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Indication

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

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 NO₂ 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 PaO₂, inspired NO₂, 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.

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†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.





INOmax[®] (nitric oxide gas)

Brief Summary of Prescribing Information

INDICATIONS AND USAGE

Treatment of Hypoxic Respiratory Failure

INOmax® 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_2) forms in gas mixtures containing NO and O_2 . Nitrogen dioxide may cause airway inflammation and damage to lung tissues.

If there is an unexpected change in NO_2 concentration, or if the NO_2 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_2 analyzer should be recalibrated. The dose of INOmax and/or FiO_2 should be adjusted as appropriate.

Worsening Heart Failure

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

ADVERSE REACTIONS

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

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

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

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

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

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

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

DRUG INTERACTIONS

Nitric Oxide Donor Agents

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

OVERDOSAGE

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

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

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Fellows Column: Servo Pressure Relationship in High-Frequency Jet Ventilation in Neonates

Anita Chadha Patel, MD FAAP, Carter Tong, BSRT, RRT-NPS, Mitchell Goldstein, MD FAAP

Introduction:

High-Frequency Jet Ventilation (HFJV) is a form of mechanical ventilation that was first established by Bert Bunnell, ScD, in the late 1900s. The HFJV became FDA approved for use in neonates in 1988. It has been shown to improve oxygenation and ventilation in premature neonates with respiratory distress syndrome, bronchopulmonary dysplasia, or evolving chronic lung disease, as well as in neonates with air leak syndromes. (1-4)

Understanding the principles through which the HFJV works is integral to understanding servo pressure and its variability. First, fresh, inspired gas actively jets down the center of the airway in a laminar fashion. It does so at very high rates, ranging anywhere from 240—660 beats per minute (bpm). By employing high rates, the HFJV utilizes very small tidal volumes, approximating 1mL/kg. The inspired gas travels down the center of the airway in a laminar fashion, where resistance to flow is lowest. In doing so, effective dead space volume becomes reduced, as only a portion of the anatomic dead space is being used. This process represents active inhalation from the HFJV.(5-7)

Following this active process, passively expired gas exits around the circumference of the airway walls in an annular fashion. Exhilation utilizes the path of least resistance, by making use of the "unused" dead space path, around the center of the highly accelerated inspired gas. The cumulative effect facilitates mucociliary clearance in the airways. (5, 7, 8) Exhalation from the HFJV is passive, as demonstrated in Figure 1.

The advantage of this type of ventilation strategy is threefold. First, the HFJV allows one to effectively ventilate and oxygenate at lower mean airway pressures than that required for conventional ventilation. Second, the use of smaller tidal volumes permits an ability to use higher positive end-expiratory pressure (PEEP) to optimize oxygenation. Higher PEEP use in HFJV has been associated with improving lung compliance and reducing ventilator

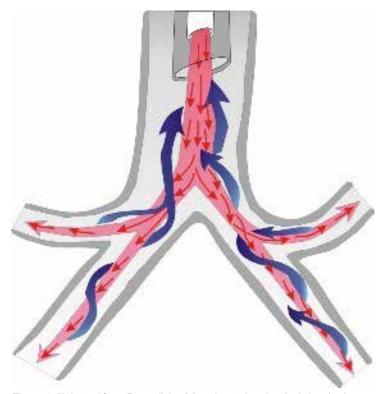


Figure 1: [Adapted from Bunnell, Inc] Accelerated and actively inspired gas travels down the center of the airway in a laminar fashion, as demonstrated in red. Passively expired gas then exits in an annular fashion around the circumference of the airway, as demonstrated in blue.

requirements. Finally, with smaller tidal volumes, lung compliance has less of an influence on gas distribution within the lungs. (7, 9-11). Progressing to the right in figure 2, at higher PEEP, this volume increases further, with a higher risk of ongoing lung injury within the volutrauma zone. In contrast, with HFJV, the smaller tidal volumes at higher rates remain to allow ventilation with ad-

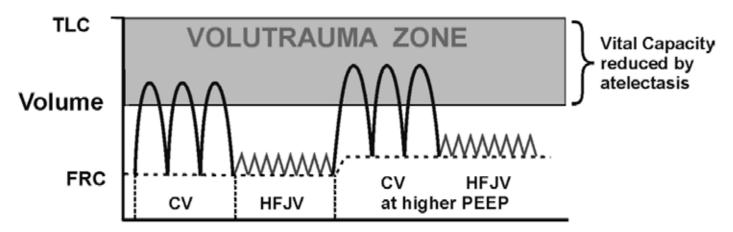


Figure 2: [Adapted from Bunnell, Inc] A conventional lung volume curve is depicted with examples of Conventional Ventilation (CV) and HFJV. As demonstrated from left to right, when ventilating to optimize Functional Residual Capacity (FRC), tidal volumes for CV are high, beyond the limits of physiologic tidal volume (TV) and risking volutrauma and subsequent lung injury, (reaching the limits of Total Lung Capacity (TLC) and reducing vital capacity).

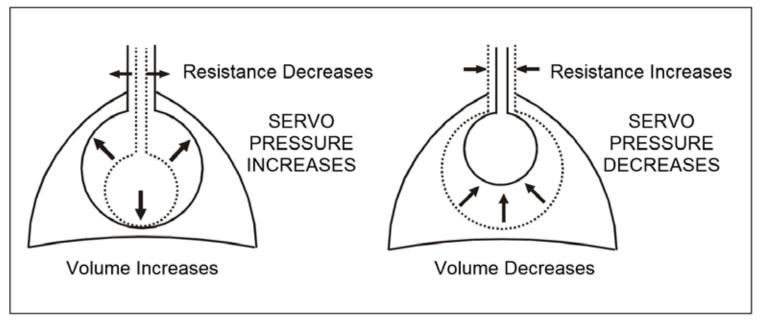


Figure 3: [Adapted from Bunnell, Inc.] Servo pressure, as affected by airway resistance and lung volumes. On the left, note that servo pressure increases as airway resistance decreases and/or while compliance is high or lung volumes increase. On the right, note that servo pressure decreases as airway resistance increases and/or while compliance is low or lung volumes decrease.

equate FRC and within a physiologic TV range, allowing us to manipulate PEEP at higher values. With higher PEEP, TV remains within a safe physiologic zone, allowing adequate ventilation as well as optimal oxygenation without risking the volutrauma seen with CV.

"The advantage of this type of ventilation strategy is threefold. First, the HFJV allows one to effectively ventilate and oxygenate at lower mean airway pressures than that required for conventional ventilation. Second, the use of smaller tidal volumes permits an ability to use higher positive end-expiratory pressure (PEEP) to optimize oxygenation. Higher PEEP use in HFJV has been associated with improving lung compliance and reducing ventilator requirements. Finally, with smaller tidal volumes, lung compliance has less of an influence on gas distribution within the lungs. (7, 9-11)"

Servo pressure (SP) in HFJV is the driving pressure required to regulate flow. SP automatically rises and falls to ensure that the positive inspiratory pressure (PIP) dialed into the ventilator is delivered, despite changes in a neonate's lung mechanics. In general, increased resistance and decreased compliance generate lower SP. In contrast, decreased resistance and increased compliance generate higher SP. (12) Lung volumes also affect servo

pressure, as demonstrated in Figure 3.

Hypothesis:

Servo pressure variability in HFJV has not previously been studied. We attempted to study changes in servo pressures for variable compliance at different pressures and rate settings in a lung model. We predicted that a relationship exists for servo pressure changes at variable settings and variable lung volumes.

Methods:

For this investigation, the HFJV Model 203 was utilized. Lung models with different compliance were predicated by utilizing









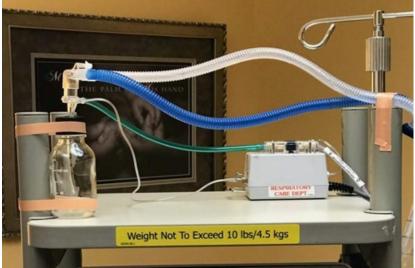


Figure 4: From left to right in a clockwise direction (a-d): A. HFJV connected to test lung model predicated by a glass bottle, via ETT and ETT adapter. B. Test lung with bottle cap sealed to ETT and connected via ETT adapter. C. Silicone gel dried in inside of bottle cap to ETT to ensure no air leak in the system. D. Test lung connected via ETT adapter to tubing attached to HFJV.

sealed glass bottles at different volumes (150 mL and 500 mL volumes). Each glass bottle represented a different lung volume. For this study, it was presumed that higher lung volumes contributed to increasing compliance for each lung model. 4mm holes were drilled into the bottle caps of each glass container. A 3.5-mm endotracheal tube (ETT) was sealed into the bottle cap using silicone gel, which, once dried, guaranteed no air leak. The ETT was then connected to the ETT adapter and subsequently connected to HFJV. See Figure 4. HFJV settings were adjusted, and subsequent SP recorded for each test lung model at 150 mL and 500 mL. Settings used included PEEP of 10-15, PIP from 20-40 at intervals of 4, rates at 240, 300, 360, 400 and 420, and with a fixed inspiratory time of 0.020 seconds.

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Additionally, Inspiratory-to-expiratory ratio (I:E ratio), change in pressure (Delta-P), and mean airway pressure (MAP) were also recorded. Data sets were mapped in graphical form using Statistica® Software Technology. Data were modeled to predict SP at each of the settings.

Results:

At the 150 mL lung volume, representative of lower lung compliance, when PEEP and rate were fixed, incremental increases in

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PEEP:	PIP:	Rate:	l- time	SERVO PRESSURE	<i>P-</i> value
10 – 15	20 - 40	240 – 420	(0.02	TREGOGRE	
(10, 11, 12, 13, 14, 15)	(20, 24, 28, 32, 36, 40)	(240, 300, 360, 400, 420)	sec)		
Fixed	Fixed	Incremental increase	Fixed	1 – 4.2	0.88
Fixed	Incremental increase	Fixed	Fixed	0.9 – 4.7	<0.0001
Incremental increase	Fixed	Fixed	Fixed	1.1 – 4.3	<0.00001

Figure 5: As depicted in the table above, each measured parameter from the HFJV is listed with its subsequent SP, i-time, and p-values for 150 mL lung volume. Note the increasing statistical significance that increases in PIP and PEEP have on SP

PEEP:	PIP:	Rate:	l- time	SERVO PRESSURE	<i>P</i> -value
10 – 15	20 - 40	240 – 420		PRESSURE	
(10, 11, 12, 13, 14, 15)	(20, 24, 28, 32, 36, 40)	(240, 300, 360, 400, 420)	(0.02 sec)		
Fixed	Fixed	Incremental increase	Fixed	1.8 – 8.5	0.88
Fixed	Incremental increase	Fixed	Fixed	2.1 – 9.2	<0.0001
Incremental increase	Fixed	Fixed	Fixed	1.9 – 8.6	<0.00001

Figure 6: As depicted in the table above, each measured parameter from the HFJV is listed with its subsequent SP, i-time, and p-values for 500 mL lung volume. Note the increasing statistical significance that increases in PIP and PEEP have on SP.

PIP led to increasing SP ranging from 0.9-4.7, which reached statistical significance (p = <0.0001). When rate and PIP were fixed, incremental increases in PEEP led to further significant ranges in SP from 1.1-4.3 (p = <0.00001). However, when PEEP and PIP were fixed, incremental increases in rate led to only modest changes in SP that were not statistically significant (p = 0.88). See Figure 5.

At the 500 mL lung volume, representative of higher lung compliance, when PEEP and rate were fixed, incremental increases in PIP led to increasing SP ranging from 2.1 – 9.2, which reached statistical significance (p = <0.0001). When rate and PIP were fixed, incremental increases in PEEP led to further significant ranges in SP from 1.9 – 8.6 (p = <0.00001). However, when PEEP and PIP were fixed, incremental increases in rate led to only modest changes in SP that were not statistically significant (p = 0.88). See Figure 6.

Furthermore, when datasets were mapped out into graphical form, using Statistica® Software Technology, planar 3-Dimensional graphs were formulated, each categorized by rate, with SP depicted for the variable PIP and PEEP. Note that the x-axis represents PIP, the y-axis represents PEEP, and SP are depicted on the z-axis. See Figure 7 –11 for summary graphs representing lung volumes comparing 150 mL and 500 mL, respectively. Also note the change in colors on each graph as they represent changes in quantitative SP values, for each variable PIP and PEEP setting.

In addition to mapping out datasets in graphical form, a quantitative relationship was calculated based on the relationship changes for servo pressure at each of the settings tested. This resultant calculation for servo pressure was generated for each dataset and shown above each summary graph, in Figures 7-11.

Servo-Pressure (150mL) =
$$-2.7602 + 0.1281x + 0.228y + 0.0004x^2 - 0.0038xy - 0.0051y^2$$

Servo-Pressure (500mL) = $-2.2726 + 0.2007x + 0.1925y - 3.4265$

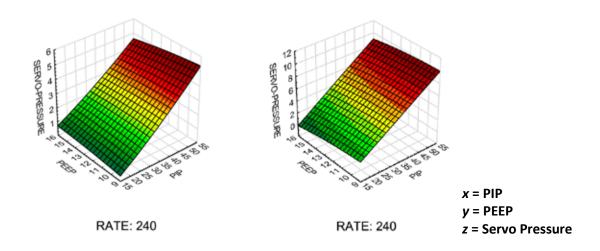


Figure 7: 3-Dimensional planar graphs for lung volumes at 150 mL (left) compared to 500 mL (right) for Rate at 240 bpm. Note the quantitative calculation for SP generated based on these results.

Servo-Pressure (150mL) = $-2.2041 + 0.1439x + 0.1073y + 0.0002x^2 - 0.004xy - 0.0004y^2$ Servo-Pressure (500mL) = $-1.4741 + 0.2033x + 0.0521y + 0.0002x^2 + 0.0007xy - 0.0101y^2$

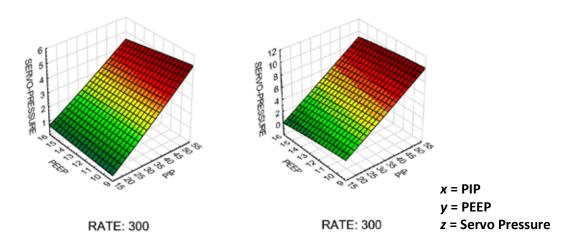


Figure 8: 3-Dimensional planar graphs for lung volumes at 150 mL (left) compared to 500 mL (right) for Rate at 300 bpm. Note the quantitative calculation for SP generated based on these results.

Servo-Pressure (150mL) = $-1.7579 + 0.132x + 0.0587y + 0.0004x^2 - 0.004xy + 0.0018y^2$ Servo-Pressure (500mL) = $-2.981 + 0.2115x + 0.2956y - 0.0003x^2 + 0.0029xy - 0.0232y^2$

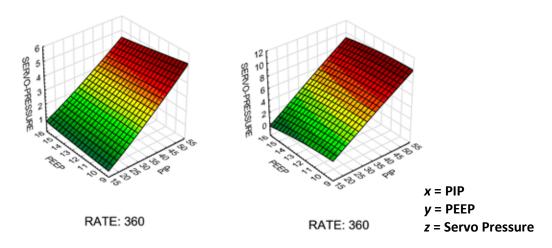


Figure 9: 3-Dimensional planar graphs for lung volumes at 150 mL (left) compared to 500 mL (right) for Rate at 360 bpm. Note the quantitative calculation for SP generated based on these results.

Servo-Pressure (150mL) = $-0.722 + 0.103x - 0.2936y + 0.0005x^2 - 0.0022xy + 0.0144y^2$ Servo-Pressure (500mL) = $-5.366 + 0.2344x + 0.5889y - 0.0004x^2 + 0.002xy - 0.0321y^2$

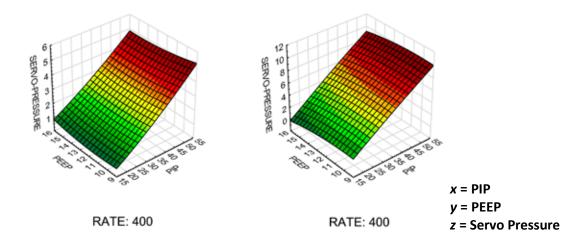


Figure 10: 3-Dimensional planar graphs for lung volumes at 150 mL (left) compared to 500 mL (right) for Rate at 400 bpm. Note the quantitative calculation for SP generated based on these results.

Servo-Pressure (150mL) = $-0.7505 + 0.1073x - 0.047y + 0.0004x^2 - 0.0021xy + 0.0037y^2$ Servo-Pressure (500mL) = $-6.0173 + 0.2565x + 0.6429y - 0.0005x^2 + 0.0008xy - 0.0331y^2$

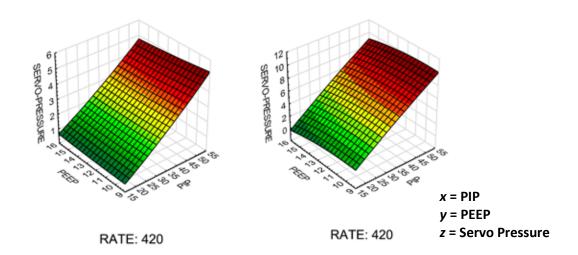


Figure 11: 3-Dimensional planar graphs for lung volumes at 150 mL (left) compared to 500 mL (right) for Rate at 420 bpm. Note the quantitative calculation for SP generated based on these results.

Discussion:

High-Frequency Jet Ventilation has been associated with significant improvement in ventilator outcomes when compared with conventional ventilation. (2, 6) In particular, it has been found to improve outcomes when lung disease is characterized by non-homogeneous parenchyma. (13) Although initially used for rescue mode ventilation strategies, HFJV has been shown to be applicable to transport and other scenarios where high-frequency ventilation is indicated. (10, 14, 15) There are certain situations where High-Frequency Jet Ventilation may outperform other oscillatory devices. (7) The evaluation of mean airway pressure, optimizing functional residual capacity is critical to the success of the modality. (3-6) Servo pressure is a method of quantifying High-Frequency Jet mean airway pressure in a way that may be important in defining optimal functional residual capacity.(1, 10-12, 16)

This study confirmed the presence of servo pressure variability. For example, low lung volumes were associated with lower SP. This relationship may potentially be representative of the presumed lower lung compliance at that lung volume. Similarly, high lung volumes were associated with higher SP. This relationship may also be based on presumed higher lung compliance at that higher lung volume. The limitation of this study in making this conclusion, however, is the presumption that larger lung volumes correlated with larger or increased compliance in the system. However, the inherent compliance of a glass bottle remains fixed and is not dynamic. This "static fixture" limits the conclusions we can

draw regarding compliance and its relationship with servo pressure. Future directions for a follow-up study may include developing a test lung model with dynamic compliance, rather than a fixed compliance system.

"An integral mathematical relationship does exist to calculate SP's, which enable adequate ventilation delivery at different lung volumes. This may be applied clinically if SP can be monitored and tracked during the time neonates spend on the HFJV."

Another limitation of this study is that airway resistance was a fixed parameter. A 3.5 mm ETT was utilized in carrying out this study, without any applied changes in this airway resistance. Therefore, changes in airway resistance were not studied against SP variability for this study. Future directions for a follow-up study may include changing the size, and hence, the resistance of the ETT while assessing servo pressure variability.

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An integral mathematical relationship does exist to calculate SP's, which enable adequate ventilation delivery at different lung volumes. This may be applied clinically if SP can be monitored and tracked during the time neonates spend on the HFJV. For impediments in ventilation or oxygenation, i.e., hypercapnea, RDS, or pneumothorax, SP can be assessed, and variable settings on HFJV can be predicated by utilizing the calculations obtained from this study. (12) However, more extensive clinical studies would first be required to evaluate this calculation and confirm its relationship in vivo.

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- QI/QA work, case studies, or a poster from a scientific meeting may be submitted..
- Submission should be from a resident, fellow, or NNP in training.
- Topics may include Perinatology, Neonatology, and Younger Pediatric patients.
- No more than 20 references.
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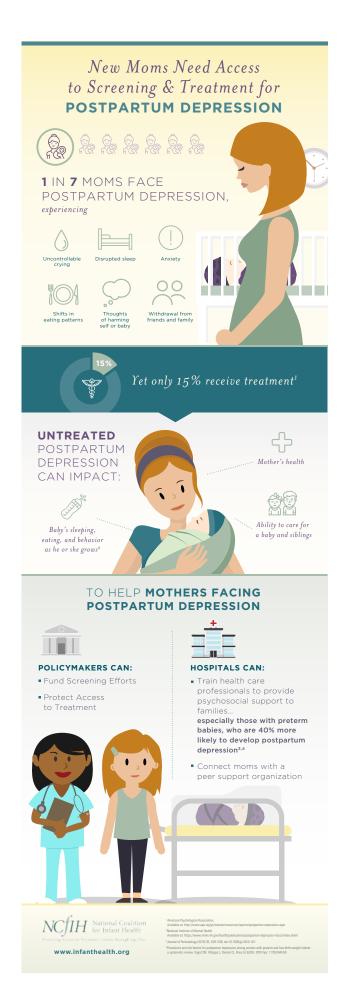
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What It's Like When Your Baby Has Died

Alison Jacobson



Saving babies. Supporting families.

Neonatology Today is proud to welcome First Candle as a regular monthly column. First Candle's efforts to support families during their most difficult times and provide new answers to help other families avoid the tragedy of the loss of their baby are without parallel.

My life is divided into two parts - before my son's death and after. Connor was my first child, and he died of Sudden Infant Death Syndrome (SIDS) at 3 months and 24 days. I barely remember the person I was. I do know that I was carefree and naive and at the same time arrogant. Arrogant to believe that unspeakable tragedy could only happen to other people. I credit Connor's death with making me empathetic - for recognizing that everyone has a story and if we open ourselves up to people, we connect through our vulnerabilities.

"Researchers now agree that the grief a parent experiences after the loss of a child is a type of PTSD. I was one of the lucky ones - I had the support of my community, family, friends, and coworkers. Others aren't as fortunate."

The time between his birth and death is also a blur – after all, it was only four short months. I remember the normal first-time mom anxieties of worrying how to hold him to give him his first bath. But I also remember quickly falling into a wonderful routine. His death was like a bomb exploding - it happened so quickly without any warning. What began as a perfectly ordinary day changed in a second with the phone call from the daycare provider who uttered one of only two sentences I remember from that day; "There's a problem with the baby. He's not breathing." After that, it was the chaos after the explosion, and all that was left was me standing in the rubble of my life.

As the CEO of First Candle, I speak to hundreds of bereaved parents - some within days of their baby's death and others many years later. (1) The new ones always ask me the same question - "When do you start feeling better?" There's never an easy answer to that. Again, it's similar to the bomb analogy. The initial pain and trauma thankfully don't last forever, but there are times when it comes back, such as seeing your friends' babies who are the same age your child would have been. The first birthday after your child has died and the first anniversary of his death is especially painful and instantly take a parent back to that day when life changed forever.

"October is Pregnancy and Infant Loss Awareness Month. It begins a time of the year that's sometimes unbearable for parents who have lost a baby. For some, they have one holiday with their baby, and the memories are bittersweet. For others, they were robbed of any holiday and live with the pain of unfulfilled dreams."

Researchers now agree that the grief a parent experiences after the loss of a child is a type of PTSD. I was one of the lucky ones - I had the support of my community, family, friends, and co-workers. Others aren't as fortunate. There are parents who, after their baby



has died, must deal with insensitive investigators and state workers and are forced to re-enact the time of death using a baby doll. Families face the reality of having their living children removed from their homes because they are suspected of abuse. Recovering from these experiences takes years and even decades.

For the first year after Connor's death, I wouldn't let anyone take a picture of me. I just couldn't bear to see how sad, old, and tired I looked. Physical ailments are common among bereaved parents. Grief causes our immune system to crash and induces chemical reactions in the body that can last over a long period of time.

- Digestive problems such as loss of appetite or overeating
- Sleepiness and sleeplessness
- Heartache and chest pain
- Forgetfulness and memory loss
- Cognitive changes including general confusion and difficulty concentrating
- Emotional changes including sadness, crying, and prolonged weeping
- Respiratory problems including shortness of breath and asthma
- Panic attacks; i.e., sweating, rapid heartbeat, numbness, and tingling
- Confusion with an associated feeling of loss of control or a feeling of "losing one's mind"

I became pregnant very quickly after Connor died, which was the right decision for our family, but my second son has intellectual disabilities, and to this day, I wonder if it's due to the stress of grief I was experiencing.

As a society, we're not good at dealing with grief, and it can ruin relationships. The rate of divorce is high among parents who have lost a baby. Men and women often express grief in different ways, and it's difficult to understand if a spouse appears not to care or shut down. We often receive calls from men who are afraid to grieve in front of their partner because they feel they need to be "the strong one." Months after my son died, a friend was talking about how exhausting it is to have a toddler. I felt like screaming that I wish I had the chance to be that exhausted and had difficulty getting over what I perceived as an insensitive and thoughtless comment.

October is Pregnancy and Infant Loss Awareness Month. It begins a time of the year that's sometimes unbearable for parents who have lost a baby. For some, they have one holiday with their baby, and the memories are bittersweet. For others, they were robbed of any holiday and live with the pain of unfulfilled dreams. Grief

comes at unexpected times – visiting malls and seeing children sitting on Santa's lap, hearing holiday carols, or even watching an especially touching commercial. I was one of the unlucky ones who never had a first holiday with my son. I recall deciding not to celebrate at all; it was just too painful. But at 6P on Christmas Eve, I changed my mind and decided to get a Christmas tree. It was as sad looking as I felt, the ultimate Charlie Brown Christmas tree. It was by no means a festive holiday, but it was a small glimmer of hope.

It's difficult for people to understand the choices a grieving parent makes or their behaviors. They don't make sense to us at times, either. All we know is that at first, we're angry, confused, sad, and numb. There's no timeline for how long these feelings last. Even when we begin emerging from the darkness of our initial grief, holidays and milestones can set us back. What we all need is patience and acceptance for how we choose to deal with our grief.

References:

1. http://www.firstcandle.org/

Disclosure: The author is the Chief Executive Officer of First Candle, Inc., a Connecticut not for profit 501c3 corporation.

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

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This activity has been approved for AMA PRA Category I CreditTM (MOC Part 2 credits pending.)



Breaking The News: Suggestions For Telling Parents That Their Baby Has Died, From A Bereaved Mother's Perspective

Nancy Maruyama, RN, BSN

Our first child and only son, Brendan, was born on a sunny June morning in 1985. Born full term, he weighed 8lbs 9oz with Apgar's of 9 & 10. He was the first grandchild on both sides. Our lives were perfect.

A mere 140 days later, on a rainy October morning, we experienced the worst day of our lives. I dropped Brendan off at the sitter's home at 7am. At 10am, I received a call that is every parent's worst nightmare. Our son was unresponsive. The sitter and I both called 911, and the paramedics arrived quickly to transport him to the nearest hospital ED.

I was working as an RN at a hospital in Chicago. As I yelled to a coworker to call my husband, I took off running to the parking structure. It was pouring rain as I drove like a maniac on the expressway to get to the hospital as fast as I could. I prayed. Praying that he was not dead, and praying to have the police stop me because I knew I should not have been behind the wheel.

In 1985, most nurses wore white uniforms, white hose, and clinic shoes. I had my name tag on that clearly identified me as a nurse. I ran to reception and when I asked for my son, I saw the color drain out of the ward clerk's face. I knew that it was not going to be good news, and her face confirmed my worst fears. I remember feeling faint and short of breath as I fell to my knees. I walked, with some assistance to "the room." You know the room. A room out of earshot of others waiting in the ED. A room that is painted a drab, pale green, that has no windows - only couches and a phone, where I waited for my husband and the doctor. Prior to my husband's arrival, the ED physician came and spoke briefly to me. He told me that they were working hard on our son and doing everything they could to resuscitate him. From seemingly out of nowhere, a chaplain appeared next to me. The doctor exited the room, as I waited for my husband and all of our family members. The chaplain did not speak, but sat next to me and held my hand until my husband arrived.

Once my husband arrived, the doctor came back in to talk with us. It was now past 1pm. Three hours had passed since Brendan arrived at the ED unresponsive. The doctor had a very kind face. He sat across from the two of us, placed his hands – one on my knee and the other on my husband's knee – looked us in the eye to tell us that they were doing all they could, however, Brendan arrived in asystole. I knew what that word meant, but at that moment, I could not comprehend what he was saying. I remember crying to him that he needed to save our baby regardless of how compromised he would

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be. He left the room only to come back to us a short time later to notify us that our son, Brendan, had died.

The events that followed really helped to set the way we would cope with our acute grief. A nurse brought us to Brendan. The room was cleared of all machines and resuscitation equipment. All of the tubes that had been placed in his body were removed. Brendan was wrapped in a warm blanket (a nurse had thoughtfully used a blanket from the warmer), and in a bassinet. Someone brought in a rocking chair to sit in while rocking Brendan. They dimmed the lights and closed the door for privacy. When I needed to take a moment, I passed by the nurses station. I cannot tell you their names, but I clearly remember the color of their hair. For a long time, I thought they had their heads down because they could not bear to look at me. I felt that I was a terrible mom. I was a nurse and I should have known that something was wrong. I thought if I had been home with him, instead of being back at work, I might have saved him. This is what I thought and felt every time I passed the nurses station. I realized later, that, because I was a nurse, they understood that they were not immune to loss, pain, or grief. They kept their heads down and hid behind their hair because there were tears in their eyes. By that time, our families had arrived and all had the opportunity to hold Brendan and say goodbye. I was not able to hold him; it was his body, but my son was gone. I have made my peace with that choice.

"The staff allowed us to stay with Brendan as long as we wished; there was no sense of urgency for us to leave. We received all of his belongings when we left, and we were so grateful for that gesture."

The staff allowed us to stay with Brendan as long as we wished; there was no sense of urgency for us to leave. We received all of his belongings when we left, and we were so grateful for that gesture. They were soiled with breast milk from the moment of death, but if you try to take it from me, there would be a fist-fight. Because we were young parents, we did not own a camera or a video camera. His belongings were really the only memento we have from that day.

Going home without him was unbearable. Later, I met a woman who, like us, had, experienced the death of her infant daughter years before. She was one of many people who held my hand and helped me to cope with Brendan's death.

Over the past 34 years since Brendan died, I have learned many things from newly bereaved parents that I want to share:

- Please use our child's name. He/she is not an it. To us, he/she is a thou.
- We know you are uncomfortable being with us; there is no way for us to make you more comfortable because we are in a nightmare. We are actually hoping for you to show us the way.
- Do not Hit and Run with the bad news. Please stay and allow

the parents to ask questions. Let them know what will happen next. Be prepared to repeat explanations several times. The parents will be in a fog. It is difficult to comprehend and absorb this tragic event.

- Use the dead words. Avoid passive words like lost, expired, or passed. As hard as it is for you to say dead and as hard as it is for us parents to hear it, it is crucial for us to be able to grasp what your meaning is.
 - o When we hear that you lost our baby, we immediately think that you put our baby on a gurney and have forgotten where you left him/her. We are trying to comprehend what it is you are saying. Also, please put up the side rails if the deceased baby is unattended on the gurney. This is important to the parents. We know that our baby won't roll off of the gurney, but it just feels wrong to us.
 - o Using the term expired sounds more like a library card and not a baby that has died.
- Please make eye contact (unless it is culturally inappropriate).
 Not making eye contact can be perceived that we are such horrid parents that you cannot stand to look at us. Please sit if we are sitting; hovering over us makes a terrible situation even more uncomfortable.
- Provide a private area or room where the family has access to a telephone while they are waiting. A staff member needs to check on family often while they are there.
- Give family permission to talk and express feelings. You are in a position of authority, and the parents will look to you for guidance
- Speaking to all family members or friends that are present will help to avoid miscommunication during this time of stress.
- Allow the family as much time as needed to hold, rock, and say goodbye to their child. A quiet room, free of resuscitation equipment, with a rocking chair and dimmed lighting is appropriate at this time.



- Explain what will happen next. Where will the baby's body be taken? When will they be able to see their child again? What about an autopsy? If the mother is breastfeeding at the time of the child's death, she will need information about how to handle this. Ask Social Services for resources that you can give the family regarding grief and bereavement support.
- Return all belongings to the family, even if they are soiled or cut.
 It is the parent's decision on whether or not to dispose of these items.
- Be prepared to answer..."Was my baby/child in pain?" "Did they suffer?" "Were they afraid?"
- Please do not try to find something positive in our loss. Avoid platitudes, religious dogma, or advice. Even if you are a bereaved parent, one can never truly know another's grief.
- It is ok to tell us that you are sorry for our loss. We know our baby's death is NOT YOUR FAULT. Your emotional side may feel a sense of responsibility because our baby could not be saved. Please be brave with us.
- Tears are also OK. There is truly nothing sadder than telling parents that their baby has died.
- Mementos are very important. A photograph, a hand or footprint, or a lock of hair will have tremendous meaning for the bereaved families. I have talked to many parents that wish they had a memento of their beloved baby, myself included.
- Families judge staff by their level of compassion as well as their medical skills. Make sure to care for yourself during stressful events. It is difficult to be present for anyone else if you do not refill your cup. Vicarious trauma is cumulative. Please remember: Physician Heal Thyself.

"It has been 34 years since our son was alive for 140 days. I believe he lived his whole life in 140 days: full tummy, love, kisses, dry diaper, hugs, and love, love, love. He has taught us many things about ourselves. He taught us not to take things for granted. He taught us that you never know what happens next. He taught us unconditional love."

It has been 34 years since our son was alive for 140 days. I believe he lived his whole life in 140 days: full tummy, love, kisses, dry diaper,

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hugs, and love, love, love. He has taught us many things about ourselves. He taught us not to take things for granted. He taught us that you never know what happens next. He taught us unconditional love.

His life and death brought me to my role in the universe. In time, we had two "rainbow" babies who are the lights of our lives. Sadly, they grieve for the brother they never knew. Brendan will always be our firstborn even though we hold him in our hearts and not in our hands. We often take family photos where one of us is holding his picture.

Please refer bereaved families to local support organizations. In Illinois, you can refer all infant deaths, birth to age one year, to Sudden Infant Death Services of Illinois, Inc. regardless of cause or manner of death. 1-800-432-7437 (SIDS) and www.sidsillinois.org. While we cannot take away their pain and suffering, we can walk alongside them and companion them through their intense grief.

Disclosure: The author has no disclosures.

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www.sidsillinois.org

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Nancy Maruyama, RN, BSN Mother of Brendan 6/1/85 – 10/18/85 SIDS Executive Director Sudden Infant Death Services of Illinois, Inc. 6010 State Route 53, Suite A Lisle, IL 60532 630-541-3901 office 630-541-8246 fax



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and provide the supporting evidence



*See the NPA's evidence-based guidelines at www.nationalperinatal.org/rsv



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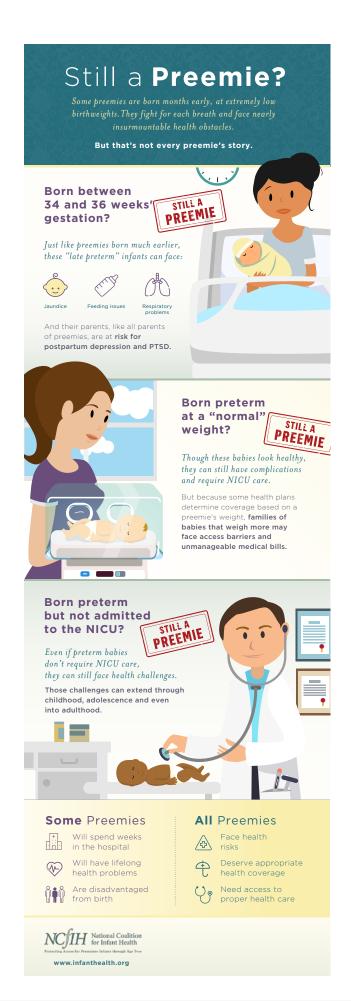
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Research, Education, Quality & Safety

Transforming Pediatric Care with Telehealth Technology

Kirby Farrell, Lindsey Koshansky, RN, MSN

NRemote patient monitoring has transformed healthcare, with evolving technology allowing physicians and patients to connect in ways never before possible. But as telehealth has evolved, most platforms have focused on serving aging populations. Pediatrics is a population that has been overlooked by telehealth developers and where an opportunity exists to fundamentally change the way young patients are treated. This is why the Locus Health platform was created.

Locus Health bridges the gap between hospital and home with an RPM platform that connects parents with their child's care team after they have been discharged following NICU stays. Locus' HIPAA-compliant modular construction allows for configuration of both the app and dashboards, providing effective remote monitoring for any population -- from chronic to complex. Locus provides a fully managed, SaaS solution that utilizes an iOS-based application to improve the home monitoring of medically complex pediatric patient populations. The platform was designed specifically to create operational efficiencies by seamlessly integrating with the providers' EMR. Most importantly, it allows doctors to spend more time caring for their patients.

Locus has been proven to reduce the length of hospital stays (1), lower readmission rates, reduce in-person clinic visits, and lower the overall cost of care. These results have led to implementation of the Locus platform at more than 25 leading Children's Hospitals in the U.S. and Canada. This rapid growth has been possible because the platform was developed by experienced healthcare professionals, notably a team of former NICU nurses, who understand the complexities of daily healthcare and the pressing need to integrate telehealth into care regimens. Building a platform that integrates into existing workflows for doctors, nurses, CIO's and hospital administrators was vital.

"Building a platform that integrates into existing workflows for doctors, nurses, CIO's and hospital administrators was vital."

Locus Health was <u>developed in conjunction</u> (2) with doctors and nurses at the University of Virginia Health System (UVA) in Charlottesville, VA. where Locus is also headquartered. In early 2018, Dr. Brooke Vergales, a Neonatologist at UVA, met with the clinical innovation team at Locus Health. Her goal was to tailor the Locus platform for premature infants admitted to the UVA Children's Hospital's NICU unit who could be discharged home sooner than the average NICU stay of about 24 days. Locus had been supporting a wide range of pediatric patient populations at UVA with its remote care management solution, and had already achieved strong improvement in clinical outcomes, including improved mortality and oral feeding rates among pediatric patients discharged home with congenital heart disease (CHD).

Dr. Vergales had several key objectives: to improve the quality and timeliness of transition home while ensuring that these premature infants thrived more quickly; to keep the care team connected in the same way they would if the infant had remained in the hospital; and to help the NICU improve its ability to admit more complex cases and maintain its high census. Dr. Vergales and the Locus team immediately focused on key metrics for evaluating the success of the program, developing targets for:

- Enrollment, targeting 10-12% of NICU admissions in the first year of the program, typically infants viewed as "feeders and growers" that did not require more complex NICU care in the hospital.
- Length of Stay (LOS), targeting more than a 5-day decrease in average length of stay.
- Transition to Oral Feeding, using nasogastric (NG) tube placement in the home (3), aiming to transition to full oral feeding more quickly than in the hospital-setting, while maintaining targeted weight gain metrics.
- Quality and clinical satisfaction with a new "Virtual Rounding" approach, as measured by daily family adherence to program tasks and the quality of data/trends collected.

Parents of the infants enrolled in the program were provided a personalized iPad with the Locus platform and mobile app installed. They were shown how to enter key metrics (e.g. daily weights, daily feeding intake, output, SpO2). In addition, the UVA team provided educational content directly through the Locus iPad app that otherwise would have been sent home in an infrequently used binder of printed papers. Parents were able to utilize secure photo and video capabilities through the Locus app to support critical interaction with the care teams, including support for lactation consults.

"Parents were able to utilize secure photo and video capabilities through the Locus app to support critical interaction with the care teams, including support for lactation consults."

Neonatology teams at UVA used the Locus platform to both round virtually on a daily basis and review alert notifications through the mobile app for clinicians, helping them manage by exception, and identify trends outside of acceptable parameters well in advance of an emergent event.

Since UVA and Locus launched the program in late spring of 2018, UVA has enrolled more than 50 infants in the program and seen a significant reduction in LOS. The reduction in LOS associated with this approach to home discharge of premature infants from the NICU is dramatic. Industry estimates indicate an average cost to payers of more than \$3,000 per day in the NICU, indicating an average payer savings of nearly \$25,000 per infant discharged to the Locus platform. At UVA's initial target enrollment rate of 10-12% of NICU discharges, this equates to about \$1.5 to 2M in payer savings annually.

However, the economic benefits of this approach do not only accrue to payers. At UVA, and many other Level III/IV NICUs

where capacity constraints exist throughout the year, the benefits to the UVA Children's Hospital associated with discharging these "feeders and growers" more quickly include an increase in average reimbursement per day in the range of \$1,500 to \$2,000, the result of making a NICU bed available to an infant with more complex care needs. Analysis of UVA reimbursement indicated an incremental revenue opportunity of up to \$1M annually as a result of this shift toward more complex admissions in the NICU. And while the program has been discharging more families sooner, the UVA NICU has maintained its census consistently above 90%.

Most importantly, the quality of care in this approach to NICU discharge management has only improved at UVA Children's Hospital: infants that would otherwise be monitored for the same potential issues in the hospital clearly are thriving more at home from a feeding and oral skills perspective, they bond with their parents more quickly in a nurturing home environment, and the care teams at UVA have been able to manage and monitor at the same quality standard while making more of the NICU available to infants that truly need in-hospital care.

The <u>feedback from both the care teams</u> (4) and the parents of these infants has been overwhelmingly positive. Flossie Horace, the guardian and grandmother of Elliyon Horace, told <u>CBS News in a report</u> (5) that aired nationally in May 2019, that the Locus Health platform has made her grandson's home recovery more manageable and reduced the number of times she has had to make the 4-hour round trip journey from her home in Roanoke to UVA in Charlottesville.

"I love the iPad. It helps out a lot. It gave me more assurance that I know what I'm doing," said Horace.

"However, the economic benefits of this approach do not only accrue to payers. At UVA, and many other Level III/IV NICUs where capacity constraints exist throughout the year, the benefits to the UVA Children's Hospital associated with discharging these "feeders and growers" more quickly include an increase in average reimbursement per day in the range of \$1,500 to \$2,000,"

References:

- "Doctors create iPad program to get NICU babies home sooner" by Julie Mazziotta, PEOPLE Magazine, March 13, 2019.
- https://people.com/health/doctors-ipad-program-nicu-babies-get-home-faster/
- 3. "UVA's pediatric remote monitoring program Building Hope



Figure 1: A family using the dashboard.

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Today, December 20

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Baby Weight (kg)

3.2 Add Notes (Optional)

Helpful Tips & Information

Make sure the scale is set to "kg" instead of "lbs," this will weigh your baby in kilograms instead of pounds. Weigh your baby naked or in a dry diaper (instructions below) after zeroing the scale at approximately the same time every day before a feeding. This allows us to assess growth and changes in your baby's fluid and hydration status. The earlier you perform the care in the day, the

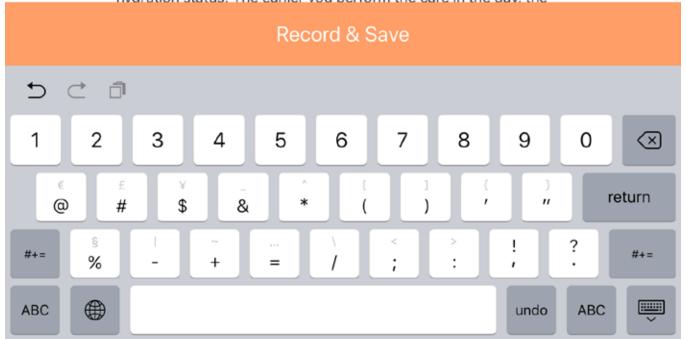


Figure 2: The dashboard along with "Helpful Tips & Information"

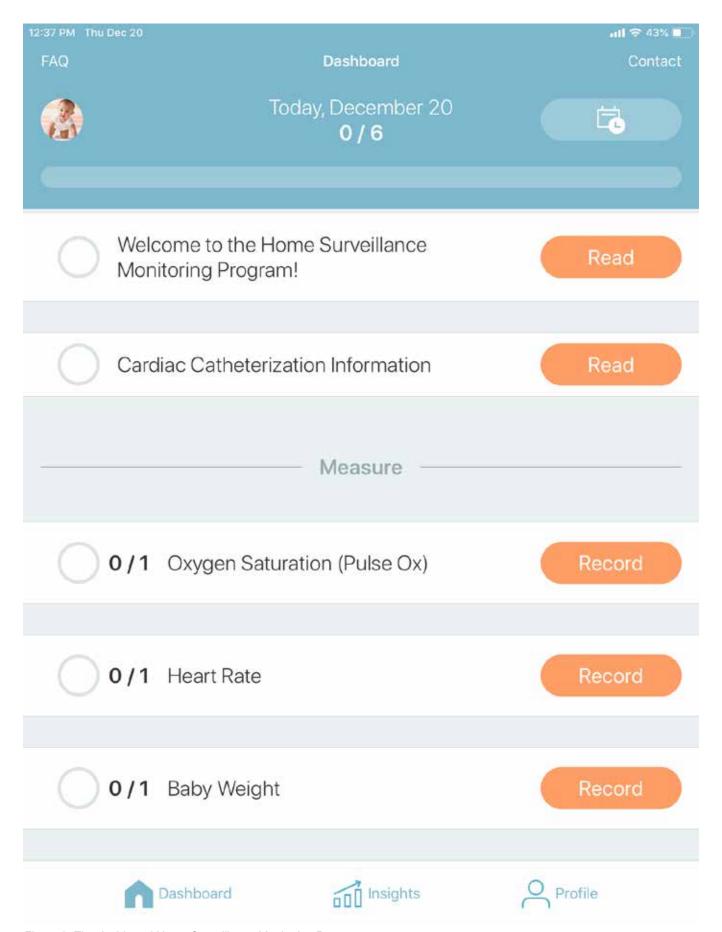


Figure 3: The dashboard Home Surveillance Monitoring Program

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Disclosures: Kirby Farrell is CEO, Locus Health and Lindsey Koshansky, RN, MSN is VP Clinical Innovations, Locus Health

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Respiratory Report: Professional Autonomy Within an Interprofessional Team "Why Have a Dog and Bark Too"

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

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

The expression "it takes a village" implies that no single person can accomplish what a group of people can. This concept is as applicable to health care as it is to raising children and maintaining a stable, high-functioning community. "Why have a dog and bark too" was the philosophy behind the model of care developed in the neonatal intensive care unit (NICU) in which I practice. In other words, why do things yourself when there are others available that can do the task, perhaps even better.

Traditionally, the term "interdisciplinary team" has referred to different branches within medicine and referred to physicians from varying fields. This model may have worked adequately in a time when medicine seemed simpler and less technology driven, but in today's world the field of medicine has become far too complex for any one profession to own and completely provide.

We have all heard the expression "jack of all trades, master of none." This is true in medicine as it is in any other multi-faceted field. While television often features physicians doing everything from starting IV's to using microscopes, the reality is much different. Automobiles, for instance, are serviced by many sub-specialties: transmission shops, auto electric shops, body shops etc. Human beings are biological machines far more complex than anything made by our own hand and require an even greater degree of sub-specialisation. Similarly, neonatology is ostensibly as different from paediatrics as paediatrics is from adult medicine; and babies of different gestational age are also very different from each other and must be managed appropriately. This requires knowledge commensurate to the task.

Many institutions continue to operate on the medical model based on the military model. A doctor gives orders which are carried out by others. This model is antiquated and inefficient, particularly when it comes to neonatology.

Humans are by nature poor multitaskers. Most people are only capable of remembering seven things at once, give or take.1 Given that an NICU may have 40 or more patients at any given time it is obvious that at some point, things are going to fall through the cracks. Relying on a single person to manage many patients leads to delays in treatment while those charged with carrying out that treatment wait for orders. For routine things this can work, but when action is urgently required it is sub-optimal. For instance, we know that careful regulation of CO₂ is critical during the first seventy-two hours of a premature infant's life in order to lessen the risk of intra-ventricular hemorrhage. Any NICU clinician knows how quickly CO₂ can change. Waiting for a physician to order the necessary ventilation changes delays that action, particularly if that physician is busy attending to other urgent issues.

An interprofessional model allows the appropriate professional to work to their full scope of practice, avoiding these delays. Also, evidence-based practice is driven by the profession most knowledgeable. For instance, respiratory therapists provide respiratory care and mechanical ventilation; similarly, dietitians for nutrition, pharmacists for medication, all of course with interprofessional input. The physician coordinates and oversees the team without directly dictating the care it provides; metaphorically the physician acts as a general contractor and sub-contracts accordingly. Bedside nurses are highly skilled professionals, and all too often must wait for an order to do what is required and are quite capable of doing. Allowing them the autonomy to do so frees up time for the physician overseeing care to attend to more pressing matters. In addition, not allowing professionals who are more knowledgeable in their respective fields to work to their full scope of practice is a source of frustration and can lead to moral and ethical distress.

"In addition, not allowing professionals who are more knowledgeable in their respective fields to work to their full scope of practice is a source of frustration and can lead to moral and ethical distress."

In an aircraft the co-pilot is expected to take control when the captain makes an error, or fails to notice a situation which jeopardizes the safety of their passengers; so should specialised professionals be free (and expected) to guide the team in their respective areas of expertise. Aircraft safety improved greatly when the top-down military approach to control in the cockpit changed to one of joint responsibility. Aviation history is replete with stories where a subordinate crew member literally watched the pilot **crash the plane** because they were afraid to speak up or take over. If a medical team operates under the same military top-down structure, it too is vulnerable to un-checked errors and omissions and is functionally not a team.

Allowing various professionals to use their knowledge and skills autonomously can provide better, more effective and efficient care. (2) While there has always been somewhat of a power struggle between various professionals (and likely always will be to a degree), allowing autonomous practice may actually improve collaboration within the team and reduce "turf wars", particularly if the team has evolved to a trans-professional one. (3) It is worth noting that the term "collegial" means "relating to or involving shared responsibility, as among a group of colleagues." In a world where most paramedical professions are regulated, they are as accountable for their actions as much as anyone else. Furthermore, interprofessional collaboration has been shown to "provide benefits to both patients and health care providers including improved communication, a reduction of errors, enhanced patient care delivery and an overall improvement in patient and staff satisfaction." (4)

Theories of Professionalism Variety of Identities Professional Identity Insecure in one's professional Overlapping identity Nursing · Overlap can be inhibiting Practice Secure in one's professional identity · not threatened, OK with overlapping scopes of practice Overlap can be liberating Respiratory Medicine Therapy

Figure 1: trans professional teams allow different professions to step into another profession's role temporarily where scopes of practice overlap. (5)

"While RRT's are paid considerably less than anesthetists, using them costs the hospital more. The health care system as a whole is not served well by this payment structure and is an impediment to the goal of utilizing all professionals to their full scope of practice."

In a special edition on health care, Harvard Business Review noted that many visits to physicians could have been to a nurse practitioner at less cost to the patient or system. Within a hospital, similar savings can be achieved through maximizing the roles of all professions. Physicians may have difficulty sharing power, but when power is shared the entire team becomes stronger and higher functioning. (5) When looking at the big picture this is true, however payment structure can be a hinderance. For instance, in Ontario, Canada, Respiratory Therapists with additional training working as anesthesia assistants are hospital employees paid out of the hospital budget. Anesthetists are not hospital employees, but rather are contracted with the institution (usually as a group). As such, they bill directly to the provincial government health plan, not the hospital. While RRT's are paid considerably less than anesthetists, using them costs the hospital more. The health care system as a whole is not served well by this payment structure and is an impediment to the goal of utilizing all professionals to their full scope of practice.

Since this is a neonatal respiratory column, I would be remiss to exclude the concept of "core therapists" in the NICU. The specialised nature of neonatology has given us neonatologists. While neonatology typically falls under the umbrella of paediatrics, neonatologists do not, as a rule, treat older paediatric patients. Similarly, NICU nurses require special training, and do not typically work in other areas, and in the unit in which I work this is also true of pharmacists, dieticians, and respiratory therapists.

My colleagues would agree that getting comfortable as a respiratory therapist in the NICU takes at least a year of full-time practice, and the learning curve is steep. Proficiency in the art of neonatal

ventilation takes considerably longer. Babies are not little adults, and micro-prems are not little babies. The management of their ventilation is very different. It is for this reason the respiratory therapists in the NICU do not rotate through other hospital areas. In other level 3 NICUs, core therapists work only in the unit with others rotating through. Those who rotate typically do not assume the same level of responsibility as those who do not. In the level 4 NICU, respiratory therapists also do not work in other areas of the facility.

It has been shown that students suffer learning loss over the summer holidays. (6) Similarly, if a therapist rotates through different areas or works less than full-time hours with no NICU experience, there is a break in learning the nuances of NICU ventilation. This results in learning loss commensurate with the time spent away from the NICU, an even steeper learning curve, and a non-linear increase in the amount of time required to become fully competent in the NICU.

To me, this makes perfect sense, yet I have encountered institutions wherein the concept of core therapists is vehemently opposed. I do not think it a coincidence that the respiratory outcomes in my unit are exceptionally good, and I firmly believe that allowing the ventilatory management of babies in the NICU to be managed by therapists who specialise in this population plays a large part in achieving those outcomes. It is also worth noting that in several other NICU's with good outcomes, ventilatory management is provided by a core group of practitioners, although not necessarily respiratory therapists. It would behoove any NICU looking to improve their own respiratory outcomes to seriously examine this concept.

"Admit to NICU, ventilation as per RRT" is the blanket "order" under which I practice. This allows me and my colleagues to operate autonomously, thus providing expert, timely care to our delicate patients. There is a caveat here: if one wants to be the captain in the cockpit, one had better know how to fly. Professional autonomy can only be achieved with proper training, knowledge, and expertise. It isn't as simple as just handing control of ventilation over to respiratory therapists, with all deference to my colleagues. For those willing to make substantial changes in a field all too often resistant to it, and make the investment in training, the payoff is, without a doubt, worth the effort.

With thanks to my colleague Lisa Golec-Harper, RRT, BSc, MHSM, MHSc (bioethics) who has shared her expertise in this area.

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From The National Perinatal Association: The Fourth Trimester: Where Has the Village Gone?

Jerasimos (Jerry) Ballas, MD, MPH

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.

to shorten gestation. Simply put, the advantage bestowed by an increasingly complex brain came with the price of needing to be born earlier so that newborns could navigate the female pelvis. Anthropologists and social scientists will point out the subsequent evolution of our early nomadic hunting and gathering ancestors into an increasingly cooperative and group-minded society (3-4). Of course, this is an overly simplified notion covering millions of years of evolution. However, it can be a powerful lens to look through when examining the paradigm of modern perinatal and postpartum care of mothers, newborns, and their families, and how that paradigm is increasingly failing our patients.

"After 40 weeks of gestation, the fragile and helpless state of a human newborn is striking when compared to the abilities of other mammals and primates born at term."

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Evolutionary biologists have long theorized that even at full term, humans are still born prematurely (1). After 40 weeks of gestation, the fragile and helpless state of a human newborn is striking when compared to the abilities of other mammals and primates born at term. Elephant and giraffe newborns walk when their feet hit the ground. Baby chimps have the kind of grasp and strength to stay firmly attached to its mother as she climbs and swings. So why would nature take such a risk with humans by selecting for such defenseless offspring (2)?

Evidence suggests that as hominids took to walking upright, the intersection between increasing brain volume and the ability to deliver offspring through a narrowing pelvis created an evolutionary pressure

As a Maternal-Fetal Medicine specialist, the majority of my interaction with patients and their families is during their prenatal care. I see fetuses in black and white on computer monitors much more often than I do in living color. I often talk in terms of estimated due dates, interval fetal growth velocity, and timing of delivery for either maternal or fetal indications (or both) in an effort to navigate a pregnancy as far as possible and as safely as possible for all involved. I still take call and cover inpatient services and get to be involved in deliveries, which never gets old and always serves to validate why I went into this field.

It wasn't until my child was born, however, that I became acutely aware of how woefully deficient postpartum support can be in this country. The pressure for my wife to return work, the use of all my vacation time as paternity leave, navigating post-partum issues within a healthcare system designed for prenatal care and delivery, all the while figuring out whom to trust with the life our newborn child when we returned to work. All of these stressors were amplified when I came to the realization that despite a full-term, uncomplicated pregnancy, we were essentially caring for a defenseless fetus that just so happened to be outside of the uterus.

When my wife (who is a pediatric neurologist in addition to an amazing mother) first introduced me to the concept of the 4th Trimester via Dr. Harvey Karp's "Happiest Baby" book, I'll admit I was a bit skeptical (5). In the end, though, I was comforted by the evidence-based strategies it provided to help soothe my daughter. Swaddling, swaying, darkening the room, feeding, and white noise (or rock n' roll music) seemed to do the trick every time, essentially recreating intrauterine life that is naturally warm, dark, noisy, and always on the move. It brought together so many of the aforementioned concepts that human newborns are not only ill-equipped to survive relatively short times alone, but that they still respond to the world around them as if they were still in utero (6). As a father, I felt empowered with some skills that could actually provide a semblance of care typically reserved for nursing mothers.

Then came that mythical 6-week mark that has become the arbitrary cutoff for the postpartum period. While my wife had the foresight to request three months of maternity leave, the majority of that time would turn out to be unpaid. On top of that, she would later be required to pay back that time by extending her training and graduating two months late. Suddenly, she found herself essentially alone because I had to return to work with no more vacation, sick time, or personal days left to use. persistent perineal pain and baby blues that seemed to deepen with more hours spent alone, the 4th Trimester began taking a turn for the worse. The concept of



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a village helping raise a child could not have felt further from the truth. Ultimately, through what seemed to be sheer will and determination at times, we weathered the storm and survived intact. I don't doubt for a second that our privilege, socioeconomic status, and combined education provided an advantage for us. What is terrifying, though, is thinking of the number of women and new families that not only lack those advantages but who may have already entered pregnancy at a distinct disadvantage.

Ask any obstetrician where this six week postpartum paradigm came from, and you'll get a variety of answers: historically, it's the time when menses typically returns, hence women are now back to "normal"; the risk of preeclampsia is virtually zero; it stems from practices that historically mark 40 days as part of religious or cultural norms (7). While the truth is likely to be found somewhere within these beliefs, it's become apparent that this "six-week" mark is not only arbitrary, but likely does more harm to new mothers, newborns and their families than we ever imagined before. Beyond incomplete physiologic and psychologic healing, there is an increasing body of evidence pointing to the economic and social damage from frequent sick day requests, decreased job satisfaction, and lower employee retention attributed to inadequate family medical leave policies (8). In terms of childcare, all one needs to do is observe the developmental leap an infant finally takes at roughly three months of age to realize the intense care needed leading up to that point. Yet, somewhere between harnessing fire and curating our lives on social media, the lessons learned by our prehistoric ancestors have seemingly been lost upon modern American society.

While we have made amazing strides in addressing pregnancy complications and modernizing intensive neonatal care, the overall support for new parents and their families continues to erode in the face of widening socioeconomic disparities, weakening worker protections, and persistent healthcare inequities (9-10). The current state of family medical leave in the United States remains appalling compared to nearly every other industrialized nation. Combined with compensation plans that disincentivizes postpartum care, disjointed healthcare safety nets that typically terminate six weeks postpartum and persistent barriers to healthcare that place undue burden squarely on women of color and other mar-

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ginalized populations, it's no wonder we continue to see research and headlines pointing out America's abysmal international standing when it comes to maternal and childhood health measures (11-15). When put into the context of our nation's overall wealth and healthcare expenditures, it makes these facts all the more damning.

"As perinatal healthcare providers, from preconception and pregnancy through postpartum and infancy, it falls on us to start bridging the gap between established prenatal paradigms and the biologic and social importance of 4th Trimester care."

As perinatal healthcare providers, from preconception and pregnancy through postpartum and infancy, it falls on us to start bridging the gap between established prenatal paradigms and the biologic and social importance of 4th Trimester care. On a provider level, the American College of Obstetricians and Gynecologists has taken the first step in broaching the subject to a wider audience by publishing Committee Opinion No. 736, "Optimizing Postpartum Care," in May of 2018(16). In this document, the argument for extending obstetric care to 12 weeks postpartum is made by citing improved surveillance for pregnancy complications, greater opportunities to promote breastfeeding, increased utilization of contraception, and seamless transitioning to well-woman care. In terms of advocacy, education and public policy, organizations such as 1,000 Days, The National Partnership for Women and Families, and 4th Trimester Project out of UNC have created invaluable resources and initiatives that further the call for paid family medical leave, equitable healthcare, and respect for reproductive rights.

On a personal level, I have not only begun restructuring my own practice to incorporate greater postpartum care in my most complicated patients, but I am proud to be the President of the National Perinatal Association as we continue moving this conversation forward at our annual conference entitled "Perinatal Care and the 4th Trimester: Redefining Prenatal, Postpartum and Neonatal Care for a New Generation" taking place March 25-27, 2020 at Children's Hospital Colorado. As an inclusive, multidisciplinary organization that provides an equal voice to parents and families, NPA is uniquely positioned to not only leverage the expertise of perinatal and neonatal providers but also to maintain genuine connections to parents and grassroots advocates. We will be exploring 4th Trimester topics ranging from improving access to postpartum care and lobbying for paid family medical leave to modernizing our perspective on infant, parental, and maternal mental health. The meeting will culminate with a series of presentations aimed at improving our understanding of optimal infant feeding and developing nationwide best practices. Combined with our poster presentations and breakout sessions, it is a conference aimed at networking and creating connections across disciplines as much as it is meant to be didactic and informative.

Ultimately, I hope to continue harnessing my own experience and expertise to improve the lives of my patients and their families as they navigate pregnancy and the 4th trimester. Taking into account the advances we have made in so many other areas of medicine that seemed foreign to us only decades ago, I have con-

fidence we can start incorporating the information from phylogenic cues handed down to us for millions of years into equitable standards of care for generations of new and expecting parents to come. As a society, we truly can't afford anything less.

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

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- gastroenterologists
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- physical therapists (PTs)
- speech therapists (SLPs)
- WIC Special Supplemental Nutrition Program for Women, Infants, and Children
- · social workers and case managers

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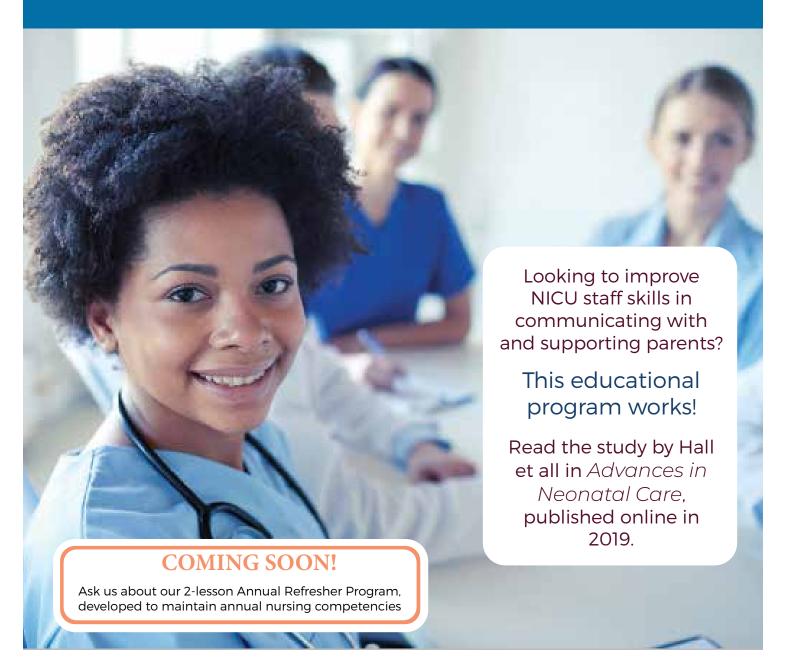




Online NICU Staff Education Program

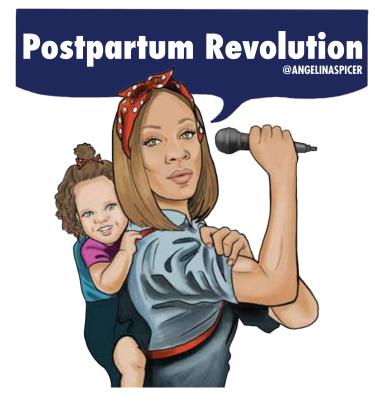
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The Story of Racing Hearts

Shabih Manzar, MD

Summary:

A case of neonatal hypoxic-ischemic encephalopathy (HIE) is presented. The findings of HIE in association with chorioamnionitis and fetal acidemia is preceded by a prolonged maternal and fetal tachycardia.

Keywords: Chorioamnionitis, Fetal tachycardia, Hypoxic Ischemic Encephalopathy (HIE)

Case:

A male infant was delivered vaginally at 393/7 weeks of gestation. Mother was an eighteen-year-old gravida1, para 1-0-0-0. She had a history of elevated blood pressures. Pregnancy medication included only prenatal vitamins. All her prenatal labs, including RPR, HIV, hepatitis B, chlamydia, and gonorrhea were negative. Significant history revealed rupture of membrane nineteen hours prior to delivery, foul-smelling amniotic fluid, and fever with a highest temperature of 102oF (38.9 °C). Fetal heart monitoring showed maternal and fetal tachycardia (Figure).

"Significant history revealed rupture of membrane nineteen hours prior to delivery, foul-smelling amniotic fluid, and fever with a highest temperature of 102oF (38.9 °C). Fetal heart monitoring showed maternal and fetal tachycardia (Figure)."

At delivery, the infant had no cry, poor tone, and poor respiratory effort. He was taken to warmer, dried, stimulated, and bulb suctioned. He was then placed on continuous positive airway pressure (CPAP), oxygen saturations improved, and the infant was transported to the neonatal intensive care unit (NICU). Apgar scores were 5 and 8 at 1 and 5 minutes, respectively. In the NICU, while on CPAP, he developed seizures and was placed on hypothermia therapy per unit protocol. The cord blood gas showed severe acidemia (Table). The infant's physical examination was significant for tachycardia and abnormal muscle tone.

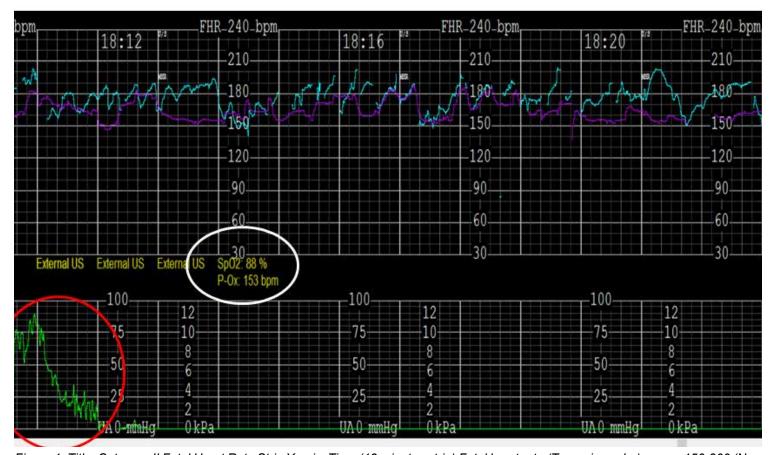


Figure 1: Title: Category II Fetal Heart Rate Strip X-axis: Time (12 minutes strip) Fetal heart rate (Turquoise color)- range 150-200 (Normal 120-160) Maternal heat rate (Purple color)-range 149-190 (Normal 70-100) Red circle: Uterine contraction White circle: Maternal heart rate and oxygen saturations

Table: Cord blood gas results

рН	7.00
pCO ₂	50
pO_2	26
HCO ₃	9.5
Base Access	-17.3

Vital signs showed a temperature of 100.9 $^{\circ}$ F (38.3 $^{\circ}$ C) and a heart rate of 191 beats per minute. The rest of the exam was normal.

The infant transitioned well post warming and started on PO feeds, which he tolerated well. The neurological exam at discharge was normal. He passed a pre-discharge hearing screen test. The infant was assessed by the pediatric neurologist and was sent home on phenobarbitone with follow up with his primary physician, neurology clinic, developmental clinic, and early steps intervention.

Discussion:

Fetal tachycardia was secondary to maternal tachycardia, which was secondary to high maternal temperature. With the history of prolonged rupture of membranes and foul-smelling amniotic fluid, the cause of maternal fever was suspected to be chorioamnionitis. Later, placental pathology showed stage 2, grade 2 chorioamnionitis.

The exact mechanism of fetal tachycardia resulting in acidemia is unknown; however, it could be postulated that tachycardia increases the oxygen demand of the fetal heart leading to hypoxia. Persistent hypoxemia then generates lactic acid and causes a shift in the buffer system resulting in acidemia. Tachycardia and cardiogenic shock that resulted in acidosis have been reported earlier (1).

Recently Toomey and Oppenheimer (2) showed an association between fetal tachycardia and acidemia. By using a logistic regression model, they found a tachycardia point estimate of 3.4 (95% CI 1.14-10.14). On careful observation of fetal heart rate (Figure), we noted a 12-minutes epoch of maternal and fetal tachycardia. Maternal oxygen desaturation down to 88% was also noted that could have lead to poor oxygen delivery to the fetus resulting in severe acidosis as noted in the cord blood gas.

The mechanism of fetal tachycardia secondary to maternal fever and chorioamnionitis, could be explained by the cytokine-mediated fetal inflammatory response, as described by Romero et al. (3).

In conclusion, simultaneous maternal and fetal tachycar-

dia, when seen on antenatal cardiotocography (CTG), is an ominous sign and a potential risk factor for fetal distress and acidosis.

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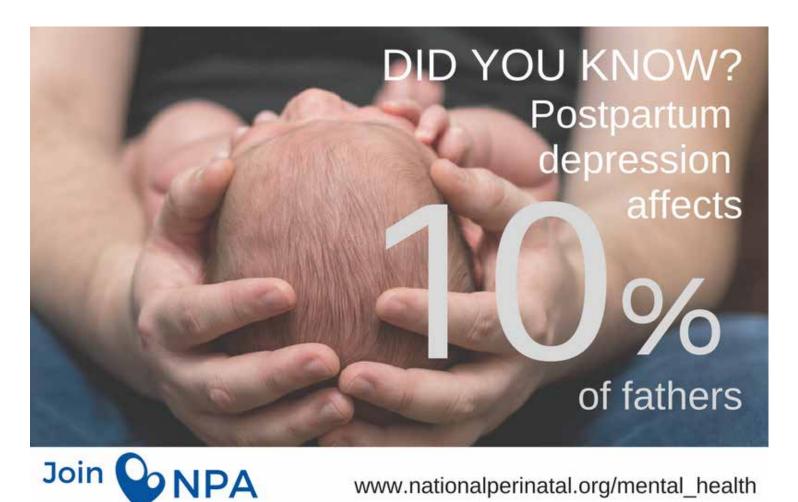
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The Gap Baby: An RSV Story



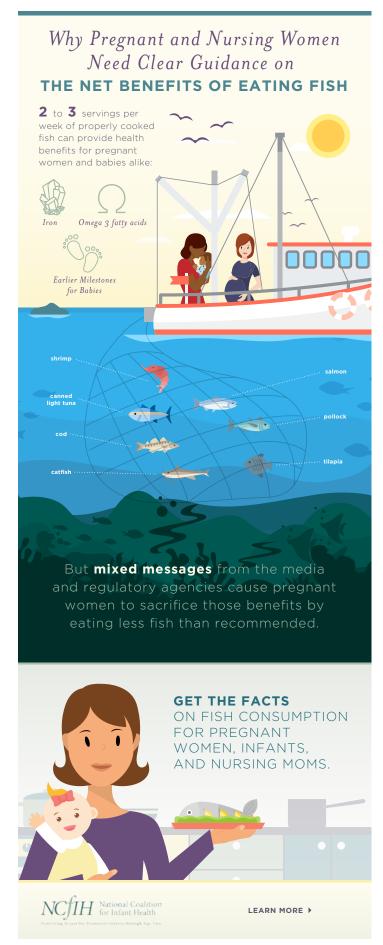
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States and Federal Government Focus on Policies to Decrease Infant Mortality Rates in the United States

Darby O'Donnell, JD Alliance for Patient Access (AfPA) Government Affairs Team

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



The NEWBORN (Nationally Enhancing the Wellbeing of Babies through Outreach and Research Now) Act (H.R. 117), sponsored by Congressman Steve Cohen (D-TN-9), was highlighted here earlier this year. (1)

The NEWBORN Act would help address the problem of infant mortality by awarding of grants to infant mortality pilot programs that seek to address one or more of the top five reasons for infant mortality: birth defects, preterm birth and low birth weight, sudden infant death syndrome, maternal pregnancy complications, and/or injuries to the infant.

This legislation is gaining traction in the House and now boasts 52 cosponsors. We await U.S. Senate introduced a similar bill.

While advocacy efforts to reduce infant mortalities rates are ongoing in the nation's capital, state health officials are amassing information that could lead to the prevention of infant mortalities in their own backyard.

One state of note: Ohio.

According to the Centers for Disease Control and Prevention (CDC data), Ohio holds a place in the top ten highest infant mor-

As the CDC notes on its website: "Infant mortality is the death of an infant before his or her first birthday. The infant mortality rate is the number of infant deaths for every 1,000 live births." (3)

In 2017, the infant mortality rate in the United States was 5.8 deaths per 1,000 live births. By comparison, Ohio's Dayton Daily News noted in 2017 - the last available year in which the CDC collected data - the state's infant mortality rate was 7.2 deaths per 1,000 live births. To be clear, that number corresponds to the reality that 982 Ohio infants died before their first birthday in 2017. (4)

"In 2017, the infant mortality rate in the United States was 5.8 deaths per 1,000 live births. By comparison, Ohio's Dayton Daily News noted in 2017 - the last available year in which the CDC collected data - the state's infant mortality rate was 7.2 deaths per 1,000 live births."

However difficult this statistic may be to comprehend, Ohio is showing small progress with a decline of 42 infant mortality deaths compared to 2016, which places the yearly total just under 1,000 children.

"This shows some progress from 2017, which is promising; however, we know that this number is far, far too high," said Reem Aly, vice president of Health Policy Institute of Ohio (HPIO) told the Dayton Daily News. "So while we're moving in the right direction, we certainly cannot stop, and there needs to be a much more aggressive intention and approach across our state." (3)

The federal policy would focus on targeting areas of the country with high rates of infant mortality and providing federal support through pilot programs to those high-risk areas.

In Ohio, the focus is similar. Hundreds of area health officials met in late September to discuss "how racial bias plays a role" and to

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evaluate community resources and their availability. Those gathered also considered prioritization of maternal health as a means to reduce infant deaths.

A \$137 million investment in the state has targeted nine counties - those that account for "66 percent of all infant deaths last year and 90 percent of black infant deaths" (3)

Over the last eight years.

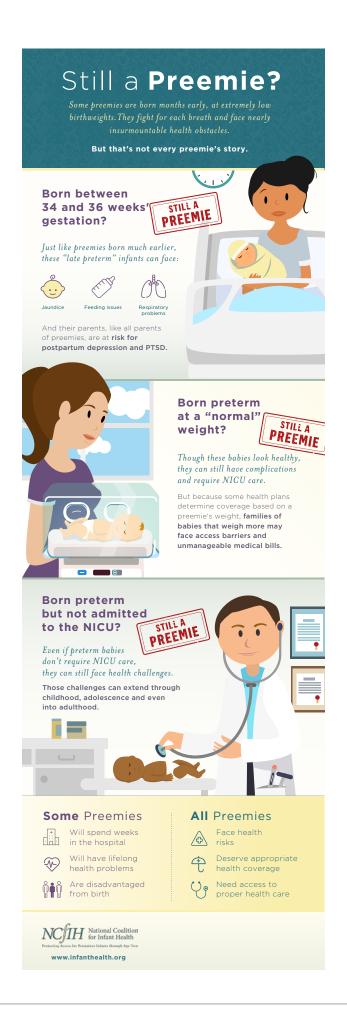
This past March, Ohio Governor Mike DeWine earmarked \$90 million in state funding over two years for home visits to at-risk pregnant women, new moms, and their children up to age 3. (3)

Additionally, the governor noted in his "State of the State" address that African American babies are dying at almost three times the rate of white babies, "leaving Ohio ranked 49th worst in the nation for deaths of African American infants."

The CDC lists the five leading causes of infant death in 2017 as birth defects, preterm birth and low birth weight, maternal pregnancy complications, sudden infant death syndrome, and injuries "(e.g., suffocation)." (2)

"The CDC lists the five leading causes of infant death in 2017 as birth defects, preterm birth and low birth weight, maternal pregnancy complications, sudden infant death syndrome, and injuries "(e.g., suffocation)." (2)"





This list fails to capture exactly the disparities between communities and from home to home, or even state to state - namely, economic disparities. Personal and governmental resources can dictate access to health care for both mother and infant.

To date, Ohio Congressman Tim Ryan (D-OH-13) and Congresswoman Marcy Kaptur (D-OH-9) are two Ohio members who are have agreed to sponsor H.R. 117 - hoping to bring more resources to their constituents.

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The author has not indicated any disclosures.

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From The National Perinatal Information Center: Postpartum Depression and the Neonatal Intensive Care Unit Eliminating the Stigma of Postpartum Depression (PPD)

Elizabeth Rochin, PhD, RN, NE-BC

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

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



National Perinatal Information Center

"When they finally wheeled me up to the NICU to see my baby, he was attached to so many pumps and machines. I couldn't even see his hands and feet. This clearly was my fault... I must have done something wrong. I couldn't even touch him to reassure him I was here for him. I didn't know what to do. My first reaction was to not become attached ... I was so afraid I was going to fall in love with my baby and then he would be gone. And the guilt associated with not wanting to be attached to my new baby was overwhelming."—A.B., Mother of a NICU Baby

Review any annual cause calendar, and you find a myriad of dates that recognize one issue or another throughout the year...World Water Day (March 22); World Cancer Day (February 4); World Penguin Day (April 25)...however, October 10th of each year highlights **World Mental Health Day**, and this day is quite applicable for the Neonatal Intensive Care arena.

Before entering the NICU space, it is of paramount importance to highlight the recent findings in California that illustrate the urgency of understanding maternal mental health through the lens of maternal morbidity and mortality. Researchers in California (Goldman-Mellor & Margerison, in press) reviewed 300 records (2010 – 2012) of women who died within one year after giving birth. The second leading cause of death was drug-related, and the seventh was by suicide. Two-thirds of the women who died had at least 1 visit to an Emergency Room or hospital before they died. In other words, these women had entered the healthcare

system, and there may have been real opportunities to meet their mental health needs prior to their deaths. Screening for depression may have provided insight into their despair.

Mothers of preterm infants are 40% more likely to develop PPD than the general population (Cherry et al, 2016). In other words, if a NICU has thirty (30) beds, it is **conceivable** that twelve (12) of the mothers in the unit are suffering from Postpartum Depression, which in turn can impact their ability to actively engage with the care of their newborn and engage in bedside rounds as the focal member of their newborn's care team.

So, what can we do as a multidisciplinary NICU care team to better identify PPD and assist mothers who are coping with their own healthcare and emotional care needs, in addition to the stressors of having a newborn in the NICU?

- Data-Driven Decisions: NPIC profiled 288,336 births during the time period April 2018 - March 2019. During this period, **40,165** deliveries were linked to a newborn with an admission to a NICU or Special Care Unit. Of these women, only 24 were discharged with the ICD-10 diagnoses of O90.6 (Postpartum Mood Disturbance, i.e., dysphoria, blues, sadness) or F53.0 (Postpartum Depression). These findings would support the development of PPD after discharge, and during their stay in the NICU within the context of the studies provided. It is critically important that we are screening all mothers appropriately and coding PPD appropriately prior to discharge. These numbers reflect real mothers who were diagnosed with PPD even before their discharge home. NPIC 's focus in 2020 and beyond is to ensure that our data has a robust and sustained focus on racial/ethnic disparities, and the social determinants of health (SDOH) that may have an impact on PPD and other maternal complications.
- 2. Access to Routine Postpartum Care: Chen and colleagues (2019) conducted a qualitative study identifying some of the barriers to NICU mothers accessing postpartum care, which included distance to clinic, a stronger focus on their newborn's health and changes to their own insurance/ability to pay. What resources do you currently have in place to support a new mother's ability to care for herself while she is making every effort to care for her newborn? If a mother finds herself far away from her provider, what options exist to provide care closer to the NICU, particularly for mothers with high-risk postpartum health concerns, such as postpartum depression, hypertension, anemia, etc.?
- 3. Identification of Postpartum Depression: In addition to routine postpartum care, it is essential to understand and

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identify those women and mothers at risk or who display signs of PPD early, or during their stay in the NICU. The American Academy of Pediatrics recommends universal PPD assessment at the one-month, two-month, four-month and six-month well assessment visits. However, if NICU stay exceeds one or more of these specific intervals, who is asking the mother if she has been assessed for PPD? What resources currently exist in your facility to assess mothers for PPD who will not be visiting their pediatrician for routine well assessment visits?

4. Supporting the Father/Significant Other: While most of the efforts surrounding PPD are directed towards the mother, there is little doubt that the father/significant other must be considered in the NICU. North American studies of paternal postpartum depression estimate that 13% of fathers experience some level of PPD after the birth of their child (Cameron, Sedov & Tomfor-Masden, 2016). Studies have also revealed that a father's depressive symptoms may mimic the mother's symptoms, and risk factors included perceived lack of support from the nursing staff, younger gestational ages, and longer periods of hospitalization (Roque et al, 2017). While naturally most time and resources are dedicated to assessment of PPD in mothers, it cannot be overstated that the impact on the mother may directly impact the father/significant other. And the cycle continues.

It is critical that we continue to collect data on PPD, follow it where it leads us, and continue to build upon best practices that continue to emerge for women experiencing PPD. It is imperative that a broad spectrum of resources and services are available in the Neonatal Intensive Care Unit that support the identification of and reduction of preventable maternal morbidity and mortality, including Postpartum Depression. It would be ideal to consider every NICU a care environment within which every day is World Mental Health Day.

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The authors have no conflicts of interests to disclose.

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When reporting on mothers, babies, and substance use

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I am not an addict.

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



I was exposed to opioids.

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



NAS is a temporary and treatable condition.

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



My mother may have a SUD.

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



I am so much more than my NAS diagnosis. My drug exposure will not determine my long-term outcomes. But how you treat me will. When you

invest in my family's health and wellbeing by supporting Medicaid and Early Childhood Education you can expect that I will do as well as any of my peers!











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Compiled and Reviewed by Mitchell Goldstein, MD Editor in Chief

FDA informs patients, providers and manufacturers about potential cyber-security vulnerabilities for connected medical devices and health care networks that use certain communication software

The FDA has issued an alert regarding potential cybersecurity issues.

For Immediate Release: October 01, 2019

Today, the U.S. Food and Drug Administration is informing patients, health care professionals, IT staff in health care facilities and manufacturers of a set of cybersecurity vulnerabilities, referred to as "URGENT/11," that—if exploited by a remote attacker—may introduce risks for medical devices and hospital networks. URGENT/11 affects several operating systems that may then impact certain medical devices connected to a communications network, such as wi-fi and public or home Internet, as well as other connected equipment such as routers, connected phones and other critical infrastructure equipment. These cybersecurity vulnerabilities may allow a remote user to take control of a medical device and change its function, cause denial of service, or cause information leaks or logical flaws, which may prevent a device from functioning properly or at all.

To date, the FDA has not received any adverse event reports associated with these vulnerabilities. The public was first informed of these vulnerabilities in a July 2019 advisory sent by the Department of Homeland Security. Today, the FDA is providing additional information regarding the source of these vulnerabilities and recommendations for reducing or avoiding risks the vulnerabilities may pose to certain medical devices.

"While advanced devices can offer safer, more convenient and timely health care delivery, a medical device connected to a communications network could have cybersecurity vulnerabilities that could be exploited resulting in patient harm," said Amy Abernethy, M.D., Ph.D., FDA's principal deputy commissioner. "The FDA urges manufacturers everywhere to remain vigilant about their medi-

cal products—to monitor and assess cybersecurity vulnerability risks, and to be proactive about disclosing vulnerabilities and mitigations to address them. This is a cornerstone of the FDA's efforts to work with manufacturers, health care delivery organizations, security researchers, other government agencies and patients to develop and implement solutions to address cybersecurity issues that affect medical devices in order to keep patients safe."

The URGENT/11 vulnerabilities exist in a third-party software, called IPnet, that computers use to communicate with each other over a network. This software is part of several operating systems and may be incorporated into other software applications, equipment and systems. The software may be used in a wide range of medical and industrial devices. Though the IPnet software may no longer be supported by the original software vendor, some



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March 4-7, 2020

Abstract due date is October 28, 2019. Late Abstracts will not be accepted.

The Gravens Conference is dedicated to providing a forum for the continuing education of NICU professionals. In particular, the conference focuses on the science of fetal and infant development, developmental care practices, NICU design, family support programs, and the influential role the NICU environment has on the neurodevelopment of the infant, and the well-being of families and staff.

The conference committee invites you to submit an abstract for a variety of presentation options: oral abstract session (20-ish minutes), workshop session (75 minutes), or poster presentation, regarding NICU design, the study of creative approaches to developmental and environmental issues of the NICU, care practices and/or programs to assist staff, parents and families. This conference offers an opportunity to share your work and experiences with colleagues.

The theme for the 2020 conference is *Biophysiology of Human Interaction*. However, the abstracts may be on any applicable NICU topic.

Abstracts should include the following sections, as applicable.

- 1. Abstract Title
- 2. Authors' names, degree(s), and institution
- 3. Background and Purpose: problem statement or hypothesis as appropriate
 What is the hypothesis, or what is the problem you are trying to solve, or what is your scientific question? Why is it important?
 State this in one or two sentences
- 4. Budget and Resources: cost of program and materials as appropriate
- 5. Program, Materials, or Methodology: also include any barriers to implementation and how they have been overcome What methods did you use to solve or research the problem? How did you collect your data? How big was your sample size? What were the main outcome measurements? This will probably be the longest part of your abstract.
- 6. Impact or Results: major accomplishment of program/materials; qualitative and quantitative data*; evidence-based results. *If providing data, it must exist; "data to be obtained by conference date" is no longer acceptable.
- 7. Bibliography: for oral presentations, at least 3 related references that support the program
- 8. Learner Objectives: 2-3

In the body of the email, please list the following:

- 1. Title of the abstract
- 2. Author's name, degree(s), credentials, and position title
- 3. Author's email address
- 4. Name of institution, city, and state. City and country if outside the US.
- 5. If the contact person is someone other than the author, please note that in the body of the email
- 6. Presentation preference: a) oral abstract session, b) workshop session, c) poster only, or d) no preference. (Please spell it out rather than provide just a lower case letter.)

Length of abstract: 1000 words maximum

Format: WORD, preference is Arial 12 pt, but font choice is optional.

Send abstract as an email attachment to Bobbi Rose at brose@health.usf.edu

You will get a reply within a day or two that the abstract was received. If you do not hear back, please call Bobbi Rose at (813) 974-6158, or send another email. Decisions by the abstract review committee for oral considerations are expected by early December 2019. Notification will be by email. The conference does not provide any support for abstract presenters, regardless of presentation outcome. Abstract presenters must register to attend the conference.

manufacturers have a license that allows them to continue to use it without support. Therefore, the software may be incorporated into a variety of medical and industrial devices that are still in use today.

Security researchers, manufacturers and the FDA are aware that the following operating systems are affected, but the vulnerability may not be included in all versions of these operating systems:

- VxWorks (by Wind River)
- Operating System Embedded (OSE) (by ENEA)
- INTEGRITY (by GreenHills)
- ThreadX (by Microsoft)
- ITRON (by TRON)
- ZebOS (by IP Infusion)

The agency is asking manufacturers to work with health care providers to determine which medical devices, either in their health care facility or used by their patients, could be affected by URGENT/11 and develop risk mitigation plans. Patients should talk to their health care providers to determine if their medical device could be affected and to seek help right away if they notice the functionality of their device has changed.

The FDA takes reports of vulnerabilities in medical devices very seriously and today's safety communication includes recommendations to manufacturers for continued monitoring, reporting and remediation of medical device cybersecurity vulnerabilities. The FDA is recommending that manufacturers conduct a risk assessment, as described in the FDA's cybersecurity postmarket guidance, to evaluate the im-

pact of these vulnerabilities on medical devices they manufacture and develop risk mitigation plans. Medical device manufacturers should work with operating system vendors to identify available patches and other recommended mitigation methods, work with health care providers to determine any medical devices that could potentially be affected, and discuss ways to reduce associated risks.

Some medical device manufacturers are already actively assessing which devices may be affected by URGENT/11 and are identifying risk and remediation actions. In addition, several manufacturers have already proactively notified customers of affected products, which include medical devices such as an imaging system, an infusion pump and an anesthesia machine. The FDA expects that additional medical devices with one or more of the cybersecurity vulnerabilities will be identified.

"While we are not aware of patients who may have been harmed by this particular cybersecurity vulnerability, the risk of patient harm if such a vulnerability were left unaddressed could be significant," said Suzanne Schwartz, M.D., MBA, deputy director of the Office of Strategic Partnerships and Technology Innovation in the FDA's Center for Devices and Radiological Health. "The safety communication issued today contains recommendations for what actions patients, health care providers and manufacturers should take to reduce the risk this vulnerability could pose. It's important for manufacturers to be aware that the nature of these vulnerabilities allows the attack to occur undetected and without user interaction. Because an attack may

be interpreted by the device as a normal network communication, it may remain invisible to security measures."

The FDA will continue its work with manufacturers and health care delivery organizations—as well as security researchers and other government agencies—to help develop and implement solutions to address cybersecurity issues throughout a device's total product lifecycle.

The FDA will continue to assess new information concerning the URGENT/11 vulnerabilities and will keep the public informed if significant new information becomes available.

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

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

Released: Thursday 12/13/2018 12:32 PM, updated Saturday 3/16/2019 08:38

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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- Network with other pediatricians, pharmacists, and other health care providers to be stronger advocates for children.
- 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-member-ship/ then click on "Other Allied Health Providers" at the bottom of the page.

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

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Dedicated to the Health of All Children

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

FDA approves first treatment for children with rare diseases that cause inflammation of small blood vessels

Rituxan approved to treat ganulomatosis with polyangiitis and microscopioc polyangiitis.

For Immediate Release: September 27, 2019

The U.S. Food and Drug Administration today approved Rituxan (rituximab) injection to treat granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA) in children 2 years of age and older in combination with glucocorticoids (steroid hormones). It is the first approved treatment for children with these rare vasculitis diseases, in which a patient's small blood vessels become inflamed, reducing the amount of blood that can flow through them. This can cause serious problems and damage to organs, most notably the lungs and the kidneys. It also can impact the sinuses and skin.

"The Rituxan application for pediatric GPA and MPA was approved under a priority



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review, and with orphan designation, to fulfil an unmet medical need for these rare and serious diseases. Rituxan provides a treatment option that has not existed until now for children who suffer from these diseases," said Nikolay Nikolov, M.D., associate director for rheumatology of the Division of Pulmonary, Allergy and Rheumatology Products in the FDA's Center for Drug Evaluation and Research.

The safety profile in pediatric patients with GPA, formerly known as Wegener's granulomatosis, and MPA was consistent in type, nature and severity with the known safety profile of Rituxan in adult patients with autoimmune diseases, including GPA and MPA. The pediatric clinical trial consisted of 25 patients ages 6 to 17 years with active GPA and MPA who were treated with Rituxan or non-U.S.-licensed rituximab in an international multicenter, open-label, single-arm, uncontrolled study. All patients were given methylprednisolone prior to starting treatment.

During the clinical trial, after a 6-month remission induction phase where patients were treated only with Rituxan or non-U.S.-licensed rituximab and glucocorticoids, patients who had not achieved remission – or who had progressive disease or an uncontrolled flare-up (when disease symptoms suddenly worsen) - could receive additional treatment, including other therapies, at the discretion of the investigator. In total, 14 of the patients were in remission at the 6-month mark. After 18 months, all 25 patients were in remission. Additional pharmacokinetic (exposure) and safety information supported the use of Rituxan in patients 2 years to 5 years of age with GPA/MPA. The most common side effects in the pediatric study were infections, infusion-related reactions and nausea. Hypogammaglobulinemia (reduced serum immunoglobulin levels) has also been observed in pediatric GPA and MPA patients treated with the study products.

The most common side effects of Rituxan are infections, infusion-related reactions, abnormally low level of lymphocytes in the blood (lymphopenia) and anemia. Health care professionals are advised to monitor patients for tumor lysis syndrome



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(a treatment complication where tumor cells are killed off at the same time and released into the bloodstream), cardiac adverse reactions, damage to kidneys (renal toxicity), and bowel obstruction and perforation (small hole formation).

The doctor and patient information for Rituxan contains a boxed warning to draw attention to increased risks of the following: fatal infusion reactions; potentially fatal severe skin and mouth reactions; hepatitis B virus reactivation that may cause serious liver problems, including liver failure and death; and progressive multifocal leukoencephalopathy, a rare, serious brain infection that can result in severe disability or death. This product must be dispensed with a patient Medication Guide that provides important information about the drug's uses and risks. Rituxan was approved to treat adult patients with GPA and MPA in 2011. It is also approved to treat four additional diseases, first gaining approval to treat Non-Hodgkin's lymphoma in 1997.

Rituxan received priority review designation, under which the FDA's goal is to take

action on an application within six months where the agency determines that the drug, if approved, would significantly improve the safety or effectiveness of treating, diagnosing or preventing a serious condition. Rituxan also received orphan drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases.

The FDA granted the approval of Rituxan to Genentech.

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

Inquiries Media: Nathan Arnold





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Initiating Breastfeeding in Vulnerable Infants

Initiating Breastfeeding is essential in vulnerable infants.

7-Oct-2019 4:05 PM EDT University of Pennsylvania School of Nursing

Newswise — PHILADELPHIA (October 7, 2019) - The benefits of breastfeeding for both mother and child are well-recognized, including for late preterm infants (LPI). But because LPI do not have fully developed brains, they may experience difficulties latching and/or sustaining a latch on the breast to have milk transfer occur. This means that these infants are at high risk for formula supplementation and/or discontinuation of breastfeeding. Without human milk, these infants lose a critical component for protection and optimal development of their brains. A first-of-its-kind study from the University of Pennsylvania School of Nursing (Penn Nursing) describes the positive human milk and breastfeeding outcomes in a program of care at the Children's Hospital of Pennsylvania for LPI born with myelomeningocele (MMC) which is also known as Spina Bifida. MMC is a condition in which the infant's backbone and spinal canal do not close before birth and it is one of the most common defects in the United States.

"This study demonstrates that with appropriate evidence-based breastfeeding interventions, mothers having infants with myelomeningocele can expect to feed their infants human milk as well as direct breastfeed," said the study's lead investigator Diane L. Spatz, PhD, RN-BC, FAAN, Professor of

Perinatal Nursing and the Helen M. Shearer Term Professor of Nutrition.

By using a unique transition-to-breast pathway program, a majority of the infants in the study were feeding unfortified material human milk at discharge. The pathway includes a personalized prenatal nutrition (lactation) consult for all mothers in the prenatal care program, which focuses on human milk as a medical intervention and the unique needs of the infant with MMC. The program also includes, among other things, early and frequent pumping to establish milk supply and skin-to-skin contact from birth, as well as the option for parents to have their infants supplemented with Pasteurized Donor Human Milk (PDHM) versus traditional formula. By having families have access to PDHM, we can keep the babies having an exclusive human milk diet which is better for the newborn's gut integrity. PDHM is used as a bridge to mom's own milk and can help parents reach their personal breastfeeding goals.

The study, "Human Milk and Breastfeeding Outcomes in Infants With Myelomeningocele," provides details about the pathway and has been published in the journal Advances in Neonatal Care. Co-author of the article is Elizabeth Froh, PhD, RN, of Children's Hospital of Pennsylvania.

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About the University of Pennsylvania School of Nursing

The University of Pennsylvania School of Nursing is one of the world's leading schools of nursing. For the fourth year in a row, it is ranked the #1 nursing school in the world by QS University and is consistently ranked highly in the U.S. News & World Report annual list of best graduate schools. Penn Nursing is currently ranked # 1 in funding from the National Institutes of Health, among other schools of nursing, for the second consecutive year. Penn Nursing prepares nurse scientists and nurse leaders to meet the health needs of a global society through innovation in research, education, and prac-

tice. Follow Penn Nursing on: Facebook, Twitter, LinkedIn, & Instagram.

NT

Low Rates of Vaccination During Pregnancy Leave Moms, Babies Unprotected

Nearly half of U.S. newborns and new moms at risk of influenza or whooping cough hospitalization or death

CDC Press Release

Embargoed Until: October 8, 2019, 1:00 p.m. ET

Contact: Media Relations

(404) 639-3286

The majority of mothers-to-be in the United States – 65% – have not received two safe and effective vaccines recommended during pregnancy to reduce the risks of influenza (flu) and whooping cough (pertussis) and protect their infants and themselves, according to a new Vital Signs report released today by the Centers for Disease Control and Prevention (CDC).

When pregnant women are vaccinated they pass on antibodies to the fetus that provide protection after birth, during the time babies are too young to be vaccinated. Newborns who get influenza or whooping cough are at high risk of hospitalization and death.

And the benefits are not just for the babies. Pregnant women have more than double the risk of hospitalization compared to nonpregnant women of childbearing age if they get influenza. Since 2010, among women ages 15 to 44 years who were hospitalized for influenza, 24% to 34% of them were pregnant – even though only approximately 9% of U.S. women in this





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age group are pregnant at any given time each year.

CDC recommends that all pregnant women should get a flu vaccine during any trimester of each pregnancy and the whooping cough vaccine (Tdap) during the early part of the third trimester of each pregnancy as part of routine prenatal care.

CDC Director Robert Redfield, M.D.

"I want to reinforce that all expectant mothers should be up-to-date with recommended vaccinations as part of their routine prenatal care," said CDC Director Robert Redfield, M.D. "CDC strongly recommends that health care providers speak with moms-to-be about the benefits of safe Tdap and flu vaccination for their health and the well-being of their babies."

CDC surveyed nearly 2,100 women ages 18 to 49 who were pregnant any time between August 2018 and April 2019. Among the survey findings:

54% of pregnant women reported getting a flu vaccine before or during pregnancy.

55% of women reported receiving Tdap during pregnancy.

Women whose health care providers offered or referred them for vaccination had the highest vaccination rates.

Black, non-Hispanic women had lower vaccination rates than women of other races and were less likely to report a health care provider offer or referral for vaccination.

Every year, too many U.S. babies or their mothers get vaccine-preventable diseases

A recent study showed that getting a flu shot reduces a pregnant woman's risk of being hospitalized due to influenza by an average of 40%. Influenza is also dangerous for babies, especially those younger than 6 months, who are too young to get a flu shot. Babies under 6 months have the highest incidence of influenza-associated hospitalizations and highest risk of influenza-related death among children. Flu vaccination in pregnant women reduces the risk of hospitalization due to influenza in their infants younger than 6 months old

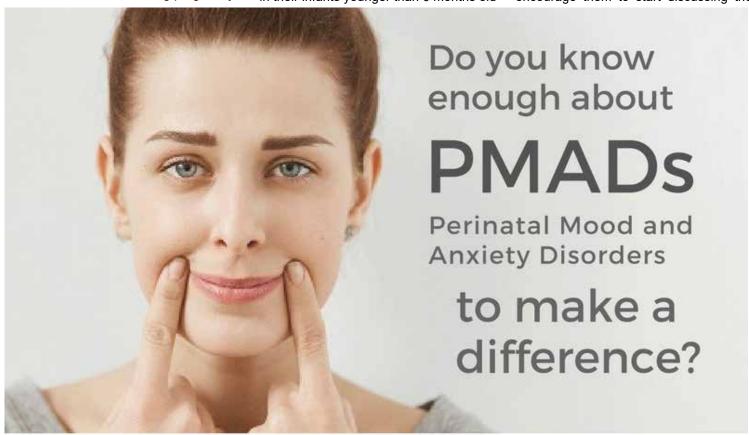
by an average of 72%.

Whooping cough can be deadly for babies, especially before they can start getting the childhood whooping cough vaccine at 2 months old. Two thirds (67%) of babies younger than 2 months old who get whooping cough need care in the hospital. Sadly, 7 out of 10 whooping cough deaths (69%) occur in this age group.

By getting Tdap vaccine during the third trimester of pregnancy, mothers build high levels of antibodies that transfer to the fetus and continue to protect the baby after birth, preventing more than 3 in 4 cases (78%) of whooping cough in babies under 2 months old. Tdap vaccination during pregnancy is even more effective at preventing hospitalization due to whooping cough in newborns.

Amanda Cohn, M.D., Chief Medical Officer

"Obstetricians and midwives are on the front line of care for expectant mothers and are the most trusted source of vaccine information for their pregnant patients. We encourage them to start discussing the





nationalperinatal.org/mental_health

importance of maternal vaccination early in pregnancy, and continue vaccination discussions with their patients throughout pregnancy," said Amanda Cohn, M.D., chief medical officer in CDC's National Center for Immunization and Respiratory Diseases."

To read more about the Burden and Prevention of Influenza and Pertussis Disease Among U.S. Pregnant Women and Infants and the entire Vital Signs report, visit: www.cdc.gov/vitalsigns.

About Vital Signs

Vital Signs is a report that appears as part of the CDC's Morbidity and Mortality Weekly Report. Vital Signs provides the latest data and information on key health indicators.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

NT

With End of New York Outbreak, United States Keeps Measles Elimination Status The United States has maintained its defenses against Measles.

FOR IMMEDIATE RELEASE October 4, 2019 Contact: HHS Press Office 202-690-6343 media@hhs.gov

CThe United States has maintained its measles elimination status of nearly 20 years. The New York State Department of Health yesterday declared the end of the state's nearly year-long outbreak that had put the U.S. at risk of losing its measles elimination status.

"We are very pleased that the measles outbreak has ended in New York and that measles is still considered eliminated in the United States. This result is a credit to the cooperative work by local and state health departments, community and religious leaders, other partners, and the CDC," said HHS Secretary Alex Azar. "But this past year's outbreak was an alarming reminder about the dangers of vaccine hesitancy and misinformation. That is why the Trump Administration will continue making it a priority to work with communities and promote vaccination as one of the easiest things you can do to keep you and your family healthy and safe."

The CDC confirmed 1,249 cases of measles between January 1 and October 4, 2019. This year marks the greatest number of measles cases in the country since 1992. While cases have been reported in 31 states, 75% of measles cases were linked to outbreaks in New York City and New York state, most of which were among unvaccinated children in Orthodox Jewish communities. These outbreaks have been traced to unvaccinated travelers who brought measles back from other countries at the beginning of October

2018.

Since measles outbreaks continue to occur in countries around the world, there is always a risk of measles importations into the U.S. When measles is imported into a highly vaccinated community, outbreaks either do not happen or are usually small. However, if measles is introduced into an under-vaccinated community, it can spread quickly and it can be difficult to control. Measles elimination status is lost immediately if a chain of transmission in a given outbreak is sustained for more than 12 months. CDC has been working with the Pan American Health Organization (PAHO) throughout the year to keep stakeholders updated on measles surveillance. CDC will also meet with PAHO's Regional Verification Commission in the coming months to review the U.S. surveillance data and verify measles elimination status.

In the last year, the United Kingdom, Greece, Venezuela, and Brazil have lost their measles elimination status. Data from the World Health Organization indicates that during the first six months of the year there have been more measles cases reported worldwide than in any year since 2006. From January 1 – July 31, 2019, 182 countries reported 364,808 cases of measles. That increase is part of a global trend seen over the past few years as other countries struggle with achieving and maintaining vaccination rates.

A significant factor contributing to the outbreaks this year has been misinformation in some communities about the safety of the measles-mumps-rubella (MMR) vaccine. Some organizations are deliberately targeting these communities with inaccurate and misleading information about vaccines. CDC continues to encourage

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parents to speak to their family's healthcare provider about the importance of vaccination. CDC also encourages local leaders to provide accurate, scientificbased information to counter misinformation.

"Our Nation's successful public health response to this recent measles outbreak is a testament to the commitment and effectiveness of state and local health departments, and engaged communities across the country," said CDC Director Robert R. Redfield, M.D. "CDC encourages Americans to embrace vaccination with confidence for themselves and their families. We want to emphasize that vaccines are safe. They remain the most powerful tool to preserve health and to save lives. The prevalence of measles is a global challenge, and the best way to stop this and other vaccine preventable diseases from gaining a foothold in the U.S. is to accept vaccines."

Before the measles vaccine was introduced in the U.S., nearly all children got measles by the time they were 15 years of age. It is estimated three to four million people were infected, and among the 500,000 measles cases reported annually, 48,000 were hospitalized and 500 people died.

Note: All HHS press releases, fact sheets and other news materials are available at https://www.hhs.gov/news.

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Last revised: October 4, 2019

NT

CDC and ATSDR Award \$7 Million to Begin Multi-Site PFAS Study

Study to determine long reaching effects of water contamination including those on infants and pregnant women..

CDC Press Release

For Immediate Release: September 23,

2019

Contact: Media Relations

(404) 639-3286

The Centers for Disease Control and Prevention (CDC) and Agency for Toxic Substances and Disease Registry (ATSDR) are announcing the start of a multi-site health study to investigate the relationship between drinking water contaminated with per- and polyfluoroalkyl substances (PFAS) and health outcomes. CDC and ATSDR are making awards, in the amount of \$1 million each, to the following institutions to look at exposures in communities listed:

Colorado School of Public Health, University of Colorado Anschutz Medical Campus, to look at exposures in El Paso County, CO

Michigan State Department of Health and Human Services to look at exposures in Parchment/Cooper Township, MI, and North Kent County, MI

RTI International and the Pennsylvania Department of Health to look at exposures in Montgomery County, PA

Rutgers Biomedical and Health Sciences – School of Public Health to look at exposures in Gloucester County, NJ

Silent Spring Institute to look at exposures in Hyannis, MA, and Ayer, MA

University at Albany, SUNY and New York State Department of Health to look at exposures in Hoosick Falls, NY, and Newburgh, NY

University of California – Irvine to look at exposures in communities near the UC Irvine Medical Center

"There is much that is unknown about the health effects of exposures to these chemicals," said Patrick Breysse, PHD, CIH, Director of ATSDR and CDC's National Center for Environmental Health. "The multi-site study will advance the scientific evidence on the human health effects of PFAS and provide some answers to communities exposed to the contaminated drinking water."

The multi-site health study was authorized by the National Defense Authorization Acts of 2018 and 2019 to provide information to communities about the health effects of PFAS exposure. This is

the first study to look at exposure to multiple PFAS at sites across the nation. The information learned from the multi-site study will help all communities in the U.S. with PFAS drinking water exposures by allowing communities and governmental agencies to make better decisions about how to protect public health.

The goal of the multi-site study is to understand the relationship between PFAS exposure and health outcomes in differing populations. The study will add to our scientific knowledge about PFAS exposure and help people understand their risks for health effects.

The scientific evidence linking PFAS exposures with adverse health effects is increasing. Some studies in people have shown that exposure to certain PFAS might affect people's health in the following ways:

- Adversely affect growth, learning, and behavior of infants and children
- Lower a woman's chance of getting pregnant
- Interfere with the body's natural hormones
- Increase cholesterol levels
- Affect the immune system
- Increase the risks for some cancers
- The multi-site study will recruit at least

2,000 children aged 4–17 years and 6,000 adults aged 18 years and older who were exposed to PFAS-contaminated drinking water. Participants and birth mothers of eligible children cannot have a history of work exposure to PFAS.

BACKGROUND

PFAS are man-made chemicals that have been used in industry and consumer products since the 1950s. They have been used in non-stick cookware; waterrepellent clothing; stain-resistant fabrics and carpets; some cosmetics; some firefighting foams; and products that resist grease, water, and oil. Scientists are still learning about the health effects of exposure to PFAS. Some studies have shown that PFAS exposure may affect growth, learning, and behavior of infants and older children; lower a woman's chance of getting pregnant; interfere with the body's natural hormones; increase cholesterol levels; affect the immune system; and increase the risk of cancer.

For more information about the PFAS multi-site health study, visit: https://www.atsdr.cdc.gov/pfas/related_activities.html#Multi-Site-Health-Study. For more information about PFAS and available resources, visit: https://www.atsdr.cdc.gov/pfas/index.html or call 1-800-CDC-INFO (232-4636).

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About the National Association of Pediat-

ric Nurse Practitioners

The National Association of Pediatric Nurse Practitioners (NAPNAP) is the nation's only professional association for pediatric nurse practitioners (PNPs) and their fellow pediatric-focused advanced practice registered nurses (APRNs) who are dedicated to improving the quality of health care for infants, children, adolescents and young adults. Representing more than 9,000 healthcare practitioners with 19 special interest groups and 50 chapters, NAPNAP has been advocating for children's health since 1973 and was the first NP society in the U.S. Our mission is to empower pediatric-focused PNPs and their interprofessional partners to enhance child and family health through leadership, advocacy, professional practice, education and research.

###

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 wellbeing of infants, children, adolescents and young adults. For more information, visit www.aap.org and follow us on Twitter @AmerAcadPeds

N٦

Use of antibiotics in preemies has lasting, potentially harmful effects

Drug resistance, unhealthy bacteria persist in gut microbiome

5-Sep-2019 5:05 PM EDT Washington University in St. Louis

V

Newswise — Nearly all premature babies receive antibiotics in their first weeks of life to ward off or treat potentially deadly bacte-

Save the Date: March 4-7, 2020 Call for Abstracts: Due Monday, October 28, 2019



rial infections. Such drugs are lifesavers, but they also cause long-lasting collateral damage to the developing microbial communities in the babies' intestinal tracts, according to research from Washington University School of Medicine in St. Louis.

A year and a half after babies leave the neonatal intensive care unit (NICU), the consequences of early antibiotic exposure remain, the study showed. Compared to healthy full-term babies in the study who had not received antibiotics, preemies' microbiomes contained more bacteria associated with disease, fewer species linked to good health, and more bacteria with the ability to withstand antibiotics.

The findings, published Sept. 9 in Nature Microbiology, suggest that antibiotic use in preemies should be carefully tailored to minimize disruptions to the gut microbiome – and that doing so might reduce the risk of health problems later in life.

"The type of microbes most likely to survive antibiotic treatment are not the ones we typically associate with a healthy gut," said senior author Gautam Dantas, PhD, a professor of pathology and immunology, of molecular microbiology, and of biomedical engineering. "The makeup of your gut microbiome is pretty much set by age 3, and then it stays pretty stable. So if unhealthy microbes get a foothold early in life, they could stick around for a very long time. One or two rounds of antibiotics in the first couple weeks of life might still matter when you're 40."

Healthy gut microbiomes have been linked to reduced risk of a variety of immune and metabolic disorders, including inflammatory bowel disease, allergies, obesity and diabetes. Researchers already knew that antibiotics disrupt the intestinal microbial community in children and adults in ways that can be harmful. What they didn't know was how long the disruptions last.

To find out whether preemies' microbiomes recover over time, Dantas and colleagues – including first author Andrew Gasparrini, PhD, who was a graduate student at the time the study was conducted, and co-authors Phillip I. Tarr, MD, the Melvin E. Carnahan Professor of Pediatrics, and Barbara Warner, MD, director of the Division of Newborn Medicine – analyzed 437 fecal samples collected from 58 infants, ages birth to 21 months. Forty-one of the infants were born around 2 ½ months premature, and the remainder were born at full

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

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

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

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

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www.99nicu.org

term.

All of the preemies had been treated with antibiotics in the NICU. Nine had received just one course, and the other 32 each had been given an average of eight courses and spent about half their time in the NICU on antibiotics. None of the full-term babies had received antibiotics.

The researchers discovered that preemies who had been heavily treated with antibiotics carried significantly more drug-resistant bacteria in their gut microbiomes at 21 months of age than preemies who had received just one course of antibiotics, or full-term infants who had not received antibiotics. The presence of drug-resistant bacteria did not necessarily cause any immediate problems for the babies because most gut bacteria are harmless – as long as they stay in the gut. But gut microbes sometimes escape the intestine and travel to the bloodstream, urinary tract or other parts of the body. When they do, drug resistance can make the resulting infections very difficult to treat.

Moreover, by culturing bacteria from fecal samples taken eight to 10 months apart, the researchers discovered that the drug-resistant strains present in older babies were the same ones that had established themselves early on.

"They weren't just similar bugs, they were the same bugs, as best we could tell," Dantas said. "We had cleared an opening for these early invaders with antibiotics, and once they got in, they were not going to let anybody push them out. And while we didn't show that these specific bugs had caused disease in our kids, these are exactly the kind of bacteria that cause urinary tract and bloodstream infections and other problems. So you have a situation where potentially pathogenic microbes are getting established early in life and sticking around."

Further studies showed that all of the babies developed diverse microbiomes by 21 months of age – a good sign since lack of microbial diversity is associated with immune and metabolic disorders in children and adults. But heavily treated preemies developed diverse microbiomes more slowly than lightly treated preemies and full-term infants. Further, the makeup of the gut microbial communities differed, with heavily treated premature infants having fewer healthy groups of bacteria such as Bifidobacteriaceae and more unhealthy kinds such as Proteobacteria.

The findings already have led Warner, who takes care of premature infants in the NICU at St. Louis Children's Hospital, and her fellow neonatalogists to scale down their use of antibiotics.

"We're no longer saying, 'Let's just start them on antibiotics because it's better to be safe than sorry," Warner said. "Now we know there's a risk of selecting for organisms that can persist and create health risks later in childhood and in life. So we're being much more judicious about initiating antibiotic use, and when we do start babies on antibiotics, we take them off as soon as the bacteria are cleared. We still have to use antibiotics – there's no question that they save lives – but we've been able to reduce antibiotic use significantly with no increase in adverse outcomes for the children."

NT



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The Neonatal Intensive Care Unit Directory

Scott Snyder, MD



The NICU Directory by Neonatology Solutions, LLC, aims to be a comprehensive, interactive, up-to-date, and FREE resource for neonatologists, neonatology fellows, and neonatal nurse practitioners to locate NICUs and neonatology programs across the United States and Canada.

"The NICU Directory by Neonatology Solutions, LLC, aims to be a comprehensive, interactive, up-to-date, and FREE resource for neonatologists, neonatology fellows, and neonatal nurse practitioners to locate NICUs and neonatology programs across the United States and Canada."

Our goal is to provide information regarding the size and scope of programs, as well as key contact names, email addresses, and phone numbers to facilitate networking, collaboration, and career planning. To do this, we need your help. Click the link to the Directory, search for your program, and update any missing or incorrect information. We greatly appreciate this grassroots effort to build a shared resource to benefit our field."

References:

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

The author is a principal of Neonatology Solutions, LLC.

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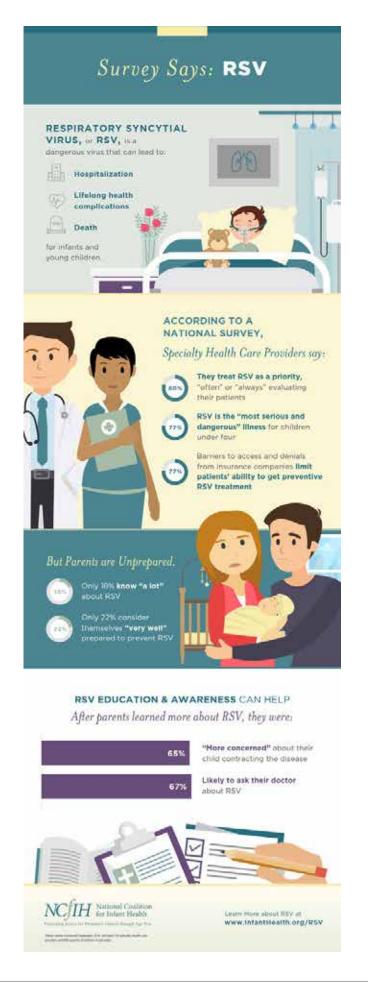
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Protecting Access for Premature Infants through Age Two

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The National Coalition for Infant Health advocates for:

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

www.infanthealth.org



Genetics Corner: Translocation Down syndrome

Daisy Hernandez, MS, LCGC Subhadra Ramanathan, MS, MSc, Robin Clark, MD

Case Summary:

A 15-week-old female was referred to Pediatric Genetics upon discharge from the NICU for translocation Down syndrome (DS). The prenatal history was uncomplicated. There were normal fetal movements. The infant was born at 36 weeks 5 days gestation by vaginal delivery to a 32 year old G2P1 mother. Birth weight was 2631 grams (2nd percentile) and head circumference was 31.5 cm (10th percentile). She was in the NICU for 2 weeks due to poor feeding and respiratory distress. She passed her newborn hearing screen. Chromosome analysis and chromosome microarray were ordered during her admission because of a clinical suspicion of DS.

Reportedly, all prenatal maternal screening tests and ultrasounds were normal and there was no indication of aneuploidy throughout the pregnancy. Parents discussed that retrospective review of the patient's detailed fetal ultrasound revealed a minor cardiac abnormality that the family was not alerted to.

Genetics Evaluation:

On physical exam, the infant had minor dysmorphic facial features suggestive of Down syndrome. She was being followed by Pediatric Cardiology for a small atrial septal defect with left to right shunting and by Hematology/Oncology for thrombocytopenia. She was s/p surgical removal of bilateral pre-auricular skin tags and a cutaneous skin tag on her right cheek.

Developmentally, the patient was doing well: she lifted her head at 2 months, rolled over at 2 months, and bore weight well, milestones that are advanced for an infant with Down syndrome. She cooed and interacted well socially. She received developmental therapy once a week that focused on motor, muscular, and speech development.

The family history was not significant. There was no family history of birth defects, developmental delay, intellectual disability, early infant deaths or multiple miscarriages. Parents are of Icelandic and Native American ancestry. Parental consanguinity was denied.

Chromosome analysis detected an 46 chromosomes, one of which was a derivative chromosome 21, that involved two copies of chromosome 21: 46,XX,+21,der(21;21)(q10;?q21). This resulted in partial duplication of the distal long arm of chromosome 21. The chromosome microarray identified a 21.2 Mb terminal duplication of chromosome 21 from 21q21.3 to 21qter, indicating partial

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trisomy for this region.

Conclusion and Counseling:

The patient has an atypical form of translocation DS due to a derivative 21;21 chromosome causing partial duplication of the distal long arm of chromosome 21. In approximately 3-5% of patients



Figure 1: At 12 months, the patient is crawling and starting to pull to a stand. Note the mild facial features of Down syndrome: epicanthal folds, round face with flat profile. Her muscle tone is remarkably good, which is atypical for DS.

"Our patient has a rare type of translocation because the breakpoint is in the long arm of one copy of chr 21, not in the centromere as expected. Our patient has a rare type of translocation because the breakpoint is in the long arm of one copy of chr 21, not in the centromere as expected."

with DS, the chromosome number is normal and the extra chromosomal material is translocated to another chromosome (2). This type of rearrangement is known as a Robertsonian translocation. Robertsonian translocations result from the fusion of two acrocentric chromosomes (chromosomes 13, 14, 15, 21 and 22), with chromosome 14 being the most common partner chromosome involved in Robertsonian translocations (2).

Our patient has a rare type of translocation because the breakpoint is in the long arm of one copy of chr 21, not in the centromere as expected. She has a partial duplication of the distal long arm of chromosome 21. This has been called "Partial Trisomy 21" in the medical literature and the phenotype may be somewhat

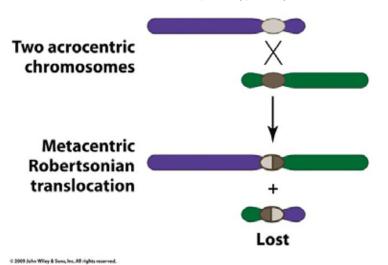


Figure 2: In a typical Robertsonian translocation, the breakpoints are in the centromeres and there are two copies of the long arms of the acrocentric chromosomes in the derivative chromosome

milder than the more typical types of DS that include a complete extra copy of chromosome 21. However, since she has three copies of the DS critical region at 21q22.13, on the distal long arm of chromosome 21, we expect her to demonstrate most of the features typically associated with DS.

This case highlights the critical importance of obtaining chromosome analysis to confirm the clinical suspicion of Down syndrome.

As stated in the previously described Down syndrome toolkit (please see the September issue of Neonatology Today for a detailed description of this toolkit) chromosome analysis is usually a confirmatory test, but it also distinguishes the more common trisomy 21 from the less common translocation and mosaic types of Down syndrome. , which differ in their recurrence risks. Chromosome analysis is therefore necessary for providing appropriate genetic counseling.

Additionally, (as previously described in the August issue of Neonatology Today) chromosome analysis is a better first-line test when an aneuploidy is suspected or when there is a family history of multiple miscarriages or infertility when a balanced translocation is suspected. Chromosome microarray analyzes DNA rather than whole chromosomes, and does not identify translocations, inversions or other structural chromosome rearrangements. Whereas, conventional cytogenetic analysis uses microscopic analysis of banded chromosomes and examines explicitly the shape and morphology of chromosomes.

Parental chromosome analysis was recommended to identify mosaicism for this derivative chromosome in one of the parents or any structural changes (e.g. Inversion) in chromosome 21 that may predispose to an unbalanced rearrangement in their future offspring and to clarify the recurrence risk for DS in future pregnancies. Approximately 25% of Robertsonian translocation DS is familial and 75% is de novo. (1) Both parents had a normal chromosome result.

The difference between prenatal diagnostic and screening test options for the detection of chromosome abnormalities was discussed with the family. Prenatal screening options, such as maternal serum screening, ultrasound and non-invasive prenatal screening (NIPS), will not identify all cases of DS. Maternal serum screening has an 80-90% detection rate for DS depending on the type of screening that is performed. (4) NIPS has a detection rate of 99% (which varies somewhat with the laboratory and the technique) for Down syndrome. (3) Additionally, approximately 30% of fetuses with Down syndrome have a major structural anomaly present on ultrasound and about 50-60% may have one or more findings on an 18-20-week ultrasound (3). Prenatal diagnostic tests, such as amniocentesis and chorionic villus sampling, have the highest detection rate for DS at > 99.5%. Prenatal genetic counseling was recommended in all future pregnancies as parental germline mosaicism cannot be ruled out. The recurrence risk

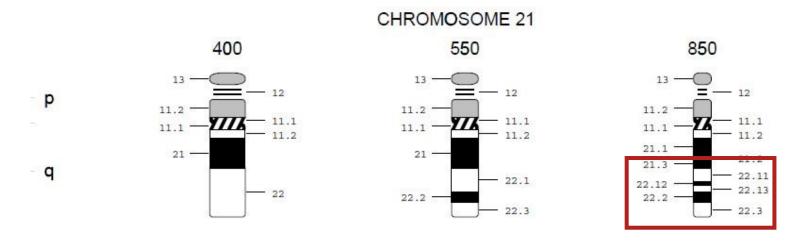


Figure 3: http://www.pathology.washington.edu/research/cytopages/idiograms/human/hum_21.pdf

The duplicated region in our patient is boxed in red.

for another child with Down syndrome is 1% above the maternal age-related risk for this family.

"Prenatal genetic counseling was recommended in all future pregnancies as parental germline mosaicism cannot be ruled out. The recurrence risk for another child with Down syndrome is 1% above the maternal age-related risk for this family."



Daisy Hernandez
Licensed and Certified Genetic Counselor
Assistant Professor, Pediatrics
Loma Linda University Health
2195 Club Center Drive, Ste A
San Bernardino, CA 92408

Practical Applications:

- Features of Down syndrome can be subtle. Be aware that the phenotype can between patients and in rare cases it can indicate partial trisomy 21.
- Use chromosome analysis as your first line test when Down syndrome is suspected. Chromosome analysis is critical for confirming a diagnosis of DS as atypical cases of DS may not be identified with chromosome microarray or fluorescence in situ hybridization (FISH).
- Parental follow up testing is necessary to clarify the recurrence risk for DS ONLY when a translocation is involved.
- Prenatal screening options for an euploidy such as maternal serum screening, ultrasound or NIPS may not identify all cases of DS.

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Permission was obtained from the patient's parents to distribute her picture for education purposes.

The authors have no relevant disclosures.

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Perinatal Substance Use

5 ways you can improve care during pregnancy and beyond

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



Educate Yourself

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



Use the Right Words

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



Screen Every Patient

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



Get Trained to Offer MAT

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

*opioid treatment program



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TOP 10

RECOMMENDATIONS FOR THE PSYCHOSOCIAL SUPPORT OF NICU PARENTS



Essential evidence-based practices that can transform the health and well being of NICU families and staff

based on the National Perinatal Association's Interdisciplinary Recommendations for Psychosocial Support of NICU Parents

1 PROMOTE PARTICIPATION

Honor parents' role as primary caregiver. Actively welcome parents to participate during rounds and shift changes. Remove any barriers to 24/7 parental involvement and avoid unnecessary separation of parents from their infants.



2 LEAD IN DEVELOPMENTAL CARE

Teach parents how to read their baby's cues. Harness your staff's knowledge, skills, and experience to mentor families in the principles of neuroprotection & developmental care and to promote attachment.



3 FACILITATE PEER SUPPORT

Invest in your own NICU Parent Support program with dedicated staff. Involve veteran NICU parents. Partner with established parent-to-parent support organizations in your community to provide continuity of care.



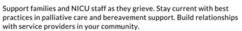
4 ADDRESS MENTAL HEALTH

Prioritize mental health by building a team of social workers and psychologists who are available to meet with and support families. Provide appropriate therapeutic interventions. Consult with staff on trauma-informed care - as well as the critical importance of self-care.



Establish trusting and therapeutic relationships with parents by meeting with them within 72 hours of admission. Follow up during the first week with a screening for common maternal & paternal risk factors. Provide anticipatory guidance that can help normalize NICU distress and timely interventions when needed. Re-screen prior to discharge.







7 PLAN FOR THE TRANSITION HOME

Set families up for success by providing comprehensive pre-discharge education and support. Create an expert NICU discharge team that works with parents to find specialists, connect with service providers, schedule follow-up appointments, order necessary medical supplies, and fill Rx.



8 FOLLOW UP

Re-connect with families post-discharge. Make follow-up calls. Facilitate in-home visits with community-based service providers, including Early Intervention. Partner with professionals and paraprofessionals who can screen families for emotional distress and provide timely therapeutic interventions and supports.

9 SUPPORT NICU CARE GIVERS

Provide comprehensive staff education and support on how to best meet families' psychosocial needs, as well as their own.

Acknowledge and address feelings that lead to "burnout."



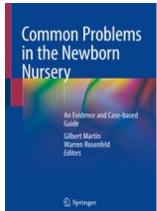
10 HELP US HEAL

Welcome the pastoral care team into your NICU to serve families & staff.

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



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- Utilizes a case-based approach

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

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

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Infant Health Policy Summit 2019

Susan Hepworth



Protecting Access for Premature Infants through Age Two

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

"The fifth annual Infant Health Policy Summit welcomed health care providers, parents, regulators, advocates and other stakeholders to explore how policy solutions can keep infants and their families safe and healthy."

Disclosures: The author does not have any relevant disclosures.

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"The National Coalition for Infant Health sponsored a diaper drive in conjunction with the summit, collecting more than 2,000 diapers for the Greater DC Diaper Bank. Learn more about the National Coalition for Infant Health's policy priorities and advocacy initiatives online at www.infanthealth.org."

Corresponding Author



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

National Coalition for Infant Health Values (SANE)

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

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

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

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

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OVERVIEW

The fifth annual Infant Health Policy Summit welcomed health care providers, parents, regulators, advocates and other stakeholders to explore how policy solutions can keep infants and their families safe and healthy.

Held in Washington, DC, the event examined issues such as:

- Medical innovation for neonates
- · Vaccine hesitancy and outbreaks of preventable diseases
- Respiratory health
- Disparities in the NICU
- · Breastfeeding and human milk
- Maternal nutrition
- Tubing safety in the NICU.

Suzanne Staebler, DNP, policy advisor to the *National Coalition* for *Infant Health* offered welcoming remarks, noting to the crowd that, "We won't shy away from tough issues and honest policy debate here. Because what's at stake is too important."

The summit, which included a series of panel discussions and on-stage interviews, was convened by the Institute for Patient Access and co-hosted by the National Coalition for Infant Health and the Alliance for Patient Access.



We can change the policies that shape these infants' lives.

"

-SUZANNE STAEBLER, DNP



BREASTFEEDING & HUMAN MILK



Describing the value of human milk as a "cornerstone issue" for the *National Coalition for Infant Health*, Medical Director **Mitchell Goldstein, MD**, moderated a discussion of how breast milk

benefits the human microbiome.



Human milk doesn't just promote "good" gut bacteria but can reduce the risk of lower respiratory infections by 50%, explained **Cynethia Bethel-Jaiteh, DNP**, of the *University of Louisville*

School of Nursing, and lower the risk of GI infections by 59%. It can also reduce the risk



of necrotizing enterocolitis, explained **Victoria Niklas**, **MD**, of *Prolacta Bioscience*.

The benefits aren't always known to parents, however. Bethel-Jaiteh noted that rates of breastfeeding lag

among black families in particular.



Meanwhile, **Deb Discenza** of *PreemieWorld* recalled her own challenges pumping breast milk for her premature daughter, born at 30 weeks gestation, while the hospital intended to give her daughter

formula. She urged parents to speak out about their preferences for their babies' nutrition.

INNOVATION FOR NEONATES

Getting infants and their families what they need also requires effective public policies. In an interview with **Amy Akers** of the *National Perinatal Association*, the *Food and Drug Administration's* **Susan McCune, MD**, described the strides that research and regulatory policy have made for neonates. She noted that safety efforts have come a long way, describing morphine-laced "syrup" promoted in the early 1900s for babies with colic or teething pains.

Legislative policies are increasingly designed to promote the development of drugs specifically tested and designed for infants, Dr. McCune explained. She noted the impact of bills like the "Best Pharmaceuticals for Children Act" in 2002, which incentivizes the development of drugs for infants.



But the process is rife with challenges. Only about 40% of pediatric drugs are successful, Dr. McCune noted. She emphasized the role of partnership, encouraging nonprofits and other stakeholders to join alongside regulators and researchers to improve options for treating infants.

TUBING SAFETY & MATERNAL NUTRITION



Infant health, safety and parent education also came to light in updates provided by *National Coalition for Infant Health* Executive Director **Susan Hepworth**.

On the topic of tubing and connector systems used in NICUs, Hepworth alluded to hospitals being pressured to incorporate a tubing connector system known as ENFit, which can present safety challenges for infants. Hepworth emphasized the importance of thoughtful consideration by hospital systems and NICUs, which should make decisions based on what's best for their patients. "When patient safety is on the line," Hepworth emphasized, "hospitals and health care providers need to be fully informed before converting to any new tubing systems."

Hepworth also addressed new guidelines on pregnant mothers and fish consumption. Recently revised FDA advice could, Hepworth noted, "help pregnant women confidently add more seafood to their diet, with the goal to have pregnant women eat, on average, as much as six times more seafood than they currently do." In past years, conflicting messages have led to confusion and left pregnant and breastfeeding women missing out on the benefits that fish offers their developing babies.



RESPIRATORY CARE

Respiratory care is one area where continued policy progress is needed. In a conversation with **Ashley Darcy Mahoney, PhD**, of *The George Washington University School of Nursing,* **Donald Null, MD**, of *UC Davis Children's Hospital* described the improvement he's seen during the course of his career. It can take "a long time" for advances to make their way through, Dr. Null noted, and even then, policy often lags behind.

Erin Thatcher of the *PPROM Foundation* knows that all too well. The mother of fraternal twins born prematurely, Thatcher described the impact of respiratory syncytial virus on her daughter, now 7, who still battles asthmalike symptoms from the disease. The effects of RSV "can last for years," Dr. Null explained.

The panel spoke about American Academy of Pediatrics guidelines from 2014, which had the effect of reducing the number of infants who receive RSV prophylaxis. Of those guidelines, Thatcher noted, "I wish they'd look at long-term outcomes...the policies are not taking into account what's happening to families."





KEYNOTE ADDRESS

Keynote speaker and *CNN* anchor **Alisyn Camerota** told her own story of prematurity, NICU care and motherhood, highlighting many of the day's themes.

Camerota recalled how a routine prenatal check-up at 30 weeks turned life changing when her doctor announced that she'd need to deliver her twin daughters within 48 hours. A rare condition was preventing one baby from receiving sufficient nutrition through the umbilical cord.

As Camerota explained, this was just one of the challenges she faced. Before her pregnancy, Camerota had struggled with infertility. After her daughters were both safely delivered and in the NICU, she faced breastfeeding challenges.

Camerota described attempting to pump breastmilk for days with no results. When she told her doctor she was ready to give up, he advised, "Give it one more day." The next day, Camerota recalled, she produced her first drops of milk.

Camerota highlighted the importance of perseverence for parents of preemies and hailed NICU staff as "angels on Earth."







VACCINE HESITANCY

As legislative efforts to curb preventable disease outbreaks unfolded in real time, the Infant Health Policy Summit took up the issue during a panel discussion entitled "Vaccine Hesitancy." Daniel Salmon, PhD, of Johns Hopkins University School of Medicine and Mary Koslap-Petraco, DNP, of Stony Brook University School of Nursing debunked widespread myths that have led to a rise in vaccine exemptions – and fueled outbreaks of preventable diseases. Topics included autism links, government overreach and misinformation about vaccine ingredients.

Confusion on these and other ideas have led to a rise in vaccine hesitancy among parents – and resulted in new laws in both California and New York to reduce vaccine exemptions that aren't medically justified.

Both Salmon and Koslap-Petraco emphasized the importance of empathizing with parents who are concerned about vaccines. They also described the value of telling stories about immunizing their own children.

"I say, 'I have six children,'"
Salmon explained of his
conversations with parents,
"'They're all vaccinated
according to the schedule
because that's the best way
to protect my children.'"

Salmon and Koslap-Petraco also noted the importance of educating parents about the potential impact of vaccine-preventable diseases like measles, rubella and hepatitis B.



NICU DISPARITIES

Good communication with parents of young children was also a central theme in a panel discussion about how to build patient-centered NICUs.

DeShay Rice-Clansy, MSW, of Atlanta's *Grady Health System* and Brigit M. Carter, PhD, RN, of *Duke University School of Nursing* described how the different demographics being served by NICUs can present strikingly different needs. One mother delivering her baby at Grady Hospital, Rice-Clansy recalled, had only a second-grade education.

Other families faced challenges as stark as homelessness, mental health issues, substance abuse and sex trafficking.

These hospitals and their NICUs must meet families where they are, explained **Suzanne Staebler, DNP**, of *Emory University*. That includes staffing the hospital with diverse health care providers. But that's not always easy. As Bridget Carter, PhD, of Duke University School of Nursing explained, the rate of diverse providers is "phenomenally low."

The National Coalition for Infant Health sponsored a diaper drive in conjunction with the summit, collecting more than 2,000 diapers for the Greater DC Diaper Bank. Learn more about the National Coalition for Infant Health's policy priorities and advocacy initiatives online at www.infanthealth.org.



Protecting Access for Premature Infants through Age Two

www.infanthealth.org





Which Infants are More Vulnerable to Respiratory Syncytial Virus?

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

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

*Source: Respirator Syncytial Virus and African Americans

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



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





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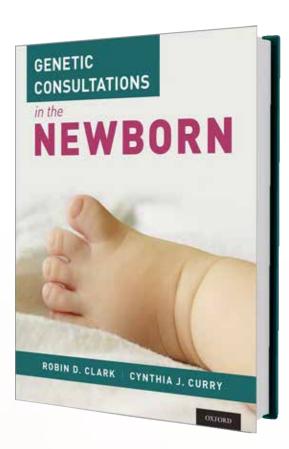


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RSV AWARENESS:

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%).



Peer Reviewed

Clinical Pearl:

Topical Therapy May Have Systemic Effects: Povidone-Iodine (Betadine®) in Ioban® Dressing

Emily Campbell, BSN, Joseph R. Hageman, MD, Catherine Kennedy, PT

I was talking with Emily Campbell, who is a NICU nurse and one of QI champions a couple of months ago. At that time, she was caring for a 5-month-old male infant with giant omphalocele, pulmonary hypoplasia, and chronic lung disease who had episodes of hypothermia and had an elevated TSH, low T4 and elevated urine iodine. He had multiple dehiscences of the omphalocele membrane and was being managed with a negative pressure wound therapy dressing consisting of gauze and secured with loban (a film dressing impregnated with lodine). Dressing changes were completed 2x/wk by Catherine Kennedy from Physical Therapy and ongoing management help from pediatric surgery and plastics services. The Pediatric endocrinology service made the association between the systemic absorption of the topical iodine and the elevated Thyroid Stimulating Hormone, low T4, and elevated urinary iodine, consistent with hypothyroidism (1-3). This clinical story brought back a memory from 45 years ago as a medical student during my senior rotation I learned about this form of hypothyroidism in caring for an infant with giant omphalocele who had topical povidone-iodine applied to the membrane to stimulate granulation and some shrinkage of the membrane.

Here is a summary of his current wound management for your review: The omphalocele wound was initially being treated with twice-daily silvadene dressing changes. The omphalocele dehisced and required intervention, and at this time, the NPWTR dressing was introduced to minimize trauma to the tissue and maintain a healthy wound environment.

"The major lesson from this presentation is to be aware of what is being applied topically to wounds, membranes, and congenital and acquired defects and how these topicals may impact other systems."

At this time, plastic surgery placed a negative pressure dressing with two drains, one in which an antibiotic solution was instilled into the gauze covering the omphalocele and wound, and the other connected to continuous negative pressure via wall suction (we used a pleur evac® to wall suction). The wound was dressed with Mepitel® (a silicone dressing to protect the fragile tissue), Acticoat® for antimicrobial protection, and gauze. Two drains were placed atop the wound, and a seal was attained using loban® to secure the dressing to the patient's skin. The use of the of negative pressure dressing decreased the need for twice-daily dressing changes and facilitated a healthy wound bed to promote granulation and wound closure.

At this time, the bedside RN, along with the pediatric endocrinology service, noted the recent introduction and continued use of loban covering several skin surfaces as the only recent change in Nathan's care that would have changed his lab results. loban®, as the name states, is impregnated with iodine and layered on the skin for containment of the negative pressure dressing and prevention of infection. The exposure to iodine caused transient hyperthyroidism that resulted in reflex hypothyroidism, as evidenced by the increased TSH and low T4 levels. Despite the recent development of hypothyroidism, endocrinology recommended the continued use of both loban® and levothyroxine.

Nathan was transferred to the Pediatric Intensive Care Unit for further management, where his omphalocele has decreased in size, and he is beginning the use of an abdominal binder for reduction at a later date.

The major lesson from this presentation is to be aware of what is being applied topically to wounds, membranes, and congenital and acquired defects and how these topicals may impact other systems. I was also able to find a case series of 4 infants with myelomeningocele who had iodine-containing ointment (Betadine®) (10%) applied to the membrane covering the defect, also developed increases in urinary iodine (4). Two of the four developed laboratory evidence of hypothyroidism necessitating levothyroxine therapy (4). Once the applications and levothyroxine were simultaneously stopped at age nine months, laboratory values normalized, and the 2 infants remained euthyroid (4).

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- Cosman BC, Schullinger JN, Bell JC, Regan JA. Hypothyroidism caused by topical povidone-iodine in a newborn with omphalocele. J Pediatr Surg 1988;23(4): 356-358.
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- 4. Barakat M, Carson D, Hetherton AM, et al. Hypothyroidism secondary to topical iodine treatment in infants with spina bifida. Acta Pediatr 1994; 83:741-743.

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Letters to the Editor

[EXTERNAL] Letter to the Editor

Marijuana during pregnancy

Wed 9/18/2019 9:39 PM

Trisha Roth <trisha.roth@icloud.com>

(Letter to the Editor)

Dear Mitch,

I am a pediatrician and have been chair of substance abuse for the local chapter of the American Academy of Pediatrics since March 1998.

I have noted that more Mom's have been using marijuana derivatives for nausea because it's natural (and more recently legal)

And of course they don't see it as a "drug".

Some people allege that the OBs have given their stamp of approval.

Lactation's consultants are letting us know!

Tox screens are letting us know the same thing.

Every where from nail salons to juice bars have added CBD to their services and products.

Perhaps someone can help me write a resolution.

Thanks

Trisha Roth, MD

Dear Dr. Roth.

The concept of substance abuse in the face of decriminalization of marijuana is a difficult one.

On the one hand, many governmental agencies have turned a blind eye to the possible effects on the child because there is very little in the way of recognition of the pregnant or lactating state in any of this legislation.

On the other hand, anecdotal evidence abounds, and as you mentioned, a number of obstetricians now advocate marijuana or its CBD derivatives for morning sickness during pregnancy.

Laws vary from municipality to municipality. Although the law sup-



ports the right to use marijuana, these laws also identify a toxic or impaired state which may be subject to prosecution. Common sense dictates that a parent should not be intoxicated under the effects of marijuana or any other substance while operating a motor vehicle, but what about when providing care for a small child? (1)

Child welfare laws are not necessarily specific for marijuana although the presence of a positive toxicology screen may invoke a mandated investigation by child protective services. In the face of legitimization of marijuana, many of these are declining to investigate further.

As Carl Sagan once noted, "the absence of evidence is not evidence of absence." Despite reassurance of certain obstetricians and lactation consultants, there is no consistent evidence of no harm from these products. I agree, someone should definitely write a resolution.

This resolution should not be confined to a locality, municipality or even a national entity. This resolution should come from the World Health Organization (WHO) and should then be codified into the laws of the world's nations. Our most fragile neonates should all benefit from an environment devoid of toxins or other substances with an unproven therapeutic indication so that they may all have the best possible chance for a normal developmental outcome.

Reference:

 Merritt TA, Kosmala K, Ames A, Miller C, Chervenak C, Goldstein M. Legalization of Recreational Marijuana: Impact of Maternal Use During Pregnancy. Volume 11, Issue 2, February 2016.

Sincerely,

Minnment !

Mitchell Goldstein, MD

Editor in Chief



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Erratum (Neonatology Today September, 2019)

Neonatology Today has identified erratum affecting the September, 2019 edition. Dr. Snyder's name is misspelled in the manuscript on "The Neonatal Intensive Care Unit Directory." We regret this error.

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

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Clearwater Beach, Florida https://health.usf.edu/publichealth/ chiles/gravens-conference

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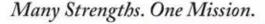
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Neonatology and the Arts

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

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

Logos and trademarks will usually not qualify for publication.

The subject is yet again birds. Dr. Goldstein went on vacation this summer and was particularly taken by a "rubber ducky" that he found at the <u>Sunset Inn and Suites in Vancouver, British Columbia</u>. This trend is taking on new and even more interesting dimensions.



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Manuscript Submission: Instructions to Authors

- 1. Manuscripts are solicited by members of the Editorial Board or may be submitted by readers or other interested parties. Neonatology Today welcomes the submission of all academic manuscripts including randomized control trials, case reports, guidelines, best practice analysis, QI/QA, conference abstracts, and other important works. All content is subject to peer review.
- 2. All material should be emailed to: LomaLindaPublishingCompany@gmail.com in a Microsoft Word, Open Office, or XML format for the textual material and separate files (tif, eps, jpg, gif, ai, psd, or pdf) for each figure. Preferred formats are ai, psd, or pdf. tif and jpg images should have sufficient resolution so as not to have visible pixilation for the intended dimension. In general, if acceptable for publication, submissions will be published within 3 months.
- 3. There is no charge for submission, publication (regardless of number of graphics and charts), use of color, or length. Published content will be freely available after publication (i.e., open access). There is no charge for your manuscript to be published under open access
- 4. The title page should contain a brief title and full names of all authors, their professional degrees, their institutional affiliations, and any conflict of interest relevant to the manuscript. The principal author should be identified as the first author. Contact information for the principal author including phone number, fax number, e-mail address, and mailing address should be included.
- 5. A brief biographical sketch (very short paragraph) of the principal author including current position and academic titles as well as fellowship status in professional societies should be included. A picture of the principal (corresponding) author and supporting authors should be submitted if available.
- 6. An abstract may be submitted.
- 7. The main text of the article should be written in formal style using correct English. The length may be up to 10,000 words. Abbreviations which are commonplace in neonatology or in the lay literature may be used.
- 8. References should be included in standard "Vancouver" format (APA may also be used). Bibliography Software should be used to facilitate formatting and to ensure that the correct formatting and abbreviations are used for references.
- 9. Figures should be submitted separately as individual separate electronic files. Numbered figure captions should be included in the main file after the references. Captions should be brief.
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