in the first days of life often precludes enteral feeds for ELBW infants. The lack of enteral nutrition during this critical post-birth period quickly leads to intestinal atrophy, (20) which places the infant at risk for feeding intolerance and also NEC. Once feeds are initiated, the immature gastrointestinal tract makes the tolerance of enteral feeds problematic, and leads to a prolonged time to reach full enteral feeds. This necessitates the provision of prolonged parenteral nutrition, via centrally-placed venous catheters, factors which increase the risk for L-OS. Also, a prolonged time to reach full enteral feeds is linked to a higher risk for NEC. (12) Fourth, ELBW infants require a prolonged hospitalization; typically 3-4 months and therefore have persistent exposure to neonatal intensive care unit (NICU) pathogens. Finally, ELBW infants develop an abnormal gastrointestinal microbiome (dysbiosis) as a result of exposure to antibiotics, delayed enteral nutrition, and immaturity in gastrointestinal function including decreased peristalsis, decreased gastric acid and enzymatic activity, reduced surface glycoconjugates, and decreased intestinal mucus. (1,21,22) Gastro-intestinal pathogens can injure the fragile immature intestinal mucosal barrier; an initial step in NEC pathogenesis. Also, decreased tight junctions between intestinal epithelial cells facilitate bacteria translocation, with subsequent L-OS.

A pathogen-predominant microbiome is an important component in the pathogenesis of both L-OS and NEC. (1,5,19,21-25) Interventions that optimize the microbiome and reduce the presence of pathogens, in the gastrointestinal tract and the oropharynx, may reduce the risk for L-OS, NEC, and VAP for the ELBW infant.

Protection against Infection with Mother's Own Milk (MOM)

Mother's milk feedings have been linked to improved health outcomes for premature infants, including protection against several prematurity-associated morbidities including NEC, L-OS, retinopathy of prematurity, chronic lung disease and adverse neurodevelopmental outcomes. (2,4,12,15,26-38) These health benefits are attributed to a multitude of potent biofactors which collectively: provide antimicrobial activity, maintain intestinal integrity, provide anti-oxidant, anti-inflammatory and immunomodulatory functions, and provide trophic/maturation effects on the intestinal mucosa. (39-44) Biofactor concentrations are highest in the milk expressed by women who deliver the least mature (ELBW) infants; (45-54) particularly in early milk (colostrum). However, even beyond the colostrum phase, concentrations of several immune and trophic biofactors remain high in preterm milk (compared to term milk) for many weeks post-delivery. 50, 53, 55 Importantly, many of these protective biofactors are also present in amniotic fluid. These gestation-specific trends in biofactor concentrations suggest that preterm milk has an important biological function for facilitating extra-uterine transition for the ELBW infant. Preterm milk is therefore uniquely suited to compensate for the ELBW infant's immunological deficiencies; providing protection against infection.

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A Universal Clinical Dilemma:

Early post-birth exposure to mother's milk may serve as a potential immune therapy for the ELBW infant. Unfortunately, enteral exposure post-birth is often delayed for several days due to clinical instability. Once the infant is stable, minimal enteral feeds are initiated via a nasogastric tube, which bypasses the infant's oropharynx. Oral feeds (breast and/or bottle) are typically not introduced until the ELBW infant reaches a corrected gestational age (CGA) of at least 32 weeks. Therefore, with our current standard of care, oropharyngeal exposure to protective (milk) biofactors is delayed for up to 10 weeks post-birth, for the least mature ELBW infants born as early as 22 weeks gestation. Unfortunately, many mothers of ELBW infants become discouraged with low milk volume and discontinue milk expression before the infant is ready to begin oral feeds. In these cases, when own mother's milk is no longer available, and standard formula is given instead, the ELBW infant's oropharynx is never exposed to





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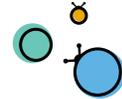
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protective biofactors post-birth. This deficit- the delay or complete lack of biofactor exposure post-birth for the ELBW infant- has never been addressed in neonatal care. In a healthy term pregnancy, the fetus receives continuous in-utero exposure to (amniotic-fluid) biofactors until 40 completed weeks of gestation. It is plausible that the delay (or lack) of oropharyngeal exposure to (immune and trophic) biofactors post-birth may be contributing significantly to the pathogenesis of prematurity-associated infectious morbidities. Oropharyngeal administration of mother's own milk, using the OPT-MOM approach, may serve as a potential natural alternative to provide a continuum of amniotic fluid effects ex-utero for the ELBW infant.

OroPharyngeal Therapy with Mother's Own Milk (OPT-MOM)

The OPT-MOM approach involves a rigorous protocol of frequent and precise dosing of mother's own milk, administered via the oropharyngeal route, for several weeks until per oral feeds can be safely introduced for the ELBW infant. The goal is to provide sustained oropharyngeal exposure to protective (immune and trophic) milk biofactors, similar to those that are naturally found in amniotic fluid. Treatments are started soon after birth, once mother's colostrum is available, and continued for many weeks without interruption.

Since OPT-MOM is intended to serve as an ex-utero substitute for biofactor-rich amniotic fluid exposure, the protocol includes the use of colostrum, transitional and mature milk for sustained dosing over several weeks post-birth; until the infant reaches 32 weeks CGA. The dosing is precise (0.2 mL; ~ 8 drops) in order to expose the infant to biofactor doses comparable to in-utero exposure. For example, based on concentrations of epidermal growth factor (EGF) and lactoferrin in human amniotic fluid and preterm milk, (45,55) a fetus weighing 1000 grams would be exposed to 38 ng of EGF and 172 mcg of lactoferrin daily via amniotic fluid (200 mL/kg fetal weight/day). Ex-utero, an ELBW infant weighing 1000 grams, would receive a 'dose' of 396 ng of EGF and 658 mcg of lactoferrin with OPT-MOM treatments every 2 hours (2.4 mL/daily), and 216 ng of EGF and 450 mcg of lactoferrin with treatments every 3 hours (1.6 mL day). Thus, OPT-MOM can potentially provide higher doses of protective biofactors for the ELBW infant, who remains in the pathogen-laden NICU, compared to the sterile in-utero environment for the fetus. The amount of milk that is needed daily for OPT-MOM treatments is minimal; less than a teaspoon (1.6 – 2.4 mL, depending on the frequency of treatments), therefore even mothers with minimal milk volume can easily provide this volume daily.

OPT-MOM: Potential Mechanisms of Action

FIGURE 1

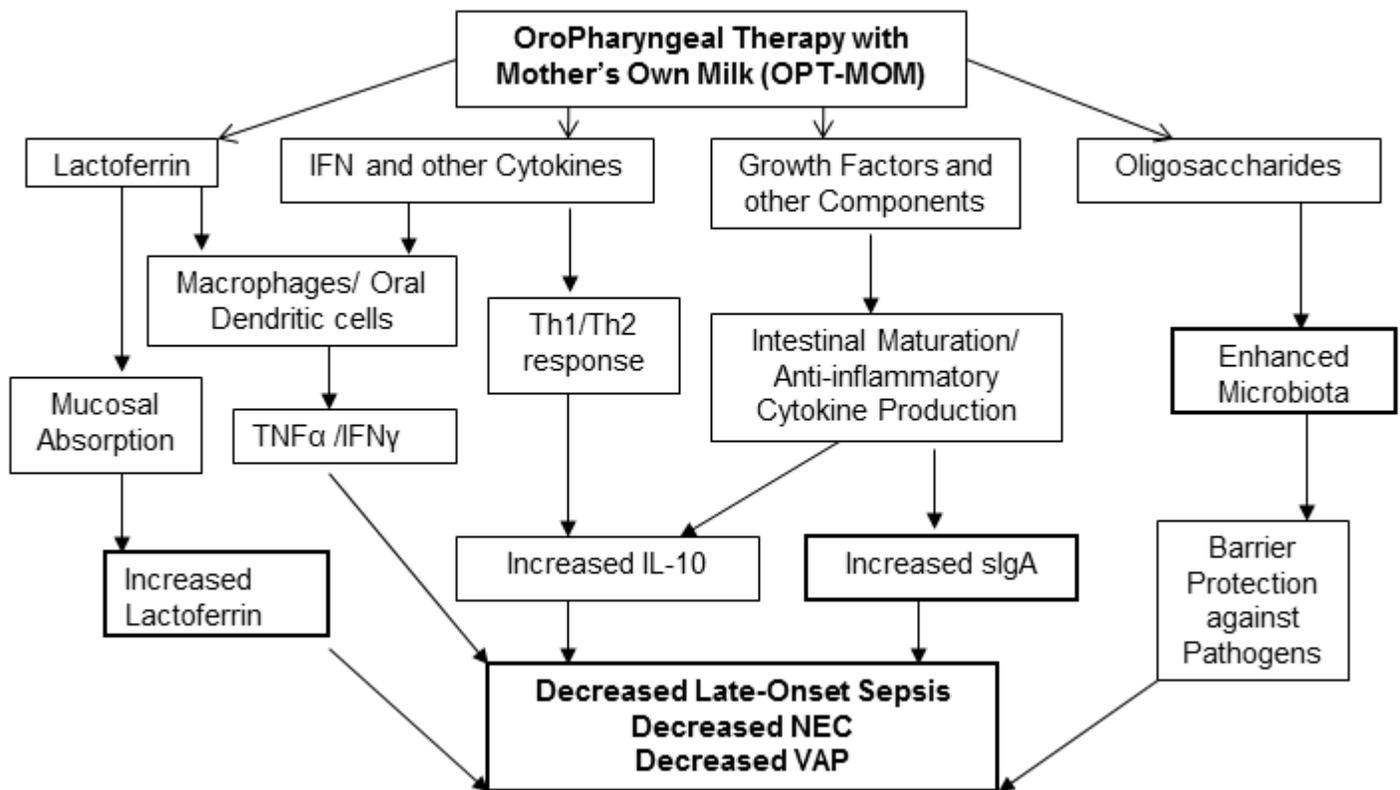


Figure 1: OroPharyngeal Therapy with Mother's Own Milk (OPT-MOM). A simplified model of the proposed mechanisms of action for protection against Late-onset sepsis, NEC and VAP, using the OPT-MOM approach, based on the known biological functions of milk biofactors.

The potential benefits of OPT-MOM are based on the following distinct mechanisms: (1) immunostimulatory effects of cytokine interaction with immune cells within the oropharyngeal-associated lymphoid tissues (OFALT), (2) passive mucosal absorption of protective (immune and trophic) biofactors, (3) barrier protection against pathogens in the oropharynx, (4) anti-inflammatory protection, (5) local and systemic effects of oligosaccharides, and (6) protective effects of antioxidants. These mechanisms are detailed elsewhere, (60, 61) but summarized below and in Figure 1.

Biofactors provide protection against L-OS with antimicrobial,

anti-inflammatory and immunomodulatory functions and the creation of a gastrointestinal microflora milieu that prevents the proliferation, and translocation of pathogenic organisms. (61) Trophic factors promote intestinal maturation, which facilitates the tolerance of enteral feeds and thereby indirectly protect against L-OS, since central venous catheters can be removed earlier.

Protection against NEC is attributed to biofactors which promote the presence of commensal bacteria; reducing dysbiosis. Also, other biofactors provide antimicrobial properties, maintain the integrity of the intestinal epithelial barrier, heal areas of intestinal

Table 1. Oropharyngeal Administration of Mother’s Milk

• Oral care/mouth care with colostrum
• Oral swabbing with colostrum
• Buccal swabbing with colostrum
• Oral colostrum
• Oropharyngeal colostrum (OC)
• Mouth feeds with colostrum
• Oral immune therapy (OIT) with colostrum
• Colostrum oral care (COC)
• Oral human milk swabbing
• Buccal administration of colostrum
• Oral colostrum priming (OCP)
• Colostrum swabbing
• Oropharyngeal Therapy with Mother’s Own Milk (OPT-MOM)
• Administración de calostro orofaríngeo

injury, decrease inflammation, provide anti-oxidant protection, promote intestinal maturation and regulate the ELBW infant's immune response. (60)

Protection against VAP is afforded by human milk oligosaccharides, secretory immunoglobulin A (sIgA) and lactoferrin, among others. Oligosaccharides and secretory IgA provide barrier protection and inhibit the adhesion of respiratory pathogens to epithelial cell surface receptors in the mucosa of the oropharynx. This may lessen the ability of the pathogens to colonize the upper respiratory tract where they could lead to subsequent VAP. Lactoferrin and oligosaccharides also provide antimicrobial, anti-inflammatory and mucosal healing properties (60,61) which serve to protect against VAP.

With OPT-MOM, the interaction of (milk) cytokines with immune cells within lymphoid tissues may provide systemic immunostimulatory effects and anti-inflammatory protection. Mucosal absorption of immune biofactors, such as lactoferrin, may provide systemic protection against infection, while absorption of trophic factors (e.g., EGF), may accelerate intestinal maturation. Oligosaccharides may also be absorbed mucosally with systemic effects or may travel to the gut; enhancing the microbiota and decreasing the risk for intestinal injury. (60,61) Oligosaccharides, sIgA, and lactoferrin, prevent pathogen attachment to the oropharyngeal and intestinal mucosa, providing protection against VAP, L-OS, and NEC. Figure 1 depicts the proposed mechanisms of action for protection against L-OS, NEC, and VAP, using the OPT-MOM approach, based on the known biological functions of milk biofactors.

Current Evidence to Support the OPT-MOM Approach

The concept of using oropharyngeal administration of mother's colostrum as a potential immune therapy for ELBW infants was first introduced into the medical literature in 2009. (62) Following the publication of this initial "theory paper," two pilot studies 56, 63 established feasibility, and results from a small randomized controlled trial (RCT) (57) were suggestive of possible immunostimulatory effects. Infants who received oropharyngeal (own mother's) colostrum, were found to have higher concentrations of urinary lactoferrin, compared to placebo-treated infants. A clinically relevant large effect size (1.30) was noted for urinary lactoferrin in treated infants, suggesting that results may have reached statistical significance with a larger sample. The most compelling finding was that treated infants reached full enteral feedings (150 mL/kg/day) on average ten days earlier (14.3 ± 5.7 vs 24.2 ± 8.7 ; $p=0.032$) compared to controls. (57) The intervention was feasible and well-tolerated by all enrolled infants. Infants were noted to begin sucking on the breathing tube when the drops were being administered.

Since these initial studies were first published, several researchers have evaluated the benefits of oropharyngeal mother's milk for premature infants; particularly with the very low birth weight (VLBW; BW<1500g) and ELBW population. Although variable terminology has been used to describe 'oropharyngeal administration of mother's milk' (see Table 1) including 'oral immune therapy' the concept is the same; placing drops of mother's milk onto the infant's oral mucosa in efforts to provide early postnatal modulation of the immune system. To date, the oropharyngeal

administration of mother's milk has been associated with many benefits for the recipient preterm infant, including: enhanced immune status (higher concentrations of serum IgA, (66) salivary sIgA, (64) urinary sIgA, (65), salivary lactoferrin, (69) and urinary lactoferrin,(67), reduced inflammation (lower concentrations of salivary IL-8 and TGF β -1 and also urinary IL-1 β ,) (65) a lower risk for clinical sepsis, (65,67) enhanced oral microbiota, (68,69) enhanced breastfeeding outcomes, (58) improved growth, 70 a reduced time to achieve full enteral feedings (67,69,70) and full per oral feedings, (69) and a reduced length of hospital stay. (69)

More recent work suggests that this intervention may also be beneficial for term infants who are unable to feed orally; including infants with cardiac disease, congenital diaphragmatic hernia, omphalocele, gastrointestinal anomalies (including gastroschisis) and also infants who are recovering from surgery. (71-74) Potential maternal benefits have also been reported. (58,74,75) Evidence suggests that mothers who provide milk for oropharyngeal administration, may be more motivated to continue milk expression ('pumping'); thus maintaining lactation during their infant's hospitalization, even while the infant is not able to feed enterally. (75) Also, the provision of oropharyngeal colostrum has been linked to sustained mother's milk feedings, for VLBW infants at six weeks of age and through discharge from the neonatal intensive care unit. 58 This suggests that providing milk for oropharyngeal administration to their preterm infant may be a strong motivating factor for mothers to continue pumping, resulting in more 'doses' of milk for the preterm infant, during the first weeks of life.

Discussion and Clinical Implications

In published reports, the oropharyngeal administration of mother's milk is described using variable terminology (see Table 1) yet the underlying premise is the same: placing drops of mother's milk onto the infant's oral mucosa so that (milk) biofactors may provide immunomodulation. While prior studies focused on the use of early milk (colostrum) for a brief 48-hour treatment period for infants who were 'nil per os', a paradigm shift has occurred and clinicians are now utilizing oropharyngeal administration of mother's own milk (inclusive of early, transitional and mature milk) for longer treatment periods; up to day of life 7. Yet, it is unlikely that brief treatment periods (2-7 days) will have a significant impact on important clinical outcomes such as NEC. The latest terminology (OPT-MOM) implies the prioritized use of oropharyngeal mother's milk, as a potent immunomodulatory therapy over several weeks post-birth. In this manner, OPT-MOM serves as an adjunct to nasogastric-tube-feedings and as a natural substitute for amniotic fluid (oropharyngeal) exposure until per oral feeds (via breast and/or bottle) can be safely introduced for the ELBW infant. A multi-center RCT is underway (funded by the Gerber Foundation), utilizing the OPT-MOM approach and evaluating its impact on clinical outcomes for recipient ELBW infants. (61)

Current evidence suggests that oropharyngeal administration of mother's own milk can be beneficial and without adverse effects for recipient infants. However, safety and efficacy have not been firmly established in an adequately-powered RCT. To date, published studies are primarily retrospective in design, utilized very small samples, and were not powered to look at clinical outcomes. Also, the treatment periods were brief, ranging from 48

hours to 7 days post-birth. An important consideration is that the immune benefits did not always persist once the treatments were stopped.

In a recent study, even with a treatment period of 5 days of oropharyngeal milk administration, the immune effects that were noted at one week of life for treated infants, were not sustained when measured at two weeks of life. (64) The authors speculate that the lack of effect on clinical outcomes may have been due to the short 5-day duration of the treatment protocol and that the immune benefits (higher concentrations of salivary sIgA) may have been sustained with longer duration of the treatment protocol. 64 In another recently published study, 68 the investigators suggest that a brief 48-hour treatment period may have limited effects on oral microbiota or clinical outcomes such as NEC, L-OS VAP, and chronic lung disease. In a third recent study, the authors suggest that more research is needed to determine if the immune effects are passive and therefore treatments should be continued and if the intervention results in temporary or sustained changes. 69 In a fourth and most recent study; a placebo-controlled RCT (n=64 VLBW infants), salivary IgA was significantly increased from baseline levels in treated infants after 7 consecutive days of treatment (0.2 mL every 4 hours x 7 days), compared to placebo controls (p=0.04) but these differences were not sustained, when measured 14 days after the treatments were discontinued. 67 Findings from these four recent studies suggest that an uninterrupted regimen of sustained and prolonged oropharyngeal exposure to protective milk biofactors, until oral feeds of mother's milk are introduced, is more likely to provide sustained immune benefits and impact clinical outcomes.

A significant limitations to published research is the wide variability in methodologies for the dose administered (ranging from 0.1 mL to 1.0 mL), frequency of treatments (every 2 to every 6 hours, also on an 'as needed' basis), duration of treatment (from 2 to 7 days), use of a syringe versus a cotton or foam swab, and the use of fresh versus frozen milk. The percent of 'planned treatments' that were actually given is typically not reported, except for four studies. (58,61,63,65) Also, the procedure for preparation of the 'dose' (ideally in a sterile manner) is usually not described.

In the majority of published studies (85%; 10 out of 12), sterile syringes were utilized to administer the treatments. (56,57,58,61,65-70) Since OPT-MOM is intended as an oral immune therapy, the milk should be treated as a 'medication' with a precise volume drawn up and administered with a sterile syringe. In this manner, appropriate doses of immune and trophic biofactors can be administered consistently with every treatment; as described in prior sections. The use of a swab to administer the milk does not provide a precise dose and is not an evidence-based approach. A cotton swab tends to absorb the majority of the milk, while a (low absorbency) foam swab will not hold and transfer an appropriate amount of milk to the mucosa, because of its low absorbency. Two published studies utilized swabs

for the oropharyngeal administration of milk. One study was a feasibility pilot; 63 therefore, the impact of the intervention on immune markers and clinical outcomes for treated infants was not measured. In the second study which utilized swabs, the immune effects of the intervention were not sustained one week after the protocol was completed. (64)

A recently published study defines oropharyngeal administration of colostrum as placing a small amount of colostrum directly onto the oropharyngeal mucosa with a sterile syringe for absorption (67) The OPT-MOM approach incorporates this technique and the use of a syringe facilitates the provision of a consistent dose of biofactors, with every treatment, so that beneficial effects are sustained. The preparation of a batch of syringes using sterile technique, for a 24-hour period of treatments, will promote patient safety.

For OPT-MOM, the use of fresh own mother's milk, administered in the order that it was expressed, is the best approach. Therefore, the infant should receive the colostrum first, with gradual progression to mature milk. In this manner, the ELBW infant will benefit from the natural transition of the milk, which is being administered oropharyngeally, and receive immune benefits similar to those that a breastfed infant would receive.

The use of donor milk for oropharyngeal administration has not been clinically investigated. Importantly, the pasteurization process destroys many immune biofactors or reduces their antimicrobial functions. For example, lactoferrin is reduced by 88%. (76) While donor milk is highly beneficial for ELBW infants, their own mother's milk should be prioritized for oropharyngeal administration. When only a small amount of mother's milk is available post-birth, the donor milk should be used for enteral feeds and the mother's own milk for oropharyngeal administration.

As with any intervention, patient safety and infection control must be prioritized. There have been anecdotal reports of some centers administering fortified breastmilk oropharyngeally to ELBW infants. The infant's nurse collects the 'dose' of milk for oropharyngeal administration at the point of care; when the infant's enteral feeding is due. A small volume of milk is collected (with a syringe or swab) from the aliquot of fortified milk that has been refrigerated and is intended for the infant's enteral feeds. This procedure is repeated every time an enteral feed is administered; between 8 to 12 times per day, depending on the feeding schedule. This practice raises several safety concerns. Repeatedly dipping syringes or swabs, into a container of milk, can potentially contaminate the milk with NICU pathogens; placing the infant at risk for infection. A recent review (79) showed that up to 40% of milk samples in the NICU are contaminated with potential pathogens, (77,78) with the most common organisms being Coagulase-negative Staphylococci, Staphylococcus Aureus, and Enterobacteriaceae. (79) Therefore preventing contamination of mother's milk must be a clinical priority. Another concern is that the milk which is refrigerated in



The National Perinatal Association (NPA) is an interdisciplinary organization that gives voice to the needs of parents, babies and families and all those interested in their health and wellbeing. Within NPA, parents and professionals work together to create positive change in perinatal care through education, parent programs, professional guidelines and events.

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the NICU and set aside for enteral feeds is typically fortified. There is no evidence to support the safety of administering fortified milk via the oropharyngeal route to ELBW infants <32 weeks CGA. Also the presence of iron-enriched fortifier in oropharyngeally-administered mother's milk reduces the immune benefits of the intervention. For example, lactoferrin is a potent biofactor with anti-microbial, anti-inflammatory and immunomodulatory effects. It is protective against L-OS and NEC, (80-83) and may also be protective against VAP, because of its ability to prevent the attachment of pathogens to the oropharyngeal mucosa. Lactoferrin's antimicrobial properties are highly dependent on its ability to compete with bacteria for iron-binding sites. The use of an iron-enriched fortifier reduces lactoferrin's bioactivity since iron-saturated lactoferrin has significantly reduced antimicrobial activity. (84,85) Lactoferrin concentrations are significantly higher in the milk expressed by women who deliver prematurely, compared to milk from mothers who deliver at term. (48,49) Therefore it is important to preserve the potent immune properties of lactoferrin, by using only unfortified milk for oropharyngeal administration and the OPT-MOM procedure.

Admission rates to the NICU (for all birth weight categories) have increased in the U.S. from 64.0 per 1000 live births in 2007 to 77.9 per 1000 live births in 2012 (relative rate, 1.22; 95% CI, 1.21-1.22 [P<.001]).⁸⁶ While OPT-MOM is primarily intended for the ELBW population, it may be very beneficial for all NICU infants who are unable to feed orally, including VLBW infants, late-preterm infants, and term infants who are unable to breastfeed.

Conclusions

The lack of oropharyngeal exposure to amniotic fluid biofactors, which provide immune protection throughout the last trimester of pregnancy, may increase the risk for prematurity-associated infectious morbidities for the ELBW infant. This deficit may be corrected by utilizing the OPT-MOM approach; a natural alternative to mimic the protective effects of amniotic fluid, until oral feeds can be safely introduced. As a potential adjunctive immune therapy, OPT-MOM requires frequent and sustained treatments administered over several weeks post-birth, with precise dosing of mother's milk. This uninterrupted protocol is more likely to lead to sustained immune benefits and positive health outcomes, for recipient preterm infants, compared to shorter protocols. However, more research is needed, with a consistent methodology, in well-designed, adequately-powered safety and efficacy RCTs. To promote patient safety, strict infection control must be a priority when administering oropharyngeal milk to infants in the NICU; especially when providing this intervention to extremely premature infants.

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The author has indicated no relevant disclosures.

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High Frequency Jet Ventilation: When to Switch and When to Start

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

Last month's topic was high-frequency oscillation (HFO) with volume guarantee (VG) adjunct and its implications on clinical practice in which I referenced a study by Durand et al. and gave an incorrect enrollment number. It was 500, not 512 — my mistake. I ended with a note on high-frequency jet ventilation (HFJV) being a topic for another discussion. Here it is.

Some may question the relevance of HFJV once HFO/VG becomes available in the U.S. and why a clinician may still want to use the jet. The NICU at Sunnybrook H.S.C. in Toronto where I practice was the first unit in Canada to fully embrace HFO/VG routinely. We also have at least seven jet ventilators in our ventilator inventory. I can say unequivocally there is a role for HFJV in a world of second-generation ventilators capable of HFO/VG. Further, I would submit that unless your toolbox includes a jet ventilator said toolbox is incomplete. There are things HFJV can do that HFO with or without VG simply cannot, and jet ventilation is the gentlest way to ventilate fragile lungs, i.e., those of the premature infant. (1)

“Small babies have small airways with high resistance. This resistance results in longer time constants and invariably air trapping to one degree or another.”

From 2017-04-01 to 2018-03-31 our total invasive ventilation hours were 52296. The modality breakdown is as follows:

Conventional:	1920
HFO:	22512
HFJV:	27864

As one can see, even though we have a full complement of ventilators providing HFO/VG our HFJV hours are actually greater than our HFO hours. Why we so often choose HFJV over HFO/VG and when we make that choice is this month's discussion.

The majority of our intubated babies are initially ventilated on HFO/VG. However, there are some who are started on HFJV and some who are switched to HFJV, usually early in their course. What follows is a guideline as to when and why babies are started on the jet or switched to it.

First-line

A jet ventilator is kept in our admission room unless all machines are in use. HFJV is a first line mode for babies who have had prolonged premature rupture of membranes, suspected or diagnosed pulmonary hypoplasia, infants who exhibit signs of persistent pulmonary hypertension, use of Nitric Oxide (iNO), extreme prematurity and very low birth weight, meconium aspiration syndrome requiring intubation, and any infant who presents with air leak. This list is not exclusive. We are not a level four facility, but diaphragmatic hernia would also be included.

The best way to treat Pulmonary Intrastitial Emphysema (PIE) and Chornic Lung Dease (CLD) is to avoid injury in the first place. As I tell those who will listen, the jet is a ventilator, not a stem cell. Best to avoid the damage by starting or switching to HFJV early rather than waiting for the damage to be done and then trying to fix it. As with any form of therapy, the worse the patient is to begin with the poorer the outcome and the longer the course. We know that the lung is most prone to damage during recruitment, and the admission room all too often sets the stage for bad things to play out on later. Those interested in ventilation practice at Sunnybrook NICU refer to this problem . (2)

Since the original FDA approval for HFJV is for air leak it makes sense these infants are on the list, but what about other applications? In practice, the jet is very effective at eliminating CO₂, even in infants with very stiff lungs who are at high risk of air leak during the recruitment phase. Initiating HFJV on these infants starting with moderately high PEEP works well and greatly decreases the risk of air leak. Timely control of CO₂ can greatly decrease the necessity for iNO, and since the jet delivers iNO rapidly and near the area of gas exchange, I believe it is also the best way to administer this drug if this therapy becomes necessary.

“Timely control of CO₂ can greatly decrease the necessity for iNO, and since the jet delivers iNO rapidly and near the area of gas exchange I believe it is also the best way to administer this drug if this therapy becomes necessary.”

Switching

What about those who end up being switched from HFO/VG to HFJV? At what point is the decision made to switch? There are many reasons, and the justification is admittedly theoretical. Having said that, our outcomes speak for themselves. Here goes.

Air Trapping

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One of the most insidious problems faced by clinicians ventilating the very small, very immature infant is air trapping. Even HFJV, while being the best mitigator of air trapping by virtue of being able to generate I:E ratios of up to 1:12, is not able to completely eliminate the risk of air trapping. How is the presence of air trapping determined? Historically, using the measured PEEP on the jet and comparing to set PEEP on the conventional background ventilator has been used, but there are limitations to this from a diagnostic standpoint. As measured PEEP approaches set PEEP, we have been told to suspect air trapping. This is true however it is not foolproof. Leak around the endotracheal tube (ETT) may reduce the utility of measured PEEP. Also, there are so many time constants at play within the lung, the conducting airways, and the ETT itself it is impossible to know if air trapping is occurring regionally rather than globally and the jet cannot detect gas that is trapped on the distal side of floppy, collapsing airways; it can only provide an average indicator of air trapping as measured at the distal tip of the ET tube.

When a baby is on HFO, there are no measurements to predict from, and chest films are the standard tool of assessment. Clinically I dread chest x-rays because all too often the interpretation is “wean the MAP” after dutifully counting ribs without fully understanding what is actually happening within the patient. Given everything about micro preemies, it stands to reason that all small babies have air trapping. Unfortunately, we can’t burp the babies’ lungs! (Actually, we kind of can with recruitment maneuvers.) An infant whose chest x-ray shows “hyperinflation” on relatively low MAP is gas trapping, and further reduction in MAP makes matters worse. These babies are switched to HFJV when adjustments to HFO are insufficient to reduce what I will refer to as inadvertent hyperinflation. Typically ventilated at a rate of 240 BPM it is my practice to set starting PEEP at the HFO MAP. This increases MAP on the jet 1-2 cm/H₂O above HFO which is usually good because insufficient MAP is part of the problem. Because the vast majority of our ventilated babies are micro preemies, it is worth noting that 240 breaths per minute (BPM) is a standard, default rate in our NICU, although some babies do very well on rates of 300 BPM, as well. Rarely is a rate of 300 BPM exceeded. It is my hope that future versions of the jet allow rates below 240 BPM since some babies show clear signs of air trapping even at that low rate and I:E ratio of 1:12. I think this alteration may also offer more flexibility for manipulating jet inspiratory time (Ti).

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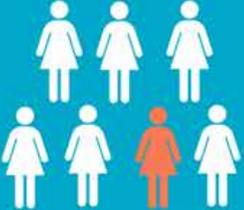
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Failure/maximal settings on HFO

Once HFO settings reach a certain level the mode's efficacy decreases as ventilatory efficiency decreases. As amplitude increases so do the inherent risks of airway instability and gas trapping. As a general rule, I do not allow amplitude to reach double the set MAP. As well, since our devices measure high-frequency tidal volume (HFVt), I will switch to HFJV as HFVt exceeds 2ml/kg and will not use 3 ml/kg (HFO/VG HFVt is typically 1-2 ml/kg). Because jet PIP is delivered above a set PEEP, there is no worry about ever increasing MAP to compensate for larger amplitudes and "more is always more." It stands to reason that the larger Vt becomes in HFO, the less lung protective the mode is, and jet breaths have been estimated to be less than 1ml/kg with up to 95% pressure attenuation at the distal airways.(3)

Pathology

While preventing CLD is the goal, infants who show early chronic changes on X-ray are usually switched to HFJV. This may be done prophylactically when an out-born micro preemie infant is brought in on conventional ventilation in an attempt to mitigate an impending inflammatory response. Any evidence of air leak also results in a switch because while HFO may reduce the occurrence of air leak; it has not been shown to improve it once there. (1) Infants with copious secretions may be jetted to facilitate clearance since the swirling motion of exhaled gas around the airway walls aids in bringing secretions to the trachea where it can be suctioned.

The notion of "non-homogeneous lung disease" suggests that there is homogeneous lung disease; however, studies have shown that there really is no such animal. Be that as it may, infants with unilateral hyperinflation (or collapse) may benefit from HFJV since it minimizes further inflation of the recruited lung while minimizing damage to the collapsed lung. Combined with positioning, conventional recruitment maneuvers as discussed below may greatly improve this pathology.

"Be that as it may, infants with unilateral hyperinflation (or collapse) may benefit from HFJV since it minimizes further inflation of the recruited lung while minimizing damage to the collapsed lung."

Last but not least, there is a trend towards early or immediate use of HFJV in the very small infant. As was the case with HFO, we find that most sub-25-week gestation infants end up being "jetted." There is a growing belief that using HFJV immediately on all micro-preemies is the best way to go. This application has to do with the inherent risk of air trapping these infants have due to very small airways with attending high resistance. Because of the nature of HFJV breaths, inspiratory time constants related to conducting airways and the fragility thereof are easier to deal with since the breath shoots down the centre of the airway without having to actually fill their volume first, and jet Ti can be adjusted as required to fine-tune not just for inspiratory resistance but also vary the composition of MAP. In my experience increasing jet Ti improves oxygenation/SpO₂ lability in some patients sometimes using lower PIP, part of the dance when using this machine. Clinicians are well advised to decrease rate when doing so if there is an apparent increase in air trapping when this is done. Because there is a degree of exhalation concurrent with inspiration during

HFJV, the increase in displaced gas may off-set the reduction in expiratory time. And it's hard to air trap if the air can't get in. If gas trapping DOES occur, lowering jet rate can maintain an expiratory time sufficient to complement the baby's expiratory time constant.

I have not discussed settings a great deal here, and I loathe "cookie cutter" recipes for ventilation. Although there is considerable variation between my personal practice and those recommended by Bunnell, Bunnell is a good starting point for reference in terms of jet usage. (3) For instance, it is rare for me to use conventional breaths for lung recruitment; perhaps because my starting PEEP is high, I find them unnecessary. This strategy is at odds with standard Bunnell guidelines, but it works. When used, I apply gentle recruitment style breaths with a PIP of 5-6 cmH₂O above PEEP, inspiratory time of 2 seconds, rate of 10 BPM, and they are used for as short a duration as possible. A low conventional rate (say 5 BPM) may also work but I believe would take longer to accomplish the task. I do not alter jet PIP, although weaning is facilitated when the lung is properly recruited. The finer aspects of these breaths may vary between clinicians, but the general style is gaining acceptance not only within my own NICU but with other jet users as well. There are other times this is done for various reasons, but when used for unilateral collapse will usually fix the problem within 12 hours. You have to like having something fixed by the end of your shift! (Another teaser for a future paper if they'll have me!)

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- 1 Bunnell, Bert J, Sc.D., *Why, When and How to HFJV, Neonatology Today, V 13 I 8, August 2018*
- 2 *Ventilation at Sunnybrook NICU is initiated, driven and managed by Respiratory Therapists assigned exclusively to the NICU and who do not rotate throughout the hospital. The unit has a history of pushing the ventilation envelope, being the first in Canada to use several modes including HFO and HFO/VG using the Drager Babylog®8000 Plus and VN-500® I have been a part of the NICU team since 1989, having done my neonatal training at Toronto's Women's College Hospital (former program location) in 1988.*
- 3 <http://www.Bunl.com/clinical>

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.

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Seeing is Believing: Neonatal Intubation Using Video Laryngoscope

Shabih Manzar, MD

Medicine is a science and art at the same time. This applies to neonatal endotracheal intubation. It is a science that requires a high level of training and once mastered it becomes an artistic skill.

Traditionally neonates are intubated using direct laryngoscope (DL). However, in recent reports, it has been observed that by using Video laryngoscope (VL) comparable outcomes could be obtained. (1,2)

“In a recent Cochrane review in the adult population, it was concluded that VL might reduce the number of failed intubations, improve the glottic view and may reduce laryngeal/airway trauma...”

In a recent Cochrane review in the adult population, it was concluded that VL might reduce the number of failed intubations, improve the glottic view and may reduce laryngeal/airway trauma, however no evidence indicates that use of a VL reduces the number of intubation attempts or the incidence of hypoxia or respiratory complications and affects time required for intubation. (3)

Does VL hold the future in neonatal intubation?

To answer this question and make it a standard of practice more studies are needed. The results of one of these studies will be available next year. This study is a multi-center collaborative sponsored by Children’s Hospital of Philadelphia. (4).

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4. <https://clinicaltrials.gov/ct2/show/NCT03194503>

Disclosure: The author has no disclosures.

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The National Perinatal Association Position Statement and Conference on Perinatal Health Care Access and Disparities

Cheryl A. Milford, Ed.S.

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

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



Access to quality health care and improving health disparities for vulnerable populations in the United States has become a public health priority. Amongst the most vulnerable populations are pregnant individuals, their infants, and families. This vulnerability is compounded further when race, socioeconomic status, gender identity and the presence of pre-existing conditions are taken into account.

The National Perinatal Association (NPA), in collaboration with the California Perinatal Quality Care Collaborative, the National Association of Perinatal Social Workers, Premie Parent Alliance, Connect2NICU and Hand to Hold, has developed a position paper addressing the topic of health-care access and disparities that will serve as the catalyst for ongoing patient advocacy, beginning at **NPA's 2019 Conference: Improving Access to Perinatal**

Care: Confronting Disparities and Inequities in Maternal-Infant Health being held April 3-5 in Providence, Rhode Island. What follows is a working summary of the NPA Disparity Workgroup's Position Paper that will be officially released at the Annual Conference.

Health care inequities have been defined by the Association of State and Territorial Health Officials (ASTHO) as "Differences in health outcomes which are . . . unnecessary and avoidable . . . unfair and unjust." (1) The impact of health care access and disparities in the perinatal period has been highlighted in the literature over the last ten years. Research has clearly demonstrated higher rates of maternal and infant mortality in African American, Latina, and Native American families. (2) In addition, poverty, rural residence, and substance use increase risks for poor outcomes. (3,4) The variables that have been noted include systemic health care barriers for access to care (i.e., transportation, employment, and clinics too far away); clinician bias and cultural ignorance; and language barriers that impact family-clinician communication. (1,5)

African-American population: women have three to four times higher rates of maternal mortality than white women. Their infants are twice as likely to die in the first year of life. (6) In addition, African-American women are more likely to experience pregnancy complications such as hypertension, gestational diabetes, and obesity, with these conditions being more severe in black women than white women. African American women have lower rates of initial breastfeeding and/or continuing breastfeeding to six months of age. (6)

Latina population: Latina women have higher rates of congenital abnormalities in their infants than other women. This may be related to low intake of folic acid in this population. (2) They are at higher risk of developing gestational diabetes, and their infants are at higher risk for being born preterm or ill, requiring NICU hospitalization. (1,7) Latina women breastfeed at a higher rate than any other group, including

white women. (1)

Asian population: Asian women may have a higher rate of gestational hypertension, especially women from the Philippines and Samoa. They are also at higher risk of developing gestational diabetes. (2)

Native American population: Native American women and Alaskan Native American women are at higher risk of gestational diabetes and often receive late prenatal care that impacts maternal and infant outcomes. (2) Low socioeconomic status and rural residence appear to be significant risk factors for these women. (3)

"Substance Use: Pregnant individuals' use of illicit substances is a health care epidemic in the United States. Neonates exposed to substances is high with more than 400,000 infants exposed to alcohol or illicit drugs in utero each year."

Additionally, there are intersecting psychosocial circumstances and family structures that make individuals vulnerable to health disparities such as:

Rural Residence: Women who reside in rural areas of the United States are at higher risk for preterm labor and preterm birth. Late prenatal care rates were higher and lower socioeconomic status, lack of health insurance and higher rates of unplanned pregnancy were all risk factors for this population, for all groups including white women. (3)

Substance Use: Pregnant individuals' use of illicit substances is a health care epi-



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demic in the United States. Neonates exposed to substances is high with more than 400,000 infants exposed to alcohol or illicit drugs in utero each year. Maternal morbidity with pain management, poor prenatal care, and poor nutrition impact the outcome of the infant including low birth weight, neonatal opioid withdrawal syndrome and extended hospitalization. Black, Latina and Native American women are identified at higher rates than whites, though it is well known that there is no statistical difference in substance use rates across all racial and ethnic groups. (8,9)

Non-traditional Families: Lesbian, bi-sexual and transgender pregnant individuals experience a lack of understanding on the part of clinicians regarding their needs and concerns. Systematic barriers include heterosexism, restrictive labor room guidelines and gender bias. This is even more significant for black, Latina and other vulnerable groups. The birth experiences are traumatic and maternal, and infant outcomes can be impacted. (6)

Based on the workgroup's literature review, expertise and lived experiences, the National Perinatal Association recommends addressing the issues of perinatal health care access and disparities by acknowledging their existence. ASTHO defines health equity as "The attainment of the highest level for all people" 1. National awareness of the barriers to health equity has been identified. (1-9)

These include:

- Language, non-English speakers
- Cultural expectations around pregnancy and birth
- Transportation
- Lack of or inadequate health insurance
- Low socioeconomic status
- Lack of local health care providers
- A limited number of clinicians who are racially and ethnically diverse
- Inherent bias in clinicians regarding racial, ethnic, substance use and non-traditional families
- Poorly educated providers on the needs and concerns of all pregnant individuals and their families
- Pregnant individuals' fears of judgmental and uncaring clinicians and resulting criminal and civil child welfare consequences related to their birthing and life decisions.

Education of clinicians is of the highest priority in this process. Inherent bias and systemic protocols both impact the ability of clinicians to care for all families equally. Conferences, position papers, and self-awareness training can all support this goal. Clinicians may be uncomfortable in addressing their inherent bias and resist

attendance at such activities. Like all areas of competency, this should be mandatory training. Racial and ethnic diverse clinicians must be increased. Education and training support financially can assist with this process.

Involvement and engagement of vulnerable populations in research and policy making are of the highest priority in this process. Many of the problems now encountered by people of color results from a long history of exploitation, discrimination or disenfranchisement in research and policymaking.

Lack of health care insurance and access to qualified clinicians must be addressed through government policy makers and agencies. Education of legislators and executives at the local, state and national level is essential for dealing with this major barrier.

Health care systems must make non-English speaking families a priority in their care model. Full-time, 24/7 translation services must be developed that acknowledges all languages in the community and provides translators in the appropriate dialects. All written and social media materials must also be available in the languages of the community.

"The National Perinatal Association is committed to integrating diverse voices, educating providers and patients and advocating for policy changes that will advance the national discussion on perinatal health care access and disparities."

It is incumbent upon policy makers, legislators, clinicians and families, and advocates to collaborate in developing solutions to support health equity in perinatal care.

The National Perinatal Association is committed to integrating diverse voices, educating providers and patients and advocating for



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policy changes that will advance the national discussion on perinatal health care access and disparities. Public health priorities can only be addressed and resolved when all stakeholders are brought together. The goal should be not only to include providers, families and family advocates, but to also bring national policymakers to the table. We hope you can join us in Rhode Island, April 3rd-5th for NPA's 40th Annual Conference and help us advance and enrich our multidisciplinary effort to address such an important topic.

For conference information and registration: <http://www.national-perinatal.org/2019conference>

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The author of this article has no conflict of interest to disclose.

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I Just Don't Have Time to Sit

Anthony Orsini, D.O.

Dr. Orsini is a full-time board-certified neonatologist and expert in compassionate communication in medicine. He is currently the Vice-Chairman of Neonatology at Winnie Palmer Hospital in Orlando, FL. He also serves as the President of Breaking Bad News (BBN), the organization he founded in 2012 that offers training services to educate professionals in the art and science of compassionate communication. Founding BBN was the culmination of his lifelong passion and over 20 years of research and development. The resulting philosophy, now known as The Orsini Way utilizes proven techniques on how to communicate with patients and families in the most effective and compassionate manner. His methods are used by thousands of healthcare professionals to successfully help professionals build relationships with patients, navigate through difficult conversations and improve the overall patient and customer experience.

Dr. Orsini's interest in compassionate communication began early in his medical training where he was drawn to the specialty of neonatology that required him first to become a pediatrician. He saw the opportunity to help people through more life and death crises presented by specializing in neonatology. He received his D.O. in Medicine from Philadelphia College of Osteopathic Medicine. Profoundly impacted by his early career experience and the discovery that even the most successful and well-respected doctors could not offer guidance on communicating catastrophic news, Dr. Orsini began developing the teachable techniques that evolved into the Orsini Way. After medical school, Dr. Orsini completed his training in pediatrics and neonatology at Thomas Jefferson University Hospitals in Philadelphia, PA. His next move to NYU Langone Medical Center as Assistant Professor of Clinical Pediatrics and Attending Neonatologist, allowed him to further develop his teaching expertise. Prior to joining Winnie Palmer Hospital, he served as a neonatologist for Atlantic Health Systems in Morristown, NJ, which later became the first BBN Center of Excellence.

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Patient Satisfaction is one of the hottest topics in medicine today, significantly affecting reimbursement, compliance with treatment plans, clinical outcomes and even the risk of malpractice lawsuits. (1-4) In order to survive in today's patient-centered, competitive healthcare system, it is essential for any healthcare provider to achieve and maintain high patient satisfaction scores. The overall patient experience is so important that in a recent leadership survey, 90% of top-level hospital

executives have identified enhancing the patient experience as was one of their highest priorities. (5)

But what is the main driver of a patient's overall satisfaction? Contrary to common belief, it is not the aesthetics of the hospital nor the amenities offered. It is not the food or even actual wait times. (6) According to Press Ganey, the nation's leading provider of patient satisfaction surveys, the ability of a clinician to communicate and build rapport with his/her patients ranks consistently as one of the top predictors of patient loyalty and therefore patient satisfaction. (7)

This should not be surprising. Patients value the interpersonal aspects of the clinician-patient relationship, such as communication, compassion and the overall sense of being treated with respect. Unlike decades past, today's patient will often favor a physician with a good bedside manner over one with a reputation for being an excellent clinician. It is therefore imperative that all physicians, nurses and team members learn how to build relationships with patients by communicating effectively.

There are many communication techniques that a healthcare professional can learn to help form relationships with their patients, even in a very short period of time. The easiest skill to learn and perhaps the most important of all communication techniques is to simply SIT DOWN.

“Patients value the interpersonal aspects of the clinician-patient relationship, such as communication, compassion and the overall sense of being treated with respect.”

Sitting down and having a conversation with a patient sends the non-verbal message that their provider is not in a hurry and genuinely wants to hear what he/she has to say. It tells the patient before a word is spoken, that their clinician is genuinely interested in him/her as a person and is not anxious to rush out to the next patient. Sitting down is the first step in forming a relationship and the bedrock of which compassionate communication is built.

Although multiple studies have validated that a seated posture enhances rapport and evokes a sense of interest, compassion and increased satisfaction, any astute observer would note that this practice is rarely seen in a hospital setting. Providers fear that sitting down will slow them down. This, however, is not the case. A 2012 study by Swayden et al. compared patient perception of provider time to actual time spent at the bedside. Researchers found that although physicians spent slightly more

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time in the room standing compared to sitting, the patient's perception of time spent in the room was significantly longer when the physician sat down. In addition, patient comments were positive 95% of the time when the clinician sat down compared to only 61% positive comments when the provider stood. This study further emphasizes the importance of non-verbal communication. Although a physician may not feel personally rushed, the act of standing during an encounter creates the misperception of hurriedness. Providers therefore should no longer fear losing time by sitting. (8)

“Although multiple studies have validated that a seated posture enhances rapport and evokes a sense of interest, compassion and increased satisfaction, any astute observer would note that this practice is rarely seen in a hospital setting.”

To further confirm the relationship between sitting and the overall patient experience, Lidgett et study the effect sitting down has on patient satisfaction scores. In the “Commit to Sit” study, researchers found that simply requiring nurses to sit with patients at least once per shift, contributed to an increased perception of compassion by patients and families resulting in a significant improvement in patient satisfaction scores (9)

So whether you are a physician, nurse or other healthcare provider, the next time you visit a patient's room SIT DOWN. You will build better relationships, improve patient satisfaction and save time.

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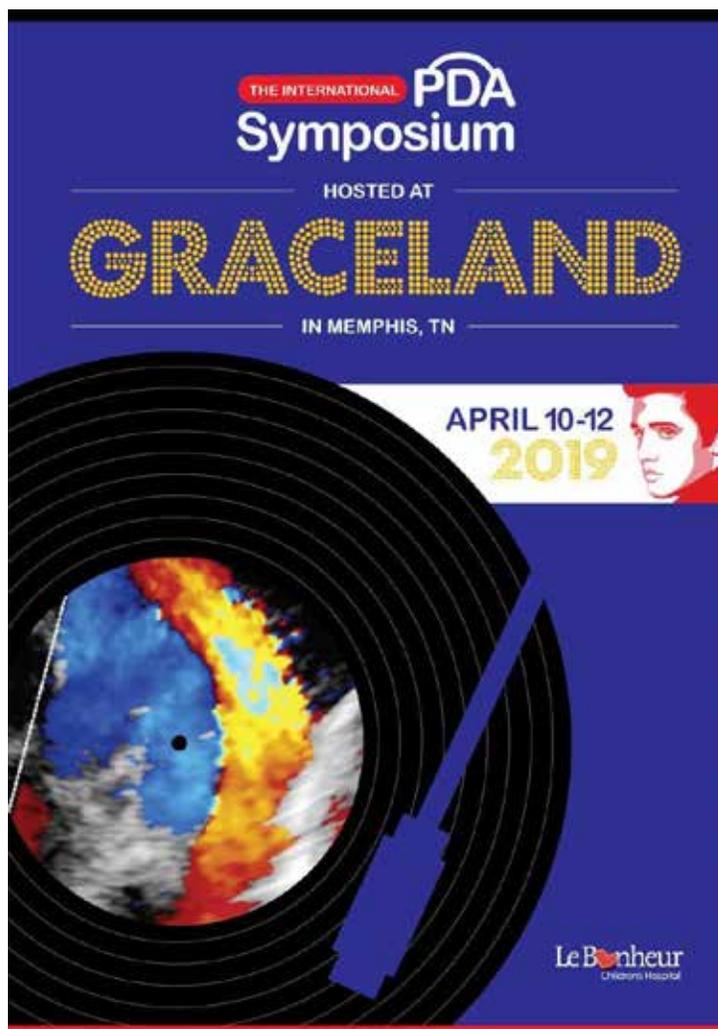
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Disclosure: Dr. Orsini is president of BBN, the organization he founded in 2012 that offers training services to educate professionals in the art and science of compassionate communication.

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Policies to Prevent Infant Mortality Crop Up in States

Darby O'Donnell, JD

The Alliance for Patient Access (allianceforpatientaccess.org), founded in 2006, is a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care. AfPA accomplishes this mission by recruiting, training and mobilizing policy-minded physicians to be effective advocates for patient access.



The majority of state legislative sessions are currently underway for 2019 sessions. Last year, many states turned their attention to studying infant mortality with goals of prevention, as well as better care and outcomes for mothers and infants. The trend is expected to continue.

States address high-risk populations and approach care options through a variety of policies and solutions in the name of infant health care.

While not an exhaustive list, below are current, policy initiatives that were cleared by state legislative bodies by the end of 2018 and are now being implemented as a new law.

NEW JERSEY (S1870)

INFANT MORTALITY STUDY

New Jersey legislation was introduced in 2018 to study and review infant mortality rates in the state. The bill requires the Child Fatality and Near Fatality Review Board to study racial and ethnic disparities on infant mortality and make recommendations for further actions to counteract these outcomes.

Bill sponsor Senator Joseph Vitale (D-Middlesex) framed his support as the following: "There has to be a greater emphasis on the health of mothers and children in every community in our state, regardless of race, ethnicity and geographic location. There simply is no excuse for not doing everything in our power to protect babies from dying within the first year of life."

A press release from legislators noted New Jersey's infant mortality rates for women of all races are lower than the national rates. However, the disparity between white and black mothers is the third largest in the country.

"A press release from legislators noted New Jersey's infant mortality rates for women of all races are lower than the national rates. However, the disparity between white and black mothers is the third largest in the country."

This bill had also been amended to include "provisions to increase breastfeeding support services among racial and ethnic populations throughout the state."

This bipartisan measure was signed by the Governor on May 30, 2018, and implementation should be underway.

NORTH CAROLINA (H471)

MATERNAL AND NEONATAL CARE

Legislators in North Carolina took a different approach to study infant mortality by focusing on the mother's "timely and equitable access" to maternal and neonatal care.

In the legislation, the Department of Health and Human Services was directed to study access issues to "high-quality, risk-appropriate" care for both mother and child.

Such subject matters as referrals to specialists and transfers of mothers to different facilities, service gaps, and the complexity levels of care available at delivering hospitals were among the requirements of the study.

The bill was signed into law on June 25, 2018.

NEW YORK (S3867A)

NEWBORN HEALTH AND SAFETY PILOT PROGRAM

New York's approach to reducing infant mortality was more narrowly-focused than others: newborns and sleep. The legislation

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was introduced in late 2017, to provide a safe sleep pilot program. So-called “baby boxes” and other products would be provided under this rule for safe sleep practices and prevention of sudden infant death syndrome. High-risk areas - those with poor birth outcomes and counties with high infant mortality rates - were designated as the beneficiaries of the pilot program.

“ The legislation sponsor’s memo notes as justification for the measure that infant deaths result from unsafe sleep practices. The memo acknowledges that while cribs meeting all federal standards are the best sleeping alternative, not all families can afford cribs. ”

The legislation sponsor’s memo notes as justification for the measure that infant deaths result from unsafe sleep practices. The memo acknowledges that while cribs meeting all federal standards are the best sleeping alternative, not all families can afford cribs. Therefore, the pilot program to provide “baby boxes” presents a safe alternative and “reduces rates of mortality” as compared to co-sleeping and other choices. The “baby box” would include other products and items to support parents, in addition to being a safe space for babies.

For funding options to support the program, the Health Department was directed to seek out donations and look to establish a public-private partnership.

The bill was enacted on October 23, 2017.

With these different approaches and new information gathered, states hope to play a leading role in the development of policies that positively impact mothers and infants.

The author has not indicated any disclosures.

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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>Some Premies</p> <ul style="list-style-type: none"> Will spend weeks in the hospital Will have lifelong health problems Are disadvantaged from birth 	<p>All Premies</p> <ul style="list-style-type: none"> Face health risks Deserve appropriate health coverage Need access to proper health care
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The Morgan Leary Vaughan Fund appreciates the support of Prolacta Bioscience and Hand to Hold for this important event and welcomes other experts, influencers, and sponsors who share our mutual mission.

Free to attend, register at speakingofnec.org

Speaking of NEC: Unplugged

The complete day of schedule* and registration details are available at speakingofnec.org

8:00–8:30 am	Breakfast and Registration Exhibits Open	12:00–1:00 pm	Lunch and Exhibit Visits
8:30–8:50 am	Welcome and Opening Remarks A Parent's Personal Story #1	1:00–2:40 pm	Post Disease A Parent's Personal Story #4 Touch Changes Everything Effects of NEC on Neurodevelopment of Preterm Infants
8:50–10:00 am	The Disease A Neonatologist's Perspective Surgical NEC	2:40–2:55 pm	Break and Exhibit Visits
10:00–10:20 am	Break and Exhibit Visits	2:55–3:45 pm	Post Disease (con't) A Parent's Personal Story #5 Short Bowel Syndrome
10:20–11:10 am	Prevention A Parent's Personal Story #2 Improving Human Milk and Breastfeeding Outcomes	3:45–4:00 pm	Wrap-Up
11:10–12:00 pm	Research & Development A Parent's Personal Story #3 Diagnostics for Necrotizing Enterocolitis: Where We Are and Where We Can Go		

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Compiled and Reviewed by Mitchell Goldstein, MD Editor in Chief

Could Omega-3 Fatty Acids Help Prevent Miscarriages?

New understanding of molecular underpinnings points to need for more aggressive treatment and earlier

Article ID: 707643

Released: 6-Feb-2019 12:20 PM EST

Source Newsroom: Columbia University Irving Medical Center

Newswise - Compounds found in fish oil prevent pregnancy complications, including preterm birth, neonatal death, and stillbirth, in mice when the complications are caused by a common oral bacteria, according to research published today in the journal JCI Insight.

The study, by scientists at Columbia University's College of Dental Medicine and Vagelos College of Physicians & Surgeons, suggests a new strategy for protecting pregnancy in women.

Why it matters

Approximately one in 10 U.S. infants are born before term. Between 10 and 30 percent of preterm births have been attributed to uterine infections with a type of bacteria commonly found in the mouth, *F. nucleatum*.

This research identifies a potential prophylactic treatment for pregnant women to lower the risk of adverse outcomes including stillbirth.

Background

"This type of bacteria is ubiquitous; everybody has it in their mouths," says Yiping Han, PhD, senior author of the new study. "The problems start when it travels to other parts of the body."

In pregnant women, the placenta is at particular risk for infection with *F. nucleatum*. Hormonal changes during pregnancy can cause inflammation and bleeding in the gums, which affects between 30 and 100 percent of pregnant women. Bleeding gums create an entryway for bacteria to leak into the bloodstream. Once in the circulatory system, the bacteria can migrate to the placenta and cause inflammation there, sometimes triggering miscarriage or stillbirth.

Isolating the inflammatory mechanism

"We knew from our previous work that uterine inflammation due to infection with this bacteria is associated with adverse pregnancy outcomes, but in order to prevent those outcomes, we needed to determine exactly how these infections trigger inflammation."

Using a mouse model, the researchers injected the bacteria into mice during their third trimester of pregnancy. As predicted, the bacteria invaded the animals' uteruses.

The researchers saw that the bacteria triggered an inflammatory response in endothelial cells within the mouse placenta, leading to preterm births.

The inflammatory response only occurred when a specific immune protein was present in the mothers' endothelial cells. In pregnant mice lacking this protein, fewer fetuses died, suggesting that inflammation ignited by this protein is critical for causing preterm births.

Omega-3's prevent inflammation, improve birth outcomes in mice

After determining how the bacteria trigger inflammation within the placenta, Han's team used cultured cells to look for ways to inhibit those mechanisms.

"We were looking for an anti-inflammatory agent that's safe for pregnant women to use," says Han.

Because omega-3 fatty acid supplements are widely used to reduce inflammation in chronic inflammatory diseases, such as heart disease and rheumatoid arthritis, Dr. Han considered fish oil, which is rich in omega-3 fatty acids. These supplements are already recommended for pregnant women to support fetal development.

The experiments showed that supplements containing omega-3 fatty acids also inhibited inflammation and bacterial growth in pregnant mice, and reduced preterm births, miscarriages, and stillbirths.

What's next

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Future URL: www.thegravensconference.com

Questions? Email the meeting planner at brose@health.usf.edu

Highlights include: Two receptions, dinner cruise, and presentation of Gravens Award



Han now hopes to begin a clinical trial to test whether omega-3 fatty acids can prevent intrauterine F. nucleatum infection and adverse outcomes in pregnant women.

Caveats

The doses of omega-3 fatty acids used in this study were far higher than those recommended for people taking fish oil supplements. The study points to a promising avenue for further research, but does not support any immediate changes in clinical practice.

More details

Yiping Han is a professor of microbial sciences in dental medicine at the Columbia University College of Dental Medicine and of microbiology and immunology at Columbia University Vagelos College of Physicians & Surgeons.

The study is titled “Omega-3 fatty acids suppress Fusobacterium nucleatum–induced placental inflammation originating from maternal endothelial cells” appeared online Feb. 7, 2019 in the journal JCI Insight.

The other contributors are Jeewon Garcia-So, Xinwen Zhang, Xiaohua Yang, Mara Roxana Rubinstein, De Yu Mao, Jan Kitajewski, and Kang Liu.

The authors report no financial or other conflicts of interest.

DOI: 10.1172/jci.insight

About Columbia University College of Dental Medicine

Columbia University College of Dental Medicine (CDM), one of the nation’s first dental schools, educates general dentists and specialists to practice dentistry as the oral health specialty of medicine. CDM provides comprehensive, precision care to over 30,000 patients each year through more than 130,000 visits, making CDM the largest source of oral healthcare to un-

derserved upper Manhattan communities. A centerpiece of the school’s offerings is the Center for Precision Dental Medicine, a clinic that will personalize care and education through big data and first-of-its-kind technology. Other programs bring oral healthcare to local schools, seniors, and community centers. For more information, visit dental.columbia.edu.

Columbia University Irving Medical Center provides international leadership in basic, preclinical, and clinical research; medical and health sciences education; and patient care. The medical center trains future leaders and includes the dedicated work of many physicians, scientists, public health professionals, dentists, and nurses at the Vagelos College of Physicians and Surgeons, the Mailman School of Public Health, the College of Dental Medicine, the School of Nursing, the biomedical departments of the Graduate School of Arts and Sciences, and allied research centers and institutions. Columbia University Irving Medical Center is home to the largest medical research enterprise in New York City and State and one of the largest faculty medical practices in the Northeast. For more information, visit cuimc.columbia.edu or columbiadoctors.org

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

Released: Thursday 12/13/2018 12:32 PM

The American Academy of Pediatrics’ Section on Advances in Therapeutics and Technology (SOATT) invites you to join our ranks! SOATT creates a unique community of pediatric professionals who

share a passion for optimizing the discovery, development and approval of high quality, evidence-based medical and surgical breakthroughs that will improve the health of children. You will receive many important benefits:

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- Invitation for special programming by the Section at the AAP’s National Conference.
- Access to and ability to submit research abstracts related to advancing child health through innovations in pediatric drugs, devices, research, clinical trials and information technology; abstracts are published in Pediatrics.

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The Section also accepts affiliate members (those holding masters or doctoral degrees or the equivalent in pharmacy or other health science concentrations that contribute toward the discovery and advancement of pediatrics and who do not otherwise qualify for membership in the AAP). Membership application for affiliates: <http://shop.aap.org/aap-membership/> then click on “Other Allied Health

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Providers” at the bottom of the page.

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

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The American Academy of Pediatrics is an organization of 67,000 primary care pediatricians, pediatric medical subspecialists and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents and young adults. For more information, visit www.aap.org. Reporters can access the meeting program and other relevant meeting information through the AAP meeting website at <http://www.aapexperience.org/>

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App Tested at Comer Children's Aims to Help Parents Track Progress of NICU Preemies

A new app has been developed for tracking the progress of preemies.

From the University of Chicago Department of Pediatrics, 2018 Annual Report

January 19, 2019

A new app used to help parents of premature infants communicate and track their babies' progress in the neonatal intensive care unit (NICU) has been advanced and tested by researchers at the University of Chicago Medicine in collaboration with PreeMe+You, a social benefit health startup.

Neonatologist Bree Andrews, MD, MPH, at Comer Children's Hospital and medical anthropologist Yaya Ren, PhD, JD, developed PreeMe+You to help guide NICU families through the overwhelming experience of having a premature infant, or preemie. Their work in the NICU revealed that gaps in patient communication with care teams were stressful to families and difficult to harmonize. This is due to the complex nature of NICU medicine, time pressures, and the rollercoaster emotional journeys of families.

"Some babies are in the NICU for many weeks, yet families' contact with the medical team is often brief," says Andrews. "That leaves a lot of time in the NICU that could be utilized to better help families understand what's going on with their babies."

To use the app, a parent creates an account and answers prompted questions about their baby's five important body functions, or biomarkers: breathing, feeding, temperature control, sleeping and growth. The app, in turn, communicates how the medical team is caring for the preemie in real time and helps parents track their baby's NICU journey, giving them a tool to always be on the same page as their medical team. In addition, the app provides curated educational information synchronized to the baby's specific stage for each biomarker. This tells parents what progress means for their

baby's individual development.

"Our goal is not to replace medical health care with technology," says Ren, "but we want to guide and reclaim meaningful, empowering, and supportive human communication and interactions between NICU families and medical staff that can be easily lost in a medical crisis."

Andrews has used the app with more than 75 families at Comer Children's and says she found it most successful with families who have babies with the biggest challenges and complications. The researchers say one goal of the app is to help families gain a sense of stability amidst a time that, for many, is filled with uncertainties.

"When people are in crisis, they need some scaffolding to help hold them up in a way that feels good for them," says Ren.

The researchers anticipate that within the year, the app will be available for iPhone and Android phones. They also designed it with the goal of being used in any NICU, anywhere in the world. More information about the app is available at PreeMe+You.

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John M. Cunningham, MD, MSc, MRCP
George M. Eisenberg Professor
Chair, Department of Pediatrics
The University of Chicago Biological Sciences
Physician-in-Chief, Comer Children's Hospital

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ATS Publishes New Clinical Guideline on Home Oxygen for Children

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SAVE THE DATE!

April 11th

9 am – 4 pm

1st annual meeting of the SoCal Small Baby Consortium

*Wong Kerlee International Conference Center
11175 Campus St. Loma Linda, CA 92350*



About the Consortium

We would like to invite you, your neonatology colleagues and NICU staff that care for small babies to join the SoCal Small Baby Consortium. The goals of the Consortium will be to share our approaches to common problems that ELBW babies face, share management protocols, identify QI projects that could be done as a group, consider multi-center research projects, and discuss possibilities for shared data collection.

Conference Schedule

- Dr. Kris Reber (from Nationwide Children's Hospital, Ohio State University) will share their group's experience with managing premature, ELBW infants and future directions for caring for these babies. She will also discuss managing feeding problems in the ELBW infant
- Dr. Valerie Chock (Lucile Packard Children's Hospital, Stanford University) will review approaches to assessment of "normal" blood pressure and adequate perfusion using near Infrared spectroscopy (NIRS) with specific emphasis on the management of PDA.
- Dr. John Cleary (CHOC) will discuss controversies in neonatal hemodynamics, review the approach for treating hypotension and the best therapies available and will also moderate a Q & A session on hemodynamic stability and approach to PDA.
- Mindy Morris, DNP (Engage/Grow/Thrive, LLC) will discuss the nursing role in improving outcomes for small babies

An organizational session will be held for planning future meetings and identifying interested people to work on improving clinical strategies for the care of small babies

Nursing CEUs and medical CMEs may be offered for those attending this meeting. ***The tuition and expense for this meeting will be covered by the Loma Linda University Division of Neonatology.***

SoCal Small Baby Consortium Planning Committee: Ana Banerji, Raylene Phillips, Munaf Kadri, Anup Katheria, Maynard Rasmussen, James Fritzell, Tony Soliman, Yona Nicolau, John Cleary, Andy Hopper

Registration:

- **Please send Cathy Winter an email at cwinter@llu.edu to reserve a space**
- **Call 909-558-7448 for additional information**

Guidelines for discharge home on oxygen presented by the American Thoracic Society.

Article ID: 707381

Released: 1-Feb-2019 9:55 AM EST

Source Newsroom: American Thoracic Society (ATS)

Newswise — Feb. 1, 2019—The American Thoracic Society has developed a new clinical practice guideline for home oxygen therapy for children. The guideline appears in the Feb. 1 edition of the Society's American Journal of Respiratory and Critical Care Medicine.

"Home Oxygen Therapy for Children: An Official American Thoracic Society Clinical Practice Guideline" makes specific recommendations for treating chronic hypoxemia in children with cystic fibrosis, bronchopulmonary dysplasia, sleep disturbed breathing, sickle cell disease, pulmonary hypertension with and without congenital heart disease and interstitial lung disease.

"Home oxygen is often needed for children with chronic lung and pulmonary vascular diseases," said lead author Don Hayes, Jr., MD, MS, MEd, medical director of the Advanced Lung Disease Program at Nationwide Children's Hospital in Columbus, Ohio, and co-chair of the working group organized by the ATS Assembly on Pediatrics. "However, there is a striking lack of empirical evidence regarding its implementation, monitoring and discontinuation in children. These guidelines, developed by a panel of highly respected experts, offer an evidence-based approach to using home oxygen to benefit pediatric patients."

The 22-member guideline panel of experts in pediatric and neonatal medicine, respiratory therapy, nursing and population health, as well as parents, wrote that chronic hypoxemia can lead to pulmonary hypertension, delays in cognitive and behavioral development, poor sleep and stunted growth.

Based on a systematic literature review, the panel defined chronic hypoxemia as lasting two weeks and diagnosed through pulse oximetry:

In children under the age of one, as spending five percent of the recording time with pe-



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ripheral capillary oxygen saturation (SpO_2) ≤ 90 percent, or, if measurements are taken intermittently, of obtaining three independent measurements of $SpO_2 \leq 90$ percent.

In children one and older, as spending five percent of the time with $SpO_2 \leq 93$ percent, or, if measurements are taken intermittently, of obtaining three independent measurements of $SpO_2 \leq 93$ percent.

Before making their recommendations, the panel reviewed available studies and other clinical practice guidelines. They relied heavily on their own clinical experience because of the paucity of high-quality studies. The panel noted that, in some instances, studies to test the benefit of oxygen therapy would never be conducted because it would likely be deemed unethical to withhold oxygen from study participants.

The panel rated the strength of study findings, along with the certainty of the panel's recommendations, using the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) system. When the panel relied heavily on their clinical observations, rather than systematic studies, GRADE required them to make their recom-

mendations with "very low confidence."

In summary, the guideline recommendations are:

Cystic fibrosis

For patients with cystic fibrosis complicated by severe chronic hypoxemia, we recommend that home oxygen therapy be prescribed (strong recommendation, very low quality evidence).

For patients with cystic fibrosis who have both mild hypoxemia and dyspnea on exertion, we suggest that home oxygen therapy be prescribed (conditional recommendation, very low quality evidence).

Bronchopulmonary dysplasia

For patients with bronchopulmonary dysplasia complicated by chronic hypoxemia, we recommend that home oxygen therapy be prescribed (strong recommendation, very low quality evidence).

Sleep-disordered breathing

For patients with sleep-disordered breathing complicated by severe nocturnal hypox-





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

Leadership

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

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

Consultation

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

emia who cannot tolerate positive airway pressure therapy or are awaiting surgical treatment of sleep-disordered breathing, we suggest that home oxygen therapy may be prescribed (conditional recommendation, very low quality evidence).

Sickle cell disease

For patients with sickle cell disease complicated by severe chronic hypoxemia, we suggest that home oxygen therapy be prescribed (conditional recommendation, very low quality evidence).

Pulmonary hypertension without congenital heart disease

For patients with pulmonary hypertension without congenital heart disease complicated by chronic hypoxemia, we recommend that home oxygen therapy be prescribed (strong recommendation, very low quality evidence).

Pulmonary hypertension with congenital heart disease

For patients with pulmonary hypertension with congenital heart disease complicated by chronic hypoxemia, supplemental oxygen will impact hemodynamics and physiology; we recommend that home oxygen therapy NOT be initiated in these children, regardless of previous reparative or palliative congenital heart surgery, until there has been consultation with a pediatric pulmonologist or cardiologist who has expertise in the management of pulmonary hypertension in this clinical setting (strong recommendation, very low quality evidence).

Interstitial lung disease

For patients with interstitial lung disease complicated by severe chronic hypoxemia, we recommend that home oxygen therapy be prescribed (strong recommendation, very low quality evidence).

For patients with interstitial lung disease who have mild chronic hypoxemia and either dyspnea on exertion or desaturation during sleep or exertion, we suggest that home oxygen therapy be prescribed (conditional

recommendation, very low quality evidence).

The panel made other recommendations related to home oxygen therapy for children, including:

Insurers should take into account that “all children require access to age-appropriate equipment and supplies that will meet their supplemental oxygen needs,” including low-flow delivery systems.

Home pulse oximetry should be used for long-term monitoring of these children.

Health care providers should follow up regularly with their patients to determine if changes have occurred in respiratory status or oxygen needs.

Decisions to wean children from oxygen therapy or discontinue its use require a medical examination that identifies “reassuring” factors related to the child’s underlying medical condition, age, achievement of developmental milestones, absence of acute illness and other factors. The decision should also be based on “reassuring objective measures of oxygenation.”

The guideline suggests that weaning can be achieved by either reducing the flow of oxygen or withdrawing its use during certain periods of the day. Either way, the panel believes weaning should be achieved gradually over the course of weeks or months. If discontinuation is achieved, the guidelines recommend that families maintain access at home to oxygen therapy for several months in the event that the child develops a viral infection or other problem that necessitates restarting oxygen therapy.

The guideline authors wrote that their recommendations concerning weaning and discontinuation of oxygen therapy were made almost entirely on the basis of their combined clinical experience. They unanimously agreed that a large, prospective trial comparing weaning strategies is needed.

“Future research is needed to further advance our understanding of and ability to utilize home oxygen therapy in children,” said Dr. Hayes, who is also medical direc-

tor of the Lung and Heart-Lung Transplant Programs at Nationwide Children’s. “Specifically, research should address the relationship between oxygen saturation levels and growth and development as well as identifying best practices for weaning and discontinuing home oxygen therapy.”

Development of the guideline was funded by the American Thoracic Society, which has published a companion patient education piece on oxygen therapy for children.

####

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Long-Term Unemployment, Clinician Shortage Linked to Increase in Babies Born with Neonatal Abstinence Syndrome

First to market diagnostic aid in measuring nutrients in human breast milk.

Article ID: 707019
Released: 24-Jan-2019 11:05 AM EST
Source Newsroom: Vanderbilt University Medical Center

Newswise — Babies born after being exposed to opioids before birth are more likely to be delivered in regions of the U.S. with high rates of long-term unemployment and lower levels of mental health services, according to a study from researchers at Vanderbilt University Medical Center and the RAND Corporation.

Studying more than 6.3 million births in a diverse group of eight states, the study found that rural counties plagued by long-term unemployment had significantly high-



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er rates of babies born with neonatal abstinence syndrome as compared to urban counties with lower unemployment rates.

Counties with shortages of mental health providers also had higher levels of neonatal abstinence syndrome as compared to other counties. The association was observed primarily in urban areas.

The study, published in the Jan. 29 edition of the Journal of the American Medical Association, is the first to examine the association between long-term economic conditions, health care provider shortage areas and the incidence of neonatal abstinence syndrome, which can occur when babies are chronically exposed to opioids before birth.

“The finding should open our eyes to the social complexities that lead to newborns being treated for drug withdrawal in our nation’s hospitals,” said Stephen W. Patrick, MD, MPH, MS, director of the Vanderbilt Center for Child Health Policy and lead author of the paper. “The opioid crisis is not just a health care problem, it is also a social problem, and solutions will need to address the social needs of com-

munities as well as the health care needs.

“As Congress considers legislation, particularly those related to building infrastructure in rural communities, it should consider that these investments may also benefit the health of communities.”

Patrick and his colleagues have shown previously that one consequence of the nation’s opioid epidemic has been a sharp increase in the number of newborns who show signs of withdrawal from opioids. From 2000 to 2014, the rate of neonatal abstinence syndrome rose from 1.2 cases per 1,000 hospital births to 8 cases per 1,000 births. In 2014, the average was one infant born every 15 minutes in the U.S. with neonatal abstinence syndrome.

While poor economic conditions have been linked to opioid use, there had been no large-scale studies examining whether those issues also are associated with newborn exposure to the drugs.

Researchers from Vanderbilt and RAND analyzed information about 6.3 million births from 2009 through 2015 in the 580 counties in Florida, Kentucky, Massa-

chusetts, Michigan, North Carolina, New York, Tennessee and Washington. Those cases were compared to the 10-year unemployment rate for each of the counties, as well as factors about health care workforce levels.

Counties with persistently elevated levels of unemployment had higher rates of neonatal abstinence syndrome. The rate of neonatal abstinence syndrome in the counties with the highest unemployment rate was 20.1 cases per 1,000 births, compared to 7.8 cases per 1,000 births in the counties with the lowest unemployment rates.

The study also found higher rates of neonatal abstinence syndrome in counties with shortages of mental health workers, primarily in metropolitan counties. Counties with shortages of mental health workers experienced 14 cases of neonatal abstinence syndrome per 1,000 births as compared to rates of 10.6 cases per 1,000 births in other counties. There was no such association with physical health providers.

“We know that individuals with mental health problems are more likely to use or

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be dependent on opioids,” said Bradley D. Stein, MD, PhD, senior author of the study and director of the RAND Opioid Policy Center. “Our findings suggest that until we can provide better access to effective mental health care, we face an uphill battle effectively addressing the opioid crisis.”

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FROM THE NATIONAL PERINATAL INFORMATION CENTER

Documenting Social Determinants of Health (SDOH)

Janet H. Muri, MBA and Sandra A. Boyle, BS

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 Data

In 2008, the World Health Organization (WHO) published the report "Closing the gap in a generation: Health equity through action on social determinants of health"¹. Since this publication, much has been written to advance the understanding and definitions of SDOH.

In 2010, the Secretary's Advisory Committee on Health Promotion and Disease Prevention included in the Healthy People 2020 objectives the need to create "social and physical environments that promote good health for all"². The framework for this objective identifies five determinant areas: Economic Stability, Education, Social and Community Context, Health and Health Care and Neighborhood and Built Environment.

Each of these areas can be viewed through multiple interacting lenses: social/political, national/international, micro/macro. As with any set of objectives however, the key is how to measure progress toward the stated goals once defined.

The Healthy People 2020 website (<https://www.healthypeople.gov>) displays state and national rates for many of the five key SDOH areas by subpopulations. In the Maternal, Infant and

Child Health (MICH) area there are 74 indicators being tracked. Most data sources are state survey, registry and surveillance data reported to the CDC/National Center for Health Statistics with the most current rates reported for 2016 but with some as old as 2010.

Data availability and lag time are always issues when trying to measure progress toward a goal. For individual providers, hospitals and systems, data availability is particularly frustrating when they are being asked to be more accountable for improvement of the health quality for not only their patients but also the larger population they serve. Challenges include, quantifying the magnitude of the problems and determining the breadth of ancillary and social services that need to be available to address them.

Coding Social Determinants of Health

The administrative/billing data set is the most universal data set available for all hospital discharges. An administrative data record with demographic, clinical, and financial data in a largely common data format is generated for every patient. Maximizing the use of this data set seems to be the most cost efficient, immediate and comprehensive way to quantify and understand vulnerable patients.

ICD 10 "Z" codes³ include a set of eight code groups that allow for the documentation of complex social problems that can adversely impact outcomes even when the best of clinical care is provided. These eight code groups fall under the category *Persons with potential health hazards related to socioeconomic and psychosocial circumstances (Z55-Z65)* and closely track with the WHO SDOH categories.

Z55 Problems related to education and literacy

Z56 Problems related to employment and unemployment

Z59 Problems related to housing and economic circumstances

Z60 Problems related to social environment

Z62 Problems related to upbringing

Z63 Other problems related to primary support group, including family circumstances

Z64 Problems related to certain psychosocial circumstances

Z65 Problems related to other psychosocial problems

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Each code group has from 3 to 24 sub-codes that target the nature of the problem more specifically: Z59.0 Homelessness; Z59.4 Lack of adequate food or safe drinking water; Z62.810 Personal history of physical and sexual abuse in childhood; Z63.31 absence of a family member due to military deployment etc.

For perinatal discharges, these codes would be used on the mother's record. They can help inform the entire care team as to the added challenges the mother, infant and family is facing and what other interventions and services should be provided, as well as why anticipated outcomes may not be seen as quickly or at all.

Use of Z codes in the NPIC Perinatal Center Data Base

For the four quarter period ending on June 30, 2018, we looked at 336,672 antepartum, delivery and postpartum inpatient discharges and found *very little use* of Z codes. The top five code groups and the percent of total coded cases were:

- .156% Z59 Problems related to housing and economic circumstances
- .078% Z62 Problems related to upbringing
- .042% Z63 Other problems related to primary support group, including family circumstances
- .031% Z64 Problems related to certain psychosocial circumstances
- .027% Z65 Problems related to other psychosocial problems

In a deep dive into the use of Z coding at a large, urban academic regional medical center with more than 3,000 annual deliveries and a greater than 50% Medicaid payer mix for obstetrical patients, we found only 1.9% of their maternal discharges with Z codes, the largest code group being Z59 Problems related to housing and economic circumstances; 28 of these mothers were coded as homeless.

Expansion of the administrative data set to include electronic medical record (EMR) data may or may not solve the problem. EMR experts at NPIC member hospitals report coded or text fields are available to document SDOH, but the degree of completion ranges from inconsistent to not at all.

Documenting maternal social challenges, either by Z codes or through an EMR field, requires providers to discuss potentially sensitive topics with their patients. Once uncovered, it also imposes on them the burden to identify internal and/or external resources to address the problems. This responsibility is a great challenge for those not used to being responsible for the breadth of social problems facing patients. However, not documenting, does not remove the impact. Documenting will at least help identify the scope of the problems and hopefully

move providers to become advocates to lessen their impact.

References:

- 1 World Health Organization, Commission on Social Determinants of Health. *Closing the Gap in a Generation: Health equity through action on the social determinants of health*. Available from : http://www.who.int/social_determinants/en
- 2 Secretary's Advisory Committee on Health Promotion and Disease Prevention Objectives for 2020. *Healthy People 2020: An Opportunity to Address the Societal Determinants of Health I the United States*. July 26, 2010. Available from <http://healthypeople.gov/2010/hp2020.htm>
- 3 <https://www.cms.gov/medicare/coding/icd10/2019-icd-10-cm.html>

The authors indicate that they have no disclosures

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Janet H. Muri has been with the National Perinatal Information Center since 1986 and it's President since 2007. Ms. Muri oversees all collection, processing and analysis of clinical and financial data submitted by NPIC member hospitals and other state, federal and private data sources related to contract work. She is the principal on many of the NPIC contracts including the Defense Health Agency Perinatal Performance Information Project, the Georgia Regional Perinatal Care Network project and the Alliance for Innovation in Maternal Health (AIM).

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Sandra A. Boyle has over 20 years experience in health care data management and analysis. She joined NPIC in 1996 as a Data Coordinator and Hospital Liaison. As Director of Data Services, Ms. Boyle is responsible for managing the recruitment, enrollment and reporting for all member and non-member hospitals, and has played an integral role in the design and development of NPIC performance measurement reporting. Ms. Boyle has a Bachelor of Science in Health Services Administration from Providence College



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36th Annual Advances in Therapeutics and Technology: Critical Care of Neonates, Children, and Adults

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

Topics and Speakers Include:

Rashmin Savant, MD BPD New Concepts in Pathogenesis and Prevention

Cynthia Blanco, MD Metabolic Disturbances of Prematurity When How and Who to Treat

Sinjo Hirose, MD Fetal Surgery

Arun Pramanick, MD Game Changers in Neonatal-Perinatal Medicine- A View Through a Retroscope

Don Null Persistent Pulmonary Hypertension in the Preterm Newborn Etiologies and Cardiopulmonary Management

Marty Keszler, MD New Modalities in High Frequency Ventilation

Mitchell Goldstein, MD Rediscovering the Denominator

Steve Derdak, DO Pediatric Origins of Adult Disease



Conference Description

This conference will present high quality education to advance pediatric health and well-being through collaboration, communication and education on the discovery and development of therapeutics and technology and their successful translation into practice. The conference aims to improve communication and relationships within industry, academia and government agencies as well as educate on the discovery, development, and implementation processes. Networking opportunities for healthcare professionals who provide care for patients with a focus on advances in therapeutics and technology will be provided. Along with featured speakers, the conference includes abstract presentations on research.

Special Panel Discussion

Avoiding the Conflict, Working to Develop Better Relations with Industry. Don Null, MD and Mitchell Goldstein, MD.

Special Lecture: President of AAP, Colleen Kraft, MD

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Special Panel Discussion:

Avoiding the Conflict, Working to Develop Better Relations with Industry. Colleen Kraft, MD, President, AAP with Don Null, MD and Mitchell Goldstein, MD

2019 Snowbird Conference Agenda

Tuesday March 26, 2019

5-5:30 Opening remarks

5:30-6:15 Abstracts

6:15-7:15 Rediscovering the Denominator Mitchell Goldstein, MD

Wednesday March 27 AM

8-9:00 Abstracts

9:00-10:00 Results of the Drager High Frequency Ventilation Study. Martin Keszler MD

10:30-11:00 Abstracts

11:00- 12:00 Game changers in Neonatal-Perinatal Medicine- A view through a retrocope Arun Pramanik MD

Wednesday PM

5:5:15 Abstract

5:15-6:05 The role of industry and physicians for improved patient care. Colleen Kraft MD

6:05-7:05- Robert deLemos Memorial Lecture

BPD New Concepts in Pathogenesis and Prevention. Rashmin Savani MD

Thursday March 28 AM

8-8:30 When, Why and How HFJV J. Bert Bunnell ScD

8:30-9:30 Metabolic Disturbances of Prematurity When How and Who to treat. Cynthia Blanco MD

9:30-12:00 Workshops

Thursday PM

5:00-6:00 Abstracts

6:00-7:00 Persistent Pulmonary Hypertension in the Preterm Newborn Etiologies and Cardiopulmonary Management. Donald Null MD

Friday March 29 AM

8-9:00 Abstracts

9:00-10:00 Pending

10:30-11:00 Abstracts

11:00-12:00 Update on Non-invasive Ventilation and Airway Clearance Techniques for Large Patients. Stephen Derdak DO

Friday PM

5:00-6:00 Use of the VDR Percussive Ventilator in Adults with various Respiratory Problems. Felix Khusid RRT

6:00-7:00 Management of Inhalation Lung Injury Biology, Medications and Respiratory Support. Leopoldo Cancio MD

Saturday March 30 AM

8:00-8:30 Abstracts

8:30 9:30 Present and Future of Telemedicine. Bill Beninat MDi

9:30-10:30 Wearable Combat Resuscitation Organ Support System. Andriy Batchinsky MD

11:00-11:15 Closing Remarks. Donald Null MD

The Future of Neonatal Care Will Happen in Copenhagen

Stefan Johansson, MD, PhD and Francesco Cardona, MD, MSc



At the virtual 99nicu Headquarters, we are now very busy with all preparations for our upcoming Meetup, AKA the Future of Neonatal Care conference. This third conference will take place in Copenhagen, 7-10 April, and we are already thrilled about what is to come.

"Our vision for the 99nicu Community (<https://99nicu.org>) is to offer an Internet platform where neonatal staff from all over the world can share questions, experiences, and expertise."

Our vision for the 99nicu Community (<https://99nicu.org>) is to offer an Internet platform where neonatal staff from all over the world can share questions, experiences, and expertise. Therefore, we are grateful to see, as in previous years, that our conference "footprints" our global outreach and attracts a truly international group of delegates. There are currently 130

delegates coming from 30 countries, from East to West, from North to South. Naturally, we have room for You as well! Visit <https://99nicu.org/meetup/> to register.

What makes the Future of Neonatal Care conference different from other meetings?

First of all, our principal idea is one of postgraduate learning. To provide evidence-based neonatal care, we all need to refresh and refine our knowledge base. That is pretty obvious, as our work as neonatology professionals gravitates around know-how. IMHO, we can all improve here.

Secondly, we believe conferences should be a place to exchange expertise and experience and give anyone a chance to ask questions. Participants at our previous conferences especially enjoyed "very good discussions" and "plenty of time for questions." We use the smartphone app sli.do (<https://www.sli.do/>) to allow immediate feedback from participants. Through polls and multiple-choice-questions during lectures, delegates learn from each other. Most importantly, lecturers also get an opportunity to comment directly on aspects popping up. Furthermore, every 45-minute session typically includes a 30-minute lecture, to give sufficient time for discussion.

Thirdly, we aim to place topics in a forward-facing context, how neonatology will develop in the future. Why do we need to know about cord clamping? How should we support the breathing of preterm infants? What inotropes shall we use when? Shall discharge MRIs be the standard of care for preterm infants? Why do we need to rehearse simulated scenarios?

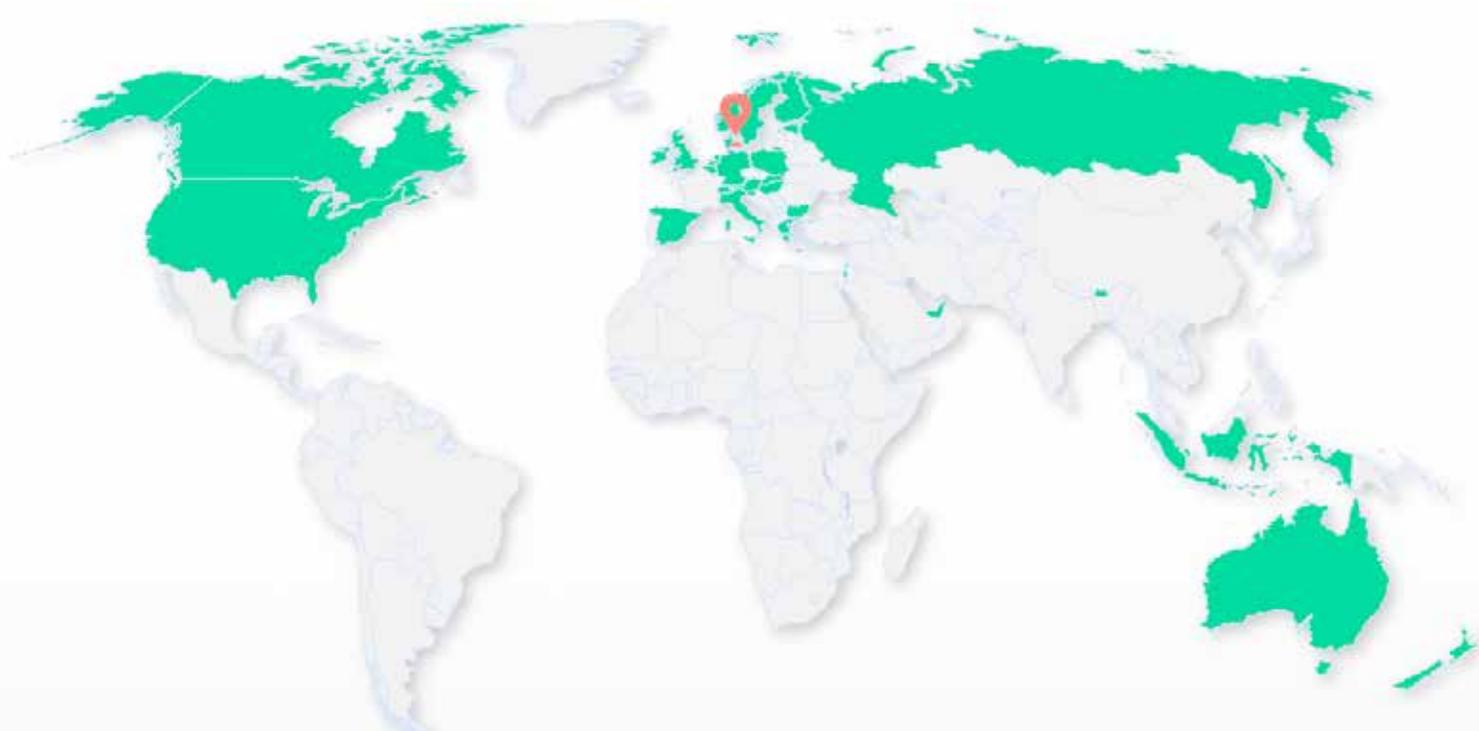
We are honored to welcome a great set of Faculty members to Copenhagen. To share a few examples:

- Barbara Schmidt and Haresh Kirpalani lead a workshop on when evidence should change the standard of care, and how to interpret non-inferiority trials
- Mortein Breindahl will lecture and lead a workshop on neonatal transports, together with Christian Heiring
- Victoria Payne will share her expertise on the prevention of CLABSI
- David Edwards will challenge our minds about MRIs in preterm infants
- Liisa Lethonen and Sari Ahlqvist-Björkroth will, for the third time, run their highly appreciated workshop on Family-based care
- Brett Manley will tell us if/how to "Go with (high) flow."
- Gorm Greisen, Ulrika Ådén, and Eduard Verhagen will engage in several lectures and a debate on practices and ethics around the border of viability, and parent-participation in decision-making.

As you can see, we have lots to look forward to! Join us at the Future of Neonatal Care in Copenhagen 7-10 April!

And yes, we will share take-home messages from the Future of Neonatal Care from our Twitter account @99nicu (<https://twitter.com/99nicu>). As in previous years, the hashtag will be





#99nicuMeetup (<https://twitter.com/hashtag/99nicumeetup>)

Stefan Johansson, MD, PhD

The authors indicate that they have no disclosures

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Neonatal Pulmonary Hypertension

Giang Truong, MD; Jennifer Lo, MD; T. Allen Merritt, MD, Mitchell Goldstein, MD

Objectives:

- 1) Cardiovascular physiology: fetal, transitional, post-natal
- 2) Pulmonary hypertension pathogenesis: acute, chronic, arterial, venous
- 3) Pulmonary hypertension: presentation, diagnosis, treatment, and outcomes

ABSTRACT:

Neonatal pulmonary hypertension, also known as persistent pulmonary hypertension in the newborn (PPHN), is characterized by elevated pulmonary vascular resistance resulting in hypoxemia. Labile hypoxemia and differential cyanosis are clinical signs of pulmonary hypertension. An echocardiogram is the best study to confirm the diagnosis of PPHN. Management is mainly supportive with goals to recruit optimal lung volume, stabilize blood pressure, optimize oxygenation, reduce shunting, sedate when indicated, and correct acidosis. There are multiple available pulmonary vasodilators. Despite maximal intervention, some patients require extracorporeal membrane oxygenation (ECMO). The purpose of this paper is to review (1) fetal, transitional and postnatal cardiovascular physiology; (2) pulmonary hypertension pathogenesis; (3) clinical presentation, diagnosis, treatment and outcomes in patients with pulmonary hypertension. (1,2)

INTRODUCTION:

Neonatal pulmonary hypertension occurs in about 2 cases per 1000 births with mortality ranging from 4% to 33%. (3) Neonatal pulmonary hypertension occurs when pulmonary vascular resistance remains elevated after birth. While many instances of PPHN are idiopathic, common known causes of PPHN include meconium aspiration (MAS), pneumonia, respiratory distress

syndrome, asphyxia, congenital diaphragmatic hernia (CDH) and Down syndrome. (14)

FETAL AND TRANSITIONAL CIRCULATION:

In fetal circulation, there is physiologic pulmonary hypertension because the lungs are fluid-filled. Similarly, the fetal systemic pressure is low because the placenta has low vascular resistance. At the time of birth, following the first breaths, the lungs are filled with air, and pulmonary vascular resistance decreases rapidly. Increase in oxygen tension associated with the extrauterine environment further vasodilates the pulmonary vasculature. At the same time, when the umbilical cord is clamped, and placental circulation is disconnected from the newborn, systemic arterial pressure rapidly rises to allow more blood to fill the lungs. (10)

“Neonatal pulmonary hypertension occurs in about 2 cases per 1000 births with mortality ranging from 4% to 33%”

PATHOPHYSIOLOGY:

Risk factors:

Prenatally, risk factors for PPHN include being of African or Asian heritage, male gender, and certain maternal conditions including obesity, diabetes or asthma. Maternal substance exposures that increase the risk of PPHN to the neonate include nicotine, SSRI use after 20 weeks of gestation, late non-steroidal anti-inflammatory drugs (NSAID) or illicit substance abuse. (14)

Antenatal risk factors include being born post-term or early term/late preterm birth, large for gestational age (LGA), delivery via Cesarean section, prolonged premature rupture of membrane,

(PPROM), chorioamnionitis, group B streptococcal infection, meconium passage before birth, perinatal acidosis, asphyxia, hypothermia, hypocalcemia, polycythemia, and other lung parenchymal diseases. (10,14)

PPHN presents in three patterns: (12)

- 1) Maladaptation: abnormally constricted pulmonary vasculature due to lung parenchymal disease.
- 2) Mal-development: abnormally constricted pulmonary vasculature in the absence of parenchymal disease.
- 3) Under-development: lungs and pulmonary vessels are underdeveloped due to decreased lung fluid or external mass effect.

Maladaptation: occurs in parenchymal diseases such as MAS, respiratory distress syndrome (RDS), and pneumonia. The underlying parenchymal disease causes hypoxia and acidosis which further leads to pulmonary vasospasm and vasoconstriction. Inflammatory cytokines (TNF, IL, PAF, ET-1) may play a role.

These cases of PPHN are often more reversible as the parenchymal disease is treated. Although the incidence has decreased likely due to a reduction in post-term births, a common case of maladaptation is meconium aspiration syndrome. Meconium aspiration causes obstruction in the airways, inactivates surfactant



and initiates the inflammatory cascade, all of which participate in the worsening of PPHN. (10,13)

Mal-development (excessive muscularization): occurs when there is normal lung parenchyma, but there are remodeled or muscularized pulmonary arteries. Most cases are idiopathic. Chronic exposure to hypoxemia (e.g., placental insufficiency, maternal diabetes) may be factors. Over-circulation of the pulmonary vasculature from intrauterine ductal closure, total anomalous pulmonary venous return (TAPVR), and chronic patent ductus arteriosus(PDA) are some other etiologies. Intrauterine exposure to selective serotonin reuptake inhibitors (SSRI), non-steroid anti-inflammatory drugs (NSAIDs), and nicotine have also been shown to be associated with mal-development PPHN. (10)

Underdevelopment (hypoplastic vasculature): occurs when prenatal conditions affect both alveolar and pulmonary arterial development. Oligohydramnios, PPRM, posterior urethral valves, renal agenesis, congenital diaphragmatic hernia (CDH) are examples of this type of process. In CDH, abdominal viscera herniate into the chest through the diaphragm defect. Although defects can be on either side or both, left-sided defects are more common. Lung development on both sides is disturbed, with the ipsilateral side more severely affected. Parenchymal lung reduction is usually present. Vascular development is altered and underdeveloped as well. There is also secondary surfactant deficiency and irregular alveolarization. Left ventricular hypoplasia has also been shown to be a contributing factor to pulmonary hypertension in CDH. (8)

Trisomy 21 is associated with pulmonary hypertension, as is alveolar capillary dysplasia, omphalocele and other disorders of physiological development. (6,12)

CHRONIC PULMONARY HYPERTENSION:

While most neonatal pulmonary hypertension cases are acute in onset and experienced soon after birth, some can progress into chronic pulmonary hypertension. Pulmonary hypertension associated with CDH or omphalocele, (1,6) for example, can continue for years, requiring chronic therapy.

Neonates may acquire pulmonary hypertension from underlying diseases, including bronchopulmonary disease (BPD) or congenital heart diseases. (1,2,5)

Pulmonary hypertension in bronchopulmonary disease (BPD) has been reported in 20-25% of patients with BPD and up to 50% in those with severe BPD3, (13)

Pulmonary hypertension in BPD is multifactorial. Poor alveolar septation, lung fibrosis, inflammation, altered microvascular development are observed in BPD. As a result, pulmonary vasculature remodels and subsequently leads to increased pulmonary vascular resistance and elevated pulmonary arterial pressures. (13)

Pulmonary venous hypertension (PVH) due to pulmonary venous stenosis (PVS) in neonates is due to the neo-intimal proliferation of myofibroblasts, progressing luminal stenosis or obliteration. (4) PVH can be congenital or acquired, isolated or associated with congenital heart disease. It is also often associated with BPD, specifically in the extremely premature infants with intrauterine growth retardation (IUGR). (15) Little is known about PVS in neonates. Diagnosis is via echocardiogram and confirmed by catheterization. Patients develop chronic pulmonary edema, pulmonary hypertension, and heart failure. Treatments are limited and overall prognosis is very poor. Some suggested therapies include balloon angioplasty, stenting, anti-VEGF, or surgical repair. (3,4,7,11)

CLINICAL PRESENTATION OF EARLY PPHN:

Generally, patients present with low Apgar scores, in respiratory distress and labile hypoxemia. They are often cyanotic with low PaO₂ and differential saturations where the postductal saturation is >5-10% lower than the pre-ductal saturation (this will not be observed if the PDA is closed).

The severity of hypoxemia is often communicated by the oxygenation index (OI):

$$OI = FiO_2 \times \text{Mean airway pressure} \times 100 / \text{post-ductal PaO}_2$$

An OI above 15 is concerning and is an indication for inhaled nitric oxide (iNO) therapy.

DIAGNOSIS:

Diagnosis of pulmonary hypertension is primarily by clinical presentation, typically respiratory distress, hypoxemia and differential cyanosis. Diagnosis should be confirmed by echocardiogram.

Echocardiographic evidence of pulmonary hypertension includes right to left shunting at the level of the PDA, right ventricular (RV) dilation and hypertrophy, ventricular septal flattening, poor RV function, and possible left ventricular (LV) dysfunction.

In patients with chronic pulmonary hypertension, pulmonary artery pressure is estimated by echocardiogram and confirmed by cardiac catheterization.

Pulmonary arterial pressure is considered elevated if:

- Mean pulmonary artery pressure > 25 mmHg
- Pulmonary artery wedge < 15 mmHg
- PVR > 3 WU.m²

MANAGEMENT: (2,9,10,12)

Treatment for PPHN is mainly supportive care while treating the underlying disease (e.g., antibiotics for pneumonia) or allowing time for the injured lung to recover.



Mechanical ventilation:

Gentle ventilator management is vital to prevent further lung injury, but atelectasis is to be avoided. Both under-inflation and over-inflation of the lungs increase pulmonary vascular resistance. The goal is to have lung expansion to 8-9 ribs, PaCO₂ 45-60, and pH 7.25-7.40. High-frequency ventilation may help optimize lung recruitment and prevent volutrauma or barotrauma associated with high peak inflation pressure or tidal volume on conventional ventilation.

Surfactant:

Surfactant inactivation and deficiency are frequently seen in neonates with aspiration, RDS, pneumonia, and meconium aspiration syndrome. In patients with parenchymal lung disease, surfactant replacement therapy has been proven to decrease needs for ECMO or death by at least three fold. Surfactant does not improve outcomes in patients with CDH. Discretion should be used in situations where CDH is complicated by other risk factors.

Oxygen:

Oxygen is a potent vasodilator. However, clinicians should be aware of oxygen toxicity. Pre-ductal saturations 90-95% may be adequate. If serum lactate levels are normal (<3 mM/L) and urine output is sufficient (>1 ml/kg/hour), a post-ductal oxygen saturation in the 70%-80% range is acceptable. Oxygen carrying capacity (OC) is equally important. 16-22 is considered the normal range. Adequate hemoglobin to maintain OC plays an important role in the management of PPHN.

High oxygen delivery above 60% and even only brief exposure to 100% have been shown to increase vasoconstriction and reduce response to iNO as well as increase rebound PPHN when weaned off iNO. (9)

Sodium bicarbonate:

Sodium bicarbonate should be used with caution. It may help correct metabolic acidosis but also produce respiratory acidosis. Carbon dioxide crosses the blood-brain freely and may decrease cerebral pH. Further, alkalosis must be avoided as it causes cerebral vasoconstriction hence reduces cerebral blood flow. Alkaline infusions are reported to be associated with increased use of ECMO.

Sedation/Analgesia/Paralysis:

During supportive care for PPHN, sedation and analgesia are often needed. Paralysis should not be used routinely. Paralysis may be required on occasion if sedation and analgesia alone are inadequate. However, paralysis can precipitate atelectasis and worsen V-Q mismatch. It has been shown that routine paralysis is associated with increased mortality. Prolonged chemical paralysis is also associated with sensorineural hearing loss in survivors of CDH.

Blood pressure stabilization: blood pressure should be targeted within the normal range for age with boluses and inotropes if necessary. The provided algorithm has specific suggestions for management of cardiac dysfunction and blood pressure support.

Pulmonary vasodilators

As mentioned earlier, oxygen is a potent vasodilator. Many patients, however, even after the above management and oxygen, remain hypoxemic. Other pulmonary vasodilators are often needed. ECMO should be considered if the patient fails medical management or deteriorates rapidly.

1. Inhaled nitric oxide: should be initiated if OI >15 and lungs well recruited. A dose of 20 ppm is considered most optimal in improving pulmonary to systemic arterial pressure ratio. Higher doses are not recommended as they do not provide better results, yet there is an increased association with methemoglobinemia.

Weaning iNO should be gradual to minimize the risk of rebound vasoconstriction. It is generally recommended that once there is improved and stable oxygenation, the first effort should be to wean inspired oxygen concentration to below 60%. Inhaled nitric oxide then can be weaned stepwise if pre-ductal saturations remain stable and within range, possibly by 5 ppm every 1-4 hours until the dose is 5 ppm, then by 1 ppm.

Contraindications:

- Congenital heart defects that depend on right to left shunting across the ductus arteriosus such as critical aortic stenosis interrupted aortic arch, hypoplastic left heart syndrome, etc. iNO may worsen cyanosis.
- iNO can worsen pulmonary edema in conditions with pulmonary overflow such as total anomalous pulmonary venous return.

2. Phosphodiesterase (PDE) 3A inhibitor: works by increasing cAMP availability and thus vasodilation. Milrinone is preferred when blood pressure is normal, but there is evidence of ventricular dysfunction. A loading dose of 50 µg/kg over 30-60 minutes followed by a maintenance dose of 0.33 µg /kg/min and titrating to 0.66 µg/kg/min and up to 1 µg /kg/min based on the response. Since milrinone has systemic vasodilation effect, it may cause hypotension. A bolus 10 mg/kg of fluid given prior to the loading dose might prevent hypotension.

3. Phosphodiesterase (PDE) 5 inhibitor: works by preventing cGMP breakdown and may work in conjunction with iNO to improve oxygenation. Sildenafil can be administered orally or intravenously although the intravenous route is preferred during acute illness due to uncertain absorption if given via the oral route. Hypotension is a common side effect. Sildenafil is given as a loading dose 0.42 mg/kg over 3 hours (0.14 mg/kg/hour), then continuous infusion at 0.07 mg/kg/hour. If intravenous preparation is not feasible, sildenafil can be given orally as a dose of 1-2 mg/kg q 6 hours.

4. Prostaglandins: A continuous drip of alprostadil (prostin) may help with vasodilation and also maintains patency of the ductus arteriosus thus reducing afterload on the RV. Little is known about the efficacy and side effects of aerosolized prostaglandin E1 and inhaled prostaglandin I2 on neonates.

In neonates with chronic pulmonary hypertension, other medications might offer benefits:

1. Endothelin receptor blocker: (Bosentan) works by decreasing vascular tone. Side effects are hepatic toxicity and anemia.

2. Prostacyclins: works by increasing cAMP and resulting in direct vasodilatation.

3. Treprostinil (Remodulin): starting dose is 2 ng/kg/min and increase gradually to a goal of 50-80 ng/kg/min over days or weeks. It can be given via IV or SQ routes. Side Effects include hypotension, pain, nausea, vomiting, diarrhea, and abdominal pain.

4. Inhaled prostacyclins (Iloprost): little is known about efficacy on neonates. The need for frequent administration (6-9 times/day) and bronchoconstriction side effects limit its use on this patient population.

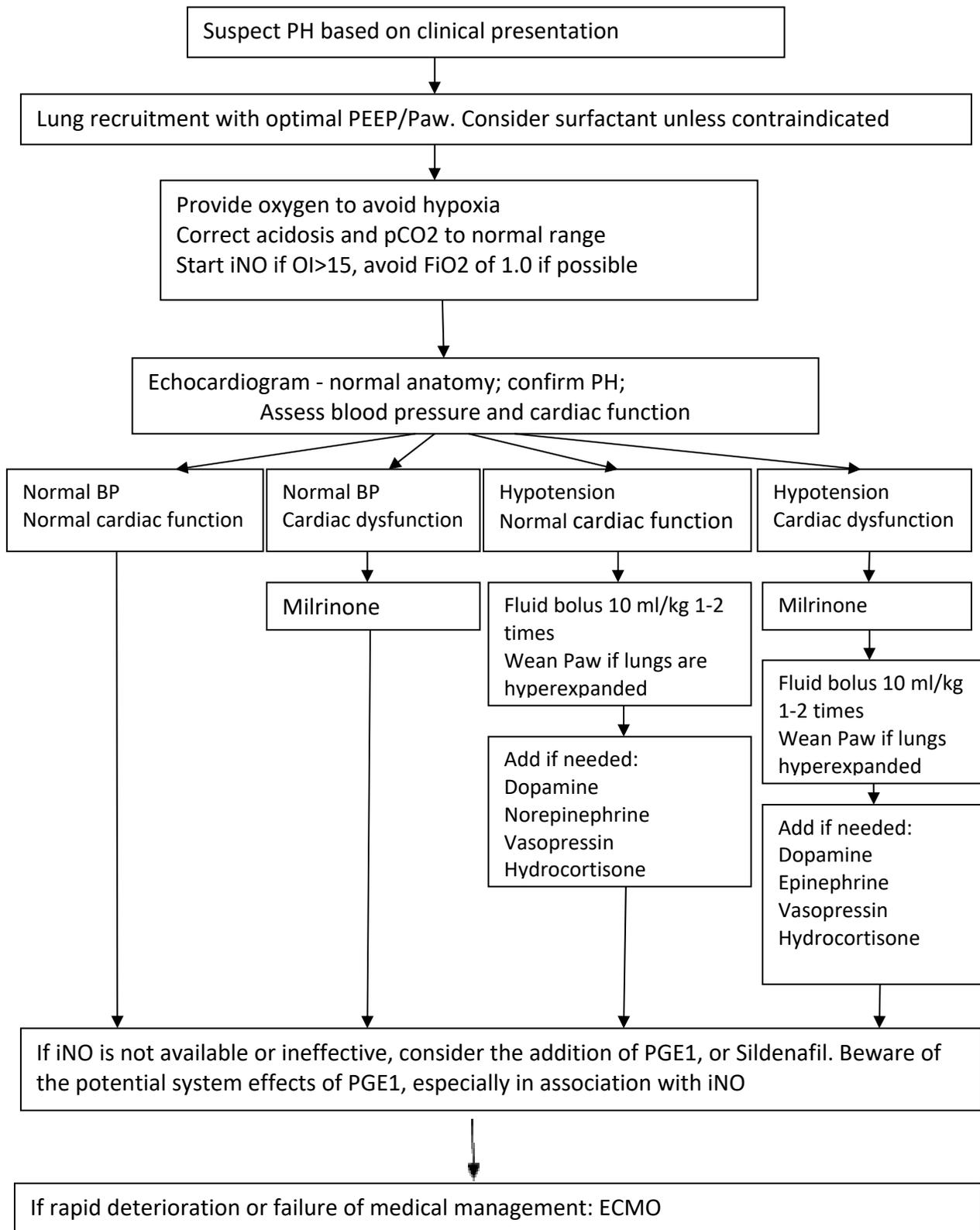


Figure: a Suggested algorithm for the management of acute pulmonary hypertension

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Disclosure: The author has no disclosures.

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Sudden Unexpected Postnatal Collapse (SUPC): One Newborn Death is One Too Many: Current Concepts

Nancy A. Garofalo, PhD APN, NNP, Matthew Pellerite, MD, Michael Goodstein, MD, David A. Paul, MD, Joseph R. Hageman, MD

Introduction

A single potentially preventable episode of Sudden Unexpected Postnatal Collapse (SUPC) and a recently publicized lawsuit in Oregon (1) generated a lot of attention about optimal and safe early skin-to-skin contact and breastfeeding after delivery of a newborn infant in hospitals everywhere (2). SUPC has been defined as a presumably healthy infant born at greater than 35 weeks of gestation age, with a 10-minute Apgar score of greater than 7, who without warning has an event resulting in temporary or permanent cessation of breathing or cardiorespiratory failure within the first postnatal week of life (3). Garofalo and colleagues modified a definition of SUPC, by Becher et al. (4), which is summarized in Table 1. (1)

Approximately one-third of SUPC episodes occur in the first 2 hours after birth, one third occur between 2 and 24 hours after birth, and one third occur between 1 and 7 days after birth (3). The majority of these cases can be potentially preventable. In a recent paper, about 53% of the SUPC cases were felt to be secondary to airway obstruction. (4)

Quality Improvement (QI) Initiatives

Here we will summarize some of the QI and educational initiatives to reduce the incidence of SUPC and near-miss SUPC. An initiative by Pearlman, Igboechi, and Paul in the Christiana Healthcare System, which was presented at the 2018 Vermont Oxford Network annual meeting, is described:

During the pre-intervention period, the clinical practice guideline for infants born vaginally recommended initiation of skin-to-skin care after an assessment by the labor and delivery nursing staff of muscle tone and breathing in infants ≥ 37 weeks. The guideline deferred initiation of skin-to-skin care for infants who were 36 weeks until a brief assessment by a pediatric provider was completed to ensure no additional supportive care was necessary. We also deferred placing the baby on the mother's chest if mothers were receiving magnesium sulfate, felt to be overly sedated, or demonstrated or verbalized signs of fatigue. Infants placed skin-to-skin were positioned, so the infant's face was visible, nose and mouth were not covered, the head was in the sniffing position and turned to one side, neck and shoulders were straight, and the

back was covered with a blanket. An apical heart rate, respiratory rate, and temperature were obtained before starting skin-to-skin care. Infants were monitored visually by the labor and delivery nursing staff. The nursing staff was asked to remain in the room with the mother and baby during skin-to-skin care. Mothers were encouraged to provide skin-to-skin care for a minimum of one hour but could opt to continue until being transferred out of labor and delivery. Breastfeeding was recommended during the first hour and, for mothers not planning to breastfeed, formula feeding within the first two hours after birth. For infants born by Cesarean section, skin-to-skin care was initiated once the mother's condition allowed.

“ SUPC has been defined as a presumably healthy infant born at greater than 35 weeks of gestation age, with a 10-minute Apgar score of greater than 7, who without warning has an event resulting in temporary or permanent cessation of breathing or cardiorespiratory failure within the first postnatal week of life.”

In response to two cases of SUPC in May 2015 despite the use of the above guideline, a bundled intervention was developed to prevent SUPC. A multidisciplinary team, including neonatology staff, labor and delivery nursing, physician and nursing leadership and representatives from the hospital Quality and Safety Department, developed the intervention. The final intervention implemented was additionally informed by a systematic review of the medical literature and communication with other large delivery centers. Post-intervention, the criteria for initiating skin-to-skin care did not change. Positioning during skin-to-skin care also was done the same way as in the pre-intervention period. In addition to the previous measures, the bundled intervention included: 1) monitoring oxygen saturation by pulse oximetry starting at 10 minutes of age and 2) The "RAPP" (respiratory activity, perfusion, and position) skin-to-skin assessment tool (5,6.) (Table 2). The oxygen saturation level was monitored by placing a Masimo pulse oximeter probe (TM, Irvine, CA) on the baby's right hand. Oxygen saturation along with other vital signs were monitored by the labor and delivery nurse and recorded every 15 minutes for the first hour after delivery and every 30 minutes subsequently for the duration of skin-to-skin care. The pulse oximeter was set to alarm for any saturation $< 90\%$. RAPP (Respiratory effort, Activity, Perfusion, and Position) was used and scoring began immediately after an infant was placed skin-to-skin by the labor and delivery room nurse. Any score < 2 in the "position field" required RN action/intervention. Mothers could opt out of skin-to-skin care at their discretion in both periods. Monitoring by pulse oximetry and RAPP scoring continued until the completion of skin-to-skin care during mother and infant's stay on Labor and Delivery.

The intervention included more objective components to identify at-risk infants using both a visual (RAPP) and auditory alarm for the labor and delivery nursing staff (pulse oximeter). The use of

TABLE 1. Diagnostic Criteria for Sudden Unexpected Postnatal Collapse

- ≥ 37 weeks' gestation at birth
- Apgar score ≥ 8 at 5 minutes of postnatal age
- Collapse within 12 hours of birth in hospital
- Required resuscitation after collapse with positive pressure ventilation
- Died or received ongoing intensive care

Modified from Becher et al, 2012. (1)

Table 1 reprinted with permission.

TABLE 2 ■ RAPPT Infant Scoring System

Sign	0	1	2
Respiratory	Apneic	Grunting/flaring/retracting/tachypneic	No distress, easy regular breathing
Activity	No response	Whimpering, crying, and/or active motion of extremities	Quiet alert, sleeping, or breastfeeding. Arms and legs at rest.
Position	Nares and/or mouth are fully occluded or not visible; and/or neck fully extended or flexed, face into chest or breast	Nares or mouth partially occluded or partially visible; and/or neck partially extended or flexed, partial head turn	Nares and mouth uncovered and visible; neck midline, hands up by neck, head turned to side
Perfusion	Pale, dusky	Acrocyanosis	Visible parts pink
Muscle tone	Flaccid, no flexion of extremities	Extremities fully flexed or vigorous motion	Extremities fully flexed and/or slow, deliberate movement
No recoil			

Abbreviation: RAPPT = Respiratory, Activity, Perfusion, Position, and Tone.

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the pulse oximeter allowed the baby to be continuously monitored while the nursing staff completed other critical tasks including charting and clinical care of the mother. The use of the RAPP assessment tool further mitigated the risks of under monitoring by standardizing vital sign measurements along with an evaluation of babies' positioning and perfusion, rather than just relying on less structured visual monitoring as was done pre-intervention.

Other healthcare facilities have also developed specific approaches to more intense monitoring of infants in the first two hours following delivery. For example, Goodstein and colleagues devised a selective approach to close monitoring and wellness checks for infants during the first 2 hours following delivery based on their York Hospital Skin to Skin Risk Assessment (Goodstein, personal communication 2019).

Garofalo and coauthors have created a SUPC educational module that is now a part of the orientation of all clinical providers who work in labor and delivery as well as in postpartum. They have used the term "pink and positioned" to summarize these concepts for the parents of the newborn when they have their baby skin-to-skin: Airway- the mother can see that the baby's nose and mouth are unobstructed. Breathing- a parent can see the rise of

the baby's chest. Color- a parent can see that the lips and tongue are pink and the baby does not look blue/dusky. This module is outlined in a recent paper in *Neonatology Today* (7).

Davanzo and colleagues have also outlined a detailed initiative to prevent SUPC, while making skin-to-skin contact and breastfeeding safer, especially during the first 2 hours of postnatal life in the care of maternal-infant dyads in Italy (8). Their initiative includes (1) a checklist for newborn infants during the first 2 hours of postnatal life, and (2) advice to mothers and healthcare professionals aimed at the prevention of SUPC during and after the first 2 hours of postnatal life. (8).

Prevention and Outcomes

Based on the international and limited U.S. literature, it is clear that not all SUPC episodes are potentially preventable (2). It is also true that the range of incidence figures for SUPC that have been reported in the literature supports the point made by many clinicians that SUPC is a "rare" event (2-11). However, I think all of us would agree that a single SUPC event, if felt to be potentially preventable, is, as we state in the title of this article, one newborn infant death too many. As we more closely examine SUPC, we also find that there are events or episodes that are referred to as "near misses" (2-11). However, up to 50% of SUPC survivors have residual neurodevelopmental impairment (4).

We have designed several initiatives based on this hypothesis: A percentage of SUPC events may be preventable by implementing a safety monitoring bundle for all newborn infants. The efficacy and generalizability of each approach need to be determined through further implementation and evaluation. Some portion of SUPC may be effectively prevented by frequent assessment post-delivery of the mother/infant dyad, and educating staff and parents to ensure that the infant is "pink and positioned" during "distraction-free" breastfeeding and skin-to-skin contact, as recommended by the AAP (12). We will present and discuss these initiatives in detail in Part 2 of our paper.

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Disclosure: The authors have no disclosures.

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Perinatal Substance Use

5 ways you can improve care during pregnancy and beyond

Pregnancy presents unique opportunities for patients to make positive changes in their substance use. When you become an informed provider you empower patients to make those changes.



Educate Yourself

Learn more about the pharmacology of substance use. Promote evidence-based care by communicating with patients in a way that separates fact from fiction. Understand the cycles of sobriety and relapse so that you can help patients plan for their recovery. Advise on the risks associated with polysubstance use.



Use the Right Words

Know the difference between substance use, substance misuse, and Substance Use Disorders (SUDs). Recognize that substance use is stigmatized and that stigma is a barrier to seeking care. Reject language that shames. Embrace the principles of Harm Reduction as a way to support any positive change.



Screen Every Patient

Talking about substance use should be a routine part of everyone's medical care. Get comfortable discussing it. Ask questions and listen to what your patients have to say. You may be the first person to ever ask.



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Medication-Assisted Treatment is the Standard of Care during pregnancy, but there are not enough providers. Contact SAMHSA to become an OTP*. Make naloxone available to all your patients who use opioids.

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The Genetics Corner: A Genetics Consultation for Agenesis of the Corpus Callosum and Poor Feeding

Robin Clark, MD and Subhadra Ramanathan, M.Sc., M.S.

Case History:

A genetics consultation was requested for a 4-day old term SGA female with poor feeding, who was prenatally diagnosed at 30 weeks gestation with IUGR and agenesis of the corpus callosum, raising concern for holoprosencephaly. The baby was conceived by intrauterine sperm injection (IUI). She was born by repeat C-section to a 29-year-old G5 P1 SAb3 mother at 39 weeks gestation. BW 2829 grams (12th %ile), HC 32.5 cm (10.6th %ile). Apgar scores were 8 at one and 9 at five minutes. She required occupational therapy to assist with oral feedings, and the NG tube was used for gavage. Brain MRI at one day of age confirmed agenesis of the corpus callosum without other CNS anomalies. Echocardiogram revealed a large PDA and PFO. Chromosome microarray was pending.

“Brain MRI at one day of age confirmed agenesis of the corpus callosum without other CNS anomalies. Echocardiogram revealed a large PDA and PFO.”

The family history was negative for consanguinity and other affected children. The mother reported that all five of her pregnancies were with the same partner. Their only other living child was conceived with IVF.

The physical exam revealed a small, mildly dysmorphic female with a large nevus flammeus on her forehead. She had several unusual facial features: large, soft anterior and posterior fontanels, down-slanting palpebral fissures, periorbital puffiness, a beaked nose with columella that extended below the alae nasi, mild micrognathia and a small posterior cleft of the soft palate. Her thumbs were broad and deviated. Her great toes were broad but not deviated. Her tone was mildly decreased.

Consultant's Report:

This baby has Rubinstein Taybi syndrome (RTS), a distinctive autosomal dominant disorder with a reported prevalence of 1/125,000 live births, which is likely to be underreported due to incomplete ascertainment. Most patients are sporadic with a negative family history. The cause of infertility in this family is unclear and may be unrelated to the diagnosis of RTS.

The diagnosis of RTS is based primarily on characteristic clinical features although there are no established diagnostic criteria. The diagnosis should be suspected in an infant with broad, angulated or abducted thumbs and great toes, a feature that is present in 96% of infants with RTS. The typical facial features, which are present in 100% of infants with RTS, include down-slanting palpebral fissures and a columella that is lower than the alae nasi. A narrow, high palate is typical but a cleft palate, which was present in this patient, is an uncommon finding in RTS. A vascular nevus on the forehead is a common sign. Growth parameters are near normal at birth, but growth retardation begins within the first months of life. Feeding is often poor due to hypotonia and gastroesophageal reflux. Agenesis or dysplasia of the corpus callosum

occurs in many patients with RTS. Other CNS anomalies, Chiari I and Dandy-Walker malformation, hydrocephalus, instability of C1-C2 and tethered cord have been reported. Seizures are present in 25%.

Congenital anomalies have been reported in most organ systems, including the heart (24-38%: ASD, VSD, PDA, Ao coarctation, AS, PS, HLHS), kidneys (52%), GI (40-74%: reflux, constipation, megacolon), and eyes (cataract, coloboma, glaucoma, strabismus), justifying a detailed evaluation in the affected newborn. Hearing loss (conductive and sensorineural) and obstructive sleep apnea can be diagnosed and treated in infancy. Moderate intellectual disability, microcephaly and short stature are typically evident in childhood. Various childhood cancers (e.g., neuroblastoma, medulloblastoma, rhabdomyosarcoma, leukemia) have been reported.



Figure 1: Note the abducted and angulated thumbs, downslanting palpebral fissures and low hanging columella in this infant with Rubinstein Taybi Syndrome. The glabellar nevus flammeus is a helpful though nonspecific sign.

Genetic tests are useful for the diagnosis of RTS, but they may not be informative. The diagnosis can be confirmed with genetic testing in 50-70% of patients with RTS. Pathogenic variants or copy number changes involving two genes, CREBBP at 16p13.3 and EP300 at 22q13, occur in 60% and 10% of cases respectively. These two genes interact closely and both act in chromatin

remodeling. Chromosome analysis and microarray may identify structural rearrangements or copy number variants at 16p13.3 or 22q13.



Figure 2: Broad, radially deviated thumb



Figure 3: Broad great toes

Interestingly, preeclampsia is common among the mothers of infants with RTS due to a variant in EP300, occurring in ~25%.

Practical applications:

1. Suspect RTS when there are broad or angulated thumbs or great toes with suggestive dysmorphic facial features, hypotonia, poor feeding or other anomalies.
2. Evaluate infants suspected of RTS for congenital anomalies in other organ systems with an echocardiogram, abdominal US, ophthalmologic exam, audiology evaluation, head ultrasound or brain MRI.
3. Expect poor feeding and, when present, evaluate for GE reflux.
4. Use syndrome-specific growth charts for infants with RTS.

5. Consider gene testing for CREBBP and EP300 (order sequencing and deletion/duplication analysis) when RTS is suspected clinically.

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How to Care for a Baby with NAS



Use the Right Words

I was exposed to substances in utero. I am not an addict. And my mother may or may not have a Substance Use Disorder (SUD).



Treat Us as a Dyad

Mothers and babies need each other. Help my mom and me bond. Whenever possible, provide my care alongside her and teach her how to meet my needs.



Support Rooming-In

Babies like me do best in a calm, quiet, dimly-lit room where we can be close to our caregivers.



Promote Kangaroo Care

Skin-to-skin care helps me stabilize and self-regulate. It helps relieve the autonomic symptoms associated with withdrawal and promotes bonding.



Try Non-Pharmacological Care

Help me self-soothe. Swaddle me snugly in a flexed position that reminds me of the womb. Offer me a pacifier to suck on. Protect my sleep by "clustering" my care.



Support Breastfeeding

Breast milk is important to my gastrointestinal health and breastfeeding is recommended when moms are HIV-negative and receiving medically-supervised care. Help my mother reach her pumping and breastfeeding goals.



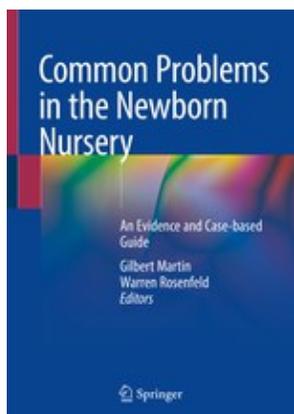
Treat My Symptoms

If I am experiencing withdrawal symptoms that make it hard for me to eat, sleep, and be soothed, create a care plan to help me wean comfortably.

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



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



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ICER vs. Infants

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.

An incomplete and poorly conceived report from the controversial Institute for Clinical and Economic Review (ICER) has set its sights on a most unbecoming target: infants with a degenerative, life-threatening neurological condition. (1)

Once dubbed “floppy baby syndrome,” spinal muscular atrophy occurs when a genetic mutation disrupts the body’s supply of motor neurons. (2) Affected infants slowly lose muscle tone and movement. They miss milestones like sitting up or rolling over. As

“But several research organizations are investigating the use of human milk for the health of infants and children – from improving the efficiency of vaccines to providing the cellular foundation of new medicines.”

their movement and mobility wane, many are bound to strollers or wheelchairs. Some require mechanical ventilation to breathe and feeding tubes for nutrition as they lose the ability to swallow.

While many rare diseases have no effective treatment, the families of spinal muscular atrophy patients will soon be fortunate enough to have two. One is FDA approved; the other is in clinical trials with FDA review anticipated this spring.

But perhaps two treatment options are too many for ICER.

In its latest evidence report, the group sets out to determine whether the two spinal muscular atrophy treatments are cost-effective. As with many of ICER’s previous reports, the exercise is premature. (3) Neither therapy has long-term data. Moreover, the newer therapy does not yet have a price. However, that does not stop ICER.

ICER concludes that neither the existing therapy, called “nusinersen,” nor a new gene therapy meets ICER’s cost-effectiveness threshold. (4,5) However, ICER also effectively pits the two drugs against each other, suggesting that the new gene therapy could at

least be more cost-effective than existing treatment – if it assumes the price point concocted by ICER.

Comparing the two drugs is hardly apples to apples. Even ICER admits it is “naïve.”

The existing treatment, nusinersen, is a periodic spinal injection that boosts the body’s production of a vital protein. It has treated thousands of patients since first approved in 2017.

AfPA member Safi Shareef, MD, a pediatric neurologist, recalled seeing a baby girl with spinal muscular atrophy who began treatment with nusinersen. “Suddenly, she started to meet her milestones. She was starting to sit up, starting to stand up,” Dr. Shareef recalled, calling the progress “miraculous.”

The newer treatment is a gene therapy, a one-time infusion that replaces the defective gene by inserting an inactivated virus into the body. The data used by ICER is from the drug’s Phase I clinical trial, conducted on 15 patients. Early results show promise, and the possibility of treatment by a single infusion, as opposed to periodic injections, is an attractive possibility.

However, neither the disease nor its treatment is one-size-fits-all. Many families would welcome a single-infusion treatment, Dr. Shareef hypothesized, though others may choose differently. “Families may elect not to do gene therapy if, for example, their child is prone to severe complications from viral illness,” Dr. Shareef explained.

The decision between treatments rightfully belongs to a patient’s family and their health care provider. Families may not have a say in the matter if insurers listen to ICER. In the past, the organization’s findings have influenced both Medicaid and commercial health plan coverage, with CVS Health announcing last year that its plan formularies could exclude drugs that did not meet ICER’s threshold. (6)

Facing a devastating diagnosis, families of infants with spinal muscular atrophy do not need ICER economists streamlining their already sparse treatment options. Moreover, they do not need deeply personal medical decisions made for them based on what is cost-effective for the system.

They need options, and they need access..

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The authors have no relevant disclosures.

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

National Coalition for Infant Health Values (SANE)

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

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

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

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



The 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



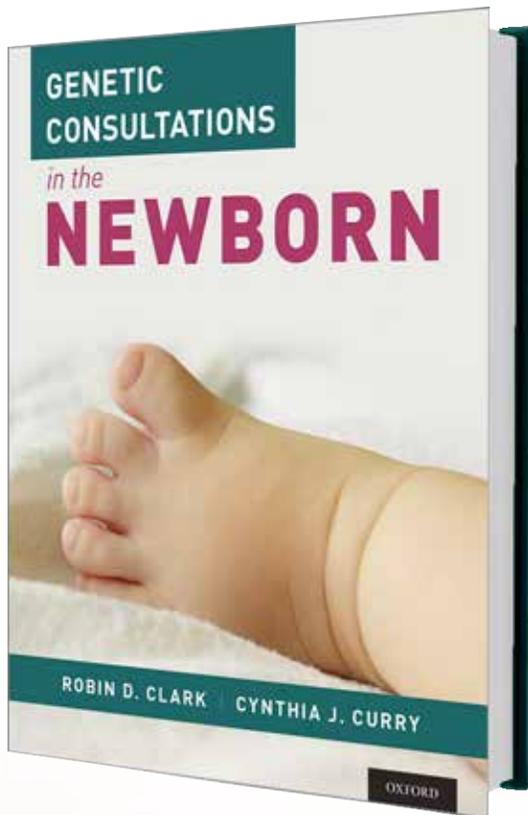
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RSV AWARENESS:

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%).



Medicolegal Forum: I've Been Sued – The Trial

Jonathan Fanaroff, MD, JD and Gilbert Martin, MD

In our last two Medicolegal Forums, we discussed the deposition – how to prepare and what to do on the day of the deposition. This column will focus on the trial – what to expect and how to behave.

Do most cases go to Trial?

No. The vast majority of medical malpractice cases are either dropped or settled before going to trial.

How long do Trials last?

Most trials last from one to three weeks, although that may vary considerably depending on the number of witnesses and complexity of the case.

What happens when a case goes to Trial?

The first step in a trial is the selection of a jury. Then both sides will present opening statements, with the plaintiff going first. After that, the plaintiff presents their case, followed by the defense. Both sides will then make closing statements, with the plaintiff again going first. The judge will then give the jury instructions, after which the jury will deliberate until they reach a verdict.

What are the elements of a malpractice lawsuit?

In order to succeed, a plaintiff must prove that malpractice has occurred. They have the burden of proof. In most cases they have to show that it is more likely than not that:

1. The physician had a duty to the patient.
2. That duty was breached by not practicing to the standard of care.
3. That the breach was the cause of an injury.
4. That the injury led to damages, either economic (medical expenses, lost earnings, etc.) or noneconomic (emotional distress, pain, and suffering, etc.)

“ Physicians are not expected to be perfect, but are expected to act as a reasonable physician would act under similar circumstances. ”

What is the ‘standard of care’?

Physicians are not expected to be perfect, but are expected to act as a reasonable physician would act under similar circumstances. Since jurors are generally not in medicine, expert witnesses are used to testify as to whether a physician breached the standard of care.

Is there a ‘dress code’ and a “behavior code”?

Appropriate dress and behavior are important. Conservative dress is recommended, as is professional behavior at all times. Similar to a job interview you are being evaluated at all times

by the jury.

What should I do at the Trial?

1. **BE PRESENT AND VISIBLE**– The jury needs to see that you are dedicated to your defense and taking the lawsuit seriously.
2. **STAY ALERT DURING THE TRIAL** – Unlike the movies, trials can last a long time. Jurors will notice if you appear disinterested or distracted.
3. **KEEP YOUR Demeanor APPROPRIATE** – Keep control even when the opposing expert is criticizing the care you provided.
4. **BE PREPARED FOR YOUR TESTIMONY** – Many of the tips provided in the last two columns concerning depositions apply. This is your chance to tell your story to the jury, who will expect you to explain what happened and why it happened. Do not use confusing medical terminology.
5. **SHOW APPROPRIATE SYMPATHY** – “I’m really sorry this happened to Susan and her family. I just don’t feel that I’m responsible for it.”

What are the consequences of settling or losing a malpractice lawsuit?

The jury may award economic and non-economic, and rarely, punitive damages. Usually, this is paid for by the insurance company. Additionally, any hospital or insurance company who pays a settlement or judgment must report the name of any licensed professional on whose behalf the payment was made to the National Practitioner Data Bank (NPDB). This includes nurses and nurse practitioners. Finally, State medical boards may investigate if a patient makes a complaint, or if a practitio-



ner is sued a number of times or there is a loss or settlement above a certain amount.

Summation: The Deposition and the Trial.

This three-part series has discussed the preparation for the deposition, the deposition itself and finally, the trial. This entire process can be lengthy, tedious and at times stressful. The personalities of the participants vary, and intimidation by opposing counsel can be part of the process. It is often difficult to separate obstetrical care from consequences to the newborn. Do we talk about the standard of care? Do we discuss causation? Is the alleged negligence real? A unifying theme for the expert witness is to be familiar with the evidence-based scientific literature. The "scales of justice" can only tilt in two directions. Thorough preparation, a grasp of the process and an organized overview of the issues involved are the basic guidelines.

The authors have no conflicts of interests to disclose.

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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 Serious Illnesses Through Early Care

Learn More about RSV at www.infanthealth.org/RSV

Monthly Clinical Pearl: Please Don't Check Gastric Residuals!

Oussama "Sam" Itani, MD, and Joseph R. Hageman, MD

When we discussed writing this clinical pearl with a number of clinicians working in the neonatal intensive care unit (NICU), from residents to neonatal attendings, the response was emotional from laughter to frustration.

“Despite lack of evidence for this practice, gastric residuals have been considered a sign of feeding intolerance and potential early stages of necrotizing enterocolitis (NEC).”

Checking gastric residuals has traditionally been an integral component of enteral nutrition of preterm infants in many NICUs over many decades. Despite lack of evidence for this practice, gastric residuals have been considered a sign of feeding intolerance and potential early stages of necrotizing enterocolitis (NEC). Consequently, it has often resulted in interruption of feeding advancement and contributed to the delayed achievement of full enteral feedings and ultimately extrauterine growth restriction especially in the smallest preterm infants. Presence of gastric residuals may be a manifestation of physiological delayed gut maturation and motility in preterm infants and do not necessarily indicate NEC unless associated with other clinical signs such as abdominal distension and tenderness, hematest positive or bloody stools, bilious aspirates (Mihatsch). Feeding intolerance has been defined as a constellation of clinical findings including gastric residuals, abdominal distension, with or without emesis and apnea/bradycardia spells (Moore)

Mihatsch had previously reported that there was no significant negative correlation between the mean gastric residual volume or the presence of gastric green residual and feeding volume on day 14. These should not slow down the advancement of feeding volumes in the absence of other clinical signs and symptoms. Although not statistically significant, Torrazza and coauthors reported infants without gastric residual assessment reached full feeds six days earlier.

Riskin and coworkers demonstrated avoiding routine gastric residual volume evaluation before each gavage feeding was associated with earlier achievement of full enteral feeding in preterm infants born ≤ 34 weeks of gestation without increasing

the risk for NEC.

In a randomized controlled study, Singh et al. demonstrated that avoiding routine assessment of gastric residual volume before feeding advancement did not shorten the time to reach full feeds in preterm infants with birth weight between 1500 and 2000 g. However, it did not increase the risk of NEC. It is likely that implementation of feeding protocols decreased the frequency of feeding interruptions due to gastric residuals and hence did not affect feeding advancement and the time to reaching full feeding volume.

Abdominal girth measurements in addition to clinical signs such as lethargy, temperature instability or abnormal laboratory and radiological studies might be a better indicator of feeding intolerance and/or early NEC. Kauer et al. has reported that monitoring abdominal girth instead of measuring gastric residuals as a measure of feed intolerance may result in earlier achievement of full feeds and lesser feed interruption days.

In a randomized controlled study, Thomas et al. also demonstrated that measurement of abdominal girth without gastric residual assessment facilitated faster achievement of full feedings without increasing the risk of NEC. Another recent study by Parker et al. found that omission of measurement of gastric residuals was associated with increased weekly enteral intake without an increase in the risk for NEC or intestinal perforation.

Our concluding message is that the volume or color of the gastric residual is not an indicator of feeding intolerance or abdominal pathology in the preterm infant unless it is associated with other concerning clinical and laboratory signs. Measurement of abdominal girth might be a better tool in monitoring feeding tolerance than checking gastric residue volume or color.

“Measurement of abdominal girth might be a better tool in monitoring feeding tolerance than checking gastric residue volume or color.”

Finally, systematic reviews have addressed factors associated with the pathogenesis. Implementation of clinical practice guidelines and feeding regimens (Jasani, Patole), antenatal steroids, utilization of human milk and potentially probiotics (Patel)

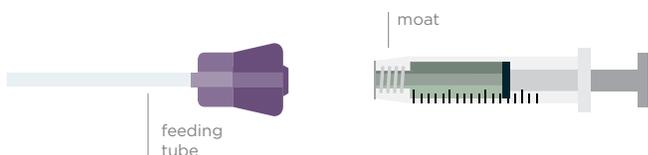
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SAFETY IN THE NICU

New tubes, new problems?

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



DOSING ACCURACY

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

INFECTION RISK

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

WORKFLOW ISSUES

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

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

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

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are probably the best preventive measures against NEC in the preterm infant (Patel).

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The authors have identified no conflicts of interest.

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Letters to the Editor

February 15, 2019

Mitchell Goldstein, MD
Editor in Chief, Neonatology Today

Dear Mitchell,

As a reviewer for Neonatology Today I have enjoyed reviewing a spectrum of interesting and clinically relevant articles. I understand that you are working through a process to award CME credits to reviewers and wondered how this is progressing as we all need our CME credits!

Thanks for your consideration,

Joseph Hageman, MD

Joe,

This is an excellent question. A number of journals have started awarding Continuing Medical Education (CME) Credits to their reviewers. We are in the early part of this process. For this to work seamlessly, the manuscript that is being reviewed would have to be determined to have educational value and relevancy.

Further, any conflicts of interest would have to be disclosed up front. The major difference between a manuscript that is being considered for publication and awarding CME comes when the disclosure is vetted. Although a commercial interest does not disqualify publication, it may result in a publication that cannot be reviewed for CME credit according to information regarding the appropriateness of academic content from the Accrediting Council for Continuing Medical Education (ACCME).

That said, we have been working with PAC-LAC, an accredited not for profit CME provider to look into this credit as a way of honoring the time and effort that our reviewers put into evaluating our manuscripts.

We would hope to be able to offer this credit before this coming summer. There will be an announcement in Neonatology Today



before we start.

Thank you again for all of your hard work and dedication.

Sincerely,

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

Mitchell Goldstein, MD
Editor in Chief

NT NEONATOLOGY TODAY

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A Delaware "not for profit" 501(c) 3 Corporation.
c/o Mitchell Goldstein, MD
11175 Campus Street, Suite #11121
Loma Linda, CA 92354
Tel: +1 (302) 313-9984
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Neonatology Today welcomes your editorial commentary on previously published manuscripts, news items, and other 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.

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Erratum (Neonatology Today January, 2018)

Neonatology Today has not identified an erratum affecting the January, 2019 edition. Corrections can be sent directly to LomaLindaPublishingCompany@gmail.com. The most recent edition of Neonatology Today including any previously identified erratum may be downloaded from www.neonatologytoday.net.

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

1 DE CADA 7 MADRES AFRONTA LA DEPRESIÓN POSPARTO, experimentando

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

15% Sin embargo, sólo el 15% recibe tratamiento!

LA DEPRESIÓN POSTPARTO NO TRATADA PUEDE AFECTAR:

- La salud de la madre
- El sueño, la alimentación y el comportamiento del bebé a medida que crece?
- La capacidad para cuidar de un bebé y sus hermanos

PARA AYUDAR A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSPARTO

LOS ENCARGADOS DE FORMULAR POLÍTICAS PUEDEN:

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

LOS HOSPITALES PUEDEN:

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

NCFIH National Coalition for Infant Health
 Promoting Access for Premature Infants through Age Two
www.infanthealth.org

¹ American Psychological Association. Accessed on: <http://www.apa.org/women/resources/reports/postpartum-depression.aspx>
² National Institute of Mental Health. Accessed on: <https://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml>
³ Journal of Perinatology (2015) 35, 529–536. doi:10.1097/JP.0000000000000147
⁴ Prevalence and risk factors for postpartum depression among women with preterm and low birth-weight infants: a systematic review. Vigod SN, Villagers L, Olesen CL. *PLoS One* 2010; 11(7): 540-50.

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www.thegravensconference.com

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

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<http://worldneonatology.com/2019/welcome-letter-2>

The 5th annual 2019 iCAN Research &
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June 23-28, 2019
Kansas City, Missouri
<https://www.icanresearch.org/2019-summit>

The AAP Experience
National Convention and Exhibition
New Orleans, LA
October 25-29, 2019.
<http://aapexperience.org/>

*For Additional Meeting
Information, visit
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NEONATOLOGY TODAY

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ISSN: 1932-7137 (Online). ISSN: 1932-7129 (Print). Published monthly. All rights reserved.

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Loma Linda Publishing Company | c/o Mitchell Goldstein, MD | 11175 Campus St, Ste. 11121 | Loma Linda, CA 92354 |

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Neonatology and the Arts

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

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

Logos and trademarks will usually not qualify for publication.

This month's selection is Loma Linda University Children's Hospital's way of saying that the baby is going home with the intent for mom to breastfeed. This design is a nice artistic tapestry rendered under privacy protection. The author is anonymous.

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