

# NEONATOLOGY TODAY

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



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### NEONATOLOGY TODAY

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## Important Safety Information

- INOMAX is contraindicated in the treatment of neonates dependent on right-to-left shunting of blood.
- Abrupt discontinuation of INOMAX may lead to increasing pulmonary artery pressure and worsening oxygenation.
- Methemoglobinemia and NO<sub>2</sub> levels are dose dependent. Nitric oxide donor compounds may have an additive effect with INOMAX on the risk of developing methemoglobinemia. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.

- In patients with pre-existing left ventricular dysfunction, INOMAX may increase pulmonary capillary wedge pressure leading to pulmonary edema.
- Monitor for PaO<sub>2</sub>, inspired NO<sub>2</sub>, and methemoglobin during INOMAX administration.
- INOMAX must be administered using a calibrated INOMax DSIR® Nitric Oxide Delivery System operated by trained personnel. Only validated ventilator systems should be used in conjunction with INOMAX.
- The most common adverse reaction is hypotension.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.**

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\*INOMax Total Care is included at no extra cost to contracted INOMAX customers.

<sup>†</sup>Emergency deliveries of various components are often made within 4 to 6 hours but may take up to 24 hours, depending on hospital location and/or circumstances.

Reference: 1. Data on file. Hampton, NJ: Mallinckrodt Pharmaceuticals.



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**INOmax**  
**Total Care®**

# INOMax<sup>®</sup> (nitric oxide gas)

## Brief Summary of Prescribing Information

### INDICATIONS AND USAGE

#### Treatment of Hypoxic Respiratory Failure

INOMax<sup>®</sup> is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilator support and other appropriate agents.

### CONTRAINDICATIONS

INOMax is contraindicated in neonates dependent on right-to-left shunting of blood.

### WARNINGS AND PRECAUTIONS

#### Rebound Pulmonary Hypertension Syndrome following Abrupt Discontinuation

Wean from INOMax. Abrupt discontinuation of INOMax may lead to worsening oxygenation and increasing pulmonary artery pressure, i.e., Rebound Pulmonary Hypertension Syndrome. Signs and symptoms of Rebound Pulmonary Hypertension Syndrome include hypoxemia, systemic hypotension, bradycardia, and decreased cardiac output. If Rebound Pulmonary Hypertension occurs, reinstate INOMax therapy immediately.

#### Hypoxemia from Methemoglobinemia

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 (NO<sub>2</sub>) forms in gas mixtures containing NO and O<sub>2</sub>. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.

If there is an unexpected change in NO<sub>2</sub> concentration, or if the NO<sub>2</sub> 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 NO<sub>2</sub> analyzer should be recalibrated. The dose of INOMax and/or FiO<sub>2</sub> 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 NO<sub>2</sub>. Elevated NO<sub>2</sub> may cause acute lung injury. Elevations in methemoglobin reduce the oxygen delivery capacity of the circulation. In clinical studies, NO<sub>2</sub> 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.

INOMAX<sup>®</sup> is a registered trademark of a Mallinckrodt Pharmaceuticals company.

# Innovative Care of the Newborn Brain: Stanford University September 26-27, 2018

Krisa Van Meurs, MD and Kathi Salley Randall, MSN, RNC, CNS, NNP-BC

On a warm late-summer morning in September 170 neonatologists and neonatal nurses from around the globe joined together to learn about how to create a NeuroNICU program, to perform an in-depth neuro exam, deepen their knowledge of therapeutic hypothermia, and focus on the clinical utility of bedside brain monitoring.

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*“The two-day conference was held at the gorgeous Frances G. Arrillaga Alumni Center in the center of Stanford University campus... Attendees were also from NICU’s as far away from California as Montreal, Florida and Brazil, and this provided for rich conversations and networking for everyone who attended. ”*

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The two-day conference was held at the gorgeous Frances G. Arrillaga Alumni Center in the center of Stanford University campus and the weather provided the attendees with the warmth and sun that we all expect from Northern California summers. Attendees were also from NICU’s as far away from California as Montreal, Florida and Brazil, and this provided for rich conversations and networking for everyone who attended.

The topics presented at this year’s conference spanned a wide range. Here are just a few highlights of talks given by our team of neonatal and neurology experts:



## Clinical findings in HIE

- **Abnormal neurologic exam:**

- Level of consciousness
- Tone
- Tendon reflexes
- Primitive reflexes
- Respiratory function
- Autonomic function

- **Other clinical findings:**

- Need for resuscitation
- Seizures
- EEG abnormalities
- Other organ injury



### Slide 1: Clinical findings in HIE

- Dr. Courtney Wusthoff, Neonatal Neurologist gave three talks at this year's Innovative Care Conference. She presented on the complexities of diagnosis and management of neonatal seizures, pitfalls of the neonatal neurological examination, and gave an excellent review of the fetal neuro-development and sequelae of disrupted development.
- Drs. Valerie Chock (Neonatologist) and Kelly Mahaney (Pediatric Neurosurgeon) teamed up for a presentation on the pathophysiology of brain injuries in term and preterm infants and discussed the neurosurgical management of at risk infants.
- Dr. Krisa Van Meurs, Neonatologist and Medical Director of the NeuroNICU, gave a presentation that reviewed HIE and hypothermia from the pathophysiology of the insult, the current evidence on the impact that hypothermia can provide to improve outcomes, and a peek at the future of neuroprotection for this high-risk population.



- Dr. Sonia Bonifacio, Neonatologist and Co-Medical Director of our NeuroNICU, gave an excellent review of neonatal stroke and facilitated one of our small group workshops on Advanced aEEG Cases.
- Dr. Susan Hintz, Director of the Johnson Center's Maternal Fetal Medicine Program presented a comprehensive overview of both short and long-term neurodevelopmental outcomes of extremely premature infants.
- Dr. Richard Shaw and Angelica Moreyra, PhD shared with the attendees a review of the results of their intervention research to reduce anxiety and PTSD in NICU parents.
- Kathi Randall, NNP our NeuroNICU Program Consultant gave a practical presentation on how we each can provide neuro-protective care on a daily basis through simple interventions like infant massage, nutrition, pain management, parental presence, and skin-to-skin care.

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***"By adding these exceptional presenters to the long list of local experts who typically present at the Stanford NeuroNICU course this two-day seminar offers the best way for anyone interested in the neonatal brain to become immersed in the best science and practical bedside approaches for caring for a variety of infants with, or at-risk for, brain injury."***

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- For infants with neurological injury, palliative and comfort care are important topics for caregivers to consider, and one of our NNP's from the LPCH NICU, Diana Kobayashi gave a great review of the literature and perspectives on how we can continue to improve in providing comfort care when critical care is no longer indicated.

### Should a baby be cooled after 6 hours?

#### How this happens:

- Arrival at a cooling center after 6 hrs of age
- Progress from stage I to II/III encephalopathy after 6 hrs of age
- Are not recognized to qualify until after 6hrs of age
- Cooling cannot be initiated within 6 hours of age (equipment or personnel not available)

**Slide 2: Clinically relevant questions regarding patient management.**



### Incidence and outcome of HIE

- Incidence ranges from 1 to 6 per 1,000 births
- Moderate encephalopathy is associated with 10% risk of death and 30% risk of disability
- Severe encephalopathy is associated with 60% risk of death and most survivors will be disabled



Wattchow et al. J. Perinatol. 2010  
doi:10.1097/01.FPN.0b013e3181c00000

Handbook of Neonatology

• Attendees at this year's conference listening to Krisa Van Meurs speaking

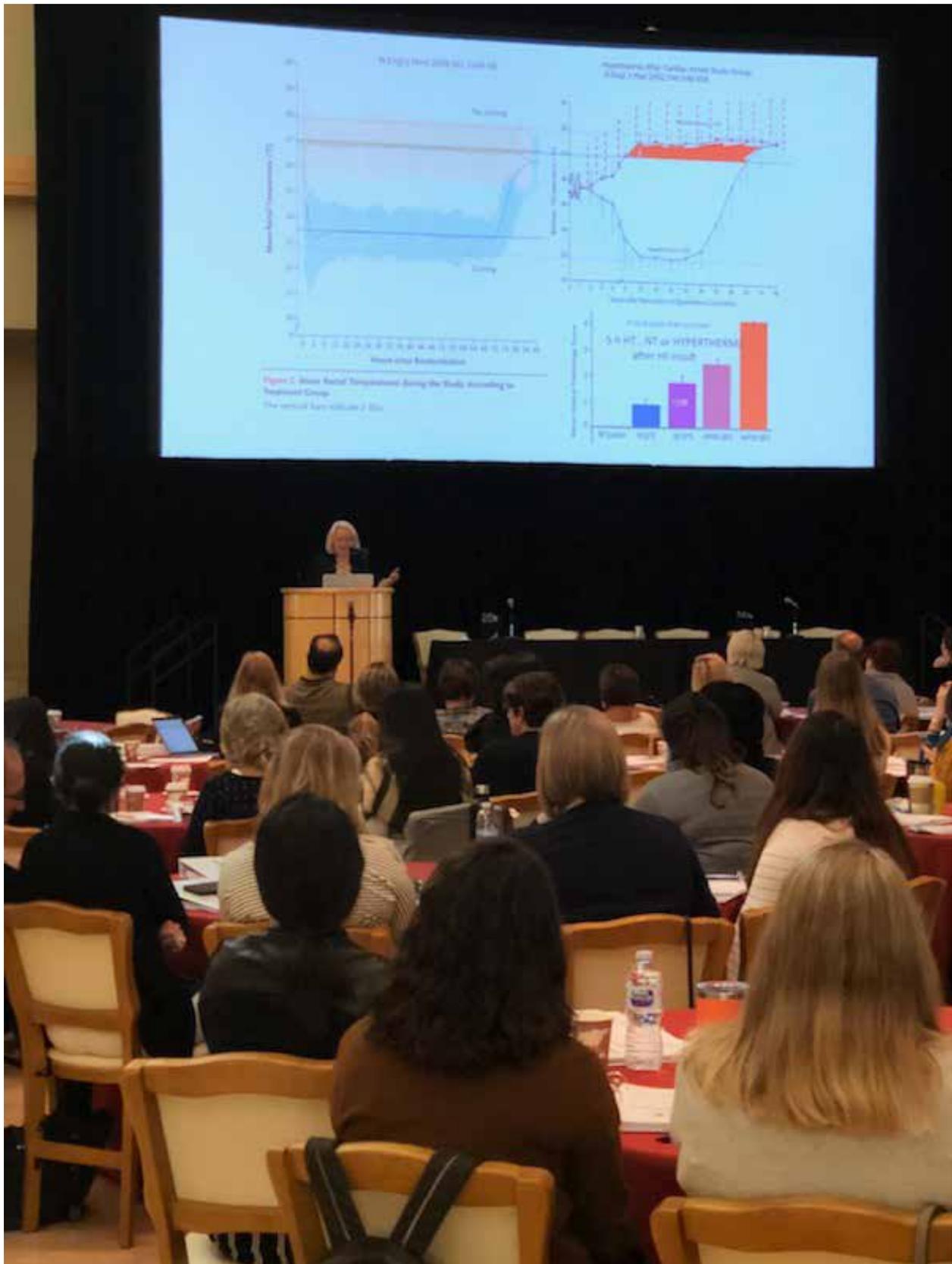


**Conference organizers caught by the camera**

We love to conclude our conference with a presentation by a parent or family and this year was no exception as we heard a passionate telling of the story of prematurity by one of our family advocates from the department of family centered care, Nina Boiadjieva.

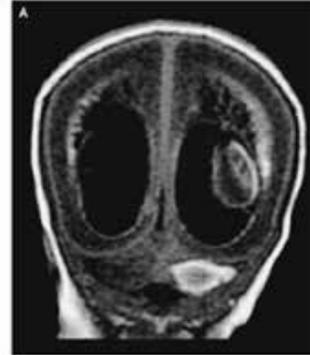
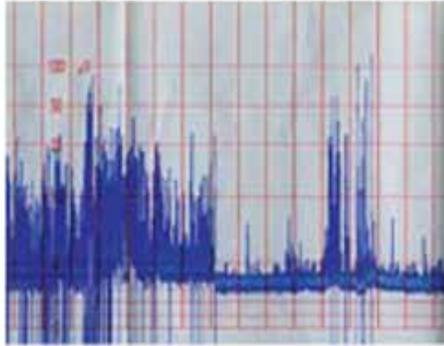
In addition to the incredible local faculty who presented on a variety of NeuroNICU topics, three international experts in the neonatal neurology field were also on the agenda.

- Dr. Lena Hellstrom-Westas, from Uppsala, Sweden, presented on the history and current use of aEEG



*Marianne Thoresen lecturing*

# Severe IVH



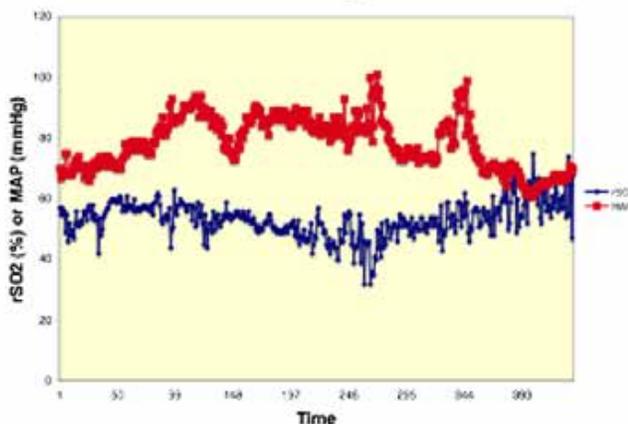
26 week infant with grade IV IVH  
discontinuous -> flat/isoelectric pattern

Olischar et al, *Acta Paediatrica* 2007; 96: 1743-1750

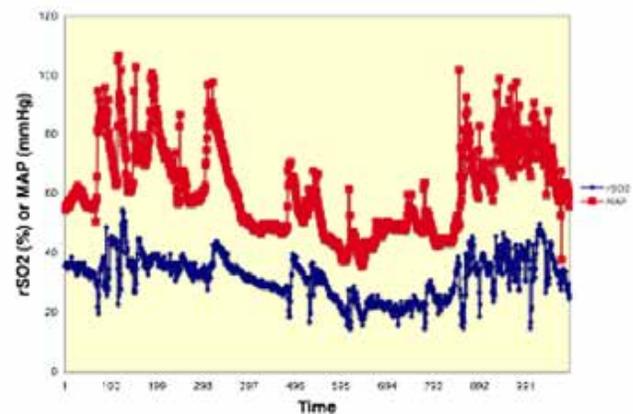
# IVH

- Cerebral autoregulation

**Intact Autoregulation**



**Impaired Autoregulation**



## NIRS Measures

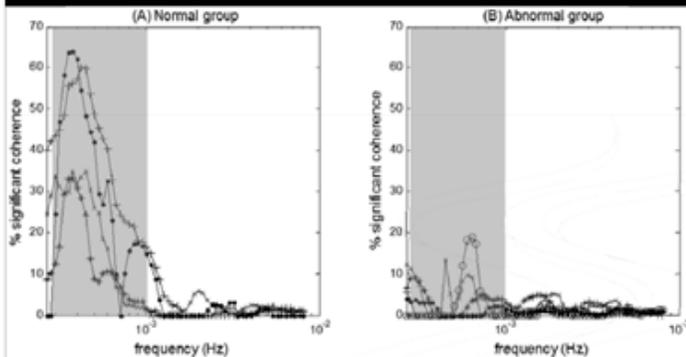
- NIRS-measured regional oximetry measures provides a non-invasive measure of end-organ oxygenation and perfusion.  
\* *correlates with jugular venous saturation*

$$rScO_2 = \frac{HbO_2}{HbO_2 + HHb}$$

$$FTOE = \frac{SaO_2 - rScO_2}{SaO_2}$$

*Understanding NIRS physiology is essential in evaluation of local cooling effects*

## Abnormal outcomes at 2 y are associated with decreased NVC

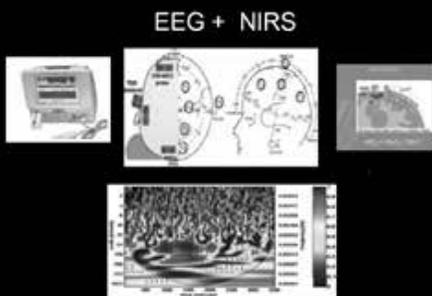


Chalak, L. Nature Scientific reports 2017

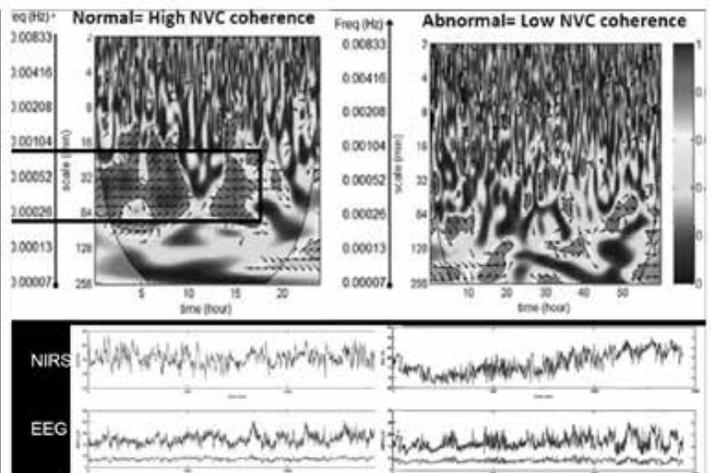
## Summary of Findings

- The *Wavelet Neurovascular Bundle* can provide dynamic measures of the cerebral autoregulation and neurovascular coupling (CA and NVC)
- These hemodynamic parameters have the potential to impact risk stratification strategies, therapeutic decision making and prediction of outcomes after birth

## Non Invasive Neurovascular Coupling



Chalak, L. Dev Neuroscience 2017

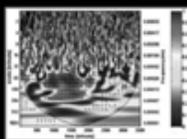


Chalak, L. Dev Neuroscience 2017

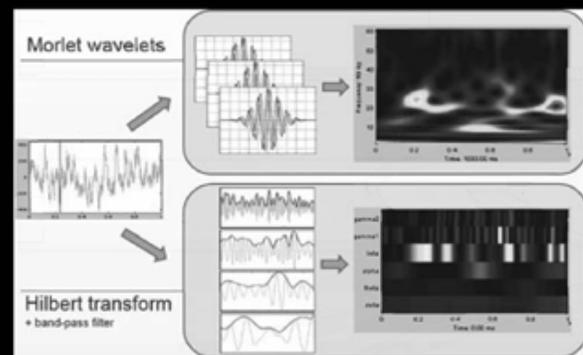
## Weather-Forecast Tool to Evaluate Neonatal Brain Health



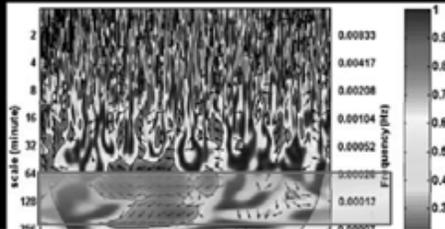
Wavelet mathematical tool provides optimal representation of BOTH time and frequency



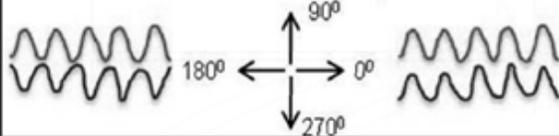
## Wavelet Paradigm Shift Prior Analyses either Frequency OR Duration



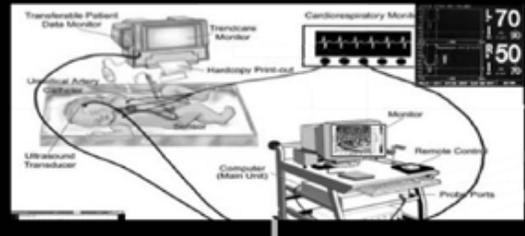
## The Wavelet Quantifies Correlation with time, frequency, gain



### Phase relationship



## Neuromonitoring at Bedside: The Wavelet NV Bundle



### Cerebral autoregulation (CA):

- BP • CBF

### Neurovascular coupling (NVC):

- EEG • CBF

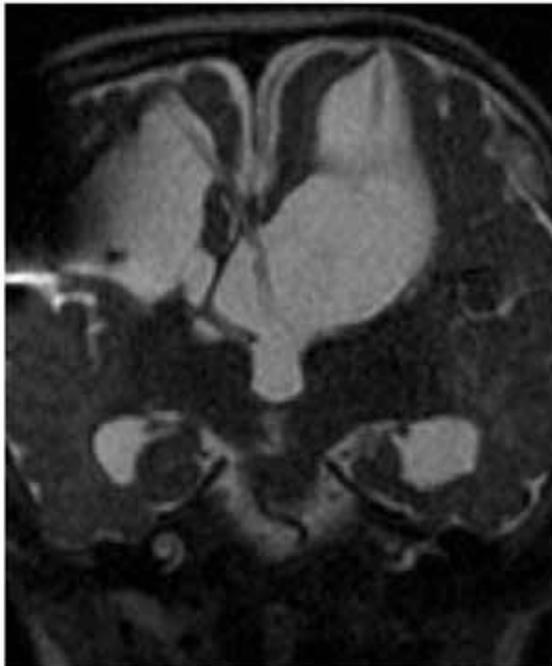
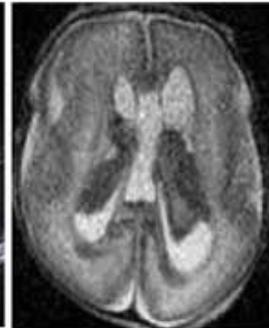
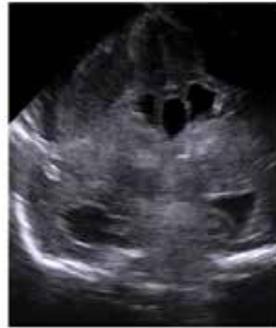


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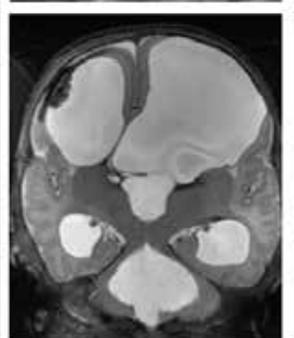
Stanford  
Children's Health

Lucile Packard  
Children's Hospital  
Stanford



## Case 2

- 25 weeks 6 days GA
- E. Coli sepsis
- Bilateral grade IV IVH, bilateral subdural hemorrhages





# The LPCH NeuroNICU Journey

## *Program Stats:*

- 1 year anniversary – 226 patients
- 2 year anniversary – 260 patients
- 3 year anniversary – 370 patients
- 4 year anniversary – 494 patients
- Total 1,350 infants



## The Neuro NICU is Multi-Disciplinary

### Neonatology & Nursing



### Pediatric Neurosurgery



### Child Neurology

### Developmental Behavioral Pediatrics/ High Risk Infant follow-up Clinic



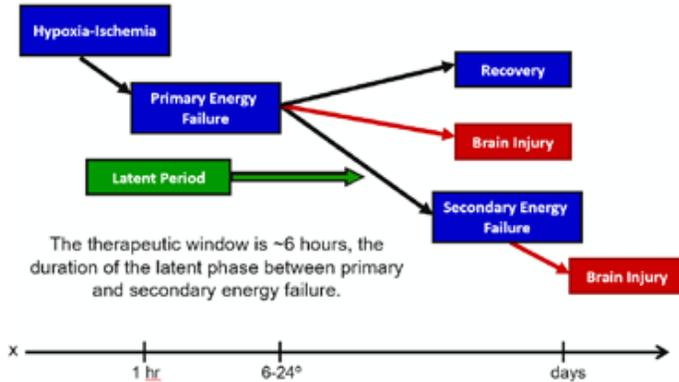
### Developmental Team



### Neuroradiology Child Psychiatry



### Mechanism of brain injury during HIE



### Slide 3: Brain Injury during HIE

#### Need for cooling plus therapies

	Controls	Cooled
Death or moderate to severe disability	62-83%	44-55%
Death	27-57%	24-38%
Cerebral palsy	30-48%	19-33%

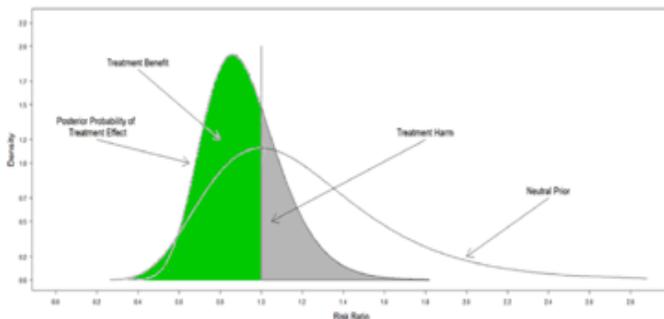
**Conclusion:** Additional neuroprotective strategies are needed to further reduce mortality and morbidity.

Shankaran S, *NEJM* (2005)  
 Gluckman P, et al. *Lancet* (2005)  
 Azzopardi D, et al. *NEJM* (2009)  
 Simbruner G, et al. *Pediatrics* (2010)  
 Jacobs S, et al. *Arch Pediatr Adolesc Med* (2011)

Stanford University

### Slide 4: Additional therapies are needed.

#### Probability of treatment benefit



**Conclusion:** 76% of newborns cooled between 6-24 hours will have some benefit.

Laptook A, et al. *JAMA* (2017) Stanford University

### Slide 5: Analysis favors treatment.

in the NICU, as well as a comprehensive review on neonatal pain and the controversies on best practices and management from her international perspective.

- Dr. Lina Chalak from UT Southwestern in Dallas, TX enchanted the audience with her elegant presentation

### Potential therapies to augment hypothermia for HIE

#### Anticonvulsant or antiexcitatory

Phenobarbital, topiramate, levetiracetam, **xenon**, magnesium sulfate, bumetanide

#### Anti-inflammatory or antioxidant

Sodium cromoglicate, minocycline, indomethacin, melatonin, N-acetylcysteine, allopurinol, pomegranate polyphenols, 7-nitroindazole, 2-iminobiotin, **necrostatin 1**

#### Multiple mechanisms

**Erythropoietin**

#### Growth factors and cell-based therapies

Nerve growth factor, insulin-like growth factor 1, brain derived neurotrophic factor, **autologous cord-blood transplantation**

Modified from Johnston MV et al. *Lancet Neurology* 2011

Stanford University

### Slide 6: Potential for Augmentation Exists.

on the neuro-vascular bundle and its delicate balance especially for those with brain injury. Both she and Dr. Hellstrom-Westas led afternoon workshops on the advanced use of aEEG and NIRS which were both extremely popular break-out sessions this year.

- And finally, Dr. Marianne Thoresen, one of the world's leading experts in neonatal physiology and hypothermia provided the attendees with an overview of the history and future of neonatal neuro-protection, including cooling, Xenon, Melatonin, mother's milk and more. And then she concluded the morning session on the 2nd day with a deep review of the pathophysiology of HIE, the mechanism by which cooling works, and bedside pearls for care that may influence these infants' outcomes.

By adding these exceptional presenters to the long list of local experts who typically present at the Stanford NeuroNICU course this two-day seminar offers the best way for anyone interested in the neonatal brain to become immersed in the best science and practical bedside approaches for caring for a variety of infants with, or at-risk for, brain injury.

If you and your team are interested in attending a future conference, the dates for 2019 are in the planning stages and we will certainly share those with you as soon as we can. To join their mailing list, click here (<https://goo.gl/forms/jN49Vy0VM0Su3XaH3>) or email Dr. Krisa Van Meurs, the Medical Director of the LPCH/Stanford NeuroNICU at: [vanmeurs@stanford.edu](mailto:vanmeurs@stanford.edu)

*The authors have indicated no relevant disclosures.*

NT

# 4 Pillars of Neuro-NICU Care



*Corresponding Author*



*Krisa Van Meurs, MD  
Rosemarie Hess Endowed Chair,  
Division of Neonatal and Developmental Medicine  
Professor-Med Ctr Line  
Department: Pediatrics - Neonatology  
Stanford University  
750 Welch Rd. #315  
Stanford, California 94305-5731  
(650) 723-5711 (office)  
[vanmeurs@stanford.edu](mailto:vanmeurs@stanford.edu)*



*Kathi Salley Randall, MSN, RNC, CNS, NNP-BC  
NeuroNICU Program Consultant, Lucile Packard  
Children's Hospital at Stanford  
President/Owner of Synapse Care Solutions  
[kathi@synapsecare.com](mailto:kathi@synapsecare.com)*

## HFO/VG: This changes everything

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

High-Frequency Oscillation (HFO) has been available to clinicians as a mode of ventilation for decades, although evidence supporting its use for decreasing chronic lung disease (CLD) has been lacking. A large study by Durand et al. of 512 infants indicated that at the least, HFO was as safe in the premature population as conventional ventilation. (1) Other studies from Europe have been more positive when looking at long term outcomes.

In the U.S., the only device available to clinicians to provide HFO has been the Sensormedics® oscillator. In Europe and the rest of the world, other ventilators are available which offer both conventional and HFO modalities. The Babylog® 8000 plus (Dräger) was the first of such devices available in Canada. It came with the advantage of volume measurement in HFO mode, later incorporated into the VN 500 as “volume guarantee” (VG) in HFO mode.

Several factors compound the difficulty faced with ventilating the micro-preemie. As resuscitation is offered to smaller and smaller babies, the inherent structure of these infants becomes increasingly important. Small babies have small airways with high resistance. This resistance results in longer time constants and invariably air trapping to one degree or another.

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

Clinicians using the Sensormedics® face a problem here for several reasons. The machine does not measure volume, and it is a very powerful ventilator; too powerful in fact for these smaller infants. Historically the workaround here has been to increase frequency to reduce the size of the resulting high-frequency tidal volume ( $V_{Thf}$ ). This, of course, creates a problem because longer time constants call for lower frequencies, not higher ones. Finally, the machine is loud, and the circuit is cumbersome which makes the interaction between infant and parent difficult.

With the advent of VG in HFO mode, this can be greatly mitigated. Typically no circuit change is required if switching to HFO mode with these machines, and since VG adjusts actual volume delivered independent of frequency, we can now decrease frequencies to allow for the longer expiratory times demanded by small patients. Because  $CO_2$  clearance is primarily a function of tidal volume ( $DCO_2 = f \cdot V_{Thf}^2$ ), a decrease in frequency and increased VT will compensate and maintain minute volume without increasing amplitude a great deal. Lower amplitude combined with the lowest possible tidal volumes theoretically should be more lung

protective.

As well, newer machines offer adjustable I:E ratios. The VN 500 will allow 1:3 I:E, and the Leoni plus, also (Lowenstein Medical) 1:3. While increasing I:E ratio does result in increased amplitude, it also mitigates air trapping; and if the resulting dynamics are more efficient, this may allow for decreased overall ventilation settings.

The other problem with higher frequencies is the nature of gas flow itself. As frequency increases, amplitude must increase to maintain volume. This eventually results in turbulent low, ventilatory inefficiency and may contribute to airway instability as amplitude approaches MAP.

The unit I practice in has been using HFO for over 20 years, first with the Babylog 8000 plus, and over the last ten years, via the Dräger VN 500 and Leoni plus. VG is used almost always in HFO mode, and we typically do not ventilate micro-preemies conventionally at all. While not hard evidence, it is our belief that this practice contributes significantly to our very low CLD rates, overall about 8% and 50% in the  $\leq 24$ -week group.

From a physiological perspective, HFO should afford these vulnerable infants more lung protection since volume ventilation is difficult when there is very limited physiologically functioning volume within their lungs. In addition, the volumes required may be impossible to deliver without air trapping due to time constants

***“When used with an understanding of both physiology and the physics of gas flow, HFO/VG as a modality offers clinicians a first line mode for lung protection provided of course that proper MAP is achieved for optimal compliance.”***

and fragile, floppy airways that are prone to rupture at the pressures often required to volume ventilate these infants.

When used with an understanding of both physiology and the physics of gas flow, HFO/VG as a modality offers clinicians a first line mode for lung protection provided of course that proper MAP is achieved for optimal compliance. This is something the HIFI trial of the early '80s should have taught us, but a lesson that seems to be lost to many clinicians.

We also ventilate extensively with the Bunnell Life Pulse Jet ventilator. The point at which this machine is used is a topic for another discussion.



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2. August 29, 2002 *N Engl J Med* 2002; 347:643-652 DOI: 10.1056/NEJMoa012750

Note: Proprietary software and devices are mentioned. This is not an endorsement of the device(s) but rather a commentary on a mode available.

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**NT**

Rob Graham, R.R.T./N.R.C.P.  
Advanced Practice Neonatal RRT  
Sunnybrook Health Science Centre  
43 Wellesley St. East  
Toronto, ON  
Canada M4Y 1H1  
416-967-8500  
Rob Graham <[rcgnrcp57@yahoo.ca](mailto:rcgnrcp57@yahoo.ca)>

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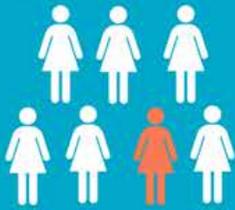
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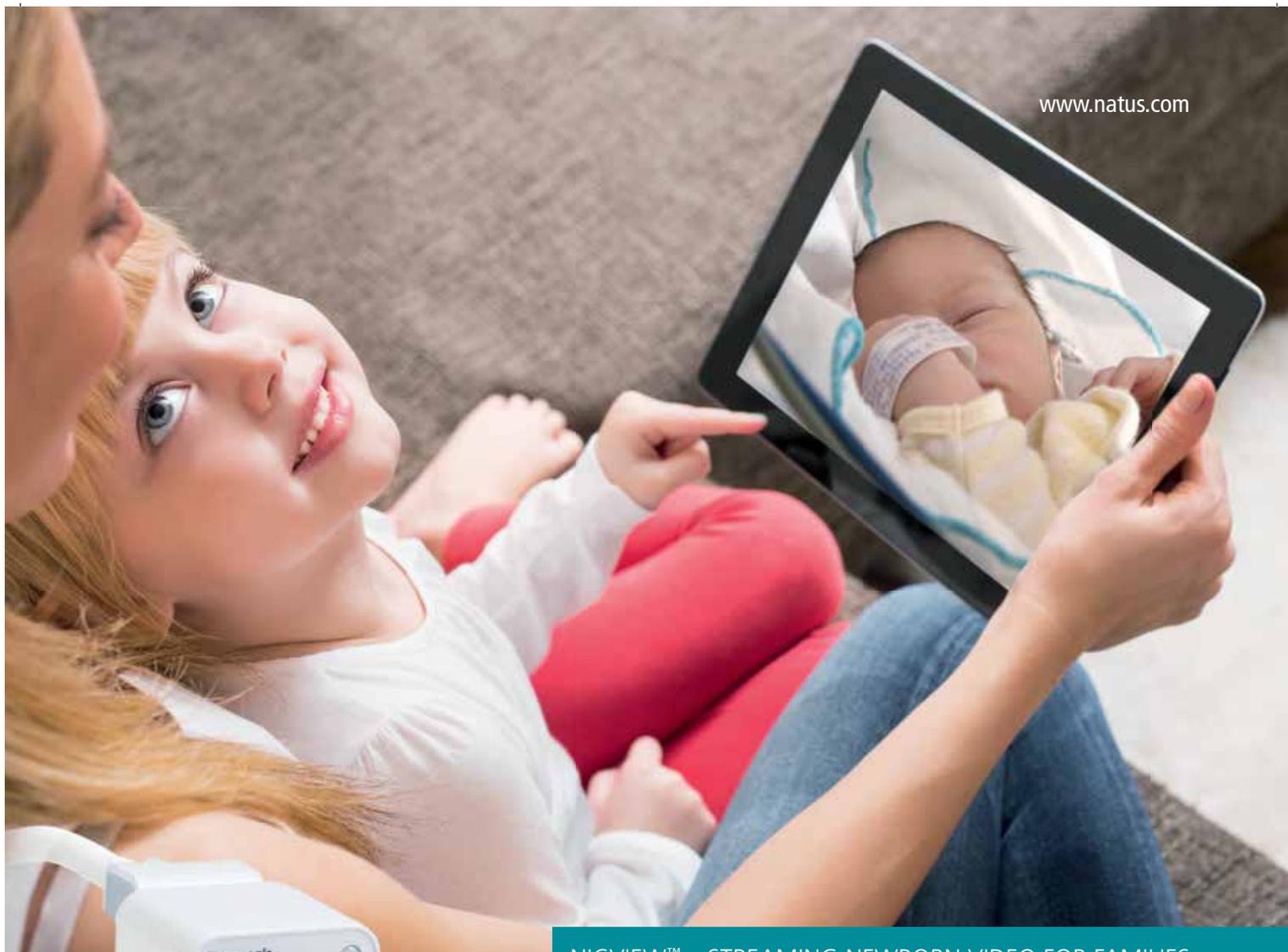
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# Truth Be Told

Terry S. Johnson, APN, NNP-BC, ASPPS, CLEC, MN

I often hear people use the phrase “truth be told” (TBT) when stating important truths that otherwise might not be known. That’s the perfect way to describe this topic – it’s full of TBTs about delivering the highest quality of care for preterm infants.

Health care professionals across the US acknowledge November as Prematurity Awareness Month. The Centers for Disease Control and Prevention (CDC) report that the incidence of preterm birth in the US has increased for the second straight year since 2016, affecting approximately 1 of every 10 infants born in the US.<sup>1</sup>

And TBT...there has been a veritable increase in clinical evidence and research supporting the use of human milk and the exclusive human milk diet (EHMD) for premature, low-birth-weight, and critically ill newborns. While the use of human milk feeding for the neonatal intensive care unit (NICU) population has increased, there has been significant variance in practice recommendations, clinical safety of milk, and procedural guidelines across the US.

It has been my privilege over the past two years to play a small role in supporting the efforts of the Academy of Nutrition and Dietetics (AND) to review and revise guidelines regarding clinical use of human milk. I am pleased to announce the recent release of *Infant and Pediatric Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities*, third edition, published by Academy of Nutrition and Dietetics (AND). (2)

The editors – Caroline Steele, MS, RD, CSP, IBCLC, FAND, Director of Clinical Nutrition and Lactation Services at Children’s Hospital of Orange County, California; and Emily A. Collins, MHA, RD, CNSC, Nutrition Services Manager, Michigan Medicine, University of Michigan, Ann Arbor, Michigan – have done an exceptional job of bringing clinical experts together to review the literature and describe standards of best practice in the use of human milk and human milk products in the health care setting.

The revised text has been significantly expanded in size and scope and includes some of the following areas of clinical practice in the use of human milk:

- Physical Facilities
- Equipment and Supplies
- Staffing and Workflow
- Expressed Human Milk Preparation and Handling
- Lactoengineering
- Donor Human Milk, Human Milk Products, and Milk Sharing
- Delivery and Bedside Management of Feedings

- Microbiology and Infection Prevention
- Quality Assurance, Monitoring, and Emergency Preparedness

As a former national patient safety fellow with the Health Research and Educational Trust of the American Hospital Association and the National Patient Safety Fellowship, I am interested in patient safety and quality improvement strategies around the preparation and utilization of human milk. Another area of interest has been the increase in informal milk-sharing practices by families in the NICU setting. These practices include such things as milk sharing between family members and purchasing unscreened milk from unidentified donors on unregulated websites.

***“In particular, the Hazard Analysis Critical Control Point (HACCP) system is a multi-step, proactive, science-based approach that can be applied to human milk feeding processes via the plan-do-check-act process.”***

I found the chapter describing the quality assurance continuum to be of value and interest in light of complex, overlapping recommendations. The Joint Commission has determined that quality indicators should focus on problem-prone, high-risk, high-volume areas, or some combination of those three. Chapter 13 reviews methods of data collection for risk analysis and ongoing system evaluation. In particular, the Hazard Analysis Critical Control Point (HACCP) system is a multi-step, proactive, science-based approach that can be applied to human milk feeding processes via the plan-do-check-act process. The HACCP plan should include measurable indicators to monitor the most important aspects of human milk preparation, storage, delivery, and bedside administration. This analysis strategy can be integrated into any facility’s existing performance improvement strategy, and it can drive evaluation of safety, efficiency, and cost-effectiveness while guiding ongoing clinical practice.

***“This analysis strategy can be integrated into any facility’s existing performance improvement strategy, and it can drive evaluation of safety, efficiency, and cost-effectiveness while guiding ongoing clinical practice.”***





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TBT...there are tremendous short and long-term benefits for the infant who receives a human milk diet, especially for preterm and low-birth-weight infants. Benefits supported by strong evidence include prevention of sepsis, necrotizing enterocolitis, decreased days of total parenteral nutrition, decreased days of interrupted feedings, and reduction in retinopathy of prematurity.

Please read on to hear from the members of the Nursing Practice Advisory Council (NPAC). NPAC is an advisory group of neonatal nursing leaders and clinicians who are passionate about human milk science and nutrition. They endorse the practice of using mother's own milk, donor milk, and human milk-based nutrition. Their mission is to impact clinical practice, education, and outcomes in the NICU population by sharing clinical expertise and emerging research in the use of an EHMD. If you have questions about implementing or supporting the clinical use of an EHMD, please email our team at [NPAC@prolacta.com](mailto:NPAC@prolacta.com).

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Disclosure: Terry Johnson is an employee of Prolacta Bioscience, Inc.

**NT**

Corresponding Author



Terry S. Johnson, APN, NNP-BC, ASPPS, CLEC, MN  
Editor, Latch  
Director, Education and Professional Development  
[NPAC@prolacta.com](mailto:NPAC@prolacta.com)

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# The Neonatal Intensive Care Unit (NICU): Self-Efficacy of Caregiving and the Lived Experience of Parents Post-NICU Discharge

Jenene Woods Craig, Ph.D., MBA, OTR/L, CNT

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*.



## Abstract:

The purpose of this study was to identify individual (parent), environmental (NICU and home), and social factors that influence parent perceptions of self-efficacy around parent-infant co-occupations of caregiving following NICU discharge. Through a qualitative, phenomenological in-depth interview methodology, this study aimed to investigate parents' perceptions, after NICU discharge, of their lived experience with their infant within the NICU, and their resultant sense of self-efficacy in caring for their infant post NICU discharge. Seven major themes emerged from the analysis of the study data. The themes were individual: (a) balancing mixed emotions, (b) having spirituality, (c) spending time in the NICU; environmental: (d) having primary-care nursing, (e) practicing

caregiving (NICU and home); and social: (f) having organizational support, and (g) having interpersonal relationships. Implications for practice include the need for elevated NICU and community practices designed to foster parental self-efficacy beliefs. Research on the instructive and supportive practices that foster parent knowledge and skill attainment, along with the development of accompanying self-efficacy is suggested.

**KEYWORDS:** Neonatal Intensive Care Unit, Self-Efficacy, Caregiving, Developmentally Supportive Care, Co-occupation.

*“At the end of what is sometimes a long stay in the NICU, parents must assume responsibility for caregiving tasks that were, up until that time, handled by NICU staff.”*

## Introduction:

Parents of premature infants must develop and maintain a strong understanding of their infant's needs in order to be prepared for home caregiving. (1) At the end of what is sometimes a long stay in the NICU, parents must assume responsibility for caregiving tasks that were, up until that time, handled by NICU staff. Monitoring changes in their infant's health can sometimes override feelings of self-efficacy regarding more typical caregiving roles such as diapering, feeding, and so forth. (1,2)

The “most deeply inter-related social occupations are co-occupations,” for which two or more people must be involved in the process. (3) Caregiving activities involve not only the parents' participation but also the infants and are described as

co-occupations. (4) The term, co-occupation, was coined by occupational therapist and mother, Doris Pierce and is used to describe “the way in which two individuals' occupational patterns can require and be shaped by each other” (p. 3), including any task and activity that is valued within the family culture in which the parent and infant are expected to engage together. (4) The concept of co-occupation was further elaborated on by Pierce (5) by utilizing the term as part of a theoretical framework of occupations, (3) with co-occupations being the most highly interactive types of occupation.

## Background:

The intense environment of the NICU can cause both psychobiological trauma to the infant, as well as emotional stress to parents. (6,7) Research has shown that, during the first years of life, parent-infant relationships may have an impact on biological growth by altering physiological or hormonal responses, eight genetic activity, (9) and neuronal networking within the brain. (10)

Additionally, separation of parent from infant in the NICU, combined with frequent occurrences of parent depression, anxiety, and stress-related incidences, affects the psychosocial development of the preterm infant. (11) An increased awareness of the escalated risk factors for parent-infant detachment, and knowledge about preventative strategies that can be initiated in the hospital are important considerations for healthcare providers in the NICU. (12) This brings importance in understanding parents' perceptions regarding their experience in the NICU, their individual feelings of caregiving self-efficacy, and ways that parents might better be supported, both while their baby is in the NICU and when home.

## Purpose:

The purpose of this study was to explore parent perceptions regarding their self-



efficacy of infant caregiving post NICU discharge. Specifically gathered were, perceptions of satisfaction of NICU experience, their involvement while in the NICU, parent knowledge regarding caring for their baby both in the NICU and post-NICU, and parent perception of autonomy while parenting in the NICU. The study emerged from a noticeable lack of detail in the literature concerning what parents' experiences are once they leave the NICU, particularly regarding parent self-efficacy of infant caregiving. Such detail is needed if professionals who are involved in the care of premature infants, both within the NICU and outside the NICU, are to understand the needs that exist from a parent's perspective to support successful parent-infant dyads.

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***“In the high tech, biomedical and often harsh, life and death environment of the NICU, partnering with parents to facilitate parent-infant attachment is crucial.”***

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#### **Significance of the Study:**

In the high tech, biomedical and often harsh, life and death environment of the NICU, partnering with parents to facilitate parent-infant attachment is crucial. Family-Centered Developmental Care (FCDC) provides the strong supportive foundation families in the NICU need to optimize the lifelong relationship between themselves and their babies, as well as to optimize the baby's physical, cognitive, and psychosocial development. (13,14) Embracing families as decision-making partners and collaborators in their baby's care has long been recognized as an optimal way of caring for babies in the NICU. (14) This is done through identification of individual infant/family vulnerabilities and strengths (7) and then finding ways to address these characteristics in the antepartum period, continuing through NICU admission, and on to NICU discharge and the transition home. (13)

Despite technological advances, there is the potential for psycho-emotional consequences of parent-infant development while their premature baby is in the NICU. (6,7) The long-term consequences of parental stress experienced in the NICU, psychobiological trauma in the child, and decreased parent self-efficacy may influence outcomes of infants and families treated in this environment. Parent perspectives may provide useful information for professionals working in NICUs, as well as post-NICU settings (e.g., NICU follow-up clinics, pediatricians, etc.). This can hopefully lead to more sensitivity and to the development of policies and procedures in the NICU that will make it more conducive for parents to be more connected to their baby(s) and more involved in the caregiving process.

#### **Theoretical Perspective:**

Within the framework of social cognitive theory lies the self-belief system or the perceived capability of one's personal functioning; self-efficacy; the foundation of human agency. (15) Self-efficacy beliefs regulate human functioning through cognitive, motivational, affective, and decisional processes that impact how one manages his or her own functioning and how one exercises control over events that affect his/her life. According to social cognitive theory, the environment maintains a strong influence on behavior, but also that individual cognitions are the primary factors in determining people's ability to construct their own realities and control how they respond. (15,16) Additionally, interactions among personal factors (e.g., cognition, affect), behaviors (e.g., parenting skills), and environmental influences (e.g., the NICU and home), shape human functioning. A paucity of research has included the explicit understanding of parent self-efficacy immediately post-NICU.

Parenting self-efficacy is the belief in one's ability to competently and effectively perform the cognitive, social, and motor behaviors related to being a parent. (17) For parents, self-efficacy potentially influences emotional, motivational, cognitive, and behavioral response to the caregiving role. (18) An essential component of making forward progress in the care and support of the parent/infant dyad that experiences the environment of the NICU is supporting parent perceptions of self-efficacy.

It is important to recognize that parents in similar situations (e.g., demographics and family similarities) can experience the NICU in different ways. Some parents, even within the same family unit, may rebound from the traumatic experience, and others may remain chronically debilitated, speaking to consideration of human resilience. How one responds, then, is a product not just of the event (NICU) alone, but rather an interplay between the environmental stressors and psychosocial factors. (19) As such, social cognitive theory adopts an agentic model of adaptation and change whereby individuals play a proactive role in influencing their functioning and the life circumstance they are traversing. With this in mind, pause was given to consider not just how the environment of the NICU can be changed to protect parents, but also to consider in what ways to support a parent's personal agentic perspective and enablement. Enabling a parent with personal resources to cultivate his or her competencies might very well im-



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pact the shaping of the post-NICU socio-emotional resiliencies of parents.

## Methods:

### Design:

For this interpretive phenomenological study, informed by Heidegger's interpretive philosophy, parents of premature infants were interviewed within the first two weeks of the infants' hospital discharge from the NICU. The fundamental objective of this qualitative research was to gain insight into and understand the meaning of this particular experience (20) and the context that influences the meaning. (21)

### Role of the Researcher:

The impetus for this study grew out of this researcher's past and present experience as an occupational therapist in several Level III NICUs around the country and additional NICU professional work. Sensitivities and background as a parent, an occupational therapist, faculty member, and NICU professional influenced the development of this research. A comprehensive understanding of caregiving tasks and ideas regarding levels of difficulty or challenge for parents was held. However, all interview discussions were approached seeking parent ideas of caregiving tasks so as not to limit discussions according to this researcher's perspective. Although other caregiving tasks remain to be explored, discussions will be limited only to the caregiving tasks discussed by participants. Those were sleep, bathing, feeding, diapering, and medical needs.

### Participants:

Parents were the primary unit of analysis. Creswell recommended "long interviews with up to 10 people" for a phenomenological study. (22) Twelve parent participants were recruited, with a final ten participating. In total, four NICUs were utilized for participant recruitment. Two parents were referred by the neonatal therapist at NICU A. Six parents were referred by the lead neonatologist over NICU B and NICU C. Two parents were referred by a NICU nurse in NICU D. Two parents were unable to participate secondary to unexpected medical complications with their infant requiring extended and undetermined length of continued stay in the NICU (NICU C). All participants (4 male and 6 female) were selected based on the following criteria: (a) parents of premature infants, (b) infants born no less than 23 and no more than 28 weeks gestation, (c) minimum 4 week stay in the NICU, and (d) discharged from the NICU 1-2 weeks prior to interview.

In an iterative process with qualitative research, eligible participants were purposefully sampled to obtain broad representation according to demographics. The ages of parents ranged from 18 to 40 years. Ethnicities of parents included five parents who were Black/African American; 4 who were White, non-Hispanic; and one who was a non-White, Hispanic parent. Education levels of parents ranged from high school to having completed a bachelor's degree. Four parents were married, one was divorced, one was not married and was a single parent, and four were not married but were co-parenting with a partner. Six participants lived in their own home, and four lived with their own parent or another older adult parent figure.

### Data Collection and Analysis:

Data were collected through semi-structured, in-depth interviews lasting between 1 and 2 hours. Interviews contained a series of

questions to ask participants and were conducted in participants' homes. These questions were used to probe for further information, deeper meanings, and to use additional questions, if necessary. (20) At the beginning of each interview, parents were provided with an overview of the study, including the purpose, benefits, and potential risks (e.g., discussing emotional subjects). Informed consent and demographics forms were also reviewed and completed. Permission was received for interviews to be audiotaped and for fieldnotes to be taken. For homes where there were two participants (e.g., mother and father of infant), interviews were held one at a time and scheduled on the same day, one interview after the other, to avoid one parent informing the other about interview questions.

Analysis of the data occurred through the constant comparative method of data analysis. (23) Verbatim transcriptions were completed by this researcher, except for participant 10 who spoke only Spanish. This researcher's graduate student, who is Hispanic, transcribed that interview which was reviewed afterward. The graduate student, who was experienced in conducting qualitative interviews, participated in a pilot participant interview in order to build context to the process. In addition to initial hand coding, final coding and qualitative analysis NVivo qualitative data analysis software was used. (24)

### Results:

Thematic coding analysis revealed seven overarching themes that parents identified as influencing their perceived self-efficacy of caregiving: individual: (a) balancing mixed emotions, (b) having spirituality, (c) spending time in the NICU; environmental: (d) having primary-care nursing, (e) practicing caregiving; and social: (f) having organizational support, and (g) having interpersonal relationships. Table 1 reflects themes that emerged from the data (Table).

### Individual factors:

Balancing mixed emotions. All parents recalled that during the initial two weeks at home, there were fluctuating emotional states that they believed were related to having had a premature infant in the NICU. These were discussed in relation to parents' confidence and belief in their capability around caring for their baby. While each parent presented unique vulnerabilities or resiliencies, all parents expressed emotions that they believed were the aftermath of having a NICU experience. Words used to describe these shifting emotions included fear, confusion, anxiety, trauma, overwhelming, at a loss, vulnerable, sad, happy, thankful, frightened, scared, nervous, elated, emotional, hopeful, love, a failure, and powerless.

When retelling their stories about when their baby was in the NICU, the expression of fluctuating emotions was alive in their descrip-

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Table 1. Overview Of Research Findings

Research	Findings
Individual factors influencing parent perceptions of self-efficacy around the co-occupation of infant caregiving?	<ul style="list-style-type: none"> <li>● Balancing mixed emotions</li> <li>● Having spirituality</li> <li>● Spending time in the NICU               <ul style="list-style-type: none"> <li>○ For self                   <ul style="list-style-type: none"> <li>▪ Learn roles</li> <li>▪ Learn routines</li> <li>▪ Parent peace-of-mind</li> </ul> </li> <li>○ For baby's needs                   <ul style="list-style-type: none"> <li>● Baby well-being</li> <li>● Baby knowledge of parent</li> <li>● Nurse accountability</li> </ul> </li> </ul> </li> </ul>
Environmental factors influence parent perceptions of self-efficacy around the co-occupation of infant caregiving?	<ul style="list-style-type: none"> <li>● NICU               <ul style="list-style-type: none"> <li>○ Primary Care Nursing</li> <li>○ Practicing Caregiving</li> </ul> </li> <li>● Home Practicing Caregiving</li> </ul>
Social factors influence parent perceptions of self-efficacy around the co-occupation of infant caregiving?	<ul style="list-style-type: none"> <li>● Having Organizational Support               <ul style="list-style-type: none"> <li>○ NICU</li> </ul> </li> <li>● Having Interpersonal Relationships               <ul style="list-style-type: none"> <li>○ Staff</li> <li>○ Support Groups/other parents</li> <li>○ Family/friends</li> </ul> </li> </ul>

Table 1: Overview of Research Findings

tions. LaTonya said she was “happy to finally have a daughter, but fearful she would not make it [survive].” Jasmine said, “I was up one minute and down the next. It was so hard to know whether to be happy or sad.” “It’s the craziest roller-coaster ride I have ever been on!” cried Sally when I met with her. Sally is the mother of Samuel, who was born at 26 weeks. “It felt great to have him in my arms, but I was afraid of hurting him,” she continued. Similarly, her husband, Thomas, talked about his shifting emotions: “I was just emotional, and I don’t get emotional usually. I was so happy to have my son, yet so worried for my wife and worried about Samuel’s survival”. The initial shock and experience of an early delivery and NICU experience was largely believed by parents to have contributed to their continued emotional vacillation once home.

In discussions regarding emotions, all parents reflected a common perception that their experience of having a baby in the NICU consumed them with fear and worry. Many of those emotions still continued at home. While each parent shared moments of having comfort and peace of mind in the NICU and at home, there existed

a constant undercurrent of both fear and worry about their baby. Louise excitedly shared, “I simply could not wait to bring my baby home! (pause) It’s a whole n’other thing when you do though (on the verge of tears). I had to do things that I hadn’t even really thought of. You know, you think about your baby coming home and then reality is different.”

Having spirituality. A second theme that emerged from parents was that of spirituality. Parents spoke about the individual ways they journeyed the NICU experience, often referred to by parents as “surviving” (Lawrence, Patricia, LaTonya). Charles’ perspective, while intended to reflect his ideas regarding the differences between dads and moms, captured the essence of what other parents shared regarding spirituality:

As a man, we want to fix everything . . . to be the strong point in our families, and we have to put that face on, no matter how hard it is. Some days was harder than others. You know, when you see Lilly turning purple and not breathing, and you know going up and down fighting the fight that she was having, it will break any

person down. . . . I didn't really have that, uh, person or place to go to recharge, you know. My family was going through the same pain. . . . To fill me with strength, I used my spirituality more than anything else.

Spending time in the NICU. All parents emphasized the importance of being with their baby in the NICU as a means to support their confidence. Categories related to supporting themselves included learning roles and routines in the NICU and spending time in the NICU to develop peace-of-mind regarding their baby's well-being. Categories that related to supporting their infant included the parent gaining knowledge of the baby, belief that their baby would know the parent better, and the belief that the parent being present would have an impact on the nurse's accountability to give quality care to their infant. Often, parents commented that being there for their baby brought a sense of parenting and knowledge. However, the parenting role in the NICU involved sharing responsibility with the NICU staff, and in identifying ways that set the parent apart as "the real" parent, as expressed by LaTonya.

There were unexpected parent roles that developed, such as becoming the advocate for their baby. Being able to make decisions for their baby while in the NICU brought a sense of primary parenting. In addition to the benefit of parents finding a voice as their infant's advocate, there were also factors of infant well-being that contributed to parenting confidence in caregiving. One such example was in doing Kangaroo Care. While each parent expressed different comfort levels in being in the NICU environment, they all expressed the opinion that being present with their baby while they were hospitalized helped build confidence that they would ultimately need once their baby went home.

#### **Environmental Factors:**

The primary themes that surfaced regarding factors of environment were: (a) NICU–primary care nursing and practicing caregiving, and (b) home–practicing caregiving.

Having Primary Care Nursing. While in the NICU, parents believed that their infant having a primary care nurse strongly contributed to the parents' efficacy. The idea of having primary nurses was a recurrent theme with parents, also allowing parents to feel more confident about who was taking care of their baby when they were not there. Having primary nurses allowed the parent to establish a shared understanding regarding types of information the parent needed, the timing of that information, a shared knowing of their baby, and a general level of confidence that the parent would stay informed. Sally and Thomas both mentioned that having primary nursing was key to their feeling more comfortable with Samuel as they believed the nurse knew both the parent and infant better. However, there was one point in their NICU stay where primary nursing was not offered. Sally began to cry while reflecting and said, "It's so, so hard to leave your baby with someone that you don't know how they're going to be with him [Samuel]." This was a common theme amongst parents around primary care nursing. Practicing caregiving. Discussions regarding home caregiving were related to the amount of time they spent with their baby in the NICU and the amount of time they had practicing various caregiving activities. The more they did while in the NICU, the better they felt about being at home. Parents all described either the need to have practiced certain caregiving activities more or that having practiced activities had contributed to their confidence.

Relative to practicing caregiving, parent reflections emerged around normalcy following the NICU. Normalcy was perceived by participants in comparing themselves with how actions and activities were completed by parents who did not have infants from the

NICU. Feeling like a more "typical parent" (Sally) was believed to come with the frequency with which they completed caregiving with their baby at home. However, while parents believed that increased practice would increase self-efficacy, several parents expressed that this might take extended time. Louise shared, "I can't do anything I used to do with Dillon [12-year-old son]. With Lilly, I am constantly sterilizing this and sterilizing that. It just doesn't quite feel normal yet."

A common theme was reported around sleep. All 10 parents reported fears related to allowing themselves to sleep when their baby was asleep at night. The primary fear was that the baby might stop breathing. The second most predominant concern was regarding feeding. Eight of the 10 parents expressed concern that they were not feeding their infant in the correct manner, or that they were not meeting a feeding schedule such as that experienced in the NICU.

Although finding normalcy was expressed through emotions of sadness and wanting, there were also joyous emotions regarding being home and doing some "normal parent thing" (Thomas). Charles captured this best when he suddenly asked, "Have you seen Lilly's room? I had so much fun putting her room together! For the longest time, I didn't do anything in there [her room]. We didn't know from one minute to the next sometimes if she would be coming home, but when we got word that she was close to discharge, I went to town on that room. It made me feel so good to see it done (pause). It still does."

#### **Social Factors:**

Social factor themes emerged around having organizational support and having interpersonal relationships.

Having organizational support. Relative to social support, parents frequently talked about the manner in which the NICU was organized. Parents spoke primarily regarding space needs, as well as policies regarding visitation. Most supportive were those NICU's who allowed parents to come and go at any time. Six of the parents expressed sadness with being "kicked out of the NICU" (Jasmine) and desired to know what was going on during those times. Parents also spoke about the discharge process in terms of so-



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cial support. Most parents believed that educational material they received was “enough”. However, parents were not prepared for what they encountered when getting home. Charles shared, “All I wanted to do was bring Lilly home! They kept making us stay day after day to room in. By that point in our stay, we knew what to do, so I didn’t understand why we couldn’t be discharged.” He continued, “But there’s something missing or something wrong. When we got home, it’s like we hit a brick wall. I know we got good information and educational stuff at discharge, but why was it that we were so anxious when we got home? . . . It’s like we never heard anything!”

Having interpersonal relationships. Four sources of interpersonal relationships were identified as themes; (a) relationships with staff, (b) support groups/other parents, (c) spouse/partner, and (d) family/friends.

Relationship with staff. All parents explicitly listed communication as a source of both increased and decreased confidence. Parents strongly held that their baby’s health and well-being depended on relationships with NICU staff. Some parents felt strong enough to have tough conversations with staff, like Charles and Louise. Other parents were explicit about not wanting to upset anyone, and so they chose to stay silent.

Charles’ example reflects collective parent perceptions regarding their communication relationships with/about staff:

You know, we were very fortunate with Dr. Tom. He would pull a chair in with us, and we could talk about anything and everything. And that level of communication just gave such a level of comfort to my wife and me that we were okay during the day [when we were not there]. You know, I was okay going to work knowing what the plan was. The last thing you want is to leave at one point and she’s [baby] on CPAP, and come back and she’s on a ventilator and you never even got a phone call or never nothing. You’re like, what just happened here, you know? But I’ll be honest, a lot of that is changed by the nurses that we have for good and bad. If we had a good nurse and somebody that would take their time and you knew we’d get her [baby] situated just right, everything was fine. But then there’s also this time when we had a nurse that was like, “Okay, we’re going to kangaroo,” slap her on you, and didn’t really have a concern for where the tubes were. Were they pulling on her? Were they pulling on her nose where she had the CPAP, . . . those type of things.. (Charles)

Support groups/other parents. All parents recommended support groups or opportunities for parents to meet other parents, however, only one NICU offered such. When asked what they would share with new parents to the NICU, Louise shared, “Know that it’s going to be where you will have good days and bad days. And the bad days, are always, always, bad. I know the bad days for me were terrible. It’s going to be great, great, and then it plummets.”

Spouse/partner. In the study, there were two married couples, one couple who lived separately with their respective parents, one couple who lived together occasionally but were mostly residing with their parents, one mother who was divorced, and one mother whose baby’s father was not involved. All but Patricia and LaTonya, the single mothers, spoke of their own efficacy as an extension of their confidence in their mate.

Family/friends. Parents’ ideas of support from family and friends were related to both the NICU environment and the home environment. Parents generally felt that support came more into play when the baby was at home. Family and friends could often not understand or appreciate the emotions that parents were going through while their baby was in the hospital.

### Conclusion:

Trauma-informed care recognizes that all NICU families are traumatized by the birth of a baby who requires admission to a NICU, and often by the NICU experience itself. (7) A substantial body of research verifies that perceived self-efficacy is a common mechanism through which mastery experiences, vicarious experiences, and social resources improve psychosocial functioning. (15 ) In consideration for literature that reflects how early experiences impact future relationships, (25,26,27) information related to how parents experienced the environment of the NICU in relation to having their baby home from the hospital was deemed important. As an occupational therapist and neonatal therapist, particular attention was given to discovering individual, environmental, and social factors that served as facilitators or barriers to self-efficacy in the co-occupation of caregiving between parent and infant. Throughout the interviews, parents revealed much about these factors that were particular to their situations and in relation to caregiving tasks important to them. Of the 10 parents interviewed, all spoke of the fear they felt when bringing their infant home. While they believed that they had been educated regarding caregiving, they described the difficulty in caring for their baby immediately post-NICU discharge.

Bandura’s summary regarding the importance of self-efficacy brings relevance to understanding the needs of NICU parents, particularly when they are home from the NICU and caring for their infants on their own:

People make causal contributions to their own psychosocial functioning through mechanisms of personal agency. Among the mechanisms of agency, none is more central or pervasive than beliefs of personal efficacy. Unless people believe they can produce desired effects by their actions, they have little incentive to act. Efficacy belief, therefore, is a major basis of action. People guide their lives by their beliefs of personal efficacy. (15)

Consistent with literature in the area of self-efficacy, (28) no clear formula emerged from this study that explicates how individual, environmental, and social factors combine to influence a parents’ increased self-efficacy. It is clear, however, that factors from all three have bearing on the parent’s perceptions in differing ways.



For example, while one parent expressed appreciation for the education he or she received from staff in the NICU, another parent described the education as less informative and how his or her own personality and other social factors came into play in his or her confidence levels. Results from this study inform professionals both within the NICU and in the community about possible ways that individual, environmental, and social factors might influence parents' perceptions of self-efficacy.

The importance of continuity of care for the neonatal intensive care unit (NICU) baby after discharge has long been recognized by hospitals and community health care providers. Although survival of premature infants in the NICU has strongly been the focus of NICU personnel, there is growing emphasis in understanding outcomes to both infants and parents post NICU discharge. (29) NICU parents are at higher risk for postpartum depression (PPD) and posttraumatic stress disorder (PTSD) during the NICU stay and afterwards, even if their baby was in the NICU only briefly. (30) Psychological distress in NICU parents is associated with a deteriorating cycle of disruptions in the parent-infant relationship, subsequent impairments in child development (cognitive, emotional, physical, and behavioral), and reciprocal negative effects on parental emotional and physical health. (31) A proactive approach to interrupting that cycle must be taken by supporting parents in the NICU and in the home environment afterward. A concerted effort in understanding the continuum of parent-infant needs, both within the NICU and post-discharge, is needed in effort to support healthy parent-infant relationships. An important predictor of how the infant grows and develops after being in the NICU is the quality of the infant's psychosocial environment, and in particular, the context of the parent-infant relationship.

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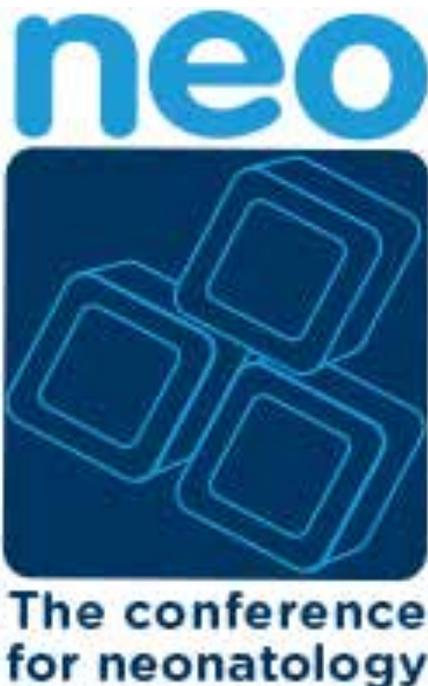
I would like to thank the families that allowed me into their world to complete this study! You have amazing journeys, and I wish you all the best!

**NT**

**Corresponding Author**



Jenene Woods Craig, Ph.D., MBA, OTR/L, CNT  
 Director of Education for National Association of Neonatal Therapists (NANT)  
 770-595-7728  
[jcraig@brenau.edu](mailto:jcraig@brenau.edu)



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# A Statistical Nightmare: The Denominator Reigns Supreme.

Mitchell Goldstein, MD

I remember learning about the denominator in elementary school. It was that divisive dividend that spoiled a perfectly good whole number and fractionated what had been previously a perfectly logical field of mathematics. I recovered quickly from my disappointment and came to respect the power of these numbers. In Neonatology, the denominator reigns supreme. How does this number that sits below the numerator become so powerful?

Let's start with something easy. We have two delivery services at

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*“In Neonatology, the denominator reigns supreme. How does this number that sits below the numerator become so powerful?”*

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two hospitals. One delivery service has a cesarean section rate of 20% one month; the other, 40%. Immediately, it is apparent that one hospital has a rate that is twice that of the other hospital. This rate is much higher than guidance on the appropriate cesarean section utilization rate. What could account for the difference between the two hospitals? Before we go down the road of looking at prematurity rate, the proportion of high-risk referrals, and utilization of perinatology consultation, we need to know the denominator. In this case, both hospitals only delivery five patients per month. The difference between the two hospitals is only one cesarean section per month (i.e., one versus two).

Most situations are more challenging. Suppose we take two fictitious Neonatal Intensive Care Units. Both are level 3b or greater NICU's. Both have a delivery service of 500 births per month, similar demographics, and a commitment to a quality process. In this vignette, each of NICU's admits 100 babies each month. In the first unit, 90% of the babies who are started on antibiotics receive 48 hours of therapy; 10% receive a full seven days. In the second unit, 10% of the babies who are started on antibiotics receive 48 hours of therapy; 90% receive a full seven days. In the first unit, the average duration of antibiotic use following admission is only 2.5 days; in the second unit, the average duration is 6.5 days. None of the babies in either unit have a positive blood culture. Which unit practices better antibiotic stewardship? Most will immediately choose the first unit. The numbers are just too compelling, but there is more information that one needs to know before answering the question.

What is the denominator? At first blush, it appears that the number is 500, but this is not the number of patients that are admitted to each NICU. 500 is the number of babies delivered each month at each hospital. The admissions to the NICU are 100 per

month. Is this the elusive denominator? No, we are not interested in the number of babies who were admitted to the NICU. Where is the denominator hiding? The denominator is the number of babies who are started on antibiotics when they are admitted to the NICU. In the first NICU, all 100 babies who are admitted to the NICU receive antibiotics. In the second NICU, of the 100 admitted, only 10 receive antibiotics.

What does this data mean in real terms? In the first NICU, ten babies receive a seven-day course of antibiotics, and 90 receive a 48-hour course. In the second NICU, nine babies receive a seven-day course, and one baby receives a 48-hour course. Since there are no positive cultures in any of the patients, it would be hard to argue that the second group is missing sepsis. Even though they treat 90% of their babies receiving antibiotics for a complete course of seven days, they treat fewer patients with a complete course of antibiotics. Most quality metrics would rank the second unit dead last in antibiotic stewardship. However, if one looks at antibiotic usage alone, the first unit uses 507 doses of antibiotics per month versus 57 for the second unit. This difference of 450 doses per month means 15 doses per day. The amount of additional nursing and pharmacy time required to fill these doses is staggering, not to mention the cost. By failing to recognize the denominator, it is easy to come to the wrong conclusion.

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*“The amount of additional nursing and pharmacy time required to fill these doses is staggering, not to mention the cost. By failing to recognize the denominator, it is easy to come to the wrong conclusion.”*

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Moreover, we are not considering the babies that never make it to the NICU. If the second unit evaluated 20 or 30 patients in the well-baby area who were never admitted to the NICU, they would not “receive credit” for avoiding antibiotic use. To improve their “statistics”, the second NICU would need to start treating all of their babies with antibiotics on admission to the NICU. Perhaps admitting those babies who would never have otherwise been admitted for 48 hours of antibiotics will make the second unit competitive with the first unit. Using this “logical” approach, the second unit would look better on the quality care matrix. This quality measure may lead to good statistics, but it is bad medicine.

*Disclosure: We have no financial disclosures or competing interest*

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*Mitchell Goldstein, MD  
Professor of Pediatrics  
Loma Linda University School of Medicine  
Division of Neonatology  
Department of Pediatrics  
mgoldstein@llu.edu*

# “Newly-Passed Law Addresses Healthy Pregnancies, Healthy Babies”

Darby O'Donnell, JD

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



Before Congress adjourned for the end of the year and the close of their 115th session, significant legislation to address maternal health care gaps was passed and signed into law by President Donald Trump.

The Improving Access to Maternity Care Act (H.R. 315/ S. 783) was authored by U.S. House Energy and Commerce Health Subcommittee Chairman Michael Burgess (R-Texas), an OB/GYN for nearly three decades in North Texas.

Safety and quality of healthcare for expectant women were the policy focus of this legislation. In addition, delivering adequate health care to women regardless of zip code was a key consideration in the bill's development.

According to talking points in support of the legislation released from Senator Tammy Baldwin's (D-WI) office:

- Every year, 1 million babies are born to mothers who did not receive adequate prenatal care.
- Babies born to mothers who received no prenatal care are three times more likely to be low birth weight and five times more likely to die than babies whose mothers received prenatal care.

The Improving Access to Maternity Care Act directs the Health Resources and Services Administration (HRSA) to identify areas where there are maternity care shortage areas, so that maternity

health care professionals may be assigned to those target areas. HRSA is also required by the act to collect and publish data on the need for maternity health care within the designated shortage areas.

For purposes of the bill “maternity care health services” includes those during labor care, birthing, prenatal care, and postpartum care.

The bipartisan legislation was endorsed by the American Congress of Obstetricians and Gynecologists (ACOG), the American College of Nurse-Midwives (ACNM), the March of Dimes, and the National Rural Health Association (NRHA).

The National Rural Health Association described the need for this legislation within the context of a growing rate of rural hospitals without any obstetrics care or lack of an obstetrics unit. The association posted, “Today, more than half of rural counties have no hospital-based obstetrics services, and the most vulnerable communities – those who are low-income, minority, remote – experience the most damaging impact. When the distance to maternity care is directly correlated with outcomes, this care shortage has a devastating effect on the health of both the mother and the infant.”

One Senate cosponsor of the bill, Senator Sherrod Brown (D-OH) described his reasons for support as such: “Healthy pregnancies lead to healthy babies, and no mother-to-be should go without the care she needs.”

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***“ With the passage of this legislation, proponents are hopeful the federal government may address workforce shortages in rural America and improve health outcomes for both mothers and children through better geographic distribution of maternity care resources.”***

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With the passage of this legislation, proponents are hopeful the federal government may address workforce shortages in rural America and improve health outcomes for both mothers and children through better geographic distribution of maternity care resources.

**NT**

*Corresponding Author*



*Darby O'Donnell, JD  
Alliance for Patient Access (AfPA)  
Government Affairs Team  
1275 Pennsylvania Ave. NW, Suite 1100A  
Washington, DC 20004-2417  
202-499-4114  
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# Medical News, Products & Information

Compiled and Reviewed by Mitchell Goldstein, MD Editor in Chief

## In Mice, Johns Hopkins Researchers Find the Cause of and Cure for Brain Injury Associated With Gut Condition in Premies

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

Article ID: 705363

Released: 13-Dec-2018 12:00 PM EST

Source Newsroom: Johns Hopkins Medicine

**Newswise** — Using a mouse model of necrotizing enterocolitis (NEC) — a potentially fatal condition that causes a premature infant's gut to suddenly die — researchers at Johns Hopkins say they have uncovered the molecular causes of the condition and its associated brain injury. The discovery enabled the team to combine efforts with colleagues studying brain inflammation and to identify potential drugs that reverse the brain injury in mice.

Details about the study and findings appear in this week's *Science Translational Medicine*.

"Up until recently, there was no clear understanding of what causes NEC, and the only approach in severe cases was to surgically remove the dead gut from the infant," says David Hackam, M.D., Ph.D., the Garrett Professor and Chief of Pediatric Surgery, a professor of surgery, pediatrics and cell biology at the Johns Hopkins University School of Medicine. "However, NEC survivors have ongoing problems, including significant cognitive impairment."

While the exact causes of NEC in newborns were unclear, the disease is known to occur in premature infants who are fed formula and suffer other stressors, such as bacterial infections. So the team developed a mouse model of NEC by separating newborn mice from their mothers and feeding them formula, subjecting them to a low oxygen chamber twice a day for four days as a stressor and making sure they had similar gut bacteria by feeding them stool from a child who had developed severe NEC. According to Hackam, not only did these mice develop NEC, their brains also showed the same injury as seen in humans and impaired brain function when older. At this point, they were ready to figure out what was causing NEC-associated brain injury in these mice.

First, they looked at whether the immune cells of the brain, so-called microglia, were activated in these NEC mice, which would signify some sort of inflammation. Indeed, the microglia were activated. Others had shown that a protein called TLR4, which binds to bacteria in the gut, is also able to activate microglia in the brain. So they genetically engineered mice to not contain TLR4 on the microglia and gave these mice NEC. The researchers found that these mice did not develop NEC-associated brain injury, suggesting that TLR4 is the cause of that injury.

The team then sought to understand what it is about this gut condition that leads to brain injury. Their previous research had revealed that TLR4 protein was also in the gut. According to Hackam, TLR4 is present in the developing fetal gut at high levels. Those levels drop in full-term infants after delivery. Infants born prematurely, however, maintain high levels of TLR4 in their gut. TLR4 in NEC guts cause cells to release another protein, HMGB1. The team engineered mice to lack HMGB1 and then gave them NEC. These mice showed less microglial activation in the brain than nonengineered mice with NEC, implying that, indeed, the HMGB1 generated by TLR4 in an inflamed gut is the cause of NEC-associated brain injury.

The work originated through a chance conversation. "One of the cool things about Johns Hopkins is that it's full of smart people studying all kinds of things. One of the first people I met when I came here in 2014 was Sujatha Kannan, who was studying brain injury in rabbits and had recently shown that an anti-inflammatory applied to the brain of rabbits could prevent cerebral palsy," says Hackam. So, Hackam and Kannan teamed up to see if this would work in NEC mice. They fed nanoparticles containing antioxidants and tagged with a fluorescent molecule to mice with NEC and examined mouse brains to see where the glowing molecules accumulated.

Sure enough, the brains glowed in the same brain regions where activated microglia are found. Additionally, these brains contained fewer activated microglia, suggesting that the nanoparticle drugs could protect the brain from NEC-associated brain injury.

"We really had to change our thinking from NEC being not only a gut condition to really being a gut-brain condition," says Hackam.

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



"While this condition manifests more immediately in the gut, neonatologists should also focus on a brain-protective strategy, which could include surgery sooner, gut rest and antibiotics.

"This is a devastating disease, but now that we more clearly understand the molecular underpinnings," says Hackam, "we are eager to see if it holds true in other models and in patients, so that we have a real chance at ultimately doing better for these babies and their parents."

In addition to Hackam, authors on this study include: Diego F. Niño, Qinjie Zhou, Yukihiro Yamaguchi, Laura Y. Martin, Sanxia Wang, William B. Fulton, Hongpeng Jia, Peng Lu, Thomas Prindle, Fan Zhang, Joshua Crawford, Zhipeng Hou, Susumu Mori, Liam L. Chen, Andrew Guajardo, Ali Fatemi, Mikhail Pletnikov, Rangaramanujam M. Kannan, Sujatha Kannan and Chhinder P. Sodhi, all of Johns Hopkins.

This work was funded by the National Institutes of Health R01GM078238 and R01DK083752. Sujatha Kannan and Rangaramanujam Kannan have filed a patent for the use of D-NAC in the treatment of neurological disorders, including NEC (PCT/US2015/045112), and Rangaramanujam Kannan and David Hackam have filed a patent C13800, "Nanoparticles for the diagnosis and treatment of neonatal necrotizing enterocolitis," which is exclusively licensed to Ashvattha Therapeutics, LLC.

COI: Under a license agreement between Ashvattha Therapeutics, LLC and the Johns Hopkins University, Dr. Kannan Rangaramanujam, Dr. Sujatha Kannan, Dr. David Hackam, and the University are entitled to royalty distributions related to technology described in the study discussed in this publication. Drs. Rangaramanujam and Kannan are founders of, and hold equity in, Ashvattha Therapeutics, LLC. Dr. Rangaramanujam also serves as the company's Chief Technology Offi-

cer, and Dr. Kannan serves as the Chief Medical Officer. This arrangement has been reviewed and approved by the Johns Hopkins University in accordance with its conflict of interest policies.

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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.

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

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

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

Mitchell Goldstein, MD, FAAP, Section Chairperson, [MGoldstein@llu.edu](mailto:MGoldstein@llu.edu) and

Christopher Rizzo, MD, FAAP, Membership Chairperson, [crizzo624@gmail.com](mailto:crizzo624@gmail.com)

Jackie Burke

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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](http://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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## Patented, Innovative Infant Incubator System for Potentially Faster, Less Expensive, Yet Healthier Care for Those Most Vulnerable

*The AmnioBed is a novel incubator system for neonatal intensive care units incorporating synthetic amniotic fluid in a self-regulating, sterile, submersion bath, providing an environment similar to what infants resided in before birth*

NEWPORT BEACH, Calif., Nov. 12, 2018 /PRNewswire/ -- The pressing need to address growing premature births in the world inspired Amnion Life, (<https://amnion.life/>), to develop the AmnioBed, an amniotic, neonatal incubator system that incorporates unparalleled technology to promote ongoing development immediately following birth. This patented, cost-efficient, incubation device features an amniotic fluid submersion bath that simulates the mother's womb, providing a potentially ideal environment to nurture infants at their most vulnerable stage of life.

Amnion Life Founder and CEO, Amir Fassih, M.D., is confident that the AmnioBed

will prove to be advantageous over radiant warmer beds and convection warmed incubators in offering improved thermoregulation, hydration, and skin protection, helping to reduce complications and save lives, while also reducing costs.

"The AmnioBed has the potential to reduce the length of stay (LOS) for infants and to improve the rate of weight gain and growth in the NICU, thus saving significant direct costs of short and long-term visits, in addition to providing infants with improved health and comfort," Fassih said.

Notable features of the AmnioBed include:

- **Sterile Synthetic Amniotic Fluid:** The synthetic amniotic fluid in AmnioBed is produced using purified water with the addition of electrolyte and minerals found naturally in Amniotic Fluid. The purified water is the same quality as used for dialysis. The AmnioBed purifies the water by taking it through six medical grade filters, eliminating all harmful substances, bacteria, and viruses. Dosing pump in the AmnioBed mixes in exact amounts of minerals and electrolytes to create sterile, synthetic amniotic fluid.
- **Built-in System for Temperature and Osmolality:** Water is warmed to proper temperature using the built-in computer system. Based on the age of the infant, operators have the option to choose the level of osmolality (a measure of how much one substance has dissolved in another substance) that they want in the fluid.
- **Sterile Cover for the Bath:** Includes infant seat with a harness that straps the infant's chest and pelvis in place, so the infant cannot accidentally get fully submerged.
- **Cap with monitoring:** Covers most of the scalp and has a strap that goes around the chin. Cap will have

an infant skin temperature sensor and O2 monitoring sensor as well as openings on the Fontanelles for ultrasound probe placement.

- **Fluid Depth Sensor:** Placed under the infant's chin and will ensure fluid in the bath never goes above the chin level. If it does, the computer will automatically lower the fluid level, and alarms will go off for nursing attention.
- **Fluid Circulation:** The fluid in the bath is continuously circulated through a UV filter and heat source to maintain sterility and temperature.
- **Fluid Clarity Sensors:** Located beneath the pelvic area, the sensor will detect stool defecated by the infant, leading to automatic flushing of the fluid and automatic replacement with fresh fluid.
- **Monitor for Mother:** Will provide direct audio/video feedback from inside the incubator that can be placed on an app, so the mother can keep in constant contact with the infant.

Amnion Life has launched an awareness and equity campaign for the AmnioBed, (<https://wefunder.com/amnionlife>), to share the potential of this promising product.

Amnion Life Amniobed-rendering-Image2

The pressing need to address growing premature births in the world inspired Amnion Life, (<https://amnion.life/>), to develop the AmnioBed, an amniotic, neonatal incubator system that incorporates unparalleled technology to promote ongoing development immediately following birth. This patented, cost-efficient, incubation device features an amniotic fluid submersion bath that simulates the mother's womb, providing a potentially ideal environment to nurture infants at their most vulnerable stage.

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In 2016, the U.S. Center for Disease Control and Prevention estimated there to be 388,130 premature births, ranking the United States as sixth in the world. Amnion Life has launched an awareness and equity campaign for the AmnioBed, (<https://wefunder.com/amnionlife>), to share the potential of this promising product among consumers, the medical community, and additional investors.

###

Established in 2016, Amnion Life is a medical company in pursuit of innovative medical devices for preterm infants. Media Contact:

George Pappas  
Conservaco/The Ignite Agency  
949-339-2002  
204660@email4pr.com  
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## Bipartisan Bill to Help Improve Access to Maternity Care Signed Into Law

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*Bill addresses areas with shortages in access to maternity services, now passed into law.*

Released: December 18, 2018

E & C Press Release

WASHINGTON, DC – Energy and Commerce Committee Chairman Greg Walden (R-OR) and Health Subcommittee Chairman Michael C. Burgess M.D. (R-TX) today released the following statements after President Trump signed H.R. 315, the Improving Access to Maternity Care Act, authored by #SubHealth Chairman Burgess, into law. The legislation helps to better identify areas in the nation with shortages in maternity care.

“With the president’s signature yesterday, we are one step closer to guaranteeing every woman has access to safe and quality maternity care,” said Chairman Walden. “This legislation will better identify areas in the nation where there are serious maternity care shortages and seek to eliminate those gaps. I commend Health Subcommittee Chairman Burgess for his dedication to providing expectant mothers the care they and their babies need.”

“As a father, an OB/GYN, and Chairman of the Energy and Commerce Health Subcommittee, I am thrilled that President Trump has signed my Improving Access to Maternity Care Act into law, delivering on our promises to America’s mothers,” said #SubHealth Chairman Burgess. “It is imperative that patients have quality, consistent access to maternity care – regardless of where they live. Expanding access to maternity care has been one of my top priorities since I left practice to serve the 26th District of Texas, and this lifesaving law is a big win for our nation’s mothers and the physicians who care for them.”

Here is the bill summary:

Preventing Maternal Deaths Act of 2017

*This bill directs the Department of Health and Human Services (HHS) to establish a program under which HHS may make grants to states for the purpose of: (1) reviewing pregnancy-related and pregnancy-associated deaths (maternal deaths); (2) establishing and sustaining a maternal mortality review committee to review relevant information; (3) ensuring that the state department of health develops a plan for ongoing health care provider education in order to improve the quality of maternal care, disseminate findings, and implement recommendations; (4) disseminating a case abstraction form to aid information collection for HHS review and preserve its uniformity; and (5) providing for the public disclosure of information included in state reports.*

*The bill defines “pregnancy-associated death” as the death of a woman while pregnant or during the one-year period following the date of the end of pregnancy, irrespective of the cause of death. It defines “pregnancy-related death” as the death of a woman while pregnant or during the one-year period*

*following the date of the end of pregnancy, irrespective of the pregnancy’s duration, from any cause related to, or aggravated by, the pregnancy or its management, excluding any accidental or incidental cause.*

*States shall develop procedures for mandatory reporting to their departments of health by health facilities and professionals concerning maternal deaths and for voluntary reporting of such deaths by family members.*

*States shall investigate each case and prepare a case summary for each case, to be reviewed by the committee and included in applicable.*

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## FDA Permits Marketing of a Diagnostic Test to Aid in Measuring Nutrients in Breast Milk

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

Public Release: December 21, 2018

Source Newsroom: FDA News Release

Today, the U.S. Food and Drug Administration permitted marketing of the Miris Human Milk Analyzer, a new diagnostic test to aid healthcare professionals in measuring nutrients in breast milk, including the concentration of fat, carbohydrate, protein, total solids and energy. The test provides healthcare professionals with a new tool to aid in the nutritional management of newborns and young infants at risk for growth failure due to prematurity or other medical conditions.

“Breast milk provides many health benefits to infants, and for many babies it can meet their early nutritional needs. But some infants — including those who may be born preterm or have certain health conditions — may need additional nutrients in order to support their optimal





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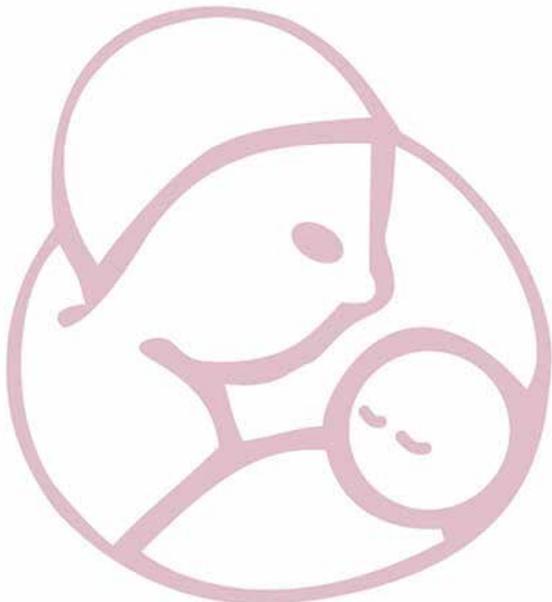
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growth,” said Courtney Lias, Ph.D. director of the Division of Chemistry and Toxicology Devices in the FDA’s Center for Devices and Radiological Health. “For the first time, doctors have access to a test to help analyze the nutrients in breast milk. While this test is not for everyone, it has the potential to aid parents and healthcare providers, mainly in a hospital setting, in better assessing the nutrient needs of certain babies who are not growing as expected.”

Some infants who are born prematurely or with health conditions may have special nutritional needs. Breast milk composition can vary in individuals, and, in certain cases, breast milk may not contain sufficient protein and energy levels for these infants with increased nutrient needs. In those instances, healthcare professionals may want to test the nutrient content of the milk to help guide nutritional care. Knowing the macronutrient content of the breast milk may help the health care team and parents make informed decisions on how to fortify the breast milk based on the individual needs of the infant.

The Miris Human Milk Analyzer uses an infrared spectroscopy system to analyze samples of human milk and provide a quantitative measurement of fat, protein and total carbohydrate content as well as calculations of the total solids and energy content contained in the milk. This is a prescription device intended for use by trained health care personnel at clinical laboratories.

The FDA reviewed data submitted by the sponsor of 112 samples of human milk to analyze the performance of the device. For the study, the sponsor tested the same 112 samples in the machine and compared them to the expected true values obtained by independent methods; both systems provided similar results for each test. The data showed that the Miris Human Milk Analyzer test was effective at determining levels of protein, fat and carbohydrate in the milk. There may be conditions that limit the information available from the Miris Human Milk Analyzer. For

example, certain medications that a nursing mother may be taking could interfere with the test’s ability to accurately measure nutrient levels in breast milk.

Health care professionals should carefully evaluate the Miris Human Milk Analyzer test results in conjunction with clinical assessments (such as weight and growth) to inform their discussions with parents in creating a nutritional management plan for an infant or newborn.

The FDA reviewed the Miris Human Milk Analyzer test through the De Novo pre-market review pathway, a regulatory pathway for low-to-moderate-risk devices of a new type. Along with this authorization, the FDA is establishing criteria, called special controls, to provide for the accuracy and reliability of tests intended to measure the nutritional content of human milk to aid in the nutritional management of certain infants. These special controls, when met along with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type. This action also creates a new regulatory classification, which means that subsequent devices of the same type, including the same intended use, may go through the FDA’s 510(k) process, whereby devices can obtain marketing authorization by demonstrating substantial equivalence to a predicate device.

The FDA granted marketing authorization of the Miris Human Milk Analyzer test to Miris AB.

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

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## CDC Updates Information for the Use and Availability of VARIZIG® (Varicella Zoster Immune Globulin [Human])

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*CDC Updates Information for the Use and Availability of VARIZIG® (Varicella Zoster Immune Globulin [Human])*

The Centers for Disease Control (CDC) has updated information related to the use and availability of VARIZIG® (Varicella Zoster Immune Globulin [Human]) for post-exposure prophylaxis of varicella in patients at high-risk, posted on its website (<https://bit.ly/2M10UR>). In the update, the CDC notes that VARIZIG is commercially available from a broad network of specialty distributors in the United States (list available at [www.varizig.com](http://www.varizig.com)).

“This update is important for effective distribution and use of VARIZIG for these at-risk patient populations,” said Saol Therapeutics Chief Executive Officer, David Penake. “VARIZIG has a strong clinical value in the patient populations it serves, and we are pleased that it is now commercially available from a broad network of US specialty distributors. It is very important that all treating physicians realize that VARIZIG can be easily obtained within 24 hours for high-risk patients following exposure to varicella-zoster virus.”

VARIZIG is an FDA-approved immunoglobulin for post-exposure prophylaxis of varicella in high-risk individuals, replacing VZIG (discontinued in 2006). VARIZIG is a hyperimmune product that contains antibodies specific for the varicella zos-



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ter virus, which causes the viral infection known as chickenpox.

#### Clinical Management of Exposure to Varicella

Despite being considered “benign” in healthy individuals, chickenpox and shingles may be responsible for health complications and death in high-risk patients.<sup>1-4</sup> These patients may be exposed to varicella through chickenpox, or shingles.<sup>4</sup> Exposure to chickenpox is considered serious and can occur in as little as 5 minutes depending on type of exposure.<sup>4</sup> The CDC recommends VARIZIG for people exposed to varicella or herpes zoster who cannot receive varicella vaccine; varicella-zoster immune globulin can prevent varicella from developing or lessen the severity of the disease. Varicella-zoster immune globulin is recommended for people who cannot receive the vaccine and 1) who lack evidence of immunity to varicella, 2) whose exposure is likely to result in infection, and 3) are at high risk for severe varicella.<sup>5</sup> Please see contraindications below in the Important Safety Information.

Evidence of immunity to varicella includes vaccination with varicella vaccine (1 dose  $\geq 12$  months through 3 years of age, 2 doses  $\geq 4$  years of age, adolescents, and adults: 2 doses), birth in the U.S. before 1980 (except for healthcare personnel, pregnant women, and immunocompromised persons), laboratory evidence of immunity or laboratory confirmation of disease, or history of varicella or herpes zoster.<sup>6</sup>

High-risk patients include newborns with mothers having varicella symptoms around delivery; pregnant women without evidence of immunity; hospitalized infants born at or before 28 weeks and weighing less than 2 lbs; and immunocompromised patients without evidence of immunity, such as cancer patients, transplant recipients, and patients with autoimmune or immune-mediated inflammatory disorders.<sup>5,7</sup>

Post-exposure Prophylaxis with VARIZIG® (Varicella Zoster Immune Globulin [Human])

VARIZIG is a single weight based IM injection intended to reduce the severity of varicella in at-risk patients.<sup>7</sup> In an open-label expanded access protocol of over 500 high-risk individuals that received VARIZIG after exposure to chickenpox or shingles, a low percentage (<10%) developed clinical varicella.<sup>7</sup> VARIZIG should ideally be administered within 96 hours for greatest effectiveness.<sup>7</sup> However, a comparison of the incidence of clinical varicella based on treatment window revealed that treatment between 5 and 10 days post-exposure was no different from treatment within 96 hours.<sup>7</sup> VARIZIG is commercially available from a broad network of specialty distributors in the United States (list available at [www.varizig.com](http://www.varizig.com))

#### IMPORTANT SAFETY INFORMATION ABOUT VARIZIG (Varicella Zoster Immune Globulin [Human])

In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, only administer VARIZIG if the expected benefits outweigh the potential risks. Thrombotic events may occur fol-



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lowing treatment with VARIZIG and other immune globulin products. Individuals known to have severe, potentially life-threatening reactions to human globulin should not receive VARIZIG or any other immune globulin (Human). Individuals who are deficient in IgA may have the potential for developing IgA antibodies and have severe, potentially life-threatening allergic reactions. Products made from human plasma may carry a risk of transmitting infectious agents, e.g. viruses and, theoretically, the Creutzfeldt-Jakob disease agent. The most serious adverse drug reactions observed in clinical trials for all subjects and patients include pyrexia, nausea, chills, and vomiting. The most common adverse drug reactions observed in clinical trials for all subjects and patients were injection site pain, headache, chills, fatigue, rash, and nausea.

For further information about VARIZIG, contact Susan Clement, Senior Director, Marketing, Saol Therapeutics, at [sclement@saolrx.com](mailto:sclement@saolrx.com).

About Saol Therapeutics

Saol Therapeutics is a commercial specialty pharmaceutical company concentrated on addressing the medical needs of underserved or unserved patient populations and the physicians that treat them.

Further information:

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

VARIZIG Full Prescribing Information  
 CDC. Updated Chickenpox (varicella): For Healthcare Professionals — 2019  
 CDC. Updated Recommendations for Use of VARIZIG — United States, 2013  
 Available VARIZIG Distributors

SOURCE:

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

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TWITTER NEWS ANNOUNCEMENT:

On its website, the CDC has updated information on the availability of VARIZIG® (Varicella Zoster Immune Globulin [Human]). The CDC notes that VARIZIG is now broadly available from a network of U.S. specialty distributors.

**NT**

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## 3D Printed Implant Promotes Nerve Cell Growth to Treat Spinal Cord Injury

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*In rat models, the novel scaffolding mimicked natural anatomy and boosted stem cell-based treatment; the approach is*



*scalable to humans and advances effort toward clinical trials*

Released: 10-Jan-2019 4:05 PM EST

Source Newsroom: University of California San Diego Health

Newswise — For the first time, researchers at University of California San Diego School of Medicine and Institute of Engineering in Medicine have used rapid 3D printing technologies to create a spinal cord, then successfully implanted that scaffolding, loaded with neural stem cells, into sites of severe spinal cord injury in rats.

The implants, described in a study published in the January 14 issue of *Nature Medicine*, are intended to promote nerve growth across spinal cord injuries, restoring connections and lost function. In rat models, the scaffolds supported tissue regrowth, stem cell survival and expansion of neural stem cell axons out of the scaffolding and into the host spinal cord.

“In recent years and papers, we’ve progressively moved closer to the goal of abundant, long-distance regeneration of injured axons in spinal cord injury, which is fundamental to any true restoration of physical function,” said co-senior author Mark Tuszynski, MD, PhD, professor of neuroscience and director of the Translational Neuroscience Institute at UC San Diego School of Medicine. Axons are the long, threadlike extensions on nerve cells that reach out to connect to other cells.

“The new work puts us even closer to real thing,” added co-first author Kobi Koffler, PhD, assistant project scientist in Tuszynski’s lab, “because the 3D scaffolding recapitulates the slender, bundled arrays of axons in the spinal cord. It helps organize regenerating axons to replicate the anatomy of the pre-injured spinal cord.”

Co-senior author Shaochen Chen, PhD, professor of nanoengineering and a faculty member in the Institute of Engineering in Medicine at UC San Diego, and colleagues used rapid 3D printing technology to create a scaffold that mimics central nervous system structures.

“Like a bridge, it aligns regenerating axons from one end of the spinal cord injury to the other. Axons by themselves can

diffuse and regrow in any direction, but the scaffold keeps axons in order, guiding them to grow in the right direction to complete the spinal cord connection,” Chen said.

#### Faster, More Precise Printing

The implants contain dozens of tiny, 200-micrometer-wide channels (twice the width of a human hair) that guide neural stem cell and axon growth along the length of the spinal cord injury. The printing technology used by Chen’s team produces two-millimeter-sized implants in 1.6 seconds. Traditional nozzle printers take several hours to produce much simpler structures.

The process is scalable to human spinal cord sizes. As proof of concept, researchers printed four-centimeter-sized implants modeled from MRI scans of actual human spinal cord injuries. These were printed within 10 minutes.

“This shows the flexibility of our 3D printing technology,” said co-first author Wei Zhu, PhD, nanoengineering postdoctoral fellow in Chen’s group. “We can quickly print out an implant that’s just right to match the injured site of the host spinal cord regardless of the size and shape.”

#### Restoring Lost Connections

Researchers grafted the two-millimeter implants, loaded with neural stem cells, into sites of severe spinal cord injury in rats. After a few months, new spinal cord tissue had regrown completely across the injury and connected the severed ends of the host spinal cord. Treated rats regained significant functional motor improvement in their hind legs.

“This marks another key step toward conducting clinical trials to repair spinal cord injuries in people,” Koffler said. “The scaffolding provides a stable, physical structure that supports consistent engraftment and survival of neural stem cells. It seems to shield grafted stem cells from the often toxic, inflammatory environment of a spinal cord injury and helps guide axons through the lesion site completely.”

Additionally, the circulatory systems of the treated rats had penetrated inside the implants to form functioning networks of blood vessels, which helped the neural

stem cells survive.

“Vascularization is one of the main obstacles in engineering tissue implants that can last in the body for a long time,” Zhu said. “3D printed tissues need vasculature to get enough nutrition and discharge waste. Our group has done work on 3D printed blood vessel networks before, but we didn’t include it in this work. Biology just naturally takes care of it for us due to the excellent biocompatibility of our 3D scaffolds.”

The advance marks the intersection of two longstanding lines of work at the UC San Diego School of Medicine and Jacobs School of Engineering, with steady, incremental progress. The scientists are currently scaling up the technology and testing on larger animal models in preparation for potential human testing. Next steps also include incorporation of proteins within the spinal cord scaffolds that further stimulate stem cell survival and axon outgrowth.

Co-authors include: Xin Qu, Oleksandr Platoshyn, Jennifer Dulin, John Brock, Lori Graham, Paul Lu and Martin Marsala, all at UC San Diego; and Jeff Sakamoto, University of Michigan.

Funding for this research came, in part, from the National Institutes of Health (R01EB021857, R21HD090662), the National Science Foundation (1644967, 1547005), the California Institute for Regenerative Medicine (RT3-07899) and the Dr. Miriam and Sheldon G. Adelson Medical Research Foundation.

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*Disclosure: Chen and Zhu have co-founded the startup, Allegro 3D, to commercialize their rapid bioprinting technology.*

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## B-Line Medical Commits to Improving Patient Safety

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*B-Line Medical supports the Patient Safety Movement Foundation and mission to eliminate preventable deaths by 2020*

(OX2020).

Released: 14-Jan-2019 8:00 AM EST

Source Newsroom: B-Line Medical

Newswise — WASHINGTON, D.C.- January, 14, 2019- B-Line Medical, an industry leader in video-driven healthcare education and outcome improvement, is pleased to announce their support and alliance with the Patient Safety Movement Foundation and their mission to eliminate preventable deaths by 2020 (OX2020).

For over 14 years, B-Line Medical has provided a learning management solution for healthcare education, created to improve the quality of healthcare training and patient safety. Hospitals such as Mayo Clinic, Cleveland Clinic and Children's Hospital of Philadelphia have all adopted SimCapture and LiveCapture in a variety of environments, including trauma bays, intensive care units, neonatal resuscitation bays, interventional radiology labs, and operating rooms. Hospitals worldwide have seen years of positive and compelling results by leveraging B-Line Medical's video and data capturing platform to help healthcare professionals improve their skills, knowledge of best practices, and their ability to work as teams within larger healthcare systems to provide the best care to patients as possible.

In creating an alliance with the Patient Safety Movement Foundation, B-Line Medical will demonstrate a number of commitments to show their support. B-Line Medical will spread the mission of OX2020 to their members and partners, participate in the PSMF's Actionable Patient Safety Solutions (APSS) workgroups

to develop a simulation plan for select APSS, disseminate APSS within their community, ask top hospitals connected with B-Line Medical to implement APSS, and make formal commitment through the PSMF to improve patient safety. Lastly, B-Line Medical will engage and share progress with the PSMF regarding their initiatives while integrating best practices into the training of affiliated healthcare system partners where appropriate and supported by the healthcare system partner's needs.

"The Patient Safety Movement Foundation (PSMF) team is very excited to welcome B-Line Medical as the third simulation partner to join our network. B-Line Medical has agreed to help the PSMF develop a simulation plan for select Actionable Patient Safety Solutions (APSS) challenges in order to improve the quality of care through video-driven solutions. We look forward to working closely with B-Line Medical to help eliminate preventable deaths together."

"B-Line Medical is built around the concept of video-driven improvement and we recognize that there is no more important issue today in healthcare than improving patient safety," says Co-Founder and CEO of B-Line Medical, Chafic Kazoun. "We feel strongly that our SimCapture and LiveCapture products can serve as a critical framework for quantifying improvement in healthcare education and significantly further the Patient Safety Movement Foundation mission."

Founded in 2005, B-Line Medical is exclusively dedicated to offering solutions that help healthcare professionals and educators improve the delivery of healthcare and enhance quality of care. Focused on the capture, debriefing, and assessment of healthcare training and clinical events, B-Line Medical's robust, yet easy-to-use web-based solutions are in use at over 500 institutions in 35 countries.

If you are interested in learning more about this B-Line Medical products and services, visit [blinemedical.com](http://blinemedical.com) or contact [info@blinemedical.com](mailto:info@blinemedical.com). For additional information about this press release, please contact Helen Woldeab, Marketing Manager, at [Helen.Woldeab@blinemedical.com](mailto:Helen.Woldeab@blinemedical.com)

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## Rutgers Campaign Seeks to Decrease Maternal Mortality Rates

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*New Jersey's second annual Maternal Health Awareness Day on January 23 brings attention to Rutgers' Stop.Look.Listen campaign, which one grieving father hopes to take national*

Released: 13-Jan-2019 1:05 AM EST

Source Newsroom: Rutgers University-New Brunswick

Newswise — Shortly after giving birth to her son Brandon in 2011, Tara Hansen – while still in the hospital – told healthcare providers her body didn't feel right. But they considered her a healthy postpartum patient and sent her home.

Six days later, she died from an infection that had occurred during the birth.

"Tara was the only person who knew something was wrong, and her complaints just kept falling on deaf ears," her husband, Ryan, said. "Everyone assumed that the pain she described was to be expected because she just had a baby."

Maternal deaths are declining worldwide, but are on the rise in the United States. The U.S. Centers for Disease Control and Prevention reported 18 pregnancy-related deaths for every 100,000 live births nationwide in 2014, up from a low of 7.2 in 1987. In New Jersey, the most recent state data shows that from 2006 to 2008, the average maternal mortality rate was 14.4 deaths per 100,000 births, with higher rates reported for black women.

Vowing to make an impact in his wife's honor, Ryan, a Rutgers alumnus, launched the Tara Hansen Foundation in 2012 and forged a partnership with Rutgers Robert Wood Johnson Medical School, where his mother, Patricia Hansen, is director of communications and public affairs.

With assistance from the medical school and Robert Wood Johnson University Hospital, the foundation developed the "Stop. Look. Listen!" campaign. Its goals are to increase public and professional awareness of pregnancy-related deaths,



empower women to report pregnancy-related medical issues, and increase awareness and responsiveness among healthcare practitioners.

The campaign prompted a New Jersey law establishing January 23 of each year as Maternal Health Awareness Day – the first of its kind nationwide.

“Pregnancy is considered a happy time in a woman’s life, and families don’t want to think about anything negative, like hypertension or diabetes,” said Gloria Bachmann, director of the Women’s Health Institute at Robert Wood Johnson Medical School, who helped create the campaign.

“Our goal is to empower women and families to advocate if they feel something is wrong and understand that no question about the mother-to-be or new mom’s health is inconsequential. For example, itchy skin could mean a liver or gall bladder problem, which was caused by the pregnancy. With ‘Stop. Look. Listen!’ clinicians need to stop whatever they are doing, look at the woman and conduct a full medical evaluation and, of course, listen carefully to what she and her family are saying about her concerns and how she is feeling,” Bachmann said.

The campaign seeks to educate all healthcare providers – not just OB-GYNs, nurses and certified nurse midwives – as well as family members and emergency room physicians, who may be the first to recognize something might be wrong with a woman who has just given birth.

“Many women have a history of good health but suffer from pregnancy-related issues during or just after delivery, such as cardiovascular diseases, blood clots, pneumonia and stroke, which can result in death,” said Bachmann.

Ryan Hansen looks forward to promoting “Stop. Look. Listen!” nationwide. “It’s frightening that most people in the United States do not consider a healthy, postpartum woman at risk for death since we are in a developed country,” he said. “This day of awareness shows that Tara’s death has meaning – to save other women’s lives.”

More information about Maternal Health Awareness Day, #123forMoms may be found here:

<http://go.rutgers.edu/hbq3qwmi>

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## Risk factors for obesity may differ for Hispanic and non-Hispanic white babies

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*New research suggests that a targeted and personalized approach would help tackle obesity in at-risk populations*

Released: 10-Jan-2019 11:10 AM EST

Source Newsroom: Springer

NNewswise — The factors that put children at risk of becoming obese within the first 12 months of their life may differ for Hispanic and non-Hispanic babies. This is a conclusion of a new study in the journal *Pediatric Research*, which is published by Springer Nature. Lead authors, Sahel Hazrati and Farah Khan of the Inova Translational Medicine Institute in the US, investigated factors associated with excess weight in the first year of life in Hispanic versus non-Hispanic white children.

Childhood obesity is a growing health concern worldwide. In recent years instances have nearly tripled, with 17 per cent of young people in the US now classified as obese. Previous studies have revealed that Hispanic children are disproportionately affected. According to a recent study, 15.6 per cent of Hispanic children aged between two and five years are obese, compared to 5.2 per cent of non-Hispanic white children of the same age.

The rate at which babies gain weight in the first few months after birth is often linked to their chances of being obese for the rest of their lives. However not enough is known about which factors might lead babies to be overweight by their first birthday.

To investigate how these factors may differ between Hispanic and non-Hispanic white families, Hazrati, Khan and their colleagues analyzed data contained in the Inova study called “The First 1000 Days of Life and Beyond”. Information

was extracted from 1009 one-year-old children, 302 (30.0 per cent) of whom were Hispanic and 707 (70 per cent) were non-Hispanic white children. Genetic data was available for 543 of the 1009 children included in the study and there was a high agreement rate between ancestry genetic data and reported ethnicity. The researchers gathered information about babies and their parents, whether they were breastfed and how soon they were introduced to solid foods and fruit juices from survey data, questionnaires and medical records.

Three in every ten (30.1 per cent) of Hispanic babies were found to be overweight aged 12 months, compared to just over one in every ten (13.6 per cent) non-Hispanic white children.

“The rate of excess weight in the Hispanic population was strikingly higher in this cohort, even at the very young age of 12 months,” states Hazrati.

Interestingly, higher father BMI and higher maternal weight gain during pregnancy was associated with excess weight in non-Hispanic white children but not in Hispanic children. On the other hand, lower maternal education was associated with excess weight in the Hispanic children.

Although various social and cultural factors were found to have varying influence on the families in the different ethnic groups, in combination these did not fully explain the marked differences in weight gain between Hispanic and non-Hispanic white children. Hazrati suggests that these findings might point to an underlying genetic predisposition and epigenetic influences towards obesity in different ethnicities.

“As there are so many different factors influencing the development of obesity in young children, health authorities should consider developing personalized guidelines targeted to different populations in an effort to stem overall obesity in the US population,” explains Khan.

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*Reference: Hazrati, S. et al (2018). Clinical and social factors associated with excess weight among Hispanic and non-Hispanic White children, Pediatric Research DOI: 10.1038/s41390-018-0264-9*

## Newborns Face Risks When Born to Women with the Flu

*Pregnant women with influenza are more likely to experience complications, but how this affects infants is unclear. A new Birth Defects Research study uncovers the potential risks to infants.*

Released: 9-Jan-2019 12:40 PM EST

Source Newsroom: Wiley

Pregnant women with influenza are more likely to experience complications, but how this affects infants is unclear. A new Birth Defects Research study uncovers the potential risks to infants.

The study included 490 pregnant women with influenza, 1451 women without influenza with pregnancies in the same year, and 1446 pregnant women without influenza with prior year pregnancies. Women with 2009 H1N1 influenza admitted to an intensive care unit were more likely to deliver preterm infants, low birth weight infants, and infants with low Apgar scores than women in the other groups.

Women with influenza who were not hospitalized, as well as hospitalized women not admitted to the intensive care unit, did not have significantly elevated risks for adverse infant outcomes.

“The message of this work is particularly timely in the midst of the current influenza season. Our study found that severely ill women with 2009 H1N1 influenza during pregnancy were more likely to have adverse birth outcomes—such as their baby being born preterm or of low birth weight—than women without influenza,” said senior author Dr. Sonja Rasmussen, of the University of Florida. “These findings support the importance of pregnant women receiving the influenza vaccine and of prompt treatment with antiviral medications for pregnant women suspected of having influenza.”

Additional Information

Link to Study: <https://onlinelibrary.wiley.com/doi/full/10.1002/bdr2.1445>

### About Journal

The journal Birth Defects Research publishes original research and reviews in areas related to the etiology of adverse developmental and reproductive outcome. In particular the journal is devoted to the publication of original scientific research that contributes to the understanding of the biology of embryonic development and the prenatal causative factors and mechanisms leading to adverse pregnancy outcomes, namely structural and functional birth defects, pregnancy loss, postnatal functional defects in the human population, and to the identification of prenatal factors and biological mechanisms that reduce these risks.

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[wiley.com](http://wiley.com).

## Smoking During Pregnancy Increases the Risk that Your Baby Will Become Obese

*Smoking during pregnancy can increase offspring risk of obesity later in life. New research identifies the potential cellular pathways that link the two.*

Released: 3-Jan-2019 11:05 AM EST

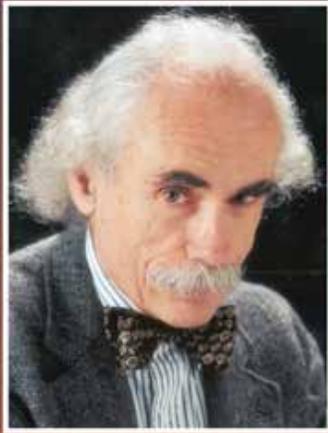
Source Newsroom: University of Kentucky

Newswise — LEXINGTON, Ky. (Jan. 4, 2019) -- Using foreskin tissue from newborn circumcisions, a group of researchers have identified a potential cellular mechanism that connects a mother's smoking while pregnant with an increased risk of offspring obesity later in life.

Obesity is considered an epidemic in the U.S., with nearly 35 percent of adults and



*8th World Congress of Pediatric  
Cardiology and Cardiac Surgery*  
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Lawrence D. Longo, MD  
Center for Perinatal Biology

SECOND ANNUAL

Longo Symposium

KEYNOTE ADDRESS

"Strategies for Finding the Early Origins of  
Cardiovascular Disease"

Kent L. Thornburg, PhD  
Oregon Health & Science University

INVITED SPEAKERS

Gautam Chaudhuri, MD, PhD  
University of California, Los Angeles

Thomas Jansson, MD, PhD  
University of Colorado

Lawrence P. Reynolds, PhD  
North Dakota State University

Philippa Saunders, PhD, FMedSci  
University of Edinburgh

Philip W. Shaul, MD  
UT Southwestern Medical Center

February 5, 2019

8:30 a.m. - 4:30 p.m.

Roger W. Barnes  
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20 percent of children six to 19 years old deemed obese. Obesity is a serious economic burden as well: more than \$150 billion is spent annually on obesity-related healthcare costs in the U.S. alone.

"It has been consistently shown that mothers who smoke during pregnancy confer increased risk of obesity to their baby, but the mechanisms responsible for this increased risk are not well understood," said the study's principal investigator Kevin Pearson of the University of Kentucky (UK). "These data mark a first step towards defining those mechanisms with an eye toward potential interventions in the longer term."

In collaboration with UK's Department of Obstetrics and Gynecology, a total of 65 new mothers were recruited for the study in two different cohorts: 46 in Cohort 1 (2012-2013) and 19 in Cohort 2 (2015-2016). All of the infants were full-term; approximately half of all new mothers reported smoking during their pregnancies. DNA and RNA were isolated from foreskin tissue which would otherwise be discarded after routine circumcisions and analyzed with a focus on chemerin gene expression.

Chemerin is a protein that is produced by fat cells and appears to play a role in energy storage. Previous research had determined that chemerin is present in higher levels in the blood of obese people. However, Pearson said, it has not been measured in neonates exposed to cigarette smoke.

Results showed that chemerin was more prevalent in the skin and isolated cells of infants whose mothers smoked during pregnancy, suggesting that smoking in pregnancy could be leading to changes in the regulation of the genes that play an important role in fat cell development and, by extension, obesity.

"Our work demonstrated that expectant mothers who smoke cigarettes dur-

ing pregnancy induce distinct changes in chemerin gene expression in their offspring," Pearson said.

The next step is to reproduce their findings in females since they were not represented in the study. Pearson et al propose to use cells from umbilical cords to do so. The group also hopes to study smoke exposure during pregnancy in genetically modified mice as both chemerin and its receptor can be removed to highlight this pathway more directly. The current and future results could provide a springboard for the development of effective treatments against pediatric and adult obesity in babies born to smokers as well as those exposed to other in utero environmental exposures.

**NT**

## Early detection: Chemists discover new signatures to identify cystic fibrosis in infants soon-



## er with better reliability

Released: 20-Dec-2018 7:05 AM EST

Source Newsroom: McMaster University

**Newswise** — Scientists at McMaster University have discovered several new biomarkers from a single drop of blood that could allow earlier and more definitive detection of cystic fibrosis (CF), a genetic disease which strikes both children and adults, causing chronic problems with the digestive system and the lungs.

The findings, published online in the *Journal of Proteome Research*, are significant because current newborn screening methods are not accurate enough to identify the disorder in the population, which can manifest itself in many different ways, requiring additional testing and causing further stress for anxious parents.

"The earlier CF is detected, the earlier it can be managed and treated, which means better health outcomes for affected infants, including their future growth and

development,” says Philip Britz-McKibbin, lead author of the study and a professor in McMaster’s Department of Chemistry & Chemical Biology, who conducted the research with graduate student Alicia DiBattista, now a postdoctoral fellow at Newborn Screening Ontario (NSO).

A tiny amount of blood is drawn from the heel of all babies as part of universal newborn screening programs that test for many rare yet treatable diseases since babies usually have no signs of disease at birth, including CF.

In the case of CF, infants are screened for a pancreatic enzyme and then a panel of disease-causing genetic mutations associated with CF. However, further testing to confirm or rule out the disease finds that most babies who screen-positive do not actually have the disease. These babies are later found to be “healthy carriers” or their results are deemed to be “false positives”.

With this in mind, researchers set out to determine whether they could discover chemical signatures in a dried blood spot that could better distinguish infants who have CF from those who do not.

Using less than a single drop of blood stored at NSO at CHEO, a pediatric health and research centre in Ottawa, researchers analyzed and compared samples from infants confirmed to have CF with the samples of both healthy and screen positive infants. They found several new compounds as well as simple amino acids directly related to affected infants with CF who otherwise have no symptoms and normal birth weight.

“These biomarkers provide new insights into the disease process early in life before symptoms are fully apparent,” says Britz-McKibbin. “Moreover, these compounds can be analyzed by mass spectrometry at incremental costs since it is already used for testing many other genetic diseases at newborn screening facilities around the world”

“Ontario started screening for Cystic Fibrosis in April 2007, and since that time over 400 children have already benefited from early recognition and early treatment. But for every one of these children, about 10 have had a false-positive result. We want to get this number down and

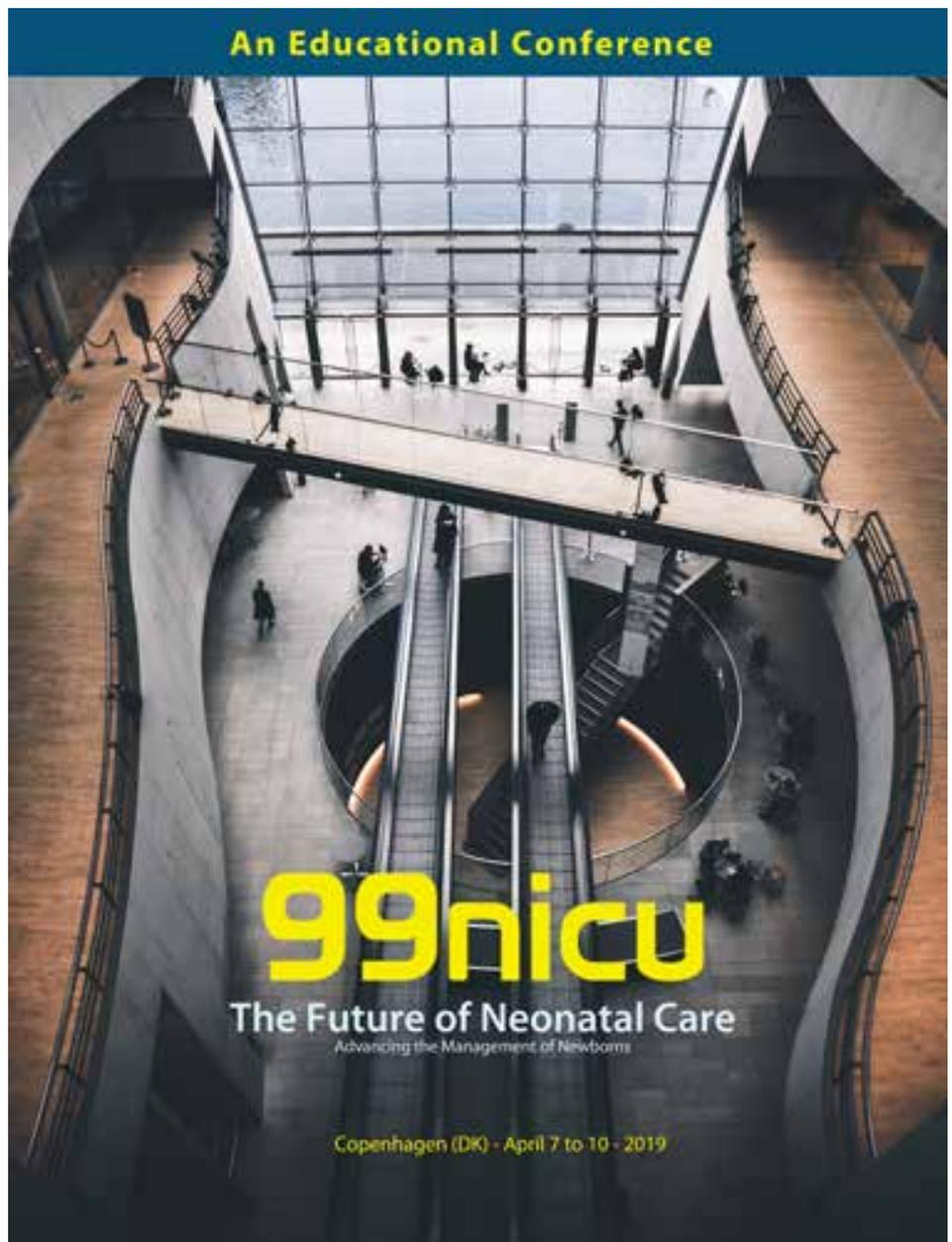
are very hopeful that the new biomarkers discovered by this research project will help us do exactly that,” says Pranesh Chakraborty, medical director of NSO at the CHEO.

In Canada, life expectancy rates have risen dramatically with the median age of survival now over 50 years, due to better treatments to improve lung function, better nutrition, lung transplants. The advent of universal newborn screening programs for CF will likely further improve the quality of life of affected patients.

“We know that early detection can have significant benefits for people living with cystic fibrosis,” said Dr. John Wallenburg,

chief scientific officer at Cystic Fibrosis Canada. “The current screening methodologies capture a broad swathe of families that then need further testing to narrow down those that are true positives. The anxiety and distress that such further testing can needlessly cause families was a major concern that slowed the adoption of newborn screening in some jurisdictions. Dr. Britz-McKibbin’s data provide insights for more specific newborn screening, as well as early manifestations of the disease.”

NT



# 36<sup>th</sup> Annual Advances in Therapeutics and Technology: Critical Care of Neonates, Children, and Adults

March 26 to March 30, 2019  
The Cliff Lodge - Snowbird, Utah

**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**

## Continuing Education Credit

The Perinatal Advisory Council: Leadership, Advocacy, And Consultation is providing physician, nursing, and respiratory continuing education units.



*Thank you to our exhibitors!*



## Featured Upcoming Conference

36<sup>th</sup> Annual Conference - Advances in  
Therapeutics and Technology

March 26-30, 2019

The Cliff Lodge and Spa in Snowbird, UT USA

### Registration:

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

### Conference Description:

Educational and networking opportunities for healthcare professionals who provide care for pediatric patients including those in critical care environments with a focus on advances in therapeutics and technologies. Includes featured speakers, workshops and abstract presentations on research on advances in these areas.

### Continuing Education Credit Provided by:

Perinatal Advisory Council: Leadership, Advocacy, And Consultation. Physician, nursing, and respiratory continuing education credit will be provided.

### 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

## Hot topics in the 99nicu forums

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



I sincerely hope you had a good start into the new year. Let me share the latest topics from our discussion boards on [99nicu.org](https://99nicu.org).

Delayed cord clamping (DCC) remains widely discussed. If everything runs smoothly during birth, it is commonly done. In situations with a depressed child or other special circumstances such as antepartum hemorrhage, it remains unclear on what approach is the most successful without having further studies. (1)

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***“Newborns born in humanitarian crisis pose a real ethical challenge for practice. Finding a solution in situations of limited resources and estimating the quality of life is not easy and has been a subject in a recent review of the literature.”***

---

Newborns born in humanitarian crisis pose a real ethical challenge for practice. Finding a solution in situations of limited resources and estimating the quality of life is not easy and has been a subject in a recent review of the literature. (2)

Every now and then users post valuable links with special interest for neonatal staff; a great resource, for example, is the NCBI bookshelf, which has several books and reports available free. If you have not come across it, be sure to look it up. (3)

Another valuable resource is free online didactic videos, e.g., by OPENPediatrics. Breastfeeding education is essential on neonatal wards, and the shared video gives good insights. This is completely in agreement with our mission for #FOAMneo. This is short for “free open access medical education,” and something we believe in very strongly. Medical education should not only be dependent on resources behind paywalls. (4)

Sometimes old posts are reactivated, and discussion continues. Fentanyl as premedication for neonatal intubation remains a hot topic. A member from Hungary shared a link to participate in their study on neonatal intubation medications. If you want to help out and share how it is done in your parts, follow the link on our forum. (5)

Naturally, we have also continued organizational work for our upcoming conference in Denmark this April – less than three more months to go. We believe we have an interesting lineup of international lecturers and we warmly invite you to join us for this unique conference.

If you are interested in our topics or have other neonatal questions you want to ask an engaged international crowd of neonatal staff, then join us on our forum on <https://99nicu.org>.

Check it out!

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

Francesco Cardona, MD, MSc

Consultant, Medical University of Vienna

Department of Paediatrics and Adolescent Medicine

Vienna, Austria

[francesco@99nicu.org](mailto:francesco@99nicu.org)

Links:

- 1 <https://99nicu.org/forums/topic/2136-placental-transfusion-in-aph/>
- 2 <https://99nicu.org/forums/topic/2144-newborns-in-crisis-an-outline-of-neonatal-ethical-dilemmas-in-humanitarian-medicine/>
- 3 <https://99nicu.org/forums/topic/2142-ncbi-bookshelf-neo->



- 4 <https://99nicu.org/forums/topic/2143-openpediatrics-boston-childrens-hospital-in-collaboration-with-the-world-federation-of-pediatric-intensive-and-critical-care-societies/>
- 5 <https://99nicu.org/forums/topic/1657-fentanyl-as-premed-for-intubation-what-is-your-experience-really/>

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**NT**

**Corresponding Author**



*Francesco Cardona, MD, MSc  
Consultant, Medical University of Vienna  
Department of Paediatrics and Adolescent  
Medicine  
Vienna, Austria  
francesco@99nicu.org*



*Stefan Johansson, MD, PhD  
Consultant Neonatologist, Sachs'  
Children's Hospital  
Associate Professor, Karolinska Institutet  
Stockholm, Sweden  
stefan.johansson@99nicu.org*



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# The Genetics Corner: A Genetics Consultation for Congenital Syphilis

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

## Case History:

This 25 week 6-day old female infant was born by C-section for premature labor and breech presentation to a 22-year-old G2P1 mother who had no prenatal care. The father of the baby was incarcerated. A fetal US was performed on the day before delivery when she presented with contractions. It revealed anhydramnios without confirmed rupture of membranes, echogenic bowel, scalp edema, ascites, fetal hydrops, and nuchal thickening. The mother was treated with Ampicillin and Gentamycin. Maternal syphilis was confirmed one day prior to delivery with a positive RPR and syphilis antibody test of 1:64. She smoked 1 ppd. The newborn responded poorly after delivery and required resuscitation with vigorous stimulation, suctioning, bagged ventilation and finally endotracheal intubation and positive pressure ventilation. Apgar scores were 1, 5 and 6 at 1, 5 and 10 minutes respectively. BW 1080 grams (97th%ile), BL 33 cm (41st%ile), HC 23 cm (36th%ile). The placental histology was pertinent for acute necrotizing chorioamnionitis. The maternal urine drug screen was positive for methamphetamine. Her HIV/AIDS screen was negative.

***“Syphilis can be vertically transmitted from the mother to the fetus at any time during pregnancy and within the first four years of maternal infection, when the chance of fetal transmission is about 70%. ”***

The infant's RPR test was positive, >10. She was treated with Penicillin for ten days. Early radiographs showed hepatomegaly with hepatic calcifications (Figure 1), and long bones showed a periosteal reaction and metaphyseal changes consistent with congenital syphilis (Figure 2). She had chronic anemia, thrombocytopenia, and total and direct hyperbilirubinemia. Hypophosphatemia, hypocalcemia, hypomagnesemia, and elevated PTH levels were noted. Over time, she developed radiographic findings of metabolic bone disease of prematurity and bronchopulmonary dysplasia. On day 57, she was endotracheally intubated and mechanically ventilated with FiO<sub>2</sub> 36%, PEEP 7, Rate 30. Head US and echocardiogram were normal. She tolerated enteric feedings with a 24 cal/oz formula but grew poorly. On day 60, her head was small: HC 27 cm, Z score -2.61. Hydrops had resolved, but hepatomegaly persisted. Ophthalmology exam revealed Stage 3, posterior zone 2 ROP with plus disease. Initially, facial features supported intrauterine compression from oligohydramnios but later dysmorphic features were evident: deep infraorbital folds, depressed nasal bridge, and protruding tongue.

Chromosome microarray revealed a small 51Kb duplication of chromosome 11p13, classified as a variant of unknown significance. The duplicated region contains two annotated genes: PAX6 and ELP4, the latter gene being disrupted by the duplication. Parental studies have been requested to determine if this is a de novo or familial variant.

## Consultant's Report:

This baby's features are most consistent with congenital syphilis, microarray results notwithstanding. Duplication of PAX6 has rarely been reported, while deletion of PAX6 and ELP4 cause aniridia, which is not present in this infant. The baby's clinical course is no doubt further compromised and complicated by her extreme prematurity, her mother's lack of prenatal care and exposure to tobacco and methamphetamine.



**Figure 1:** Multiple punctate calcifications in the liver of this infant with congenital syphilis illustrate the hepatic injury that is caused by this devastating infection.

Congenital syphilis alone is enough to account for most of this baby's serious problems. It is a devastating disease that is responsible for hundreds of thousands of stillbirths and neonatal deaths each year throughout the world. In 2016, the Centers for Disease Control and Prevention reported that the incidence of congenital syphilis was 15.7/100,000 live births, which followed a steady increase in reports since 2012 when the rate was 8.4/100,000 live births.

Syphilis can be vertically transmitted from the mother to the fetus at any time during pregnancy and within the first four years of maternal infection, when the chance of fetal transmission is about 70%. The highest transmission rates from mother to child occur in the early (primary, painless chancre, and regional lymphadenopathy) and secondary (rash, fever, malaise, arthralgias, lymph-

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Figure 2: Periosteal reaction and metaphyseal irregularities are signs of congenital syphilis in these long bones.

adenopathy) phases of the mother's syphilis infection. During the latent phase of syphilis infection, after 1-3 months when signs of primary or secondary syphilis have resolved, and there are no symptoms, but antibody tests are positive, only about 2% of exposed fetuses become infected.

Congenital syphilis causes perinatal death in more than 40% of untreated affected pregnancies. Of the deaths caused by congenital syphilis, 75% are stillborn, and 25% are in the neonatal period. Infected infants, especially term infants can be asymptomatic at birth. If untreated, symptoms of poor feeding and rhinitis ("snuffles") develop by five weeks of age, which are followed by a papular desquamative rash of the palms, soles, mouth, and anus.

Infected preterm infants are more often symptomatic at birth, and their symptoms are generally more severe than infected term infants. Severely ill infected infants have non-immune hydrops fetalis and often present with hepatomegaly, splenomegaly, anemia, and pneumonia. Characteristic facial features include frontal bossing, high arched palate, and depressed nasal bridge. More than 90% of symptomatic infants have radiographic changes of the long bones, specifically metaphyseal irregularities and periosteal thickening. So-called saber shins are late sequelae of periostitis of the tibia. The CNS is involved in about 50% of symptomatic infants. Neurosyphilis, which is not necessarily confined to late syphilis, is nevertheless rare in the newborn period. It may present with deafness, cranial nerve palsies, diabetes insipidus, leptomeningitis, hydrocephalus, paresis, and convulsions and intellectual disability. The late manifestations of congenital syphilis, which are evident after age 2, include the dental anomalies (Hutchinson teeth, mulberry molars), uveitis, and eighth nerve deafness that makeup Hutchinson's triad.

Effective prenatal care may mitigate many of the worst aspects of congenital syphilis by diagnosing and treating with antibiotics and other interventions. The *hydrops fetalis* associated with syphilis, which is secondary to fetal anemia, has been effectively treated with intrauterine transfusion. In this case, even with effective antibiotic therapy, the effects of congenital syphilis, which in this case, should include the ramifications of the preterm delivery, will have



serious and life-long consequences for this child.

### Practical Applications:

1. The incidence of congenital syphilis is rising in the United States and throughout the world.
2. Seven percent of nonimmune hydrops is due to infection. Consider congenital syphilis in any infant with *hydrops fetalis*.
3. Because maternal syphilis is highly correlated with fetal loss, check the results of maternal syphilis tests when evaluating a stillborn infant.
4. Syphilis and HIV infection are correlated so test for both when either is suspected, especially in the context of lack of prenatal care, incarceration, high-risk sex behaviors, sex work, and illicit drug use.

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NT

#### Corresponding Author



Robin Clark, MD  
Professor, Pediatrics  
Loma Linda University School of Medicine  
Division of Genetics  
Department of Pediatrics  
rclark@llu.edu



Subhadra (Subha) Ramanathan, M.Sc., M.S.  
Licensed and Certified Genetic Counselor  
Assistant Professor, Pediatrics  
Loma Linda University Health  
2195 Club Center Drive, Ste A  
San Bernardino, CA 92408  
SRamanathan@llu.edu

## 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.



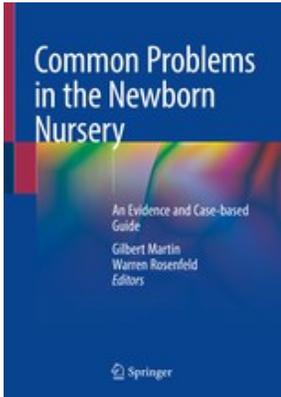
### Treat My Symptoms

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



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



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## What's Human Milk Good For?

Susan Hepworth and Mitchell Goldstein, MD



*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.*

Dubbed “liquid gold,” human milk offers a nutritional elixir for infants. And that has researchers asking an intriguing question: How else could human milk be used to optimize health?

They aren't the first to wonder. As reported by STAT News, some cancer patients have tried drinking breastmilk in hopes of therapeutic benefits.(1) And bodybuilders have purportedly tried it in hopes of boosting their muscle mass with the milk's dense nutritional content. Neither has proven effective.

***“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.”***

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.

A team of researchers based at Carnegie Mellon University, for instance, is exploring how breast milk cells manage to get from an infant's intestinal tract to other areas of the body. (2) Solving the mystery could be the first step toward using breast milk or its cells to target conditions affecting various parts of the infant's body. Meanwhile, a team at Baylor College of Medicine is studying the relationship between the sugars in breastmilk and the GI infection known as rotavirus. (3)

Interest in the research stems in part from growing awareness of human milk's known powers. In addition to boosting immunity for infants and providing an optimal source of nutrition, human milk reduces the impact of the deadly intestinal infection NEC, or necrotizing enterocolitis – especially in premature infants.

And that begs the question: If the benefit of human milk is so obvious that researchers are searching for additional uses, why can many infants, including preemies, still not access it? Because mothers of preemies typically cannot produce the quality or quantity of breast milk their infant needs, the use of donor human milk or human-milk based fortifiers can be critical in giving those babies optimal nutrition.

But not all hospitals offer donor milk or human milk-based fortifiers, and not all health plans cover the related costs. Meanwhile, mothers who want to breastfeed may not have access to a hospital-grade breast pump to make that possible.

New uses for human milk present an exciting prospect. But while researchers continue exploring those possibilities for the future, policymakers would do well to make human milk and human milk-based fortifiers more widely available to the infants and preemies who could benefit from them now.

References:

1. <https://www.statnews.com/2018/12/18/breast-milk-therapeutics/>
2. <http://whitehead.cheme.cmu.edu/research.html>
3. <https://www.bcm.edu/news/pediatrics/mothers-milk-neonatal-rotavirus-infection>

*The authors have no relevant disclosures.*

NT



Susan Hepworth  
Director  
National Coalition for Infant Health  
1275 Pennsylvania Ave. NW, Suite 1100A  
Washington, DC 20004  
[info@infanthealth.org](mailto:info@infanthealth.org)



Mitchell Goldstein, MD  
Professor of Pediatrics  
Loma Linda University School of Medicine  
Division of Neonatology  
Department of Pediatrics  
[mgoldstein@llu.edu](mailto:mgoldstein@llu.edu)

### 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.

**NCfIH** National Coalition  
for Infant Health

Protecting Access for Premature Infants through Age Two

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



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

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

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

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## NEW YEAR'S RESOLUTIONS PREEMIE PARENT STYLE

AS I BEGIN 2019 I RESOLVE TO MAKE THIS YEAR THE BEST YEAR YET FOR MY PREEMIE AND MY FAMILY.

### MY RESOLUTIONS:

I WILL REMIND MYSELF THAT I AM THE EXPERT OF MY PREEMIE.

I WILL FOCUS ON WHAT MY PREEMIE IS DOING WELL RIGHT NOW AND CELEBRATE IT.

I WILL NOTICE WHEN SOMETHING IS A CHALLENGE FOR MY PREEMIE AND ADVOCATE FOR HIM/HER.

I WILL BE A STRONG ADVOCATE FOR MY PREEMIE IN THE NICU, AT HOME, AT SCHOOL AND BEYOND.

I WILL ADVOCATE FOR MY CHILD DURING RSV SEASON, GIVING A VOICE TO HIM/HER.

I WILL RESPECT DIFFERENCES OF OPINION WITH FAMILY AND FRIENDS BUT SEEK OUT MY OWN TRUTH IN REGARDS TO MY CHILD.

I WILL FOCUS ON EXTRA SELF-CARE THIS YEAR AS I NEED TO BE THE BEST I CAN BE FOR MY BABY. I WILL CONSIDER GETTING THERAPY TO HEAL THE TRAUMA OF HAVING A PREEMIE.

I WILL DO WHAT I CAN TO PROVIDE MY PREEMIE WITH BREASTMILK BUT KNOW THAT IN THE END THAT SELF-CARE IS VITAL.

I WILL UNDERSTAND THAT BREASTFEEDING IS NOT ALWAYS DOABLE AND EVEN PUMPING CAN BE A HUGE CHALLENGE FOR MANY. I WILL CELEBRATE JUST TRYING COUNTS.

I WILL REACH OUT TO A PREEMIE ANGEL PARENT BY PHONE, BY EMAIL, BY SOCIAL MEDIA AND SAY THEIR ANGELS' NAME BECAUSE WE ARE ONE COMMUNITY, ONE FAMILY ALWAYS.

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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: The Expert Deposition: Part 2: The Day Of....

Jonathan Fanaroff, MD, JD and Gilbert Martin, MD

Depositions are a key aspect of the Discovery process, which simply refers to all of the pretrial activities in a civil lawsuit. In the last Medicolegal Forum we discussed the importance of preparation for a deposition. This column will focus on the actual deposition – what to expect and how to behave.

Where and When is the deposition held?

You will receive a subpoena listing the date, time, and location of the deposition. They are not held at the court, but at a location determined by the lawyers involved in the case. It may be at a law office, a court reporter's office, or at the hospital. You do have some input with scheduling and should schedule the deposition with adequate time to prepare.

Who will be at the deposition?

There may be a number of people present at the deposition. The plaintiff's lawyer will be there and in many Obstetric and Neonatal malpractice cases there are multiple defendants, each with their own lawyers. The plaintiff (often the baby's parents) who have filed the lawsuit may attend as well. Additionally there will be a Court reporter and a videographer if the deposition is videotaped, which is often the case. It is not unusual to have some lawyers present and others participate via telephone or video conferencing.

Is there a 'dress code' and a "behavior code"?

While you may or may not be videotaped and you are not meeting the Queen, appropriate dress and behavior is important. Conservative dress is recommended, as is professional behavior at all times. Similar to a job interview you are being evaluated at all times for your potential impact on a jury, so annoying habits like chewing gum or checking your phone every five seconds will be noted by opposing counsel. Your attorney can make suggestions regarding any of your distracting mannerisms which can be interpreted as nervousness to the jury. Image is extremely important. Focus directly on the attorney asking the questions. Electronic equipment (cell phones, pagers) should be turned off. Speak directly into the microphone. Do not appear impatient and be aware of your non verbal behavior.

---

***“ Speak directly into the microphone. Do not appear impatient and be aware of your non verbal behavior.”***

---

What should I do at the Deposition?

1. TELL THE TRUTH – remember you are under oath just as if you were in a courtroom. The attorney questioning you is not under oath and can make untrue statements. Think of your testimony as if you were meeting a person for the first time. Simple yes or no answers are often the preferred way of answering questions. Truthfulness and humble answers are uniformly best.

2. ANSWER WHAT YOU KNOW – “I don't know” or “I don't remember” are perfectly acceptable answers and preferable to guessing. The more the expert witness tries to avoid sim-

ply saying, I don't know, is unreasonable since there are many questions that can be asked and not answered simply. Avoid using “hedge words”. These include, it's possible or I think so. It is better to use the word “probability” rather than “possibility”. Seasoned attorneys will often ask a compound question and stipulate a “yes” or “no” answer. If the question is compound you do not want to agree or disagree with the entire question. Your attorney should be able to object if necessary.

3. LISTEN CAREFULLY TO THE QUESTION – How you answer the question matters. If you don't understand the question, ask for clarification. If you don't remember the question, ask for it to be repeated. Pay particular attention to hypothetical questions and compound questions. Opposing counsel may repeat the same question over and over again with different syntax or grammar. This can be annoying to the expert witness who oftentimes becomes impatient and upset. If the opposing attorney notes that you are becoming frustrated the questions may become even more hostile. If you remain calm and speak effectively the attorney may look like a “bully” to the jury. Sometimes some of the questions and your answers can be embarrassing:

Question: Isn't it true that you earned over \$800,000 last year in expert fees?

Answer: I am not sure.

Question: Isn't it true that you did not pass your certification examination until the third attempt?

Answer: Yes

These simple questions are embarrassing but under law they are permissible.

4. ANSWER ONLY WHAT IS ASKED – Lawyers rarely ask questions at a deposition that they don't already know the an-



swer. But the attorney has a narrow understanding of the science, and the expert has more “expertise”. It is usually incorrect to volunteer information for it can later lead to a new line of questioning. However, you can bring out the limitations of the attorneys knowledge by careful responses.

Question: You know that baby Thompson was suffering from the neonatal abstinence syndrome and should have been transferred from your community hospital to an academic center where the care would have been more complete. Isn't that true?

Answer: No

Question: What do you mean “no”? Care is uniformly better at an academic center. Isn't that true? Answer: That is a broad statement and not always correct.

Question: Let's go back to your first answer about not transferring the infant from your community hospital to an academic center for treatment of the neonatal abstinence syndrome.

Answer: Sir, with all due respect, studies have shown that there are no significant differences in infants managed in a community hospital compared with academic centers. The use of standardized protocols has erased any potential difference.

5. LISTEN CAREFULLY TO YOUR ATTORNEY'S OBJECTION – Your attorney is not allowed to speak with you privately after a question has been asked, so an objection may be directed at you as well as opposing counsel. For this reason you should pause briefly before answering the question to give your attorney a chance to object. This pause is critical for if there is an objection, stop testifying and let the attorneys bicker and leave you out. Often the expert will have extra time because of the objection process to formulate a better answer.

6. GOING “OFF THE RECORD” – Off the record simply means that the court reporter is no longer recording what is being said. It doesn't mean that if you offer statements off the record that they cannot be used against you.

7. KEEP YOURSELF COMFORTABLE – If you don't feel com-

fortable you won't look comfortable! You are welcome to ask for breaks anytime as long as there is not a question pending. Take water and bathroom breaks as needed, generally at least once an hour for a few minutes. If the deposition is long, stop for lunch or a snack to keep your energy up.

8. BE PLEASANT, CONFIDENT & COOPERATIVE – portions of a videotaped deposition may be played for the jury at trial in an effort to discredit your testimony. How you say it is as important as what you say. Do not demonstrate exasperation at the question or appear bored. Opposing counsel is always interested in the manner of your response to questions; often your response is more important than the answer itself. Confidence is paramount but arrogance is not. Remember that the expert witness is offering an opinion based-upon expertise in the subject matter. The expert witness is not an advocate.

9. SHOW UP PREPARED – Depositions are generally not pleasant. Preparation with your attorney will help decrease anxiety and give you an idea of what to expect. It is best to over prepare rather than to appear complacent.

*The authors have no conflicts of interests to disclose.*

**NT**

*Corresponding Author:*



*Jonathan Fanaroff, MD, JD, FAAP  
Professor of Pediatrics  
Case Western Reserve University School of Medicine  
Director, Rainbow Center for Pediatric Ethics  
Rainbow Babies & Children's Hospital  
Cleveland, Ohio  
Jonathan.Fanaroff <jmf20@case.edu>*



*Gilbert I Martin, MD, FAAP  
Division of Neonatal Medicine  
Department of Pediatrics  
Professor of Pediatrics  
Loma Linda University School of Medicine  
gimartin@llu.edu  
Office Phone: 909-558-7448*

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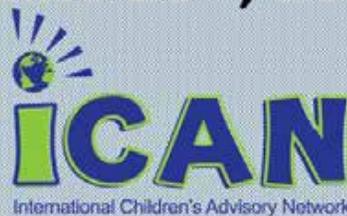
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# Monthly Clinical Pearl: What Do You Mean He Has an Intraventricular Hemorrhage??

Joseph R. Hageman, MD

It was 1983, and it was my first time instilling surfactant, and everything had gone so well. This 24-week gestation male infant had weaned to room air and CPAP, and we were starting gastric tube feedings. My colleague, Elaine Farrell, brought the portable ultrasound machine around to screen each at-risk infant for evidence of periventricular/intraventricular hemorrhage (PVH/IVH) as per the recommendations of Luann Papille and co-authors (1). I still remember thinking “this baby cannot have, does not have, a PVH/IVH as he had not become acidotic or had a drop in his hematocrit! No problem, here Elaine....” Then Elaine put the probe on his anterior fontanelle and scanned him and said “Joe, he has a grade II IVH” .... Wow was I surprised and immediately felt defensive.

***“This was the beginning of our awareness of the fact that our very low birthweight infants, even if they received surfactant and did not develop respiratory distress syndrome (RDS) were still at risk for PVH/IVH (1).”***

This was the beginning of our awareness of the fact that our very low birthweight infants, even if they received surfactant and did not develop respiratory distress syndrome (RDS) were still at risk for PVH/IVH (1).

Since that time, the pathophysiology of PVH/IVH has been characterized and is felt to involve an element first of ischemia, then, increased passive perfusion because of impaired cerebrovascular autoregulation in the preterm infant (2). The focus of these hemorrhagic lesions is in the periventricular germinal matrix with its fragile vascular network (2). The grading system proposed by Papille et al. has stood the test of time and is still used clinically in many hospitals. The only difference in the sequence of pathophysiology is in the grade IV PVH, which is now felt to be a venous hemorrhagic infarction in the drainage area of the periventricular terminal vein (2,3).

The questions we had then and clinicians and families ask now is “Is there anything we can do treat this and what does this mean for this infant’s long-term outcome?”. Once the hemorrhage has occurred, close monitoring of the infant’s neurological status,

growth, and head circumference are really important, especially if the hemorrhage is Grade III or IV. Also, screening head ultrasounds are an important way to monitor resolution or for the development of post-hemorrhagic hydrocephalus (PHH) (2,3). Management of Grade III IVH has included serial lumbar punctures and the placement of a ventricular reservoir; however, a recent Cochrane collaboration evaluation by Whitelaw and Lee-Keeland failed to demonstrate any improvement in long-term neuro-developmental outcomes over conservative management (4).

The additional question to ask is “Is there anything we can do to prevent this in our babies in the future?” For the future, Prevention can continue to be achieved with antenatal corticosteroids and some studies have shown prevention with postnatal indomethacin prophylaxis (2). In addition to pharmacological strategies, researchers are spending time focusing on genetic and environmental approaches.

#### References:

1. Papille LA, Burstein J, Burstein R, Koffler H. Incidence and evolution of subependymal and intraventricular hemorrhage in infants with birthweights less than 1500 g. *J Pediatr*. 1978;92:529-534.
2. MacKendrick W, Hageman JR, Zaritzky M. Hemorrhagic and ischemic brain injury in the preterm infant. In Hoenig JD, Chu A, Hageman JR (eds). *Essential Guide to Clinical Neonatology*. New York, Nova Scientific Publishers, 2017, pp.289-298.
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The author has identified no conflicts of interest.

NT

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Please submit your manuscript to: [LomaLindaPublishingCompany@gmail.com](mailto:LomaLindaPublishingCompany@gmail.com)

Corresponding Author



Joseph R. Hageman, MD  
Senior Clinician Educator  
Pritzker School of Medicine  
University of Chicago  
MC6060  
5841 S. Maryland Ave.  
Chicago, IL 60637  
Phone: 773-702-7794  
Fax: 773-732-0764  
[jhageman@peds.bsd.uchicago.edu](mailto:jhageman@peds.bsd.uchicago.edu)

Clinical Pearls are published monthly.

Submission guidelines for "Clinical Pearls":

1250 word limit not including references or title page.

May begin with a brief case summary or example.

Summarize the pearl for emphasis.

No more than 7 references.

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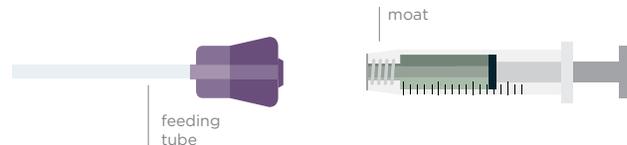
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# Letters to the Editor

From: Aaron Reed <areed@ssgfo.com>  
Sent: Thursday, 12/20/2018 3:19 PM  
To: LomaLindaPublishingCompany@gmail.com  
Subject: Good Afternoon - Quick Question

Good afternoon

Just wondering about our amazing newsletter. How does one go about submitting an article? Do you feature neonatology related companies? We are a new startup developing a revolutionary new incubator system for Premies in the hospital NICU. Our website features a lot more information that I can post on this email. See [www.amnion.life](http://www.amnion.life)

Look forward to hearing from you.

Sincerely  
Aaron Reed

---

From: Loma Linda Publishing Company <lomalindapublishing-company@gmail.com>

Sent: Thursday 12/20/2018 4:06 PM

To: 'Aaron Reed' <areed@ssgfo.com>

cc: Andrea Goodman <andrea.schwartzgoodman@neonatology-today.net>

Subject: RE: Good Afternoon - Quick Question

Aaron,

We are happy to consider any manuscript provided to us. We do have a peer review process. Industrial support or sponsorship does not disqualify a publication from acceptance, but we are mindful of making sure that what we publish is evidence-based. That said, disclosure is required but not used in a negative way. We are entirely open access in the real sense. There is no charge to publish even with extensive color graphics, and we never charge a fee for subscriptions.

We look forward to your input and support.

We are ad and grant supported. I have cc'd this to Andrea Good-



# 99nicu

man who will be happy to work with you should this be an option. That said, we will be publishing your press release from the link that you sent me as a news item for the January issue.

Sincerely,

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

Mitchell Goldstein, MD  
Editor in Chief

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c/o Mitchell Goldstein, MD  
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](mailto:LomaLindaPublishingCompany@gmail.com).

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**Erratum (Neonatology Today November, 2018)**

Neonatology Today has not identified an erratum affecting the December, 2018 edition. Corrections can be sent directly to [LomaLindaPublishingCompany@gmail.com](mailto:LomaLindaPublishingCompany@gmail.com). The most recent edition of Neonatology Today including any previously identified erratum may be downloaded from [www.neonatologytoday.net](http://www.neonatologytoday.net).

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Mitchell Goldstein, MD  
 Professor of Pediatrics  
 Loma Linda University School of Medicine  
 Division of Neonatology  
 Department of Pediatrics  
[mgoldstein@llu.edu](mailto:mgoldstein@llu.edu)



*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 misma o al bebé
- Distanciamiento de amigos y familiares

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

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

- La salud de la madre
- La capacidad para cuidar de un bebé y sus hermanos
- El sueño, la alimentación y el comportamiento del bebé a medida que crece<sup>2</sup>

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

**NCJH National Coalition for Infant Health**  
[www.infanthealth.org](http://www.infanthealth.org)

<sup>1</sup>American Psychological Association. Accessed on <http://www.apa.org/pressroom/resources/healthcare/postpartum-depression.aspx>  
<sup>2</sup>National Institute of Mental Health. Accessed on <http://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml>  
<sup>3</sup>Journal of Perinatology (2015) 35, 525–526. doi:10.1097/01.jp.0000000000000000  
<sup>4</sup>Prevalence and risk factors for postpartum depression among women with preterm and low birth-weight infants: a systematic review. Virgés SN, Villegas L, Cisneros CL, Roca EE. BJOG. 2016 Apr; 113(5):540-50.

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[www.cme.hsc.usf.edu](http://www.cme.hsc.usf.edu) or

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### Publication

Mitchell Goldstein, MD

Loma Linda Publishing Company

11175 Campus Street

Suite #11121

Loma Linda, CA 92354

[www.NeonatologyToday.net](http://www.NeonatologyToday.net)

Tel: +1 (302) 313-9984

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

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Mitchell Goldstein, MD

Neonatology Today

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[LomaLindaPublishingCompany@gmail.com](mailto:LomaLindaPublishingCompany@gmail.com)  
[MGoldstein@llu.edu](mailto:MGoldstein@llu.edu)  
Professor of Pediatrics  
Loma Linda University School of Medicine  
Division of Neonatology, Department of Pediatrics  
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T. Allen Merritt, MD - Senior Associate Editor for Contributions & Reviews  
[AllenMerritt.md@gmail.com](mailto:AllenMerritt.md@gmail.com)  
Professor of Pediatrics  
Loma Linda University School of Medicine  
Division of Neonatology, Department of Pediatrics  
Loma Linda University Children's Hospital



Larry Tinsley, MD - Senior Managing Editor  
[LTinsley@llu.edu](mailto:LTinsley@llu.edu)  
Associate Professor of Pediatrics  
Division of Neonatology-Perinatal Medicine  
Loma Linda University Children's Hospital



Anamika Banerji, MD, MS - Fellowship Editor  
[Abanerji@llu.edu](mailto:Abanerji@llu.edu)  
Assistant Professor of Pediatrics  
Associate Program Director, Neonatal-Perinatal Fellowship  
Division of Neonatology-Perinatal Medicine  
Loma Linda University Children's Hospital



Munaf Kadri, MD - International Editor  
[MKadri@llu.edu](mailto:MKadri@llu.edu)  
Executive Board  
UMMA Clinic  
Los Angeles, CA  
Assistant Professor Loma Linda  
Loma Linda University Children's Hospital



Michael Narvey, MD - Canada Editor  
[MNarvey@exchange.hsc.mb.ca](mailto:MNarvey@exchange.hsc.mb.ca)  
Section Head of Neonatology  
Children's Hospital Research Institute of Manitoba



Joseph R. Hageman, MD - Clinical Pearls Editor  
Senior Clinician Educator  
Pritzker School of Medicine  
University of Chicago  
[jhageman@peds.bsd.uchicago.edu](mailto:jhageman@peds.bsd.uchicago.edu)



Clara Song, MD - Social Media Editor  
Assistant Professor of Pediatrics, Children's Hospital at OU Medical Center  
University of Oklahoma Health Sciences Center  
[clara-song@ouhsc.edu](mailto:clara-song@ouhsc.edu)



Thomas A Clarke, MD - Western Europe Editor  
[tclarke347@gmail.com](mailto:tclarke347@gmail.com)  
Emeritus Consultant in Neonatology  
The Rotunda Hospital,  
Dublin, Ireland



Jan Mazela, MD - Central Europe Editor  
[janco@pol-med.com.pl](mailto:janco@pol-med.com.pl)  
Associate Professor  
Poznan University of Medical Sciences  
Poznan, Greater Poland District, Poland



Stefan Johansson, MD PhD - Scandinavian Editor  
[stefan.johansson@99nicu.org](mailto:stefan.johansson@99nicu.org)  
Consultant Neonatologist, Sachs' Childrens Hospital  
Associate Professor, Karolinska Institutet  
Stockholm, Sweden



Francesco Cardona, MD - European Editor at Large  
[francesco@99nicu.org](mailto:francesco@99nicu.org)  
Consultant, Medical University of Vienna  
Department of Paediatrics and Adolescent Medicine  
Vienna, Austria



Andrea Schwartz Goodman, MSW, MPH  
Senior Editorial Project Director  
[Andrea.SchwartzGoodman@NeonatologyToday.net](mailto:Andrea.SchwartzGoodman@NeonatologyToday.net)  
Washington, D.C.



Herbert Vasquez, MD - Arts Editor  
[VasquezH1@gmail.com](mailto:VasquezH1@gmail.com)  
Associate Neonatologist  
Citrus Valley Medical Center, Queen of the Valley  
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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.

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This month's selection is from Dr. Gilbert Martin. The cartoon displayed is of something we as Neonatologists are often accused of. Although we must be practice and evidenced based in our approach, there may still be some place for "unrestrained therapeutic exuberance."

Herbert Vasquez, MD



Associate Neonatologist  
 Queen of the Valley Campus  
 Citrus Valley Medical Center  
 West Covina, CA  
 VasquezH1@gmail.com

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### Manuscript Submission: Instructions to Authors

1. Manuscripts are solicited by members of the Editorial Board or may be submitted by readers or other interested parties. Neonatology Today welcomes the submission of all academic manuscripts including randomized control trials, case reports, guidelines, best practice analysis, QI/QA, conference abstracts, and other important works. All content is subject to peer review.

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

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

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

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

6. An abstract may be submitted.

7. The main text of the article should be written in formal style using correct English. The length may be up to 5,000 words. Abbreviations which are commonplace in neonatology or in the lay literature may be used.

8. References should be included in standard JAMA format. Bibliography Software should be used to facilitate formatting and to ensure that the correct formatting and abbreviations are used for references.

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

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