

NEONATOLOGY TODAY

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



Volume 15 / Issue 1 | January 2020

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ISSN: 1932-7137 (Online), 1932-7129 (Print)
All editions of the Journal and associated
manuscripts are available on-line:
www.NeonatologyToday.net
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Interpreting Umbilical Cord Blood Gases: Normal Cord Blood Gases

Jeffrey Pomerance, MD, MPH

Case 1: Normal Umbilical Cord Blood Gases

The mother was a 34-year-old, gravida 1, para 0, aborta 0, with an uncomplicated intrauterine pregnancy at 40 4/7 weeks. The fetal heart rate tracing showed mild, variable decelerations. After 11 hours of labor, the mother was taken to the delivery room and vaginally delivered a male infant with Apgar scores of 7 and 9 at one and five minutes, respectively.

Cord blood gas results were as follows:

	Umbilical Vein	Umbilical Artery
pH	7.35	7.28
Pco ₂ (mm Hg)	38	49
(kPa)*	5.07	6.53
Po ₂ (mm H)	29	18
(kPa)*	3.87	2.40
HCO ₃ ⁻ (mmol/L)	20	22
BD (mmol/L)	4	4

* kPa, kilopascal, the unit of measure used in many countries outside the United States, 1kPa = 7.50 mmHg

Interpretation

These blood gas results represent the mean normal umbilical cord blood gas values as defined by a study published in 1985 of 146 uncomplicated term vaginal deliveries by Yeomans, Hauth, Gilstrap, and Strickland. The range of normal values from which these means were derived is found in Table 1 below.

Umbilical Cord Blood Gases Degree of Respiratory Acidosis		
	Venous Pco ₂ (mmHg) (kPa)	Arterial Pco ₂ (mmHg) (kPa)
No Respiratory Acidosis (Normal Range)	27 – 49 3.57 – 6.56	32 – 66 4.29 – 8.77
Mild Respiratory Acidosis	50 – 65 6.67 – 8.67	67 – 80 8.80 – 10.67
Moderate Respiratory Acidosis	66 – 80 8.80 – 10.67	81 – 95 10.80 – 12.67

Severe Respiratory Acidosis	81 – 95 10.80 – 12.67	96 – 110 12.80 – 14.67
Very Severe Respiratory Acidosis	≥ 96 ≥ 12.80	≥ 111 ≥ 14.80

Table 1

Reprinted with permission from Elsevier, in part from Yeomans ER, Hauth JC, Gilstrap LC III, Strickland DM. Umbilical cord pH, PCO₂, and bicarbonate following uncomplicated term vaginal deliveries Am J Obstet Gynecol 1985;151:798-800.

Data are mean values ± 2 standard deviations (SD).

* Base deficit, estimated from data.

** 1 kPa = 7.50 mmHg; 1 mmHg = 0.133 kPa

Note: "Normal" is arbitrarily defined as the mean ± two times the standard deviation (approximately 95.4% of a normally distributed population).

These values should be used in interpreting the umbilical cord blood gas sets presented in the remainder of this text. While subsequent studies generally involving larger numbers also have defined normal umbilical venous and arterial blood gas values, or sometimes only umbilical artery blood gas values in both term, (6) and preterm infants, (4,5,7) the findings are very similar, differing only in the range of the standard deviations.

“Compared to the umbilical venous cord values in healthy term infants after vaginal delivery, (3) values in the umbilical vein obtained prior to delivery in unsedated, non-laboring patients at 35 weeks’ gestation by cordocentesis, showed higher pH (7.41 vs. 7.35) and PO₂ (35 vs. 29 mmHg), and lower PCO₂ (36 vs. 38 mmHg) and base deficits (1 vs. 4 mmol/L). (11)”

White et al (8) found that despite the intention to obtain both an umbilical venous and an umbilical arterial sample, this was successful only 64% of the time. Both Armstrong and Stenson (9) and Westgate et al (6) emphasized that “Both artery and vein

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cord samples must be taken and the results screened to ensure separate vessels have been sampled." The American Congress of Obstetricians and Gynecologists also recommends attempting to obtain both "venous and arterial blood cord samples ... for blood gas analysis." (10)

Compared to the umbilical venous cord values in healthy term infants after vaginal delivery, (3) values in the umbilical vein obtained prior to delivery in unselected, non-laboring patients at 35 weeks' gestation by cordocentesis, showed higher pH (7.41 vs. 7.35) and PO₂ (35 vs. 29 mmHg), and lower PCO₂ (36 vs. 38 mmHg) and base deficits (1 vs. 4 mmol/L).(11) Similarly, when umbilical artery samples obtained from healthy term infants born by cesarean section in the absence of labor were compared with infants born by vaginal delivery, pH was higher by 0.04 on average.(12) Increasing the duration of the second stage of labor also was significantly related to deteriorating umbilical artery blood gas values with the base deficit rising by about 1 mmol/L per hour. (13) Even uncomplicated labor and vaginal delivery exacts a toll on fetal acid-base values, although modest and apparently of little clinical importance.

The standard deviations provided by Yeomans, Hauth, Gilstrap, and Strickland (3) assume the distribution of values to be normal or bell-shaped. In reality, they are all skewed distributions with the long thin tail to the left. However, I do not believe that any of the cord blood gas interpretations are influenced by this deviation from the bell-shaped curve. The average PO₂ in umbilical venous and arterial blood gases are 29 and 18 mmHg, respectively. The standard deviations are approximately six mmHg in each. In the umbilical arterial blood gas, plus or minus two standard deviations includes values between six and 30 mmHg. Surprisingly, a PO₂ below the normal range is poorly associated with asphyxia. However, PO₂ is informative when it is above the normal range. This suggests contamination by an air bubble(s) or, if in a venous sample, a period of slow flow through the placenta with associated increased time for down-loading of oxygen from the mother to the fetus via the umbilical vein and uploading of carbon dioxide from the fetus to the mother.

There are no agreed-upon definitions of what constitutes mild, moderate, or severe respiratory or metabolic acidosis. However, to allow for easier discussion and consistency within this text, I have set arbitrary definitions (see Tables 2 and 3 below). One must appreciate that nothing is known to occur clinically as a value crosses from one range into another. By and large, clinical relationships operate on a continuum. The concept of fetal respiratory acidosis is peculiar as the presence or absence of fetal breathing has no relationship to fetal respiratory acid-base status. The placenta acts as the "lung" for the fetus. Nonetheless, within this text, the terms respiratory acidosis or alkalosis will be used conventionally, i.e., to define the contribution of PCO₂ to the acid-base status.

Umbilical Cord Blood Gases Degree of Respiratory Acidosis		
	Venous Pco ₂ (mmHg) (kPa)	Arterial Pco ₂ (mmHg) (kPa)
No Respiratory Acidosis (Normal Range)	27 – 49 3.57 – 6.56	32 – 66 4.29 – 8.77
Mild Respiratory Acidosis	50 – 65 6.67 – 8.67	67 – 80 8.80 – 10.67

Moderate Respiratory Acidosis	66 – 80 8.80 – 10.67	81 – 95 10.80 – 12.67
Severe Respiratory Acidosis	81 – 95 10.80 – 12.67	96 – 110 12.80 – 14.67
Very Severe Respiratory Acidosis	≥ 96 ≥ 12.80	≥ 111 ≥ 14.80

Table 2

Defining degree of respiratory acidosis in umbilical cord blood gases

Rounded from Table 1

Umbilical Cord Blood Gases Degree of Metabolic Acidosis		
	Venous BD (mmol/L)	Arterial BD (mmol/L)
No Metabolic Acidosis (Normal Range)	0 to 8	0 to 8
Mild Metabolic Acidosis	9 – 12	9 – 12
Moderate Metabolic Acidosis	13 – 16	13 – 16
Severe Metabolic Acidosis	17 – 20	17 – 20
Very Severe Metabolic Acidosis	≥ 21	≥ 21

Table 3

Defining the degree of metabolic acidosis in umbilical cord blood gases Rounded from Table 1

It is of note that while an elevated arterial PCO₂ is associated with increased cerebral blood flow in the term (14) and preterm human newborn, this response to arterial PCO₂ is attenuated in seriously asphyxiated term infants and in mechanically ventilated preterm infants prior to intracranial hemorrhage.(15) For further discussion of this topic, see Volpe JJ, Neurology of the Newborn, 5th edition. (16)

Elevated values of PCO₂ in cord blood (low pH but normal base deficit) have not been associated with poor neurological outcome. When combined with metabolic acidosis (low pH and elevated base deficit), the risk of neurological injury increases. (17) Respiratory acidosis may be associated with a better outcome in the absence of severe metabolic acidosis.(18,19)

Typically, arterial base deficit measured within the first hour of life is approximately 3 mmol/L higher than in arterial cord gases, including newborns who were not asphyxiated at birth. (20) Thereafter, the values return to normal. The arterial base deficit may increase by much more than this and persist longer in asphyxiated newborns whose umbilical arterial blood flow has slowed or stopped altogether, and no longer fully reflects fetal status. In nearly all severely asphyxiated newborns, perfusion at the time of birth is poor to nonexistent. Of course, poor perfusion includes

the umbilical circulation as well. The umbilical arteries will only reflect fetal tissue status up until the time flow in them stops. Lactic acid produced from hypoxia/anoxia at the tissue level will not be cleared to the central circulation and subsequently to the umbilical arteries. Therefore, in an asphyxiated newborn, an umbilical artery cord blood gas sample may seriously underestimate the acidosis in the fetus and newborn. As the infant is resuscitated, circulation improves, and tissue lactic acid is cleared into the central circulation (acid washout). Accordingly, a postnatal base deficit obtained from an asphyxiated newborn within the first hour after delivery is frequently found to be higher (worse) than in the umbilical arterial cord blood gas and is among the most accurate prognosticators of neurological outcome. (18)

Key Points

- Elevation of PCO₂ has not been associated with poor neurological outcome unless combined with metabolic acidosis.
- Low pH, combined with an elevated base deficit, has been associated with poor neurological outcome.
- Working definitions of respiratory and metabolic acidosis are presented. Nothing is known to happen clinically as a value crosses from one range of respiratory or metabolic acidosis into another.
- Typically, arterial base deficit increases by approximately 3 mmol/L in follow-up blood gases taken within the first hour of life, even in newborns who were not asphyxiated at birth.

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Disclosure: The author has no disclosures.

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Corresponding Author



Jeffrey Pomerance, MD
Emeritus Professor of Pediatrics,
UCLA
Former Director of Neonatology,
Cedars-Sinai Medical Center, Los Angeles
Jeffrey Pomerance <jpomerance@msn.com>

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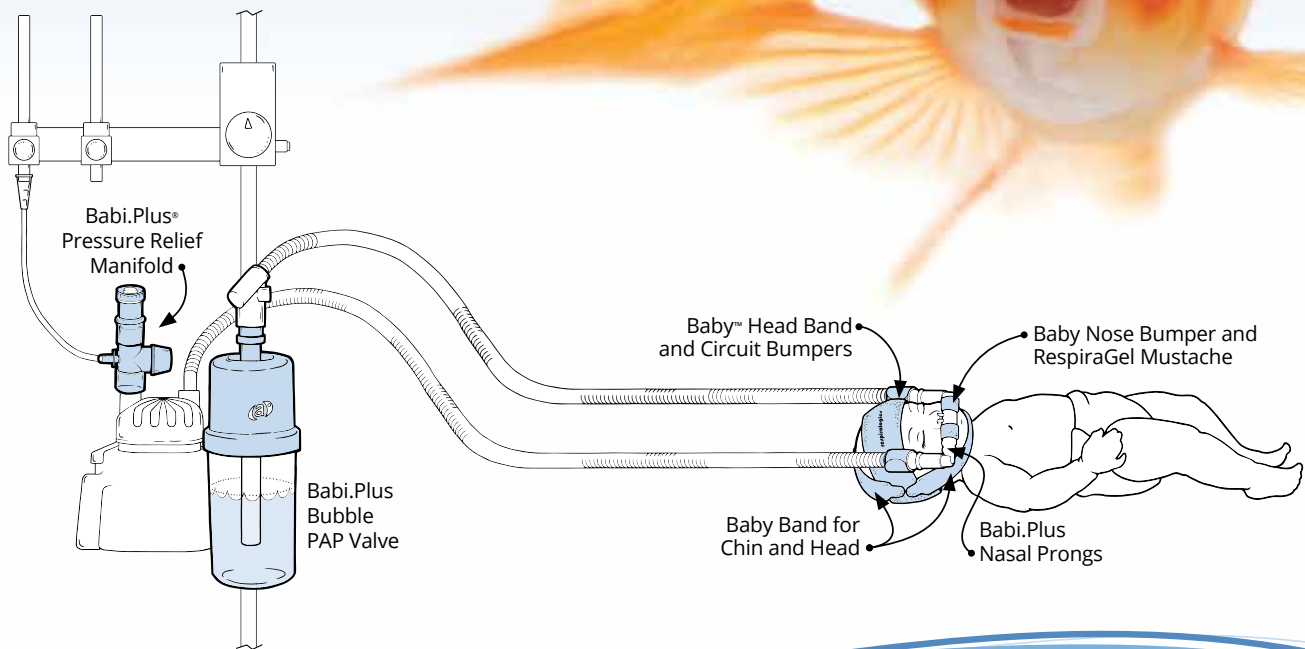
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Fellow Column: Pediatric Multiseptate Gallbladder - Case Report

Yomara S. Mendez BS, Laura F. Goodman MD,
Andrei Radulescu MD PhD

Abstract

Multiseptate gallbladder (MSG) is a rare congenital anomaly characterized by abnormal partial internal divisions of the gallbladder. Clinical presentation spans from asymptomatic to biliary symptoms such as nausea, vomiting, and right upper quadrant abdominal pain. The literature regarding this anomaly is limited, with only a few reported cases in the pediatric population.

Here we present the case of a full-term, otherwise healthy girl who has had recurrent episodes of diarrhea, since two months of age, and on a hospital admission at 11 weeks, was found, on a right upper quadrant ultrasound, to have MSG, with otherwise normal extrahepatic duct anatomy. She has been followed since discharge with repeated ultrasounds and liver function tests and has remained asymptomatic.

As long as she remains asymptomatic with stable ultrasound and normal liver function tests, and has no associated symptoms, we will continue to manage her nonoperatively.

Keywords: multiseptated gallbladder, pediatric, congenital anomaly

Introduction

Multiseptate gallbladder is a rare congenital anomaly, scarcely reported in children. MSG is most commonly characterized by its honeycomb appearance, which results from multiple thin septations (1,2). It most likely results from incomplete vacuolization of the developing gallbladder bud or persistent "wrinkling" of the gallbladder wall. (3-5) The amount of gallbladder involvement by the septae varies from those limited to only one area of the gallbladder, to the involvement of the entire lumen. Within this anomaly, there is a female predominance, with a reported female to male ratio of 1:2 (1).

Most of the cases of MSG are reported in adults and are diagnosed around the time of symptoms onset. Asymptomatic pediatric reports are rare, and management is not clearly defined.

"Multiseptate gallbladder is a rare congenital anomaly, scarcely reported in children. MSG is most commonly characterized by its honeycomb appearance, which results from multiple thin septations (1,2)."

Case Report

The patient is a 17-month old girl born at 38 weeks gestation via cesarean section, birth weight 3118 grams. Her mother had ges-

tational diabetes. After a murmur was detected, she was found on echocardiography to have mild supra-avalvular pulmonary valve stenosis, patent foramen ovale, and small patent ductus arteriosus, which closed by five months of age. Additional medical problems include cow milk intolerance and gastroesophageal reflux (chronic vomiting). She was admitted to the hospital for diarrhea at 11 weeks of age and treated for dehydration. During this hospitalization, a right upper quadrant ultrasound was performed, demonstrating gallbladder septations, with otherwise normal extrahepatic ductal anatomy. (Figure 1) Her liver function tests were normal, with a total bilirubin level of 0.1 mg/dL. The patient was seen in the clinic at five months of age with a repeat right upper quadrant ultrasound that re-demonstrated the previous findings of a septated gallbladder. A subsequent clinic visit at 17 months was normal, with appropriate growth and development. She remains asymptomatic, and follow-up is planned annually, with ultrasound and liver function tests.

"Variant imaging modalities can be used to diagnose MSG ranging from ultrasound (US) to magnetic resonant cholangiography (MRCP). US was used in our case because of its safety and accessibility, without requiring sedation for this young child."



Title	Authors	Year	Patient age	Management
Multiseptated Gallbladder: A Case of Recurrent Abdominal Pain in Childhood	Haslam et al. (4)	1966	15.5 years	Cholecystectomy
Ultrasonic appearance of multiseptate gallbladder: report of a case with coexisting choledochal	Pery et al. (7)	1985	8 years	Cholecystectomy & choledochoduodenostomy
The multiseptate gallbladder. A rare malformation of the biliary tract	Fremond et al. (8)	1989	13 years	Cholecystectomy
Multiseptate gallbladder in a child: incidental diagnosis on sonography	Adear et al. (9)	1990	12 years	Non-operative
Partial multiseptate gallbladder: sonographic appearance	Straus et al. (10)	1993	3,9,16 years	Not detailed
Non-communicating multiseptate gall bladder and choledochal cyst: a case report and review of publications	Tan et al. (11)	1993	14 years	Cholecystectomy & hepatojejunostomy
Multiseptate gallbladder in a child with chronic abdominal pain: ultrasonography, magnetic resonance imaging, and magnetic resonance cholangiography findings	Kocakoc et al. (12)	2003	9 years	Cholecystectomy
Clinical and ultrasonographical findings in patients with multiseptate gallbladder	Erdogemus et al. (13)	2004	10, 12 years	Cholecystectomy
Ectopic pancreas associated with choledochal cyst and multiseptate gallbladder	Bhadir et al. (14)	2006	15 days	Excision of cyst with Roux-en-Y anastomosis
Multiseptate gallbladder in a child with recurrent abdominal pain	Demirpolat et al. (15)	2010	5 years	Non-operative
Multiseptate Gallbladder in an Asymptomatic Child	Wanaguru et al.(1)	2011	9 months	Non-operative
Multiseptate Gallbladder: Clinical and Ultrasonographic follow-up for 12 Years	Geremia et al. (16)	2013	12 Years	Non-operative
Multiseptate Gallbladder in an Asymptomatic Pediatric Patient	Ortola et al. (17)	2015	5 months	Non-operative
A Multiseptate Gallbladder in a 16-Year-Old Boy with Abdominal Pain	Edelman et al. (2)	2016	16 years	Cholecystectomy
Multiseptate Gallbladder in a Child: A Possible Cause of Poor Growth?	Mendola et al. (18)	2017	3 years	Cholecystectomy
Laparoscopic Cholecystectomy for Symptomatic Multiseptate Gallbladder	Sabra et al. (19)	2017	12 years	Cholecystectomy
Multiseptate Gallbladder in a Child	Bertozzi et al. (20)	2019	7 years	Cholecystectomy

Table 1. Reported cases of pediatric MSG as well as management strategies

Discussion

The first report of MSG was described by Simon and Tandon in 1963, in which they documented that the septation of the gallbladder results from the incomplete cavitation of the developing gallbladder buds, leaving the lumen divided (6).

Other theories have been postulated by Bhagavan et al. [5] suggesting that MSG may be a result of the solid embryonic gallbladder growing faster than its bed and investing peritoneum, causing

aberrant bends and kinks, in addition to possible wrinkling, lobulation, and clefting of the gallbladder that may result in multiseptation. (1)

There are only a handful of such reports on pediatric patients, and two previous cases reported amongst children less than one year of age. The management described ranged from nonoperative with observation, to cholecystectomy in older children. [table 1]

Asymptomatic patients are very rare in literature, and more so

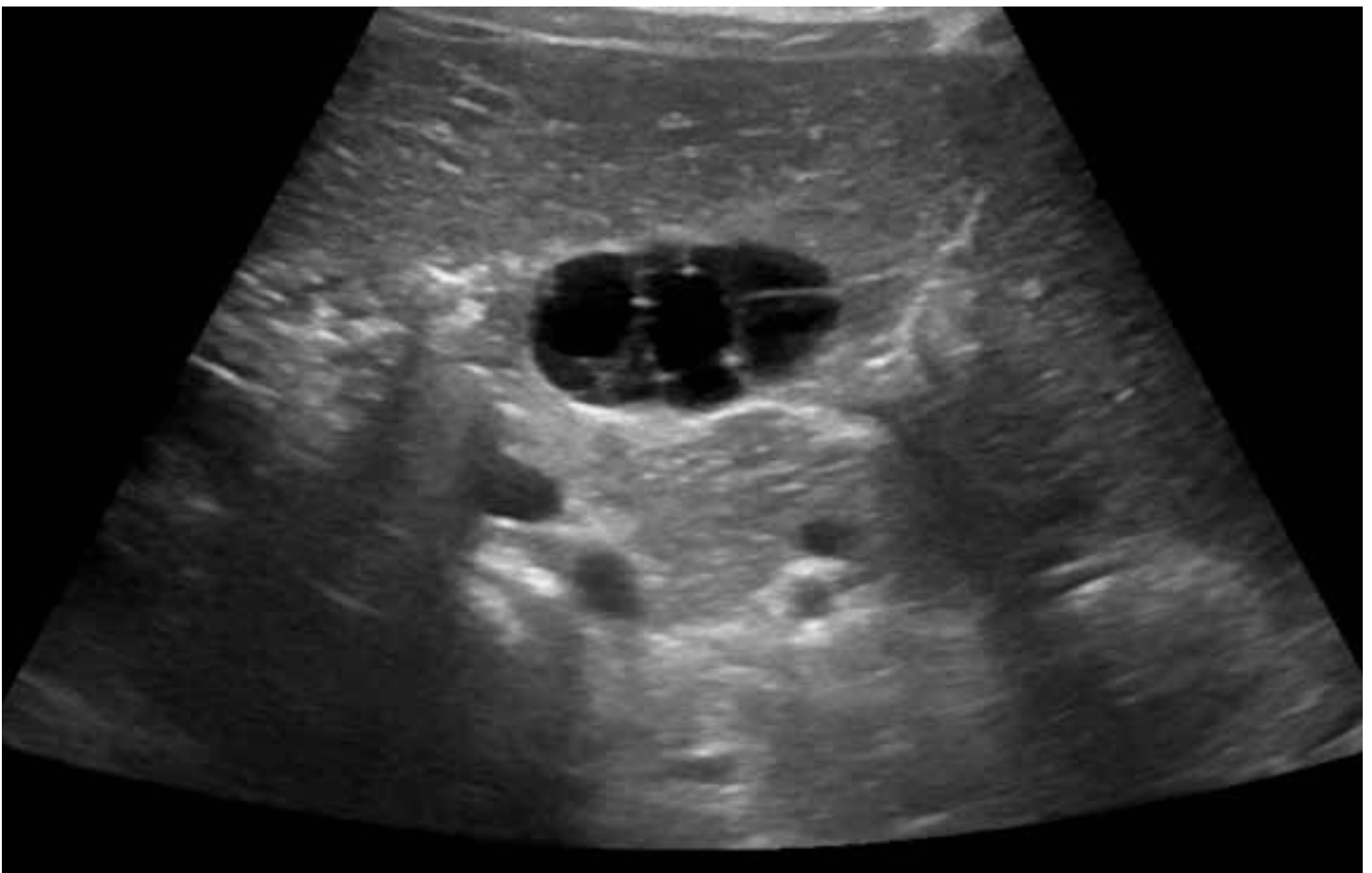
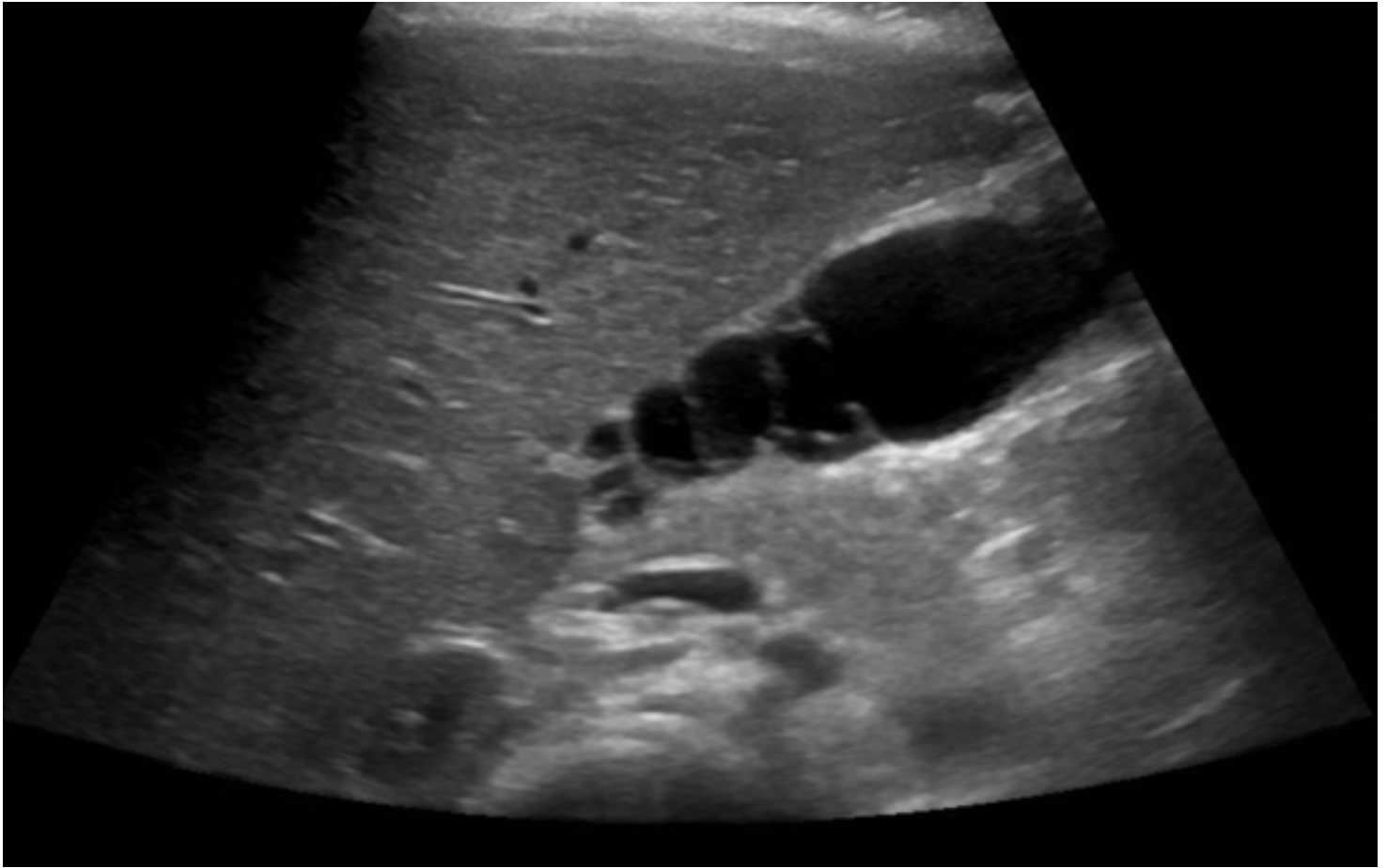


Figure 1 (page 10). Ultrasound of MSG showing multiple thin internal septations with a honey-comb appearance

amongst pediatric patients. Most patients present later in life with long-term abdominal symptoms such as recurrent right upper quadrant or epigastric pain, nausea and vomiting, and gastrointestinal complaints. Septa of the gallbladder are hypothesized to cause impaired gallbladder motility, leading to stasis of bile flow. This stasis may lead to the symptoms described above. (3)

Variant imaging modalities can be used to diagnose MSG ranging from ultrasound (US) to magnetic resonant cholangiography (MRCP). US was used in our case because of its safety and accessibility, without requiring sedation for this young child. MRCP has the advantage of better delineating the biliary tree and excluding associated bile duct anomalies, which are of importance for future surgical planning. There is no reported association between uncomplicated MSG and malignancy, despite the known link between biliary tract anomalies and cholangiocarcinoma. (1)

Of the 20 reported cases in the pediatric population, eight had cholecystectomy for symptoms related to MSG, three had associated choledochal cysts and were successfully treated with excision of the extrahepatic biliary tree combined with hepatojejunostomy or choledochoduodenostomy, and five children with uncomplicated and asymptomatic MSG, management was non-operative with long term follow up. [table 1] Just as in our case, patients under one year of age were all managed non-operatively with long-term follow up.

Conclusion

Multiseptated gallbladder is a very rare congenital anomaly found incidentally in the neonate population. Observation is the common management strategy in younger children, and in the presence of symptoms, cholecystectomy is advised in the teenage population.

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Disclosure: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. The authors have no financial disclosures

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Yomara S. Mendez BS
 Division of Pediatric Surgery,
 Loma Linda University Children's Hospital,
 11175 Campus Street, Room 21111,
 Loma Linda, CA, USA



Laura F. Goodman MD
 Division of Pediatric Surgery,
 Loma Linda University Children's Hospital,
 11175 Campus Street, Room 21111,
 Loma Linda, CA, USA

Corresponding Author



Andrei Radulescu, MD PhD
 Loma Linda University Medical Center
 11175 Campus Street, CP21111
 Loma Linda, CA 92350
 Phone: (909) 558-2822
 Fax: (909) 558-7978
 Email: aradulescu@llu.edu

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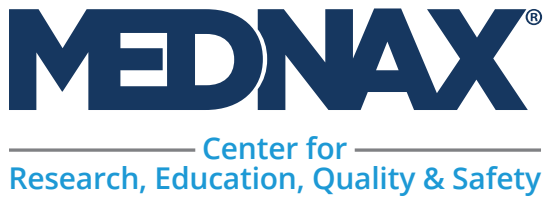
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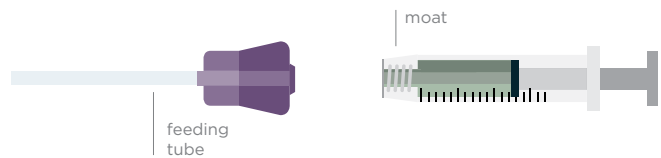
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A new tubing design meant to eliminate tubing misconnections has introduced new challenges for the NICU population. Pediatric providers must deliver medication in small volumes to tiny patients with high levels of accuracy. The new tubing design, known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



DOSING ACCURACY

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

INFECTION RISK

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

WORKFLOW ISSUES

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

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

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

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The End of an Error. Complexities in Infant Feeding Management

Kelley Karp MSN, BN RN



Saving babies. Supporting families.

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

Introduction

We all know that the NICU is an intense and complex clinical environment where you are dealing with the most precious of patients. Infant feeding preparation and management involves multiple processes and players. This complexity presents many opportunities

“We all know that the NICU is an intense and complex clinical environment where you are dealing with the most precious of patients. Infant feeding preparation and management involves multiple processes and players. This complexity presents many opportunities for error.”

for error. Here we will just begin to scratch the surface of the why.

Cognitive Demands

To try to work through the many pieces of this puzzle and understand what is happening and why we first need to start by looking at some of the cognitive reasons errors occur.

Distractions in healthcare delivery and their implications for patient safety are well established in the literature. One well-documented example of these phenomena is erroring during medication preparation and administration.

In 2012 the Institute of Safe Medication Practices (ISMP) published an article speaking to distractions in healthcare-related to medication preparation and administration.

They discussed that nurses, pharmacists, and technicians are distracted and interrupted as often as once every two minutes (1,2,3). Medication error risk increases by 12.7% with each interruption (1,4).

When interruptions occur, our prospective memory, or the ability to remember to do something that must be deferred, is impaired (1,2). When an individual makes a plan to complete a task, a signal is set to remind them actually to complete that task. In the case of a distraction, the individual has pulled away from the task they are set to perform. If that signal is encountered in the future, that reminder is supposed to be triggered (1,5). What if that signal does not happen? What if that reminder is not triggered?

Example: An RN is in the middle of mixing a feed. He or she then has to leave the feeding prep process and area to attend to a crisis alarm. What happens next? What is the cue to remember to go back to what they were doing (or delegate it out)? Do they see the clock and realize the feed is late? Does someone ask them if they need their patient fed? Do they see another staff member feeding a baby and remember? Do they remember where in the process they were? Do they remember it at all?

In the event an individual does remember to go back to the initial task, they risk omitting or duplicating steps. In certain situations, the entire workflow may need to be repeated, which can be extremely problematic, depending on what they were doing. Adding insult to injury, in an attempt to complete the new task, the individual has an increased likelihood of committing an error with either of the tasks because “the stress of the distraction or interruption causes cognitive fatigue, which leads to omissions, lapses, and mistakes (1).”



To every NICU nurse who has cared for these precious babies we say.....
"Thank you."

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

At First Candle we're educating parents, grandparents and caregivers about safer sleep to make sure all babies reach their first birthday. Learn more at firstcandle.org

Mental Validation

Now let us build a little more on these phenomena. On top of the interruptions and associated cognitive failures, you have to take into account all of the mental validations needed to manage the processes for infant feeding.

Pulling from an FMEA at a large urban hospital, they found as many as 15-20 mental validations are required to prepare feedings for one infant. Validations such as; patient verification, order verification, complex recipe management, combing for volume and fortification, expiration updates, parsing out feedings, planning for real-time and future feeding times, thawing milk, and freezing milk.

NICU nurses generally have 2-4 infants in their care, eating 3-4 times in a 12 hr shift. A nurse/tech could realistically prepare 12 feeds in one day. This would be >180 mental validations in one shift for one clinician specifically related to feeding preparation. These tasks can overlap multiple times throughout a typical shift, leaving every validation point open to potential error. When you consider the need for validation amidst the likely impact of distractions

“These tasks can overlap multiple times throughout a typical shift, leaving every validation point open to potential error. When you consider the need for validation amidst the likely impact of distractions and interruptions, the opportunity for error is high.”

tions and interruptions, the opportunity for error is high.

Conclusion

What impacts errors and our ability to detect and prevent them continues to be a complex conversation. Amongst all the distractions and mental validations, we are relying on humans to not only detect but prevent dozens of potential failure points, the majority of which go undetected, unappreciated, unreported, and unresolved.

Unfortunately, at this time, there are no universally accepted national standards to regulate safety management for the preparation and administration of infant feedings in hospitals.

There are many more factors that impact the opportunity for error

than what we have reviewed here. To find out more information about the impact of error in infant feeding management, please go to <https://www.keriton.com/products#>

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Disclosure: The author is an employee of Keriton

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Kelley Karp MSN, BN RN
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Still a Premie?




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

But that's not every preemie's story.


Born between 34 and 36 weeks' gestation?

STILL A PREMIE

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

-  Jaundice
-  Feeding issues
-  Respiratory problems

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




Born preterm at a "normal" weight?

STILL A PREMIE

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

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

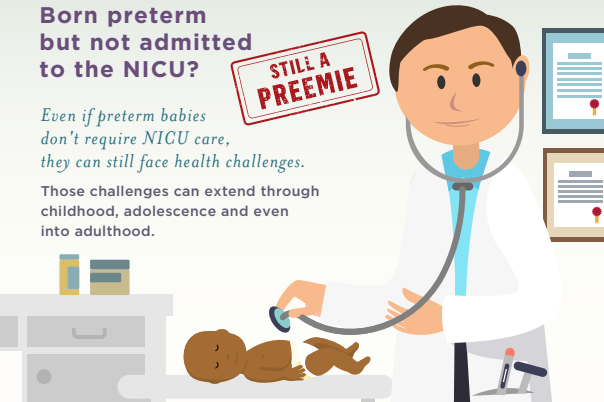


Born preterm but not admitted to the NICU?

STILL A PREMIE

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

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



Some Preemies	All Preemies
 Will spend weeks in the hospital	 Face health risks
 Will have lifelong health problems	 Deserve appropriate health coverage
 Are disadvantaged from birth	 Need access to proper health care

NCJFH National Coalition for Infant Health
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www.infanthealth.org

The Survey says RSV



What you need to know about RSV

RSV stands for **Respiratory Syncytial Virus**

RSV is a **Really Serious Virus**

WHEN IS RSV SEASON?

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

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

National Perinatal Association

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

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5 THINGS

YOU CAN DO
TO CELEBRATE



NICU AWARENESS

1

Educate Yourself

Did you know that more than half of the babies admitted to NICUs were not born prematurely? See our fact sheets.

2

Post on Social Media

See examples at nicuawareness.org and nationalperinatal.org/NICU_Awareness

3

Recognize NICU Staff

Let them know the difference they are making in our babies' lives. Write a note, send an email, or deliver a gift to show them that you appreciate them.

4

Share Your Story

Most people have never heard of a NICU before. Let others know about the extraordinary care that NICUs provide.

5

Join Our Community

Get involved. Become a member of our organizations and share your talents.

This project is a collaboration between



www.nicuawareness.org

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Raising Global Awareness of RSV

Global awareness about respiratory syncytial virus (RSV) is lacking. RSV is a relatively unknown virus that causes respiratory tract infections. It is currently the second leading cause of death – after malaria – during infancy in low- and middle-income countries.

The RSV Research Group from professor Louis Bont, pediatric infectious disease specialist in the University Medical Centre Utrecht, the Netherlands, has recently launched an RSV Mortality Awareness Campaign during the 5th RSV Vaccines for the World Conference in Accra, Ghana.

They have produced a personal video entitled “*Why we should all know about RSV*” about Simone van Wyck, a mother who lost her son due to RSV. The video is available at www.rsvgold.com/awareness and can also be watched using the QR code on this page. Please share the video with your colleagues, family, and friends to help raise awareness about this global health problem.



The Root Causes of Preventable Patient Harm

Robert M Turbow, MD, JD and Jonathan M Fanaroff, MD, JD

Abstract:

“... all of us will likely experience a meaningful diagnostic error in our lifetimes...” (IOM 2015). Medical Errors are a common cause of death in the United States,(1) but there is evidence that healthcare-related harm can be prevented. This article addresses the “root causes” of the Patient Harm epidemic.

This article considers the “why” and the “how” of medical errors. Despite having well-trained, intelligent, compassionate caregivers that have modern equipment like surgical robots and telemedicine, we still get it wrong so often. Why tolerate a system that does not prioritize patient safety?

A Root Cause Analysis (RCA) is often performed after a patient is harmed in order to determine not just *what* happened, but more critically, *why*. Why did the surgeon and the entire operating room team miss the fact that the operation was being done on the wrong side? Why did the highly experienced nurse give the medication to the wrong patient? Only by understanding factors associated with an error can steps be taken to prevent a recurrence. If we performed an RCA on the entire healthcare system, we would find a number of “root causes” including complicated systems, competing values, distracted caregivers, confusing and disconnected information technology (IT) systems, unsafe cultures, “drift” behaviors, and a lack of board-level oversight of patient safety.

“If we performed an RCA on the entire healthcare system, we would find a number of “root causes” including complicated systems, competing values, distracted caregivers, confusing and disconnected information technology (IT) systems, unsafe cultures, “drift” behaviors, and a lack of board-level oversight of patient safety. ”

The Patient Harm epidemic will continue until caregivers and the public insist on a system that prioritizes safety. Progress will only come with acknowledging the problem and refusing to accept the current level of preventable harm.

I Introduction:

“... all of us will likely experience a meaningful diagnostic error in our lifetimes...” (2) So begins the most recent report from the Institute of Medicine (IOM). Fifteen years ago, it was revealed that the number of people killed by medical mistakes in this country would fill up four jumbo jets every single week. That jarring statistic emerged from the IOM report, “To Err is Human: Building a Safer Health Care System.” (3) The report focused national attention on the issue of patient safety, and

subsequent data has confirmed the magnitude of the problem. In 2010, a combined statement was published by The Joint Commission (TJC) and The Office of the Inspector General (OIG), describing a random chart audit completed by physicians. TJC and OIG reported that 27% of Medicare beneficiaries had been harmed by the healthcare system. Not all of the harm is preventable, and not all of the preventable harm is due to negligence. However, it is critical to consider the “root causes” of the Patient Harm epidemic. Many practitioners are vaguely aware of the statistics. While the data are controversial, medical errors may be between the 3rd and 6th leading cause of death.(3) The IOM estimated 98,000 deaths per year is likely a dramatic underestimate, and improvements are coming far too slowly. (4) Still, there is evidence that with appropriate measures healthcare related harm can be prevented.

This article focuses on the “why” and the “how” of medical errors. In the United States and the entire developed world, we generally have well-trained, intelligent, compassionate caregivers that want to help others. The individuals have modern equipment like surgical robots and telemedicine. How do we get it wrong so often with such tragic results? Why do we continue to tolerate a system that does not prioritize patient safety?

“This article focuses on the “why” and the “how” of medical errors. In the United States and the entire developed world, we generally have well-trained, intelligent, compassionate caregivers that want to help others. The individuals have modern equipment like surgical robots and telemedicine. How do we get it wrong so often with such tragic results?”

II How Did We Get Here -- The Root Causes of Patient Harm:

A Root Cause Analysis (RCA) (5) is often performed after a patient is harmed in order to determine not just *what* happened, but more critically, *why*. Why did the surgeon and the entire operating room team miss the fact that the operation was being done on the wrong side? Why did the highly experienced nurse give the medication to the wrong patient? Why did the respiratory therapist leave the breathing tube in the esophagus? Only



by understanding factors associated with an error can steps be taken to prevent a recurrence. What if we performed an RCA not on a single patient event, but the entire healthcare system? Such an RCA might find a number of “root causes,” including complicated systems, competing values, distracted caregivers, confusing and disconnected information technology (IT) systems, unsafe cultures, “drift” behaviors, and a lack of board-level oversight of patient safety.

1- Complicated Systems

[N]o industry in the world has to deliver on so many different service lines. We have some 6,000 different drugs and more than 4,000 different kinds of procedures, and providing them currently entails 35 million hospital admissions, 120 million ER visits, 400 million imaging procedures, almost 1 billion office visits, and 3.5 billion prescriptions each year. What science has given us is extreme complexity. And, our system cannot handle it.

-Atul Gawande, Testimony Before the House Committee on Energy and Commerce Subcommittee on Health, March 10, 2009

Medicine used to be safe but largely ineffective. Healthcare was often limited to hand-holding and reassurance. Now, it is highly effective and highly dangerous.(6)

For anyone that works at the bedside, this is not new information. We are constantly facing new “Quality measures”, human factors, extraordinarily complex IT systems, sicker patients that live longer with more chronic illnesses, and an ever-changing doctor-patient relationship. Peter Drucker, the highly respected expert in international management, has noted that healthcare is “...the most difficult, chaotic, and complex industry to manage today.” (7)

Additionally, it is no longer enough for a physician to understand their respective medical specialty, how to diagnose, and how to treat. Physicians are expected to be well-versed in ethics, law, business, computers, and interpersonal psychology.

2- Competing Values

It is comforting, yet highly inaccurate, to think that safety is the highest value in the United States (U.S.) healthcare system. Charles Vincent has described the comparison between the healthcare system and executives that run an energy company.

“Safety is not our top priority. Getting oil out of the ground is our priority. However, when safety and productivity conflict, then safety takes precedence.” (8)

For most at the bedside, patient safety is the most important consideration. This is clearly not the case for the healthcare system as a whole. If we subscribe to the idea that every system is perfectly designed to get the results that it gets,(9) then we have designed (or tolerated) a system that may be one of the leading causes of death in the U.S.

Historically, physicians and nurses have been the loudest voice to advocate for patient safety. Increasingly, however, physicians are “employed” by large entities, so the concept of an “independent medical staff” is rapidly dissipating. A physician who questions unsafe practices risks being labeled as “disruptive,” “negative,” or “not a team player.” Similarly, nursing staffing ratios are an extremely volatile topic. Nurse labor costs are the largest expense in most hospital budgets. If cost-containment is the major focus, then there is a major incentive to decrease staffing. At the same time, there is clear evidence that understaffing increases the risk of patient death. A retrospective study at the Mayo Clinic found that mortality risk increased

two percent per shift when a unit is understaffed and four percent for a high turn-over shift.(10) The same study found that more than one-third of patients were exposed to three or more understaffed shifts.

A hospital Emergency Department can be a telling example of “competing values.” ED’s are often under tremendous pressure to meet “throughput” or “efficiency” metrics. While “door to doc” time can be an important safety consideration, moving too quickly is also dangerous. Getting patients properly triaged and admitted to the proper service is vital; however, many hospital systems measure the speed of their ED team year to year. Therefore, an extremely efficient and fast-moving ED will be asked to “go faster” the next year. When a team is moving as fast as they possibly can and then are asked to move even faster the next year, there is a potential for tragic errors. Twelve-year-old Rory Staunton, for example, was treated in a hospital’s Emergency Department for dehydration. Rory was discharged home hours before the complete blood count (CBC) result showed a massive left shift, strongly suggesting sepsis rather than dehydration. Unfortunately, the lab was never checked, and Rory subsequently died of septic shock. The New York State Department of Health found a “systemic failure related to the reporting and follow up of abnormal laboratory results.” (11)

3- Electronic Distraction

Look around in any restaurant, hardware store, or hospital committee meeting. How many people are staring at their phones, tablets, and computers partially or completely disengaged from their physical environment? Hospital team members text on their way to work and, worse, text at the bedside in the midst of patient care, with serious safety consequences. At one academic medical center, a resident in the midst of discontinuing a warfarin order on her smartphone received a text about an upcoming party. The resident confirmed she was attending the party but never completed the order, and three days later, the over anticoagulated patient developed a cardiac tamponade and required emergency open-heart surgery. (12)

Electronic distraction is also a problem in the operating room (OR). A recent article in *Perfusion* noted that the majority of cardiopulmonary bypass technicians admit to having updated social media and web browsed while they had a patient on the pump. (13) The behavior was not just texting and responding to e-mails (which would be concerning enough). The technicians admitted to being engaged in social media, and the majority of technicians admitted that they knew what they were doing was wrong. Anesthesiologist Peter Papadakos, who has written on this topic, cites disturbing examples of electronic distractions in the OR, including a neurosurgeon making more than ten personal calls during a single operation and a nurse checking airfares during surgery. Dr. Papadakos states, “My gut feeling is lives are in danger.” (14)

4- The Unfulfilled Promise of Health IT systems-

EMR’s were touted as making everything safer and more efficient, and in many cases, they have had the exact opposite effect. A recent article in the *American Journal of Emergency Medicine* noted that the average ED physician clicks their mouse 4000 times during a 12 hours shift.(15) While there are data that certain types of medication errors are less frequent with CPOE, most agree that Health IT is still an undelivered promise.(16)

It is possible that 15 years in the future, caregivers will look back on this period as the “dark ages” of health IT. It is not that caregivers have not embraced technology. Most carry

their smartphones, tablets, and use home entertainment centers that rival the complexity of the previous generations' super-computers. Rather, Health IT systems have profoundly altered workflow and process. The introduction of Health IT systems has been linked to increased mortality in children in PICU's. (17) There are also data on how this increased mortality can be avoided.(18, 19) Yet, there is widespread unfamiliarity with this impactful and timely literature. Those that are currently practicing medicine are well-aware of the distractions related to Health IT systems., and the media is becoming increasingly aware as well. In a New York Times article titled "Patients vs. Paperwork," a nurse laments: "Computer documentation in health care is notoriously inefficient and unwieldy, but an even more serious problem is that it has morphed into more than an account of our work; it has replaced the work itself."(20)

5- Not appreciating the importance of culture-

Many older physicians likely recall their early days of medical school and residency. Many young doctors were told, "you can call me, but it will be seen as a sign of weakness." Where did Patient Safety fit into that paradigm? The answer....it did not.

Since 2010, there has been a small but growing body of literature that safe culture translates directly into safer patient care. Based on the work of Peter Pronovost's team, a variety of safety initiatives (including care bundles) were instituted in Michigan. The Keystone Project fundamentally transformed ICU care in the United States and around the world. One of the more remarkable findings from the Keystone Project was that the ICU's with the safest culture scores also had the lowest incidence of bloodstream infections (BSI's)(21) and ventilator acquired pneumonia (VAP's).(22)

The link between "culture" and improved outcomes was also noted in the surgery literature. In a study involving 22 hospitals, it was observed that operating rooms with the safest culture scores had significantly lower serious post-operative complications following bariatric surgery.(23) Similarly, ineffective communication and lack of psychological safety have been associated with the highest postoperative mortality.(24)

The Emergency Department literature also supports the link between culture and safety. In a 2012 article from Annals of Emergency Medicine, it was reported that the ED's with the safest culture were more likely to catch a medication error (intercepted "near misses").(25)

There are still those in medicine that think safety culture means "group hug." On the contrary, there is now data from multiple medical specialties that having a safe culture is correlated with fewer patient injuries and death. In fact, safety attitude has been linked to decreased BSI's, VAP's, hospital-acquired ulcers, patient falls, CHF readmission and the list goes on.

6- Drift Behavior-

"Drift" has been described as the normalization of deviant behavior. A telling example is compliance with speed limits while

driving. No one sped on their driver's test. As drivers become more comfortable with the operation of a vehicle, they often will exceed the posted speed limit. 5 mile per hour over the speed limit, becomes 10, becomes 15, and soon we arrive at the current state of our highways. Likewise, as we become more comfortable, the "danger" of our behavior becomes more remote.

Baby Boy Martinez is scheduled to have his right kidney removed. When he awakens, the parents note a bandage on the left side of his body. How could this happen?

A recent article in the journal Surgery reported 60% non-compliance with the surgical checklist at a Children's Hospital.(26) One of the conclusions drawn by the authors was that their OR's had an unsafe culture. Not following checklists is an example of "drift behavior" The team does not "perceive" the danger in their collective drift behavior.

Of course, drift behavior is not limited to the operating rooms. The same behavior is seen when nurses "workaround" bar-coded medication systems using methods such as affixing patient labels to their computer workstations.(27) Poor system design is a major contributor to this and many other "drift" behaviors and workarounds.

7- Slow Adaptation of Evidence-Based Practice-

In the 1840s, the world's largest maternity clinic had a major problem. The maternal mortality rate in the medical student ward was 29%, compared to 3% in the midwifery ward.(28) Obstetrician Ignaz Semmelweis suspected infection as the culprit and required hand washing using chlorinated water prior to deliveries. Despite the fact that mortality rates immediately decreased, Dr.Semmelweis faced ridicule and criticism when he presented his findings to fellow physicians. Other physicians of the day, such as Charles Meigs, essentially stated that gentlemen do not need to wash their hands, and it was over a century before a concerted effort was made to improve hand hygiene. (29, 30)

Hand hygiene is not the only evidence-based practice that the medical profession has been slow to adapt. Indeed, while millions of dollars are spent on clinical research, it is very difficult for research findings to be incorporated, "given how slowly important new treatments are disseminated into practice and how resistant practitioners are to withdrawing established treatments from practice even once their utility has been disproved."(31)

8- Safety Begins in the Boardroom

Physicians generally receive very little training about the business side of medicine, let alone corporate structure. The board of trustees has ultimate responsibility for overseeing the quality of care provided at hospitals in this country, sitting above even the Chief Executive Officer. Boards used to focus mainly on the financial side of hospital operations. After two serious medical errors at the prestigious Dana-Farber Cancer Institute, however, including the death of *Boston Globe* reporter Betsy Lehman from a chemotherapy overdose, it became clear that safety must be a priority at all levels, not just a staff subcommittee. After the errors at Dana-Farber "sweeping" changes were made following a "critical examination of how the organization delivered care and conceived its mission."(32) This included strengthening the trustee-level quality committee.

III- Conclusions:

This article has attempted to outline a RCA of patient harm, but ultimately the goal of an RCA is not to discuss what has hap-

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pened in the past but to figure out how to improve systems in the future. After a number of high profile aviation accidents in 1996, the airline industry began a concerted effort to improve safety and achieved a 65% drop in fatal airplane crashes in 10 years.(33) Similar to aviation, the nuclear industry, fire-fighting, law enforcement, military, and healthcare sectors attempt to achieve "high reliability."(34-35)

Health care aims to be highly reliable, and every year additional resources are devoted to the substantial issue of Patient Harm. Unfortunately, resources alone are not enough. After all, billions of dollars have been poured into electronic medical records without a clear benefit to quality or safety. The healthcare industry has made some progress, but there is much more to be done to change the culture and improve the process of care. As distinguished leader Colin Powell has noted, "There are no secrets to success. It is the result of preparation, hard work, and learning from failure."(36)

The Patient Harm epidemic will continue until caregivers and the public insist on a system that prioritizes safety. Safety is a board-level priority, and progress will only come with acknowledging the problem and refusing to accept the current level of preventable harm.

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

The authors have no conflicts of interests to disclose.

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Corresponding Author:



Bob Turbow, M.D., J.D.
 Neonatologist and Chief Patient Safety Officer
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Forward with a Backward Glance 2019 in Review with Updates for 2020

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.

This column is the first-anniversary one. If you, dear reader, have gained anything from their perusal, I am fulfilled. I will start the new year with a review of the past year with applicable updates in this short column.

"This column is the first-anniversary one. If you, dear reader, have gained anything from their perusal, I am fulfilled. I will start the new year with a review of the past year with applicable updates in this short column."

My first column in NT January 2019, introduced high-frequency oscillatory ventilation with volume targeting (HFO/VG) to some. The surmised benefits thereof were based on gas flow properties and ventilatory efficiency. I can update that with a study out of Turkey supporting HFO/VG in terms of maintaining CO₂ and volume stability. (1) Another out of Taiwan favours HFO/VG. (2)

Since stable CO₂ levels are important to prevent brain bleeds, this shall also serve as my update on the last column of 2019 on respiratory care and neurodevelopmental outcomes.

February's column featured high-frequency jet ventilation (HFJV). Always evolving, the list of indications for considering HFJV, whether rescue or first intention, grows with experience and sharing stories at Snowbird (small plug). Because of the compact size and battery, the model 204 "new jet" makes transporting from the resuscitation area to the bedside much easier. As a result, this may increase first-intention use.

"Always evolving, the list of indications for considering HFJV, whether rescue or first intention, grows with experience and sharing stories at Snowbird (small plug)."

March featured non-invasive ventilation (NIV). With experience,

I suspect the selection of patients for this modality will become more appropriate and deliver better results as a result. When used appropriately, NIV has the greatest potential to decrease chronic lung disease (CLD).

In hindsight, April's column on hyperinflation was appropriate. April or November, many of us have been made fools of by misinterpreting CX-rays as hyperinflation when, in fact, they indicate air trapping. I have no update here, and this is a topic that cannot be emphasized enough. Look up, read, repeat until it is reflected in clinical practice. This column also segued into May's column on non-invasive nasal jet-assisted ventilation (NINJA).

I have not made as much headway as I would have liked with NINJA. More data is required to assess what jet settings are appropriate with different size cannulas in order to deliver the pressure required by the patient. As the column generated some interest, I promise to revisit this topic in 2020.

June's submission featuring tricks to help in dire situations is another column that bears review if only to keep fresh in mind.

Minimally invasive surfactant therapy (MIST or less invasive surfactant administration – LISA) presented in July is quickly becoming routine practice. As patient selection becomes more appropriate, this practice should also see better outcomes. Challenges remain in terms of what device should be used to deliver surfactant. The catheter must be stiff enough to direct while also being compatible with luer lock syringes. The practice in the unit, where I am employed, is currently to use a 5 Fr umbilical catheter. The visualisation of the vocal cords with the nasal CPAP apparatus in place is perhaps the most challenging aspect of MIST. Be that as it may, the necessity of giving a second dose of surfactant via endotracheal tube has decreased in our unit to about 25%. The issue of chemical leaching from medical devices is also garnering more attention.

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

I have no updates for August through November columns on the management of transient tachypnea of the newborn (TTN), the edge of viability, professional autonomy, and outborn micro-premies. While December's column was addressed in the first paragraph, I might add an interesting article in November's Neonatology Today on reducing Fentanyl use in extremely low birthweight infants. It is a good companion piece to it since it is often respiratory care providers who ask for narcotics.

Topics to look for in the coming months will include recruitment maneuvers in HFJV and NINJA. Suggestions for topics of discussion are most welcome.

May 2020 bring good things to all. I shall endeavour to continue

presenting topics of interest, controversy, and discussion.

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


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Corresponding Author



*Rob Graham, R.R.T./N.R.C.P.
 Advanced Practice Neonatal RRT
 Sunnybrook Health Science Centre
 43 Wellesley St. East
 Toronto, ON
 Canada M4Y 1H1
 Email: Rob Graham <rcgnrcp57@yahoo.ca>
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The National Perinatal Association and 1,000 Days Partner to Support Paid Family Leave Legislation

Cheryl A. Milford, Ed.S.

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

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



Educate. Advocate. Integrate.

The National Perinatal Association (NPA) partners with other nonprofits in the perinatal community to support optimal perinatal care in the United States. In 2019, NPA became partners with 1,000 Days to advocate for paid family leave legislation at the federal level

Established in 1977, the National Perinatal Association has a forty- three-year history of leadership and advocacy in improving perinatal care. NPA has been a home for new ideas and progressive practices since its founding. The National Perinatal Association (NPA) is an interdisciplinary organization of professionals, parents, and advocates that is the leading voice in perinatal care in the United States. We educate, advocate, and integrate all voices with equality and respect to support pregnant

women, infants, and their families and the professionals who care for them. NPA works to create positive change in perinatal care by partnering with healthcare, government, and nonprofit organizations.

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

NPA brings all stakeholders to the table to promote optimal perinatal care in the United States. Our uniqueness in the non-profit sector is our commitment that all voices are heard equally and respectfully. The NPA is defined by families and professionals working together with advocates to support practice and policy changes based on evidence-based literature and family experiences.

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

the first 1,000 Days.

With the backing of the U.S. Government, the Government of Ireland, the Bill & Melinda Gates Foundation, and several non-profit organizations, 1,000 Days began its work as a partnership to drive greater action and investment to improve nutrition for women and young children throughout the world. In 2015, the work expanded to focus on the issues that impact the nutrition and well-being of mothers, babies, and toddlers in the U.S., particularly the most vulnerable.

1,000 Days is the leading non-profit advocacy organization working in the U.S. and around the world to ensure women and children have the healthiest first 1,000 days. 1,000 Days’ mission is to make the well-being of women and children in the first 1,000 days a policy and funding priority.

The NPA’s and 1,000 Days’ partnership was formalized in early 2019. It was clear that our missions and interests were compatible and could advance optimal perinatal care in the United States. Such partnerships strengthen our voices in advocacy, education, and collaboration.

Paid Family Leave has been found in other countries to improve maternal and child health. Pregnancy, childbirth, and the transition to motherhood is a critical period in a woman’s life. Paid Family Leave gives mothers the time they need to heal from their pregnancy, establish breastfeeding, improve maternal mental health, and decrease healthcare inequities.

Given the significant levels of postpartum depression in the United States, Paid Family Leave can decrease this mental health issue by giving mothers time to become attached to their babies and take care of themselves. The United States is the only wealthy country in the world that does provide paid leave for new mothers. It continues to be supported in other countries because it improves maternal and child outcomes. It is cost-effective as well



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as important for the basic unit of all societies, the family.

With strong advocacy from the perinatal community, including NPA and 1,000 Days, Congress included 12 weeks of paid parental leave for federal workers in the National Defense Authorization Act (S. 1790). President Trump signed the legislation on December 20, 2019. This was an essential first step, with the federal government being the largest employer in the United States.

The National Perinatal Association and 1,000 Days continue to support and advocate for H.R. 1185-FAMILY Act in the House of Representatives. Bipartisan sponsors Representatives Christopher Smith (R) and Rosa DeLauro (D) introduced the legislation in early 2019. As of December 31, 2019, the legislation had 203 bipartisan co-sponsors. The bill supports 12 weeks of paid leave and is based on the California Paid Parent Leave Act of 2019, which provides 12 weeks of paid parental leave.

“As of December 31, 2019, the legislation had 203 bipartisan co-sponsors. The bill supports 12 weeks of paid leave and is based on the California Paid Parent Leave Act of 2019, which provides 12 weeks of paid parental leave.”

The Subcommittee on Worker and Family Support is holding hearings on this legislation. The National Perinatal Association and 1,000 Days have signed onto letters of support from the perinatal community, which includes many of NPA's nonprofit partners.

It is crucial that perinatal professionals and families contact their congressman to advocate for paid family leave, HR1185 FAMILY Act. The perinatal community can provide the rationale and expertise to the House to pass this legislation. We are all advocates for mothers, infants, and their families. You can contact your repre-

sentative at (202) 224-3121. The House Switchboard will connect you. It is a very quick call, and you can make a difference in how we care for families in the first 1,000 Days.

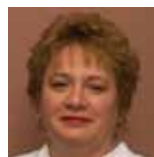
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Disclosure: The National Perinatal Association www.nationalperinatal.org is a 501c3 organization that provides education and advocacy around issues affecting the health of mothers, babies, and families.

NT

Corresponding Author



Cheryl A. Milford, Ed.S.
Educational Psychologist
Vice-President of Development
Family Advocacy Network Co-Chair
National Perinatal Association
cmilford@nationalperinatal.org

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Learn about the programs in your community. Seek out other families like yours. Then ask for help. Working together we can create a community where our children will grow and thrive.

Special Health Needs

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

NICU babies have a higher risk for re-hospitalization. So every medical appointment is important. Especially during cold and flu season when these babies are especially vulnerable to respiratory infections.

Who Can Help

- pediatricians
- neonatal therapists
- pulmonologists
- neurologists
- gastroenterologists
- cardiologists
- nutritionists
- CSHCN - Programs for Children with Special Health Care Needs

Special Developmental Needs

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

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

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

Who Can Help

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

Special Educational Needs

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

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

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

Who Can Help

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



My NICU Network



National Perinatal
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REGISTER: Members \$375 Non-Members \$475
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* early bird rates end Dec.30

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Snowbird, Utah

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

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

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

Advances in Therapeutics and Technology

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March 24-28 2020

For more information, contact:

Perinatal Advisory Council: Leadership,
1010 N Central Ave | Glendale, CA 91202

(818) 708-2850

www.paclac.org

Call for Abstracts – Deadline December 15, 2019

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

Exhibitor and Sponsorship Opportunities

For more information on how to exhibit at the conference or become a sponsor, please download the prospectus: Exhibitor / Sponsorship Prospectus

Ready to become an exhibitor or sponsor? Please download the registration form from the site (Exhibitor & Sponsorship Registration Form) and mail your completed form and payment to:

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If you would like to pay by credit card, please complete the credit card authorization form and email it along with the Exhibitor & Sponsorship Registration Form to asimonian@paclac.org.



Join  NPA

www.nationalperinatal.org/mental_health

THE BRETT TASHMAN FOUNDATION

The Brett Tashman Foundation is a 501(c)(3) public charity. The mission of the Foundation is to find a cure for Desmoplastic Small Cell Round Tumors (DSRCT). DSRCT is an aggressive pediatric cancer for which there is no cure and no standard treatment. 100 percent of your gift will be used for research. There is no paid staff. To make your gift or for more information, go to TheBrettTashmanFoundation.org or phone (909) 981-1530.

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The Gap Baby: An RSV Story



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



The National Coalition for Infant Health advocates for:

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

www.infanthealth.org



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Take our free
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Nurses Association.

Maryland Nurses Association
is an accredited approver by
the American Nurses
Credentialing Center's
Commission on Accreditation.



Federal Public Health Policy 2020 Brings Focus on Sudden Unexplained Infant Death (SUID) and Infant Health Outcomes

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.



As Congress returned to Washington, DC, after the new year, healthcare continues to be a major focus, including two pieces of legislation directly related to infant mortality and infant health outcomes:

- H.R. 2271, the Scarlett's Sunshine on Sudden Unexpected Death Act;
- H.R. 4801, the Healthy Start Reauthorization Act.

A January 8th U.S. House Energy and Commerce Committee Health Subcommittee hearing titled, "Legislation to Improve Americans' Health Care Coverage and Outcomes," shed light on these bills.

H.R. 2271

H.R. 2271, the Scarlett's Sunshine on Sudden Unexpected Death Act, advances current efforts to further understand both sudden unexplained infant death (SUID) and sudden unexplained death in childhood (SUDC). H.R. 2271, introduced by Congresswoman Gwen Moore (D-WI), would improve the comprehensiveness and standardization of child and infant death investigations. The legislation was introduced in April 2019 and, to date, has the bipartisan support of 62 cosponsors.

Senator Bob Casey (D-PA) and recently retired Senator Johnny Isakson (R-GA) have introduced a related bill in the Senate, S. 1130. Senator Casey noted in a press release announcing the introduction of the legislation that 3,600 infants each year pass away from "unexplained causes."

<https://www.casey.senate.gov/newsroom/releases/casey-colleagues-introduce-bipartisan-bill-to-address-unexpected-child-infant-deaths>

The legislation is named for 16 month-old Scarlett Pauley, who died suddenly in January 2017. According to her parents, Stephanie Zarecky and Ryan Pauley explained: Scarlett was a healthy, thriving baby who went to sleep and never woke up.

"The legislation is named for 16 month-old Scarlett Pauley, who died suddenly in January 2017. According to her parents, Stephanie Zarecky and Ryan Pauley explained: Scarlett was a healthy, thriving baby who went to sleep and never woke up."

Many cases like baby Scarlett's result in parents learning only an "unknown" or ambiguous cause of their child's death, where the tragedy may have been preventable by screenings or research into sleep-related disorders. H.R. 2271 and S. 1130 would require the Centers for Disease Control and Prevention (CDC) to review and improve procedures for the comprehensive death scene investigations involving cases of SUID and SUDC. The hope is that more medical research, data collection, and procedural improvements in crime scene investigations will lead to a better understanding of and even prevent future SUID and SUDC events. The bill also calls for additional family support services for those who have lost a child to SUID and SUDC.

Endorsements for the bill have come from: the American Academy of Pediatrics (AAP), March of Dimes, Children's Hospital Association, Cribs for Kids, First Candle, SUDC Foundation, KID: Fighting for Product Safety, and the Aaron Matthew SIDS Research Guild of Seattle Children's Hospital.

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H.R. 4801

The Subcommittee also considered H.R. 4801, the Healthy Start Reauthorization Act, to enhance programs that support perinatal health, reduce infant mortality, and improve long-term health outcomes. House Energy and Commerce Chairman Frank Pallone, Jr. (D-NJ) noted that “Despite serving communities that have had much higher rates of infant mortality, Healthy Start grantees have shown their ability to bring their communities’ overall infant mortality rate below the national average, demonstrating the program’s success and the need to expand and strengthen it.”

<https://energycommerce.house.gov/newsroom/press-releases/pallone-remarks-at-hearing-on-legislation-to-improve-americans-health-care>

“Healthy Start grantees have shown their ability to bring their communities’ overall infant mortality rate below the national average, demonstrating the program’s success and the need to expand and strengthen it.”

The bill provides for the reauthorization of the Healthy Start Program for five years at \$135 million annually, an increase of \$15 million per year above the most recent authorized level.

The Healthy Start Program “provides grants to state and local community organizations in targeted areas with infant mortality rates that are at least 1.5 times the national average and/or with high indicators of poor perinatal outcomes, particularly among black and other disproportionately affected populations.”

<https://energycommerce.house.gov/sites/democrats.energy-commerce.house.gov/files/documents/Memo%2010819%20hearing%20Legislation%20to%20Improve%20Americans%20Health%20Care%20Coverage%20and%20Outcomes.pdf>

This legislation was introduced in October 2019 in both the House and Senate. The Healthy Start Program was last reauthorized in 2008.

More Information

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

Infants need drugs tested and approved just for them.

Center for Clinical Trials and Biometrics | NCJFH National Coalition for Infant Health

Still a Premie?

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

But that's not every preemie's story.

Born between 34 and 36 weeks' gestation?

STILL A PREMIE

Just like preemies born much earlier, these “late preterm” infants can face:

- Jaundice
- Feeding issues
- Respiratory problems

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

Born preterm at a “normal” weight?

STILL A PREMIE

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

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

Born preterm but not admitted to the NICU?

STILL A PREMIE

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

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

Some Premies	All Premies
Will spend weeks in the hospital	Face health risks
Will have lifelong health problems	Deserve appropriate health coverage
Are disadvantaged from birth	Need access to proper health care

NCJFH National Coalition for Infant Health
Protecting Access for Premature Infants through Age Two
www.infanthealth.org

For more information, a House Energy & Commerce Health Subcommittee hearing memorandum for January 8, 2020, can be found here:

<https://energycommerce.house.gov/sites/democrats.energy-commerce.house.gov/files/documents/Memo%20010819%20hearing%20Legislation%20to%20Improve%20Americans%20Health%20Care%20Coverage%20and%20Outcomes.pdf>

The bills still need to pass through Health Committees and both the House and Senate to become law. To contact your lawmaker and voice your support for either of these bills, please visit www.house.gov and www.senate.gov.

References:

1. <https://www.casey.senate.gov/newsroom/releases/casey-colleagues-introduce-bipartisan-bill-to-address-unexpected-child-infant-deaths>
2. <https://energycommerce.house.gov/newsroom/press-releases/pallone-remarks-at-hearing-on-legislation-to-improve-americans-health-care>
3. <https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Memo%20010819%20hearing%20Legislation%20to%20Improve%20Americans%20Health%20Care%20Coverage%20and%20Outcomes.pdf>
4. <https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Memo%20010819%20hearing%20Legislation%20to%20Improve%20Americans%20Health%20Care%20Coverage%20and%20Outcomes.pdf>


The author has not indicated any disclosures.

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Corresponding Author



Darby O'Donnell, JD
Alliance for Patient Access (AfPA) Government Affairs Team
1275 Pennsylvania Ave. NW, Suite 1100A Washington, DC
20004-2417
202-499-4114
info@allianceforpatientaccess.org



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ON FISH CONSUMPTION
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Protecting Access for Premature Infants through Age Two

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BRETT TASHMAN
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The Brett Tashman Foundation is a 501(c)(3) public charity. The mission of the Foundation is to find a cure for Desmoplastic Small Cell Round Tumors (DSRCT). DSRCT is an aggressive pediatric cancer for which there is no cure and no standard treatment. 100 percent of your gift will be used for research. There is no paid staff. To make your gift or for more information, go to "TheBrettTashmanFoundation.org" or phone (909) 981-1530.



The Brookdale Hospital Medical Center is looking for a Board eligible or certified Neonatologist to cover the Neonatal-Perinatal Service. The hospital has a 30 bed Level III NICU equipped with Ventilators, high frequency oscillators, Nitric Oxide and whole-body cooling. Full support from pediatric subspecialties available 24 hours a day. The department has a robust Pediatric residency program and the candidate can have an academic title from New York Medical College.

The candidate should be Board certified in Pediatrics and Board eligible/certified in Neonatology. He/She should have excellent communication skills with an interest in academic pursuits and be committed to the community we serve. The candidate is expected to participate in quality and performance improvement projects.

Please contact Marina Weisz MBA |Administrator | Pediatrics; Tel: 718-240-7333; email: MWeisz@bhmcny.org or Kusum Viswanathan, MD, FAAP, Chair, Department of Pediatrics, Tel: 718 240 5904; email: kviswana@bhmcny.org

Respiratory Syncytial Virus:

How you can advocate for babies this RSV season

Track national data and trends at the CDC's website www.cdc.gov/rsv



Identify babies at greatest risk



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

Teach families how to protect



their babies from respiratory infections

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



Use your best clinical judgement



when prescribing RSV prophylaxis

Tell insurers what families need



and provide the supporting evidence



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

Survey Says: RSV

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

- Hospitalization
- Lifelong health complications
- Death

for infants and young children



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

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



But Parents are Unprepared.

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



RSV EDUCATION & AWARENESS CAN HELP

After parents learned more about RSV, they were:

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



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

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

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OPIOIDS and NAS

When reporting on mothers, babies, and substance use

LANGUAGE MATTERS



I am not an addict.

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



I was exposed to opioids.

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



NAS is a temporary and treatable condition.

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



My mother may have a SUD.

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



My potential is limitless.

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



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



To every NICU nurse who has cared for these precious babies we say.....
"Thank you."

first candle

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

At First Candle we're educating parents, grandparents and caregivers about safer sleep to make sure all babies reach their first birthday. Learn more at firstcandle.org



Nurses: parents trust you.

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

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

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



Eunice Kennedy Shriver National Institute
of Child Health and Human Development



Compiled and Reviewed by Mitchell Goldstein, MD Editor in Chief

Trump Administration takes historic steps to lower U.S. prescription drug prices

Proposed rule could allow certain prescription drugs to be imported from Canada; draft guidance explains how manufacturers could import drugs, biological products originally intended for sale in another country

For Immediate Release:
December 18, 2019

Today, President Trump, along with the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration, issued a notice of proposed rulemaking (NPRM) that, if finalized, would allow for the importation of certain prescription drugs from Canada. In addition, the Administration is announcing the availability of a new draft guidance for industry that describes procedures drug manufacturers can follow to facilitate importation of prescription drugs, including biological products, that are FDA-approved, manufactured abroad, authorized for sale in any foreign country, and originally intended for sale in that foreign country.

The NPRM issued today is the first step in implementing a provision of federal law that would allow for the importation of certain prescription drugs from Canada under specific conditions that ensure the importation poses no additional risk to the public's health and safety while achieving a significant reduction in the cost of covered products to the American consumer. The draft guidance issued today describes procedures for a drug manufacturer to submit documentation that demonstrates that the product offered for import from any foreign country is, in fact, an FDA-approved drug product, including that it is manufactured in accordance with the FDA-approved application.

"Today's announcement outlines two pathways for the safe importation of certain prescription drugs to help provide safe, effective, more affordable drugs to American patients," said Health and Human Services Secretary Alex Azar. "These are historic actions by HHS and the FDA, and they represent the bold nature of President Trump's agenda for lowering drug costs. The President has recognized the opportunity to lower costs for American patients through safe importation, and we at HHS and FDA are delivering on that possibility through a safe, commonsense approach."

The NPRM would allow states and certain other non-federal government entities to submit importation program proposals to the FDA for review and authorization. An importation program could be co-sponsored by a pharmacist, a wholesaler, or another state or non-federal governmental entity. Referred to as Section 804 Importation Programs, these programs would be authorized by the FDA to manage the importation of certain prescription drugs that are approved in Canada and also meet the conditions in an FDA-approved drug application. Eligible prescription drugs would have to be relabeled with the required U.S. labeling prior to importation and undergo testing for authenticity, degradation, and to ensure that the drugs meet established specifications and standards. Notably, these programs would also have to demonstrate significant cost reductions to the American consumer.

neo



The conference for neonatology

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The National Urea Cycle Disorders Foundation



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

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CALL FOR ABSTRACTS

The 33rd Annual Gravens Conference on the Environment of Care
for High Risk Newborns

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.**

“The FDA continues to assess and act on multiple opportunities to promote competition that can, in turn, help reduce drug prices and improve access to medicines for Americans,” said Assistant Secretary for Health Brett Giroir. “The proposed rule and draft guidance include procedures intended to protect the public’s health and safety. We look forward to receiving public comment on these draft policies, and we will take timely comments into account as we work to finalize the rule and guidance. Our ultimate goal is to provide a robust program that clearly lays out procedures to import drugs that could provide lower prices while also maintaining the high quality Americans expect.”

Of note, the draft guidance describes procedures drug manufacturers could follow to obtain an additional National Drug Code (NDC) for certain FDA-approved prescription drugs, including biological products, that were originally manufactured, and intended to be marketed, in a foreign country. The use of an additional NDC would allow greater flexibility for drug companies to offer these products at a lower price than what their current distribution contracts require.

The draft guidance also recommends that the drug manufacturer include a statement on the product’s label and in the prescribing information to assist pharmacists to accurately identify, dispense and bill for these products. Prescription drugs, including biological products, imported under the pathway described in the draft guidance could be available to patients in a variety of settings, including hospitals, health care providers’ offices, or licensed U.S.

pharmacies, and would include the FDA-approved labeling (including prescribing information).

Comments on the NPRM are being accepted for 75 days after publication in the Federal Register and comments on the draft guidance are being accepted for 60 days after publication in the Federal Register.

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.

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Inquiries

Media:

Michael Felberbaum

240-402-9548

Consumer:

888-INFO-FDA

NT

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

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

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

- Connect with other AAP members who share your interests in improving effective drug therapies and devices in children.
- Receive the SOATT newsletter containing AAP and Section news.
- Access the Section’s Website and Collaboration page – with current happenings and opportunities to get involved.
- 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

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based on the “Interdisciplinary Recommendations for Psychosocial Support for NICU Parents.”

Contact sara@mynicunetwork.com for more information.

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Keynote Speakers



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Peter Lachman



Mary Dale Peterson

Featured Panelists



Carole Hemmelgarn



Jeremy Hunt



Raj Ratwani

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

Mitchell Goldstein, MD, FAAP, Section Chairperson, MGoldstein@llu.edu and

Christopher Rizzo, MD, FAAP, Membership Chairperson and Chair Elect, crizo624@gmail.com

Jackie Burke

Sections Manager

AAP Division of Pediatric Practice

Department of Primary Care and Subspecialty Pediatrics

630.626.6759

jburke@aap.org

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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/>

NT

Statement on low-cost biosimilar and interchangeable protein products

Screening for Duchenne Muscular Dystrophy is now attainable.

For Immediate Release:

December 17, 2019

Statement From:

Deputy Commissioner for Policy, Legislation, and International Affairs - Food and Drug Administration
Anna Abram

Director - Center for Drug Evaluation and Research

Janet Woodcock M.D.

Ensuring an efficient pathway to bring potentially lower-cost biosimilar and interchangeable protein products to market is key for expanding access to these products and increasing competition, ultimately helping American patients.

In March 2020 most protein products that were approved as drug products (including every insulin currently on the market) will open up to biosimilar and interchangeable competition. However, "chemically synthesized polypeptides" are excluded from this transition, which means that a product that falls within this category won't be able to come to market as a biosimilar or interchangeable product, but will have to come to the market under a different pathway. Such a product would also not be able to come to market through the generic drug pathway because the originator product will have been classified as

a biologic, and will not be available for copying. This exclusion could hurt potential competition because it means that if a developer were to chemically synthesize a copy of a protein product (e.g., an insulin copy), the product would not be able to come to market through the abbreviated biosimilar or interchangeable pathway, but instead would have to submit a new drug application, which could be much more resource-intensive.

Removing this exclusion will help patients because it provides the potential for chemically synthesized follow-on insulins and other protein products to come to market through more efficient abbreviated pathways, regardless of how they are manufactured. In addition to expanding access to lower-cost biosimilar and interchangeable protein products, removing this exclusion will help to promote potential innovation in manufacturing methods, which could lead to future efficiencies in manufacturing processes.

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.



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Inquiries

Media:

Michael Felberbaum

240-402-9548

Consumer:

888-INFO-FDA

NT

New CDC Report: STDs Continue to Rise in the U.S.

For immediate release: Tuesday, October 8,
2019

Contact: National Center for HIV/AIDS, Viral
Hepatitis, STD, and TB Prevention

(404) 639-8895 | NCHHSTPMediaTeam@cdc.gov

October 8, 2019 – Growing threat of newborn deaths from syphilis

Combined cases of syphilis, gonorrhea, and chlamydia reached an all-time high in the United States in 2018, according to the annual Sexually Transmitted Disease Surveillance Report released today by the Centers for Disease Control and Prevention (CDC). Sexually transmitted diseases (STDs) can have severe health consequences. Among the most tragic are newborn deaths related to congenital syphilis, which increased 22 percent from 2017 to 2018 (from 77 to 94 deaths).

The new report shows that from 2017 to 2018, there were increases in the three most commonly reported STDs:

There were more than 115,000 syphilis cases.

The number of primary and secondary syphilis cases – the most infectious stages of syphilis – increased 14 percent to more than 35,000 cases, the highest number reported since 1991.



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Among newborns, syphilis cases increased 40 percent to more than 1,300 cases. Gonorrhea increased 5 percent to more than 580,000 cases – also the highest number reported since 1991.

Chlamydia increased 3 percent to more than 1.7 million cases – the most ever reported to CDC.

“STDs can come at a high cost for babies and other vulnerable populations,” said Jonathan Mermin, M.D., M.P.H., director of CDC’s National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. “Curbing STDs will improve the overall health of the nation and prevent infertility, HIV, and infant deaths.”

Antibiotics can cure syphilis, gonorrhea, and chlamydia. However, left untreated, STDs can be transmitted to others and produce adverse health outcomes such as infertility, ectopic pregnancy, and increased HIV risk. Congenital syphilis – syphilis passed from a mother to her baby during pregnancy – can lead to miscarriage, stillbirth, newborn death, and severe lifelong physical and neurologi-

cal problems

Syphilis in newborns is a tragic consequence of the growing STD epidemic

The 40 percent increase in congenital syphilis cases continues a dangerous trend seen in recent years. Although most states reported at least one case of congenital syphilis, five states – Texas, California, Florida, Arizona, and Louisiana – accounted for 70 percent of cases in the U.S.

Early prenatal care and STD testing are essential with each pregnancy to safeguard mothers and their babies from the dangers of syphilis. CDC recommends syphilis testing for all pregnant women the first time they see a healthcare provider about their pregnancy. Women who are vulnerable for acquiring or who live in high-prevalence areas should be tested again early in the third trimester and at delivery.

“There are tools available to prevent every case of congenital syphilis,” said Gail Bolan, M.D., director of CDC’s Division of STD Prevention. “Testing is simple and can help women to protect their babies from syphilis





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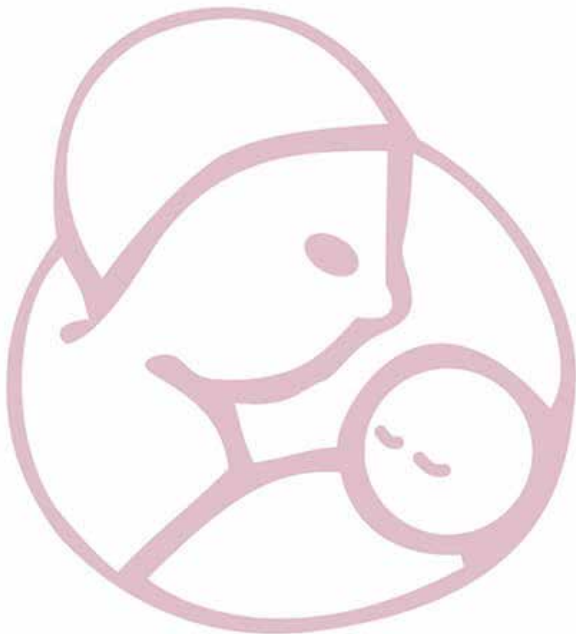
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– a preventable disease that can have irreversible consequences.”

The national rise in congenital syphilis parallels increases in syphilis among women of reproductive age. From 2017 to 2018, syphilis cases increased 36 percent among women of childbearing age. Addressing rising syphilis incidence is critical to prevent congenital syphilis. Women can protect themselves by practicing safer sex, being tested for syphilis by a health care provider, and if infected, seeking treatment immediately and asking her partner to get tested and treated to avoid reinfection.

Multiple factors drive the continued increase in STDs

Data suggest that multiple factors are contributing to the overall increase in STDs, including:

Drug use, poverty, stigma, and unstable housing, which can reduce access to STD prevention and care

Decreased condom use among vulnerable groups, including young people and gay and bisexual men

Cuts to STD programs at the state and local level – in recent years, more than half of local programs have experienced budget cuts, resulting in clinic closures, reduced screening, staff loss, and reduced patient follow-up and linkage to care services

Urgent action needed to break the cycle of STD increases

CDC continues to work on multiple fronts to address the nation's STD epidemic. For example, CDC provides resources to state and local health departments for STD prevention and surveillance. CDC's current funding program for health departments, Strengthening STD Prevention and Control for Health Departments, supports several high-priority strategies and activities, including eliminating congenital syphilis. As part of this program, CDC supports health departments in conducting disease investigations, responding

to public health outbreaks, providing training for health care providers, community engagement and partnerships, and other efforts.

The U.S. Department of Health and Human Services, which includes CDC, is developing a Sexually Transmitted Infections (STI) Federal Action Plan (STI Plan) to address and reverse the nation's STD epidemic. The STI Plan is being developed by partners across the federal government, with input from a wide array of stakeholders, and will be released in 2020. See www.hhs.gov/STI for more information.

However, urgent action from all types of stakeholders is needed to help control the increases in STDs. Health care providers should make STD screening and timely treatment a standard part of medical care; this work can start with taking a complete sexual history. In addition, state and local health departments should strengthen the local public health infrastructure needed to prevent and control STDs, and ensure resources are directed to the most vulnerable populations.

For more information from CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, visit www.cdc.gov/nchhstp/newsroom/.

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

NT

Leading Children's Health and Medical Groups Respond to

Appeals Court Decision to Overturn Affordable Care Act's Individual Mandate

12/19/2019 *The ruling leaves children and families facing uncertainty at a time when more children are uninsured*

Washington, DC—In response to the decision issued by the U.S. Court of Appeals for the 5th Circuit to overturn the Affordable Care Act's (ACA) individual mandate and instruct the lower court to determine whether any provisions of the law can remain intact, the American Academy of Pediatrics, Children's Defense Fund, Family Voices, First Focus on Children, Georgetown University Center for Children and Families, March of Dimes and the National Association of Pediatric Nurse Practitioners issue the following statement:

"Our organizations represent children, pregnant women, families, children's health care providers and advocates across the country. We are alarmed and disappointed by the ruling out of the 5th Circuit Court of Appeals to overturn the ACA's individual mandate that places the entire ACA at risk. The decision leaves millions of children and families who depend on the ACA's vital services and protections facing an uncertain future as the lower court will now determine how much of the law will still stand.

"This uncertainty comes at a time when the number of children without health insurance has increased to more than 4 million nationwide. What these families need is stability and consistent access to health insurance for their children, and this ruling does the opposite.

"The ACA, including its Medicaid and CHIP provisions, has made tremendous improvements to children's health care in the nine and a half years it has been in place. Young adults can remain on their parents' insurance plans until they turn



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26. Insurance companies can no longer refuse to cover those with pre-existing conditions or charge them more for coverage. Annual and lifetime limits on coverage no longer exist. And the list goes on.

"While these protections and improvements remain in place for now, we are concerned about what the future holds for the children and families who depend on these and other provisions of the ACA. We are hopeful that a decision will be rendered swiftly and that the law will be upheld so that all children and families can get the care they need."

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About the American Academy of Pediatrics

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 aap.org and follow us on Twitter @AmerAcadPeds.

NT

PerkinElmer Provides Newborn Screening Solution for Duchenne Muscular Dystrophy as part of PPMD's New York State Pilot Program

First Infant Recently Screened for Most Prevalent Type of Muscular Dystrophies


11/18/2019

WALTHAM, Mass. – January 13, 2020 – PerkinElmer, Inc., a global leader committed to innovating for a healthier world, today announced that it is providing the newborn screening assay for Parent Project Muscular Dystrophy's (PPMD's) Newborn Screening Pilot for Duchenne Muscular Dystrophy (Duchenne). PPMD is a

nonprofit organization leading the fight to end Duchenne. PerkinElmer's GSP® Neonatal Creatine Kinase –MM (CK-MM) kit recently received U.S. Food & Drug Administration (FDA) approval. This solution is the first commercially available assay for screening newborns affected by Duchenne muscular dystrophy (DMD).

Duchenne is an X-linked recessive disease and is the most common pediatric onset form of muscular dystrophy, affecting approximately 1 in 5,000 live male births. The disorder is caused by mutations in the dystrophin gene. Without dystrophin, a patient's muscles progressively weaken and deteriorate, ultimately resulting in premature death from poor respiratory function and cardiac failure.

"PPMD is excited that the team at PerkinElmer will be providing the newborn screening assay for our recently launched newborn screening program," said Pat Furlong, President & CEO, PPMD, the largest and most comprehensive nonprofit organization in the U.S. focused on ending Duchenne. "We believe that potential Duchenne treatments will benefit



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from early interventions and are grateful to collaborators like PerkinElmer, ACMG, through the NIH-funded Newborn Screening Translational Research Network (NBSTRN), and the State of New York for their participation at this critical moment in Duchenne therapy development. I am a firm believer that knowledge is power in our fight to end the progression of this deadly disorder. Early diagnosis will mean early intervention."

New York State recently screened the first infant for Duchenne as part PPMD's Newborn Screening Pilot. PerkinElmer is collaborating with the New York State Department of Health on a two-year project that will screen approximately 100,000 infants using its GSP CK-MM assay. Results from the state's Duchenne screening pilot will provide options for new and early treatments, helping to lay the framework for further Duchenne newborn screening programs in the U.S. and globally.

"As the global leader in newborn screening, we're excited to play an integral role on this innovative program to advance detection of Duchenne," said Petra Furu, Ph.D., General Manager, Reproductive Health, PerkinElmer. "Screening newborns ensures timely treatment for a disease that may otherwise go undetected for years, affording them a better chance at improved health outcomes."

For more information on PerkinElmer's GSP Neonatal CK-MM assay and other newborn screening solutions, please visit: newbornscreening.perkinelmer.com.

About PerkinElmer

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unique solutions to serve the diagnostics, life sciences, food and applied markets. We strategically partner with customers to enable earlier and more accurate insights supported by deep market knowledge and technical expertise. Our dedicated team of about 13,000 employees worldwide is passionate about helping customers work to create healthier families, improve the quality of life, and sustain the wellbeing and longevity of people globally. The Company reported revenue of approximately \$2.8 billion in 2018, serves customers in more than 180 countries, and is a component of the S&P 500 index. Additional information is available through 1-877-PKI-NYSE, or at www.perkinelmer.com.

Ruixin Zhu | Public Relations Intern
PerkinElmer | For the Better
ruixin.zhu@perkinelmer.com
Phone: +1 781.663.6946 | Mobile: +1 617.971.6306
940 Winter Street, Waltham, MA 02451
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NT

NIH grant to improve neonatal brain injury detection using photoacoustic imaging technology

15-Jan-2020 3:50 PM EST
Wayne State University Division of Research

Newswise — DETROIT — Hypoxic-Isch-

emic brain Injury (HII) is a severe injury caused by oxygen deprivation to the brain at or near time of birth in preterm or low birth weight newborns. It is very important to recognize HII as soon as possible because early intervention improves outcomes. Preterm neonates experiencing HII are at risk for developing hypoxic-ischemic encephalopathy, cerebral palsy, periventricular leukomalacia, and hydrocephalus.

Kamran Avanaki, Ph.D., assistant professor of biomedical engineering in Wayne State University's College of Engineering, received a two-year, \$725,000 R01 grant from the National Institute of Biomedical Imaging and Bioengineering of the National Institutes of Health for the development of a novel point-of-care 3D neonatal photoacoustic tomography (3D-nPAT) to improve the detection and measurement of hypoxic-ischemic in neonates without the need for sedation, radiation or radio-nuclides.

"3D-nPAT is safer and less costly than current, clinically-used neuroimaging methods," said Avanaki. "It will allow for earlier treatment, which could circumvent neural complications and improve functional outcomes from cerebral palsy and cognitive impairments."

This project is a collaboration between the Wayne State University Department of Biomedical Engineering, the neonatology program in Wayne State's School of Medicine, the Department of Biomedical Engineering at the University of Michigan and the Department of Neonatology at Harvard Medical School. The team plans to fully test the 3D-nPAT technique for future potential clinical use.

The grant is the latest in a series of funding sources secured by Avanaki as his lab

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continues to break new ground in diagnostic imaging technology. He received an additional four-year, \$1.5 million R01 grant last spring.

"The proposed 3D-nPAT instrument will provide neonatologists with an affordable, fast, portable and non-invasive functional imaging tool to map hypoxic-ischemic injuries to the neonatal brain that currently requires the use of multiple specialized systems," said Avnaki. "With this grant and the earlier R01, we are planning to revolutionize neonatal brain imaging management."

The grant, "3D Neonatal Photoacoustic Tomography (3D-NPAT) to Detect Hypoxic-Ischemic Brain Injury in Preterm Neonates," was awarded through the National Institutes of Health's BRAIN Initiative (Proof of Concept Development of Early Stage Next Generation Human Brain Imaging) from the National Institute of Biomedical Imaging and Bioengineering. The grant number is EB028661.

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About Wayne State University: Wayne State University is one of the nation's pre-eminent public research universities in an urban setting. Through its multidisciplinary approach to research and education, and its ongoing collaboration with government, industry and other institutions, the university seeks to enhance economic growth and improve the quality of life in the city of Detroit, state of Michigan and throughout the world. For more information about research at Wayne State University, visit research.wayne.edu.

NT

Study Answers When Moderate to Late Pre-term Babies Go Home

For the first time, families can get a data-based estimate at the time of admission

15-Jan-2020 11:40 AM EST Ann and Robert H. Lurie Children's Hospital of Chicago

Newswise — "When is my baby going home?" is one of the first questions asked by families of infants admitted to the neo-

natal intensive care unit (NICU). Now clinicians have a data-based answer. Moderate to late preterm babies (born at gestational age of 32 to 36 weeks) who have no significant medical problems on admission are likely to be discharged at 36 weeks of postmenstrual age (gestational age plus age since birth), according to a study published in the American Journal of Perinatology. Small for gestational age infants and those with specific diagnoses may stay longer.

"For the first time, practitioners have tangible data on length of stay to counsel parents at the time of their preterm baby's admission," says lead author Alanna Higgins Joyce, MD, MPH, a hospitalist at Ann & Robert H. Lurie Children's Hospital of Chicago and Assistant Professor of Pediatrics at Northwestern University Feinberg School of Medicine. "Our results may decrease parent stress and help families prepare for their baby's arrival home."

Previously, length of stay predictors were signs of the infant's physiological maturity, which were only available near the end of the hospital stay. Infants born at less than 37 weeks of completed gestation comprise almost 10 percent of births in the United States. Most preterm infants are born between 32 and 36 weeks of gestation.

To establish a reliable length of stay estimate at the time of a preterm baby's admission, Dr. Higgins Joyce and colleagues from Lurie Children's conducted a retrospective chart review over six years, encompassing 3,240 moderate to late preterm infants born in a large, urban NICU. They found that the mean length of stay for these infants was 17 days, ranging from 30 days for infants born at 32 weeks of gestation to about a week for infants born at 36 weeks.

"While these results come from just our hospital, we hope other centers can confirm that many parents of premature infants can anticipate having their babies home with them earlier than previously expected," says senior author Patrick Myers, MD, neonatologist at Lurie Children's and Assistant Professor of Pediatrics at Northwestern University Feinberg School of Medicine.

Research at Ann & Robert H. Lurie Children's Hospital of Chicago is conducted through the Stanley Manne Children's Research Institute. The Manne Research

Institute is focused on improving child health, transforming pediatric medicine and ensuring healthier futures through the relentless pursuit of knowledge. Lurie Children's is ranked as one of the nation's top children's hospitals by U.S. News & World Report. It is the pediatric training ground for Northwestern University Feinberg School of Medicine. Last year, the hospital served more than 220,000 children from 48 states and 49 countries.

NT

Certified nurse-midwives lead collaborative care model as solution to obstetrician shortage

Shortage of OB's requires investigation into alternative models of care

15-Jan-2020 11:00 AM EST
Mayo Clinic

Newswise — LA CROSSE, Wis. — Fewer physicians are pursuing careers in obstetrics, in part because of the intense, round-the-clock demands of the job and a high burnout rate. An unusually large number of practicing obstetricians are expected to retire within the next decade, which will add to an already acute physician shortage.

One solution to this staffing challenge is a collaborative care model used at Mayo Clinic Health System — Franciscan Healthcare in La Crosse, where certified nurse-midwives lead the care team. Certified nurse-midwives provide care for obstetric patients who are at low to moderate risk as part of a team model described in Mayo Clinic Proceedings: Innovations, Quality & Outcomes.

Patients choose whether to use the care model, which ensures that a certified nurse-midwife is in the hospital around the clock, with generalist obstetricians on call, when needed. The nurse-midwife cares for obstetric patients only, and admits labor induction, pre-labor and active labor patients. The report says the model could be used by similar hospitals that do not employ obstetricians dedicated to la-

bor and delivery.

"Across the country, hospital delivery units are facing a shortage of obstetricians due to a change in the workforce and increasing demands," says Gokhan Anil, M.D., an OB-GYN at Mayo Clinic Health System in Mankato, Minnesota, and first author of the report. "Innovative approaches to staffing are needed to serve the needs of the patient, increase collaboration and improve patient safety."

The collaborative care model has had several positive outcomes since it was implemented in July 2014. The primary cesarean section birth rate has declined, as have vaginal operative deliveries. And the rate of vaginal births after C-section has increased. Admissions to the neonatal ICU decreased from 14.9% in 2012 — before the care model was offered — to 10.9% in 2017.

"This approach also has resulted in a shorter length of stay in the hospital for our patients, which always is a good thing for patients, especially a new mother and

child," says Dr. Anil, who previously was on staff at Franciscan Healthcare.

The model has won high marks from patients and helped address staffing challenges.

"Based on previous research and our experience, women who receive midwife-led continuity of care are less likely to need an intervention and are more likely to be satisfied with their care," says Costa Sousou, M.D., chair of the Department of Obstetrics and Gynecology at Franciscan Healthcare. "This team approach allows us to continue to provide high-quality care with a more sustainable and cost-effective staffing model. We think it's a model that other institutions may find worth exploring."

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*About Mayo Clinic Health System
Mayo Clinic Health System consists of clinics, hospitals and other facilities that serve the health care needs of people in more than 60 communities in Iowa, Minnesota and Wisconsin. The community-based providers, paired with the re-*

sources and expertise of Mayo Clinic, enable patients in the region to receive the highest-quality physical and virtual health care close to home.

NT

Technology Protects Respiratory Tract of Premature Infants Who Need Assisted Ventilation

Researchers from the Technion Faculty of Biomedical Engineering are the first to point to the damage of the jet of air exiting from the endotracheal ventilation tube

13-Jan-2020 3:30 PM EST
American Technion Society
Newswise — A new artificial model of premature infants will make possible experiments that are expected to reduce injury to

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infants on respirators. The study, published in the Journal of The Royal Society Interface was conducted by doctoral student Eiram Nof and Professor Josué Sznitman of the Technion Faculty of Biomedical Engineering, in collaboration with Professor Dan Waisman, director of the Newborn Unit at the Carmel Medical Center.

More than 10% of babies worldwide are born prematurely. Infants in general, and premature babies in particular, are limited in their function in various aspects since their organs have not been able to develop properly. One of these is the respiratory system, which reaches full function only late during fetal development. This is the reason why premature birth is often characterized by respiratory distress, in part due to the lack of a unique soapy substance (surfactant), that prevents the collapse of the lungs and facilitates breathing.

Fortunately, modern medicine is able to cope with this problem and save premature infants, mainly by providing an exterior surfactant that is delivered in conjunction with a ventilation machine - a breathing apparatus that pumps air into the baby's respiratory tract through an orally inserted tube.

However, in its current form, the use of a respirator is not without problems. One of the possible side effects in premature infants using a ventilation machine is damage to the lung tissue. There is no standardization for choosing ventilator operating parameters like the percentage of oxygen in the infused air, the volume of air, the pressure, the rate, and more. Doctors do their best to make adjustments based on each infant's condition and to minimize injury. Yet, many infants are injured during this process that is nevertheless vital to saving their lives.

This is where the unique model developed by the Technion researchers comes into the picture. After prolonged research activity at the levels of mathematical modeling of respiratory airflows, Mr. Nof and Prof. Sznitman developed a physical silicone model that simulates - in 3D and in real size - the upper respiratory tract of a premature baby.

The researchers were surprised to discover a phenomenon not mentioned at all in the medical literature: an air jet at the exit of

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

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www.99nicu.org

the tube inserted into the mouth of the baby. "Until now, it was known that the tube could cause abrasive injury to the delicate tissue but the effects of the airflow were overlooked," said Nof. "In the present study, we discovered for the first time, that due to its location inside the baby's trachea, this jet exerts strong shear forces on the epithelial tissue - the layer of cells that covers the upper airways. These forces can cause damage, including inflammation, which poses a real risk to the premature infant."

The researchers examined these findings in a silicone model and found that indeed, the jet exerts friction on the lung tissue that can cause significant damage. With further study, they intend to grow live biological cells onto the model and examine the effect of the jet on them.

The good news, however, is that from the findings, the researchers have made recommendations as to the desired respiratory protocols. In their estimation, adjusting respiratory protocols to the flow configuration in the baby's respiratory system may reduce the damage described here and improve the chances of these infants to develop a proper respiratory system.

These conclusions are in line with the overall trend in the premature department of the Rambam Health Care Campus - a trend to reduce invasiveness in treatment and to reduce the use of invasive respiration as much as possible.

According to Dr. Liron Borenstein, senior physician in the Department of Neonatology and Neonatal Intensive Care at Rambam, "With advances in medicine, we are today able to treat younger premature infants and more complex illnesses. However, respiratory morbidity is still a significant factor in premature infant mortality and morbidity. The technology presented in this

article - creating a model of a healthy, specific area and exploring the forces exerted on the tissue by an air jet created under invasive respiration - can advance us in understanding the mechanisms leading to the damages of ventilation that we want to prevent and in developing gentler breathing techniques that are appropriate for the premature infant population."

For more than a century, the Technion – Israel Institute of Technology has pioneered in science and technology education and delivered world-changing impact. Proudly a global university, the Technion has long leveraged boundary-crossing collaborations to advance breakthrough research and technologies. Now with a presence in three countries, the Technion will prepare the next generation of global innovators. Technion people, ideas, and inventions make immeasurable contributions to the world, innovating in fields from cancer research and sustainable energy to quantum computing and computer science to do good around the world.

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Neonatology Solutions NICU Directory - 830 Units Nationwide

Scott Snyder, MD



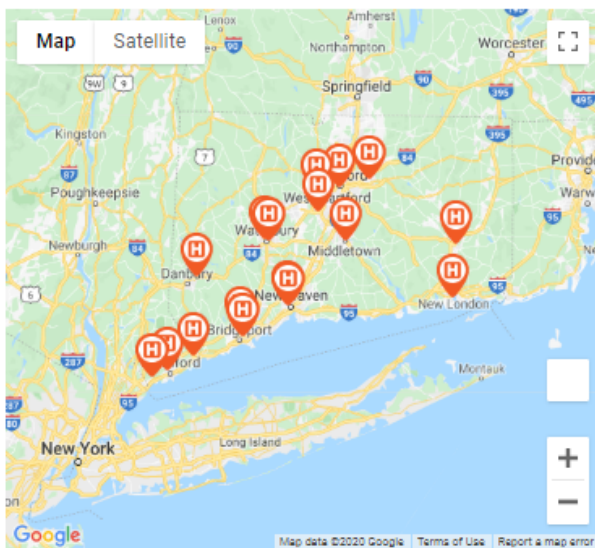
We are pleased to report continued progress on the development of the Neonatology Solutions NICU Directory. We have

now reached 830 NICUs, with the recent addition of NICUs in NY, NJ, MD, PA, and DE.

Additionally, we have begun development of State Summary Pages to provide an overview of the neonatal care offered. The State Summary Pages provide information on the number of Level II, III, and IV NICUs, neonatology groups, VON members, current job postings, upcoming conferences, and also links to state-based resources.


[NICU Directory](#)
[Neo Conferences](#)
[Career Planning](#)
[Clinical Guidelines](#)
[Parent Education](#)


Connecticut



17 NICUs

281+ Beds

Level IV

2

Level III

11

Level II

4

Neonatology
Groups

7

Neonatal-Perinatal
Fellowship Programs

2

Vermont Oxford
Members

10

Job Postings = 3 positions

Skip To: [Neonatology Groups](#) [Fellowship Programs](#) [Job Postings](#) [Upcoming Conferences](#) [VON Members](#) [Helpful Resources](#)

NICUs (columns can be sorted)

Hospital	Level	Beds ^
St. Mary's Hospital	Level II	9 Beds
Greenwich Hospital	Level III	10 Beds
Waterbury Hospital	Level III	14 Beds
Lawrence and Memorial Hospital	Level III	14 Beds
Norwalk Hospital	Level III	16 Beds
Hospital of Central Connecticut	Level III	16 Beds
Stamford Hospital	Level III	16 Beds
Bridgeport Hospital	Level III	20 Beds
Danbury Hospital	Level III	21 Beds
Saint Francis Hospital and Medical Center	Level III	28 Beds

We currently have summaries completed for the following states – CT, ID, KY, MA, ME, NC, NH, ME, RI, SC, VA, VT – and will be continuing to build these summary pages as NICU data is compiled for each state and the Directory reaches completion.

At Neonatology Solutions, our goal is to provide the most comprehensive information on the web regarding the size and scope of NICU programs, as well as key contact names, email addresses, and phone numbers to facilitate networking, collaboration, and career planning for fellows and neonatologists.

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

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

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

References:

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

The author is a principal of Neonatology Solutions, LLC.

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Corresponding Author



Scott Snyder, MD, FAAP
System Medical Director
St. Luke's Neonatology
Founder
Neonatology Solutions, LLC
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expert care for

the full spectrum of disorders



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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

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VERY LOW BIRTHWEIGHT BABIES are at risk for Necrotizing Enterocolitis (NEC), which:

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

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

When that happens:

5%	17%
1%	12%

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

Very low birthweight babies who get NEC

Very low birthweight babies requiring surgery to treat NEC

30% of very low birthweight babies requiring surgery will die from NEC

HOW TO HELP PREVENT NEC: EXCLUSIVE HUMAN MILK DIET

What is an Exclusive Human Milk Diet?

- NO cow's milk
- NO sheep's milk
- NO goat's milk
- NO formula

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

Why is An Exclusive Human Milk Diet Important?

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

When a very low birthweight baby can access an EXCLUSIVE HUMAN MILK DIET:

- Mortality is reduced by **36%**
- Feeding intolerance decreases
- Chances of NEC are reduced by **37%**

HUMAN MILK = MEDICINE

NEC is a life-threatening condition that can be deadly. If the digestive tract doesn't work, it's a sign of human milk. Help your baby receive it. If you're not sure, talk to your doctor about your baby's specific human milk needs and request resources to find your healthy milk source.

LEARN MORE

NCfIH National Coalition for Infant Health

Genetics Corner: Prenatal Diagnosis of Klinefelter Syndrome

Robin Clark, MD

Case Summary:

A one-day-old 39-week 1-day gestation male was referred for a genetics consultation because he had been prenatally diagnosed with Klinefelter syndrome, initially by NIPT and then confirmed by amniocentesis. His mother, a 26-year old G3P1SAb1TA1 female, delivered him vaginally by spontaneous vertex delivery. Apgar scores were 81 and 95. Growth parameters were normal: BW 3.27 kg, BL 52 cm, HC 34 cm. The baby had had no complications and was rooming in with his mother.

During her pregnancy, the mother had a normal sequential (1st and 2nd trimester) maternal serum screening test. A noninvasive prenatal test (NIPT) that utilized cell-free fetal DNA techniques was abnormal with an increased risk for a sex chromosome aneuploidy. An amniocentesis, performed for this indication, confirmed 47,XXY, in each of 15 metaphases. The fetal US at 26w 3d showed no major anomalies but abnormal toes on both feet, suggesting syndactyly.

Genetics evaluation:

On physical exam, the baby cried but calmed with sucking. He was nondysmorphic and normocephalic. He had a single transverse palmar crease on the right palm. His fingers were long as were his feet. His 4th and 5th toes were overlapping, but there was no syndactyly. He had dermal melanocytosis on his lower back. His genitalia were unremarkable with a normal, deeply pigmented, rugated scrotum bilaterally descended testes and an uncircumcised phallus of normal length (2 cm) and caliber. His neuro exam was normal with good tone, symmetric movements, a strong grasp and a lusty cry.

The family history was significant for a 25-year old maternal uncle with 21-hydroxylase deficiency and a 33-year old maternal aunt, who was hirsute and short with polycystic ovaries, but who had not been formally diagnosed with congenital adrenal hyperplasia (CAH). The mother was tested for CAH carrier status in this pregnancy, with positive results, confirming a heterozygous pathogenic sequence change in CYP21A2: p.V282L, a known, mild (non-classical) variant. The father of the baby, a healthy 31-year old, had not yet been tested for CAH carrier status. Consanguinity was denied. The parents had two previous pregnancies together that ended in a miscarriage and a therapeutic abortion. There was no other history of congenital anomalies or chromosome abnormalities.

Conclusions and Counseling:

Klinefelter syndrome (KS) occurs in males with an extra X chromosome. In 90% of affected males, the chromosome complement is 47,XXY. Mosaicism with a normal cell line is present in 7%: 46,XY/47,XXY. Rare and more severe variants are found in 3%: 48,XXXY, 48,XXYY, 49,XXXXY. The extra X chromosome is maternally derived in 50%.

Although KS is relatively common, occurring in 1/600 male births, it is not commonly diagnosed in the newborn period. Less than 10% of affected males are diagnosed before puberty. Another 25% of males with KS are diagnosed in adulthood. The majority, approximately 65%, are never diagnosed throughout their lifespans.

The widespread acceptance of NIPT as a screening tool has in-

creased the prenatal diagnosis of Klinefelter syndrome. NIPT, which is offered as early as ten weeks gestation, utilizes cell-free fetal DNA circulating in the maternal bloodstream. Although it is highly accurate (91% sensitivity, 99.6% specificity), NIPT is not a diagnostic test. A positive NIPT test should be confirmed with chromosome analysis, either prenatally, with invasive testing by amniocentesis or chorionic villous sampling, or postnatally, with a blood sample. Although prenatal diagnosis with amniocentesis is considered reliable, confirming the prenatal diagnosis of a chromosome anomaly in a blood sample settles any doubts that parents may have, which would be understandable when the phenotype is normal as it usually is in KS.

Babies with KS are usually healthy and nondysmorphic. This infant had few if any signs that would have suggested a chromosome abnormality. His condition would have certainly gone undetected without NIPT screening and prenatal diagnosis.

“This infant had few if any signs that would have suggested a chromosome abnormality. His condition would have certainly gone undetected without NIPT screening and prenatal diagnosis.”

The classic features of KS are more evident near puberty when hypergonadotrophic hypogonadism and/or tall stature may become apparent, or even later, in adulthood, because of azoospermia and infertility. Intelligence is usually normal though it may be 9-10 points lower than unaffected siblings. Behavioral (shyness, anxiety, depression, low self-esteem) & learning problems (reading/language disability, memory), ADHD, executive dysfunction, and motor delays are common. In a study of 43 boys with KS, aged 8-18, among those diagnosed postnatally, developmental delay (11.6%) was the most common reason for ordering the karyotype (Close 2015).

Speech delay and language disabilities are common in KS. In general, boys with prenatally diagnosed Klinefelter syndrome do better than those who are postnatally diagnosed. However, feeding difficulties, which may be the earliest evidence of oral motor dyspraxia in KS, have been seen in almost half of a cohort of prenatally diagnosed infants with 47,XXY.

Early diagnosis of KS raises questions about which, if any, interventions may be beneficial in infancy and childhood. Androgens, specifically testosterone, affect typical brain development in males and an early androgen deficit in KS may impact motor, language, cognitive and social function in KS. Although there are no guidelines for hormone replacement therapy in Klinefelter syndrome, testosterone therapy has typically been offered near puberty. However, recent studies have reported positive effects of early androgen therapy on the behavioral phenotype of boys with 47,XXY. Early therapy with androgens, which reinforces a naturally occurring testosterone peak at 2-4 months of life, has improved neurodevelopmental performance related to cognitive functioning, visual and motor skills, and language development in treated boys compared to untreated controls with Klinefelter syndrome. Samangoo-

Sprouse et al. (2015) treated 29 prenatally diagnosed boys with KS with three monthly injections of testosterone enanthate (from 4-15 months) and compared them with 57 controls with 47,XXY, who did not receive hormone therapy. They found significant differences in social communication and social cognition scores and on measures of initiation, externalizing, affective and aggressive behaviors. Ross et al. (2017) conducted a randomized, double-blind, placebo-controlled clinical trial in which 84 boys with Klinefelter syndrome, aged 4-12 years, were treated with daily Oxandrolone or placebo for 24 months. Their study showed benefits in visual-motor function and improvement in anxiety/depression and social problems scales in the treated group. Flannigan et al. (2018), in their meta-analysis on the behavioral effects of early androgen supplementation in KS, reviewed three retrospective studies and two randomized controlled trials and concluded that these studies showed an improvement in several aspects of social and cognitive functioning, with benefits that were "very encouraging."

Finally, it is intriguing to speculate that this baby boy may have benefitted from his mother's carrier status for 21-hydroxylase deficiency because even a mild, non-classical allele could have modestly increased maternal adrenal androgen production during his intrauterine life. It is also possible that, if he were also a CAH carrier, his own excess adrenal androgen production might ameliorate his Klinefelter syndrome-associated hypogonadism.

"Flannigan et al. (2018), in their meta-analysis on the behavioral effects of early androgen supplementation in KS, reviewed three retrospective studies and two randomized controlled trials and concluded that these studies showed an improvement in several aspects of social and cognitive functioning, with benefits that were 'very encouraging.'"

Practical Applications:

1. Klinefelter syndrome is underdiagnosed. Expect more boys with Klinefelter syndrome to be prenatally diagnosed as NIPT becomes a routine screening test in pregnancy.
2. Order chromosome analysis (not a microarray) to confirm a prenatally diagnosed sex chromosome abnormalities or a positive NIPT test. NIPT is considered a screening test, not a diagnostic test.
3. Half of the babies with Klinefelter syndrome may have feeding problems, which are early manifestations of the oral-motor dyspraxia of this condition.
4. Early androgen hormone therapy during infancy may offer behavioral, social, language, and cognitive benefits to boys with Klinefelter syndrome.

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The authors have no relevant disclosures.

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Corresponding Author

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

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Your Pregnancy and Substance Use

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



Get Prenatal Care

Start early. Go to all your visits. Empower yourself with information so you can make smart decisions. Build relationships with providers who understand Substance Use Disorders (SUDs) and know how to help. Partner with them to reach your goals. But remember, you do not need to be abstinent from substance use to get care. Go now.

Reduce Your Use

There are simple things you can do to limit the harm substances might do.

- Use fewer substances
- Use smaller amounts
- Use less often
- Learn how to use safer

Reducing or quitting smoking is a good place to start. Set your goals, then ask for help. One of the best things you can do is to stop using alcohol. We know that even small amounts are risky. And when combined with benzos and opioids, alcohol can kill.

Use Opioid Agonist Therapy (OAT) if you are opioid dependent

Methadone and Buprenorphine (Subutex® or Suboxone®) are the "Standard of Care" during pregnancy because they:

- Eliminate the risks of illicit use
- Reduce your risk for relapse
- Can be a positive step towards recovery

Take Good Care of Yourself

You deserve a healthy pregnancy & childbirth.

- Eat healthy and take your prenatal vitamins
- Find the right balance of rest and exercise
- Surround yourself with people who care

Your Health Matters



Academy of Perinatal Harm Reduction

www.perinatalharmreduction.org



www.nationalperinatal.org

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

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



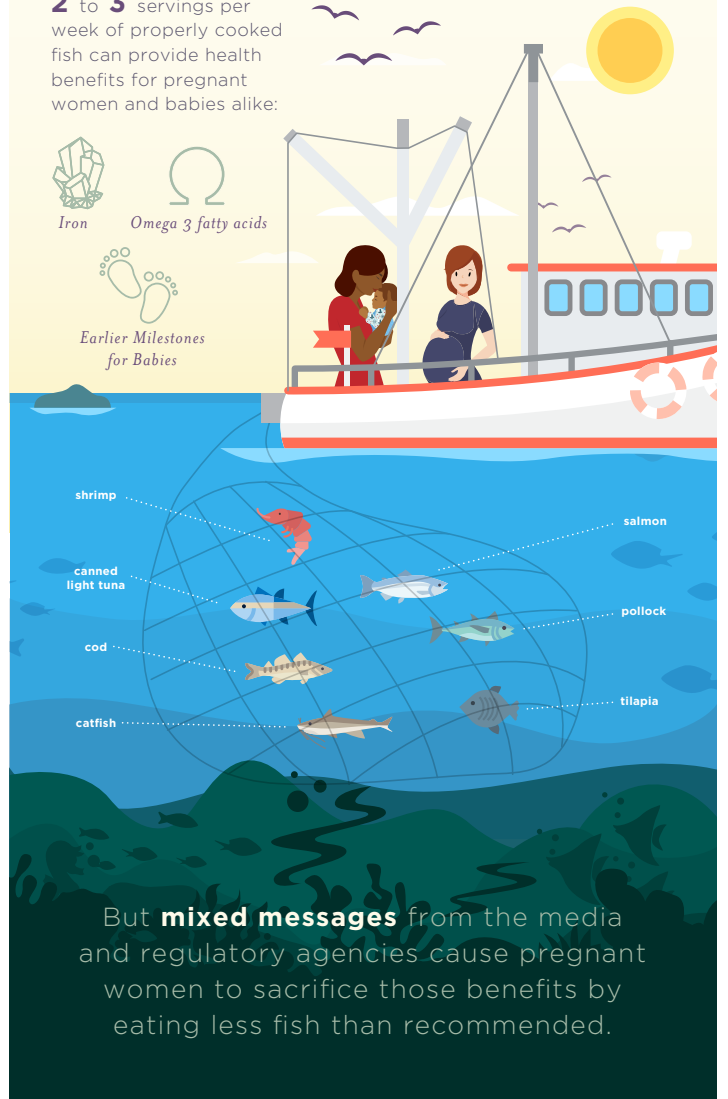
Iron



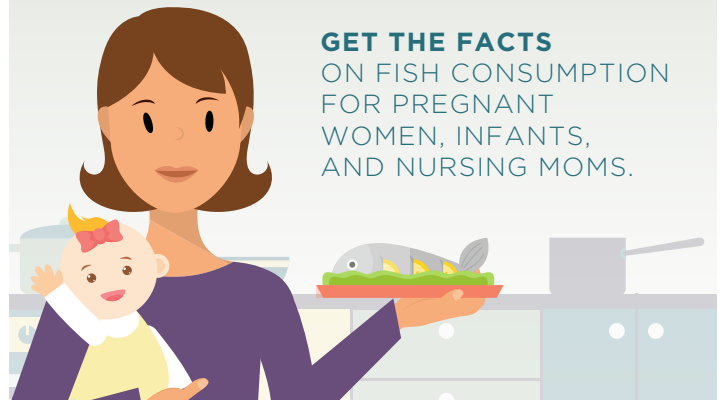
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Earlier Milestones for Babies



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ON FISH CONSUMPTION FOR PREGNANT WOMEN, INFANTS, AND NURSING MOMS.

NCfIH National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

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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



End the Stigma and Criminalization of Drug Use

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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.



5 SCREEN EARLY AND OFTEN

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.



6 OFFER PALLIATIVE & BEREAVEMENT CARE

Support families and NICU staff as they grieve. Stay current with best practices in palliative care and bereavement support. Build relationships with service providers in your community.

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."

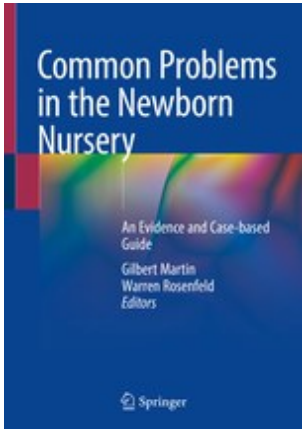


10 HELP US HEAL

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

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



Common Problems in the Newborn Nursery An Evidence and Case-based Guide

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- **Written by experts in the field in a clear, easy-to-use format**
- **Utilizes a case-based approach**

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

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

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

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Human Milk's "Secret Ingredients"

Susan Hepworth and Mitchell Goldstein, MD



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

Researchers may have pinpointed the "secret ingredients" that allow human milk to protect newborns against a life-threatening condition called necrotizing enterocolitis. They are HMOs – human milk oligosaccharides. (1)

Up to 200 different types of HMOs exist, and consuming a diversity of HMOs has been linked with enhanced immune system development, growth, and possibly brain development. The list of benefits grows with the results of a new study. Researchers revealed that extremely low birth weight babies who received human milk with a broader array of HMOs had a lower risk of developing necrotizing enterocolitis, or NEC.(2)

Human milk has long been recommended to reduce the risk of NEC in premature babies, yet some babies fed human milk exclusively still develop the condition. This new information clarifies which components of human milk, specifically which HMOs, provide the protective effect.

"Human milk has long been recommended to reduce the risk of NEC in premature babies, yet some babies fed human milk exclusively still develop the condition. "



Known as prebiotics, HMOs feed good bacteria, called probiotics – essential to building a healthy intestinal gut that can fight viruses. Prebiotics can also limit the growth of harmful, infection-causing bacteria. HMOs are the third most abundant component of human milk, after fats and carbohydrates.

The health benefits of human milk are well documented. It provides antibodies to ward off GI and ear infections; it lowers babies' risk of asthma, allergies, and respiratory illness, among other benefits. A broader understanding of HMOs' function now bolsters that list.

However, it also underscores a painful disparity. Not every baby has access to human milk. Not all mothers produce milk or enough milk, and some babies are adopted or in foster care. Where available, human milk banks that provide donor milk can help to meet that need. Nevertheless, access and cost remain barriers. There are not enough banks or donated milk.

“Not every baby has access to human milk. Not all mothers produce milk or enough milk, and some babies are adopted or in foster care. Where available, human milk banks that provide donor milk can help to meet that need.”

Moreover, cost is an issue. Processing and safely delivering human milk is expensive. Not all insurance companies provide coverage for the cost of human milk or human milk-based fortifiers, despite their demonstrated health benefits for fragile infants.

Broader coverage policies could increase access to many, benefiting babies' health and shielding insurance companies from the expense of dangerous and avoidable conditions like NEC.



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Disclosures: The authors do not have any relevant disclosures.

NT

National Coalition for Infant Health Values (SANE)

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

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

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

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



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Corresponding Author



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



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

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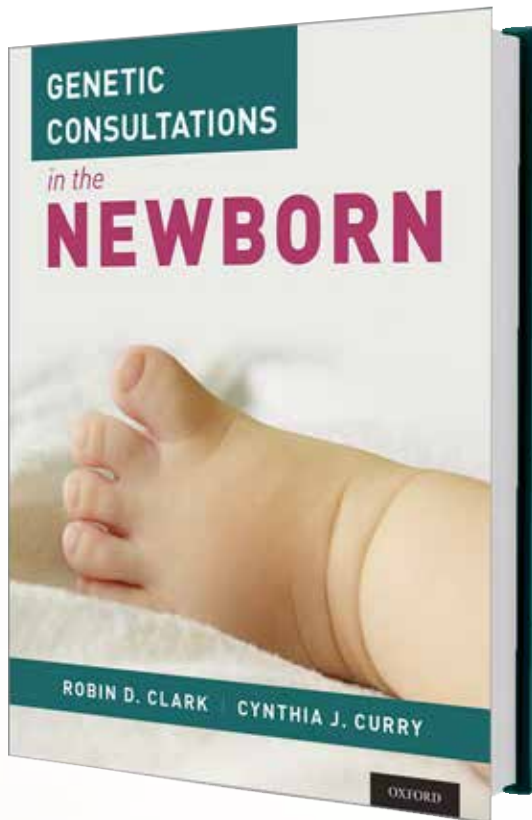


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RSV AWARENESS:

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

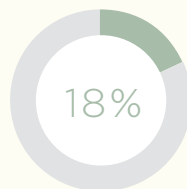
Preparedness

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.

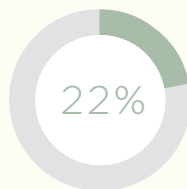
Specialty health care providers reiterated these concerns; 70% agreed that parents of their patients have a low awareness of RSV. Meanwhile, specialty health care providers themselves actively monitor for RSV. They reported that:

PARENTS

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

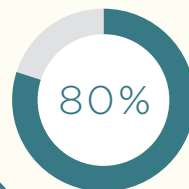


Only 22% of parents consider themselves “very well prepared” to prevent RSV.

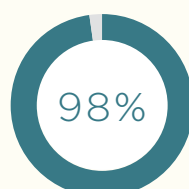


SPECIALTY HEALTH CARE PROVIDERS

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%).



Clinical Pearl: “What Does Research Analysis of “Big Data” Really Mean to the Pediatric Provider Regarding Sudden Unexpected Infant Death and Safe Sleep Recommendations?”

Tatiana M. Anderson, PhD and Kelty Allen, PhD

The digitization of population health data has led to a large amount of “big data” and stimulated a rapid growth of data science in medicine. Data is generated in high volume, in a large variety of formats, and amasses so fast that it cannot be analyzed using traditional data-processing methods (1). The combination of big data, the exponential growth of computational power (2) and the availability of open-source programming tools together with advances in machine learning and analytics techniques have created the perfect storm for the growing importance of big data in healthcare. Turning this firehose of data into meaningful insights can lead to better decision making in the clinic, provide higher quality patient care, and ultimately save lives.

The literature contains many papers on the value and vision of big data in medicine (3-7) and is rife with real-world applications exemplifying the power of data science especially in the fields of medical image processing, signal processing, and genomics (8,9). Here, we do not wish to add another overview of the benefits of big data in healthcare and instead offer the reader a non-technical, step-by-step understanding of the processes by which our team uses large datasets to lead to actionable insights for medical professionals in an effort to decrease instances of sudden infant death syndrome (SIDS) and sudden unexpected infant death (SUID). This has been possible through a unique collaborative partnership between researchers at Seattle Children’s Research Institute, data scientists at Microsoft, and top medical researchers in the SIDS/SUID field.

“This has been possible through a unique collaborative partnership between researchers at Seattle Children’s Research Institute, data scientists at Microsoft, and top medical researchers in the SIDS/SUID field.”

Our primary data source has been the Birth Cohort Linked Birth – Infant Death data files publicly available through the Centers for Disease Control’s National Center for Health Statistics (10). A data scientist starts by uploading data from every live birth in the United States for any number of years between 1983-2014 (the most current year available). This includes a total of over 10 million live births per year. If there is an early death, the death certificate is linked to the birth certificate, so we can search for cause of death codes established in the International Classification of Diseases 10th edition (ICD-10) that are specific to the umbrella category ‘SUID’ including SIDS (R95), unknown or ill-defined cause of death (R99), and accidental strangulation or suffocation in bed (W75). There are approximately 3,500 cases of SUID in

the United States annually. While instances of a SIDS diagnosis have decreased, the number of R99 and W75 diagnoses have increased (a phenomenon called ‘diagnostic shift’ or ‘diagnostic transfer’ (11)) such that overall SUID cases have been stagnant for the last couple of decades.

After uploading, the data is stored in a cloud-based database using Microsoft Azure. The publicly available data is deidentified, meaning that it does not include any private, personally identifying information such as names, addresses, geographic locations, etc. Data scientists can then pull subsets of the data from the database and use programming languages, such as Python or R, and open-source libraries to begin preliminary analysis.

Whether a specific hypothesis is in mind or not, the first step involves data exploration to start to learn patterns and look for anomalies or missing data. At this stage the data scientist is often in close communication with colleagues and medical experts to better formalize the hypothesis, question, and best analysis method for obtaining results. The goal is to produce novel findings that are, of course, clinically relevant.

Some special techniques are necessary due to the fact that SUID is a rare event. In 2017 0.09% of live births died of SUID in the US. If the data scientist wanted to build a model that, for example, predicted SUID risk by the number of cigarettes a mother smoked during pregnancy, the model could not be trained using the whole population. The machine learning model optimizes for accuracy, precision, and recall for predicting ‘SUID’ vs. ‘not SUID’, and thus the best model would “learn” to predict ‘not SUID’ on every data point giving an accuracy rating of 99.91%! To avoid this issue, we use a technique called down-sampling, wherein the model uses a representative sample of non-SUID infants about 10 times the size of the SUID population. This type of model cannot be used to “predict” SUID in the real world, however, statistics such as adjusted odds ratio are reliable.

Writing code can be tedious, but running the code is often very fast. Because of this, it is usually worth it to try several kinds of models to see what works best with the data. For example, if we are trying to understand which features are associated with increased or decreased risk of SUID or calculate the adjusted odds ratio of SUID in one population compared to another, our team has used logistic regression, generalized additive models, and Bayesian networks as well as other standard classifiers like random forest and support vector machines.

From here, we work to compile a valuable story, often consulting with pediatricians, epidemiologists, and medical researchers to get feedback on what is interesting, novel, and actionable. In other words- how do we go from “statistically significant” to “this is what this means for your patients”.

One of the best examples of this journey end-to-end is a manuscript that was published by members of our team in April 201912.

The association between maternal smoking and an increased risk of SUID has been well-documented, however, since we are working with such large data sets, we were able to define this relationship with much higher, single-cigarette resolution. We found that smoking a single cigarette a day, on average, during pregnancy doubles the risk of SUID. There was a linear increase in risk between smoking 1 and 20 cigarettes. Smoking in the 3 months before pregnancy and quitting by the first trimester still increased SUID risk by approximately 50%. Decreasing cigarette consumption during pregnancy decreased SUID risk. Through this story we were able to provide solid, actionable data and asked clinicians to 1) urge patients to quit smoking well before trying to become pregnant, 2) unequivocally tell patients that the best way to lower SUID risk is to quit smoking, and 3) tell patients that refuse or are unable to quit that even reducing the number of cigarettes makes a positive difference.

Thanks to this incredible partnership, we currently have two published manuscripts (12,13), two in the review process, and several in various stages of analysis/drafting. In an effort to continue the momentum and foster new ideas and collaborations, Seattle Children's Hospital and Microsoft jointly host an annual "SIDS Summit", a two-day conference dedicated to SIDS, SUID, and infant mortality in Seattle. We bring together researchers, data scientists, clinicians, geneticists, pathologists, medical examiners, and bioinformaticians to present their latest research and tackle the issues from multiple angles of expertise.

We believe that this partnership can serve as a template model for a host of other issues, for example diabetes, cancer, or the current opioid epidemic. With ever-increasing amounts of medical data being collected and data science as one of the fastest growing career fields, the time is ripe to leverage big-data to help drive evidence-based care and prevention.

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Conflicts: The authors have no conflicts to disclose

NT

Corresponding Author



Tatiana M. Anderson, PhD
Neuroscience Postdoctoral Fellow
Seattle Children's Research Institute
Center for Integrative Brain Research
Tatiana A <tatiana.m.anderson@gmail.com>



Kelty Allen, PhD
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Which Infants are More Vulnerable to Respiratory Syncytial Virus?

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

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

*Source: Respirator Syncytial Virus and African Americans

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

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



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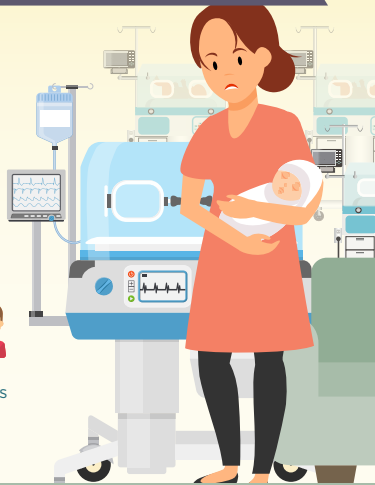
Preterm infants are:

2x more likely to have developmental delays

5x more likely to have learning challenges



1 in 3 preterm infants will require support services at school



Early intervention can help preterm infants:



Enhance language and communication skills



Build more effective learning techniques



Process social and emotional situations



Address physical challenges



Prevent mild difficulties from developing into major problems

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

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



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

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Survey Says: **RSV**

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

- Hospitalization
- Lifelong health complications
- Death

for infants and young children.



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

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

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

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



But Parents are Unprepared.

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

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



RSV EDUCATION & AWARENESS CAN HELP

After parents learned more about RSV, they were:

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



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Letters to the Editor

January 16, 2019

Mitchell Goldstein, MD

Editor-in-Chief, Neonatology Today

Dear Dr. Goldstein:

I have really enjoyed reading the clinically relevant articles published in Neonatology Today. My understanding was that we were working toward being cited in PubMed at some point in time. How are things progressing with the "certification"?

Sincerely,

Joseph R. Hageman, MD.

Dear Dr. Hageman,

Thank you for your question. Citation in PubMed has been a serious goal for some time. The process is long and by no means certain. The requirements are detailed here <https://www.ncbi.nlm.nih.gov/pmc/pub/addjournal/>.

To summarize,

1. The journal must have an ISSN (a "record for the journal in the official Register of the ISSN International Centre")
2. The journal must provide the National Library of Medicine with ready access to its issues.
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As of approximately March 2018, we assumed the complete publishing of Neonatology Today. We are very close to starting the submission process.

After submission of the application, there is a review process that involves checking that our journal meets the specified requirements including publication in the life sciences, ascertaining our peer review process, and demonstrating that the majority of our published manuscripts are of the appropriate type.

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Sincerely,

Mitchell Goldstein, MD

Editor in Chief

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

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

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Erratum (Neonatology Today December, 2019)

Neonatology Today has identified no erratum affecting the December, 2019 edition.

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

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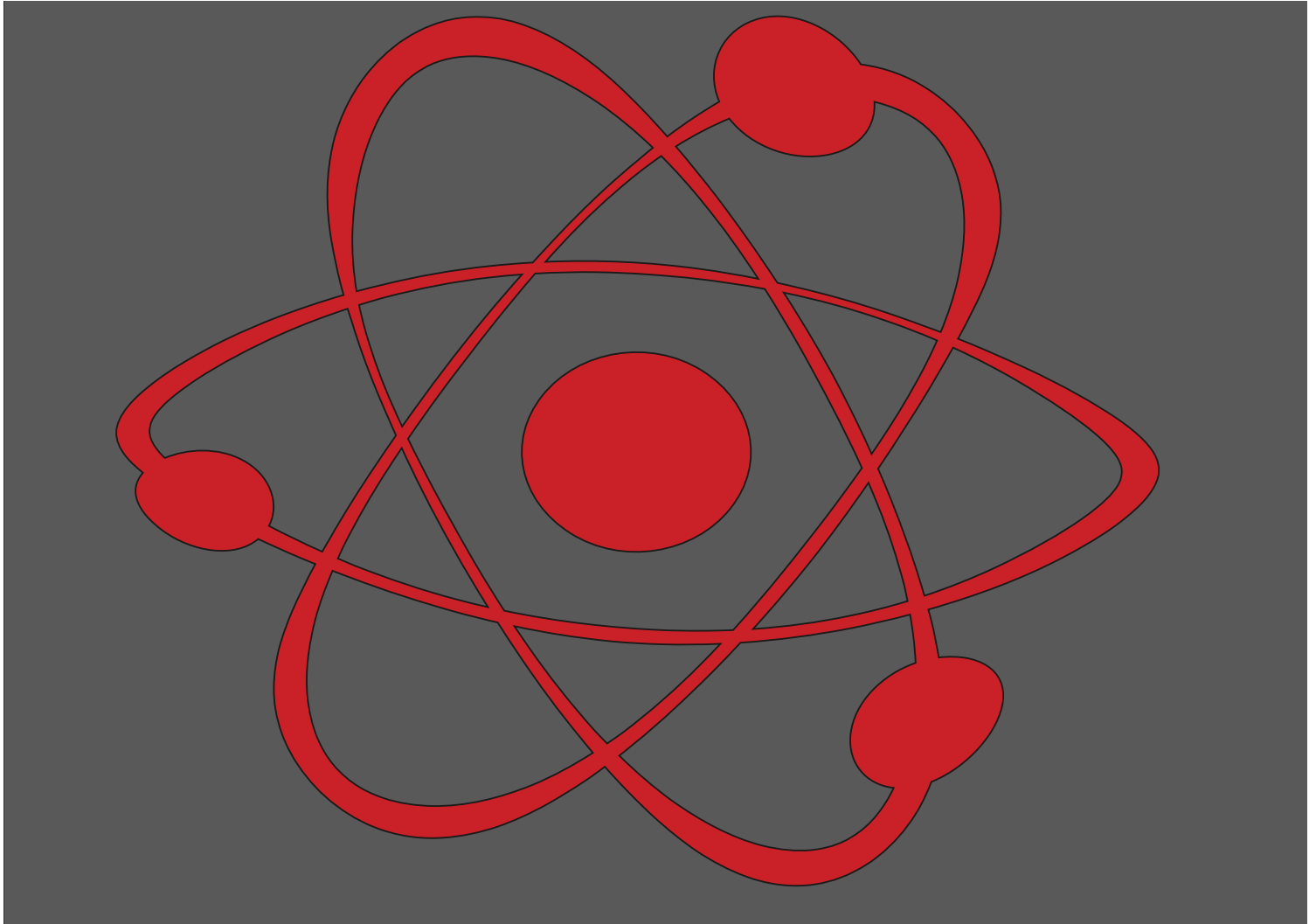
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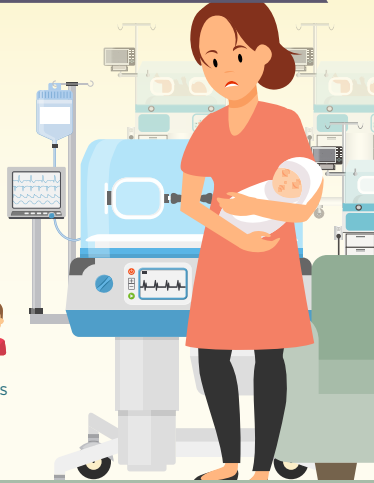
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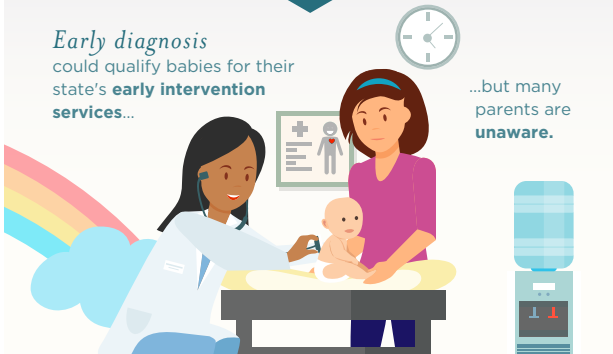
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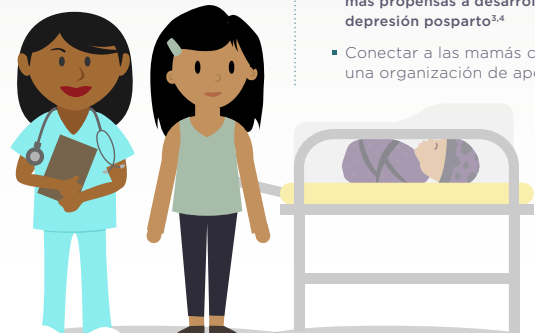
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² National Institute of Mental Health. Accessed on: <http://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml>
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Philadelphia, Pennsylvania

<https://www.stchristophershospital.com/SitePages/For-Health-Professionals/Continuing-Medical-Education/Day-With-The-Newborn.aspx>

NEO

The Conference for Neonatology
February 19 – 21, 2020.

San Diego, CA

<http://www.neoconference.com/>

Specialty Review in Neonatology
February 17-22, 2020

<http://specialtyreview.com>

36th Annual Children's National Symposium ECMO and Advanced Therapies

February 23 - 27, 2020

Children's National

Keystone, Colorado

<https://web.cvent.com/event/a92c867d-d0d2-4eb5-888b-3b1672487c03/summary>

33rd Annual Gravens Conference on the EOC for High Risk Newborns

March 4 - 7, 2020

University of South Florida Health
Clearwater Beach, Florida

<https://health.usf.edu/publichealth/chiles/gravens-conference>

26th Annual Cool Topics in Neonatology

March 6 - 8, 2020

California Association of Neonatologists
Coronado, California

<https://caneo.groupsite.com/main/summary>

The 37th Annual Advances in Therapeutics and Technologies Conference

March 24-28, 2020

Snowbird, UT

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

Perinatal Care and the 4th Trimester: Redefining Prenatal, Postpartum, and Neonatal Care for a New Generation
March 25 - 27, 2020

Aurora, Colorado

<http://www.nationalperinatal.org/2020conference>

1st Annual Innovations in Maternal, Fetal, and Neonatal Medicine
March 27 - 29, 2020

Johns Hopkins All Children's Hospital

St. Petersburg, Florida

<http://www.cvent.com/events/the-annual-innovations-in-maternal-fetal-and-neonatal-medicine-the-continuum-of-care-conference/event-summary-772b578c0e5348d3bba8a80915ffcac8.aspx>

Pediatric Academic Societies 2020 Meeting

April 29 – May 6, 2020

Philadelphia, PA

<https://2020.pas-meeting.org/>

Innovations in Neonatal Care
August 10 - 12, 2020

Mednax

Austin, Texas

<http://www.innovationsconference.com/>

AAP National Conference & Exhibition

October 18 - 20, 2020

American Academy of Pediatrics
San Diego, California

<https://aapexperience.org/>

For up to date Meeting Information, visit NeonatologyToday.net and click on the events tab.

NEONATOLOGY TODAY

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ISSN: 1932-7137 (Online).

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

Publication

Mitchell Goldstein, MD

Loma Linda Publishing Company

11175 Campus Street

Suite #11121

Loma Linda, CA 92354

www.NeonatologyToday.net

Tel: +1 (302) 313-9984

LomaLindaPublishingCompany@gmail.com

Editorial and Subscription

Mitchell Goldstein, MD

Neonatology Today

11175 Campus Street

Suite #11121

Loma Linda, CA 92354

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For information on sponsorships or recruitment advertising call Andrea Schwartz

Goodman at: +1 (302) 313-9984 or send

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Academic Neonatologist Opportunity in Southern California

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

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

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

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

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

This opportunity is not eligible for a J1 Waiver.



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For more information please contact:

Elba Fayard, MD
Division Chief of Pediatric Neonatology
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EOE/AAE

Who We Are

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

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

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

Contact Us

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

If you are an individual who understands and embraces the mission and purpose of Loma Linda University and its entities as premier Seventh-day Adventist Christian institutions, please visit our website or call 1-800-722-2770. EOE/AA/M/F/D/V



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Peer Reviewed Research, News and Information in Neonatal and Perinatal Medicine
Loma Linda Publishing Company | c/o Mitchell Goldstein, MD | 11175 Campus St, Ste. 11121 | Loma Linda, CA 92354 |
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Editorial Board



Mitchell Goldstein, MD - Editor-in-Chief
LomaLindaPublishingCompany@gmail.com
MGoldstein@llu.edu
Professor of Pediatrics
Loma Linda University School of Medicine
Division of Neonatology, Department of Pediatrics
Loma Linda University Children's Hospital



T. Allen Merritt, MD - Senior Associate Editor for
Contributions & Reviews
AllenMerritt.md@gmail.com
Professor of Pediatrics
Loma Linda University School of Medicine
Division of Neonatology, Department of Pediatrics
Loma Linda University Children's Hospital



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



Elba Fayard, MD - Interim Fellowship Editor
Efayard@llu.edu
Professor of Pediatrics
Division Chair
Division of Neonatology-Perinatal Medicine
Loma Linda University Children's Hospital



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MKadri@llu.edu
Executive Board
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Los Angeles, CA
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MNarvey@exchange.hsc.mb.ca
Section Head of Neonatology
Children's Hospital Research Institute of Manitoba



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University of Chicago
jhageman@peds.bsd.uchicago.edu



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OU Medical Center
University of Oklahoma Health Sciences Center
clara-song@ouhsc.edu



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tclarke347@gmail.com
Emeritus Consultant in Neonatology
The Rotunda Hospital,
Dublin, Ireland



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



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



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



Arun Pramanick, MD - India Editor
aprama@lsuhsc.edu
Professor, Pediatrics,
Louisiana State University School of Medicine,
Shreveport, LA



Andrea Schwartz Goodman, MSW, MPH
Senior Editorial Project Director
Andrea.SchwartzGoodman@NeonatologyToday.net
Washington, D.C.



Herbert Vasquez, MD - Arts Editor
VasquezH1@gmail.com
Associate Neonatologist
Citrus Valley Medical Center, Queen of the Valley
Campus, West Covina, CA



Giang Truong, MD - QI/QA Editor
GTruong@llu.edu
Associate Professor of Pediatrics
Division of Neonatology-Perinatal Medicine
Loma Linda University Children's Hospital



Theodor Yasko, MD, MBA
Special Projects Coordinator
tyasko@gmail.com

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

Neonatology and the Arts

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

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

Logos and trademarks will usually not qualify for publication.

Dr. Mitchell Goldstein gives us another type of bird this month. This is a thunderbird from the pacific northwest. The continuum of birds goes on.



Herbert Vasquez, MD

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

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.

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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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