NEONATOLOGY TODAY

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

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Volume 20 / Issue 7 July 2025

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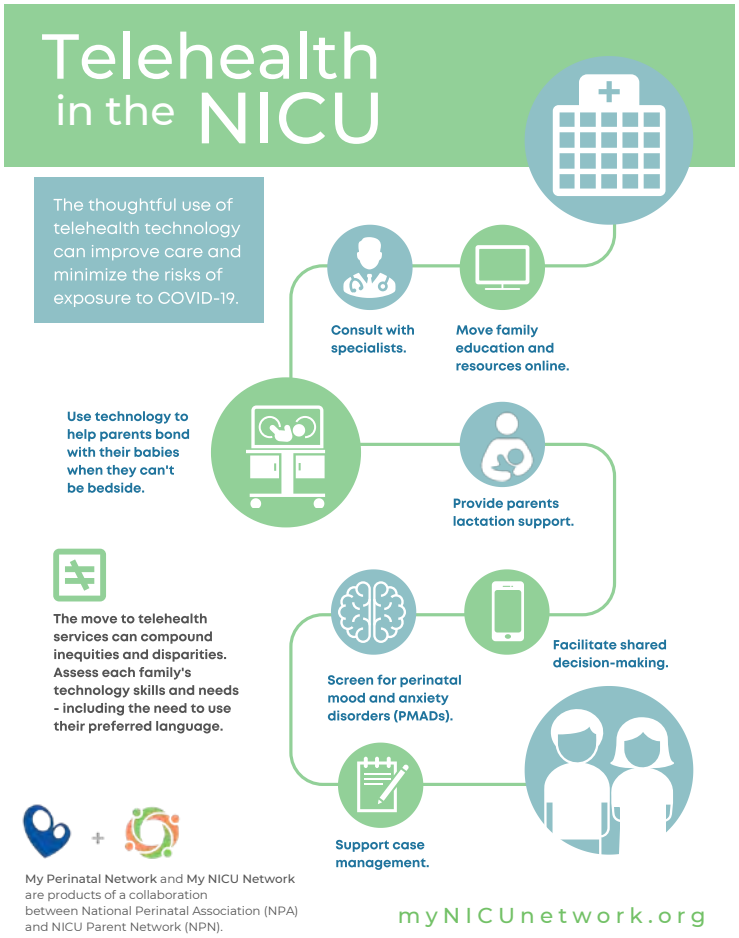
NEONATOLOGY TODAY

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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
www.Twitter.com/NeoToday

NT

Loma Linda Publishing Company
A Delaware "not for profit" 501(C) 3 Corporation.
c/o Mitchell Goldstein, MD
11175 Campus Street, Suite #11121
Loma Linda, CA 92354
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Pictured: Baby Kole with his Dad

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Health and Wellness: The Gut Microbiome

Hun-Seng Chao, MD

We healthcare workers work hard to care for our patients, but we sometimes forget to care for ourselves. In this series, I will discuss health and wellness, two things most of us never really learned much about in medical school, including nutrition, ways to prevent disease, and how vitally important our lifestyle is to our health. It will occasionally be relevant to our patients but is mainly directed toward healthcare workers. I am not an expert in this topic, but I will share with you what I have learned over the past few decades since med school from multiple research-backed sources, including functional medicine, functional nutrition, integrative medicine, and others, as well as allopathic medicine. Of course, this is not intended to be medical advice or to diagnose or treat any illness or condition.

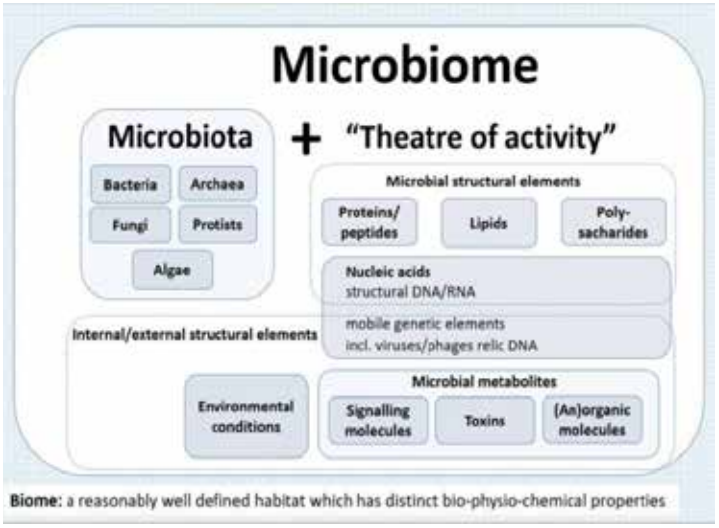
I do not know about you, but I recall learning very little about nutrition in medical school, and you could pretty much list it all on the one hand—maybe two hands: vitamin D deficiency causes rickets, vitamin C deficiency causes scurvy, etc. There were many things we did not know then. Moreover, back in the Dark Ages, we also believed that killing bacteria was almost always good, but we realized that antibiotics allowed the overgrowth of pathogenic organisms, like *Clostridium difficile*, which causes severe colitis.

"There is controversy about the exact definition of 'microbiome,' and the one that's still the most widely accepted is from Whipps: 'A convenient ecological framework in which to examine biocontrol systems is that of the microbiome. This may be defined as a characteristic microbial community occupying a reasonably well-defined habitat with distinct physio-chemical properties. The term thus not only refers to the microorganisms involved but also encompasses their theatre of activity.' The term 'microbiota' refers to the organisms in the microbiome."

Nevertheless, what do bacteria have to do with nutrition and metabolic diseases? A lot, it turns out. While I am not aware of much research into the body's microbiome back then, in recent years, we have come to learn more about our gut microbiome and its vital role in metabolism, physiology, nutrition, and immune function. Dysbiosis, or an imbalance of the gut microbiome, has been associated with gastrointestinal conditions, like inflammatory bowel disease (IBD)(1), as well as systemic conditions, like obesity (2), type 2 diabetes (3), cancer (4, 5), atopic diseases (6), and neurologic diseases (Parkinson's, Alzheimer's, Multiple Sclerosis, and possibly autism)(7, 8).

(I have to admit I used the terms "microbiome" and "microbiota" interchangeably. However, that is incorrect. There is controversy about the exact definition of "microbiome," and the one that's still the most widely accepted is from Whipps: "A convenient ecological framework in which to examine biocontrol systems is that of the microbiome. This may be defined as a characteristic microbial community occupying a reasonably well-defined habitat with distinct physio-chemical properties. The term thus not only refers to the microorganisms involved but also encompasses their theatre of activity" (9). The term "microbiota" refers to the organisms in the microbiome.)(Figure 1)

Figure 1. Definitions of Microbiome and Microbiota. (Berg, http://creativecommons.org/licenses/by/4.0/) (10)

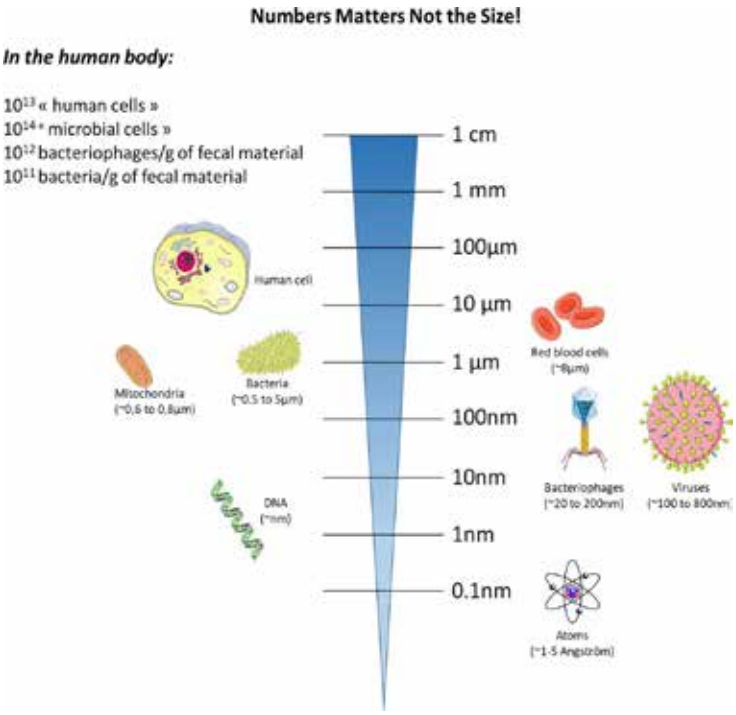


THE MICROBIOME

Our microbiota encompasses several trillion intestinal microorganisms, including bacteria, archaea, viruses (including bacteriophages), and fungi, most of which are commensal and mutualistic. They vastly outnumber the number of human cells. Our body's DNA is only at most 1% human. (Figure 2)

"Our microbiota encompasses several trillion intestinal microorganisms, including bacteria, archaea, viruses (including bacteriophages), and fungi, most of which are commensal and mutualistic. They vastly outnumber the number of human cells. Our body's DNA is only at most 1% human."

Figure 2. Relative sizes of major host cells and their components versus those of bacteria and viruses. (Cani, http://creativecommons.org/licenses/by/4.0/) (11)



"While there are over 50 bacterial phyla, the microbiota is dominated by two—Bacteroidetes (approximately. 30%) and Firmicutes (approximately. 60%)—followed by Actinobacteria, Verrucomicrobia, and Proteobacteria. Bacteroidetes are composed chiefly of Gram-negative organisms and include Bacteroides and Prevotella. Gram-positive or -negative Firmicutes include Lactobacillus, Eubacterium, and Clostridium. The Firmicutes: Bacteroidetes ratio appears to reflect the degree of maturation of the gut microbiota..."

They inhabit all surfaces of the human body, including the skin, mouth, lungs, vagina, and especially the gastrointestinal tract, which is the primary interface between us and the food we take in. An integrated gene catalog of the human fecal microbial metagenome found almost 9.9 million microbial genes across the 1200 persons studies in the U.S.A., China, and Europe (12). Most individuals usually have around 1000 different species and 7000 different types of bacteria in their gut. Anaerobes make up the overwhelming majority of the gut bacteriome—they outnumber aerobes and facultative anaerobes by up to 100-fold (13). While there are over 50 bacterial phyla, the microbiota is dominated by two—Bacteroidetes (approximately. 30%) and Firmicutes (approximately. 60%)—followed by Actinobacteria, Verrucomicrobia, and Proteobacteria. Bacteroidetes are composed chiefly of Gram-negative organisms and include *Bacteroides* and *Prevotella*. Gram-positive or -negative Firmicutes include *Lactobacillus*, *Eubacterium*, and *Clostridium*. The Firmicutes: Bacteroidetes ratio appears to reflect the degree of maturation of the gut microbiota and is significantly much lower in infants and the elderly compared with adults—0.4 in infants, 10.9 in adults, and 0.6 in the elderly (14).

Due to many years of coevolution of microbes and mammals, the microbiota has become essential parts of the establishment and development of the immune system, protection against the overgrowth of pathogens, regulation of the intestinal endocrine system; synthesis of vitamins, neurotransmitters, and multiple other compounds; and numerous other functions (15).

In a series of three articles, we will explore the various functions of the gut microbiota on the development of the immune system, their effects on metabolism and the gut-brain axis, and the corresponding problems associated with dysbiosis. This article will focus on the development of the immune system (of great relevance to our patients) and the host protection function of the microbiota.

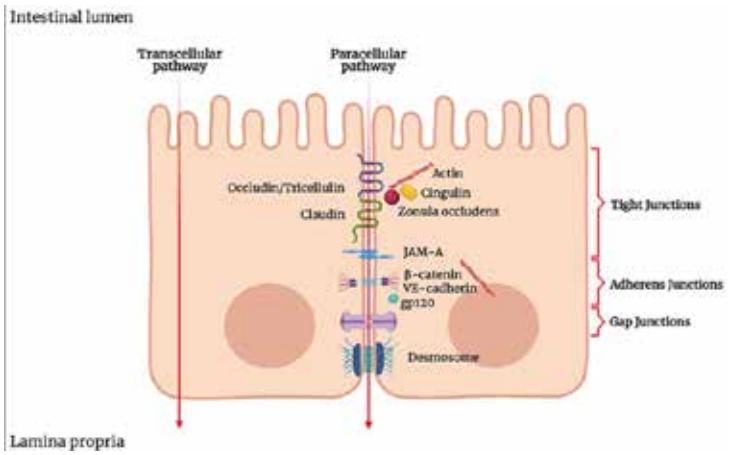
"Due to many years of coevolution of microbes and mammals, the microbiota has become essential parts of the establishment and development of the immune system, protection against the overgrowth of pathogens, regulation of the intestinal endocrine system; synthesis of vitamins, neurotransmitters, and multiple other compounds; and numerous other functions."

First, let us review some anatomy, histology, and physiology, some of which I had not learned in med school. We will be getting into a lot of basic science and animal research in this article since this type of research is often difficult to do directly on humans—inducing necrotizing enterocolitis is frowned upon and cannot get through hospitals' internal review boards for some reason.

As you may recall, the intestine is made up of multiple layers—the mucosa, submucosa, muscularis propria, and the outer serosa. The mucosa comprises the epithelium, lamina propria, and muscular mucosa. A complex of junctions holds together the epithelial layer; from the lumen side outward, these include tight junctions, adherens junctions, and desmosomes. (See Figure 3)

The integrity of these junctions, especially tight junctions, is vital to prevent intestinal permeability (better known as "leaky gut"), which may occur with dysbiosis, obesity, medications, infections, inflammation (IBD or Crohn's), or diet (high-fat, gluten, etc.). Increased intestinal permeability allows toxins, undigested food particles, and microorganisms and their components (like

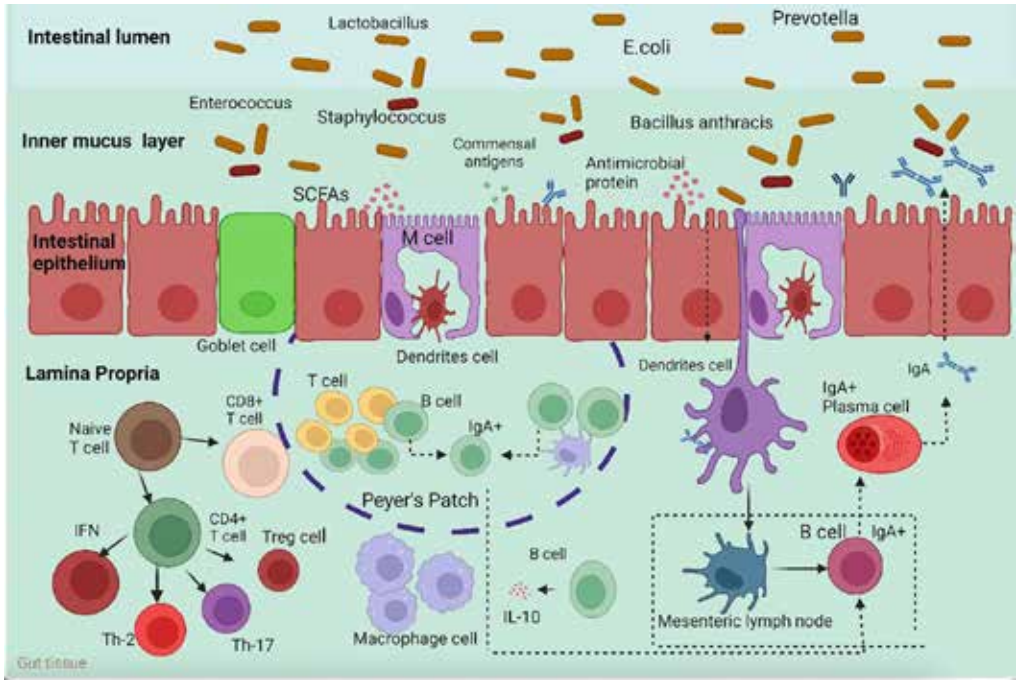
Figure 3. "Schematic representation of the junctional complex in the intestinal epithelium. Molecules can cross the intestinal epithelial monolayer through the intercellular space (paracellular route) or the cells (transcellular route). The junctional complex involved in the paracellular pathway includes tight junctions, adherens junctions, gap junctions, and desmosomes. Tight junctions are composed of transmembrane proteins such as claudins, occludin, junctional adhesion molecule (JAM), and zonula occludens proteins (ZOs). ZOs act as scaffold proteins, connecting claudins and occludin to cytoskeletal actin." (Barbara, Creative Commons Attribution License (CC BY)(16)



lipopolysaccharides [LPS]) to cross the epithelium and interact with the intestinal immune system. These activate dendritic cells and macrophages, leading to a pro-inflammatory state, which may contribute to autoimmune and metabolic diseases (like obesity and diabetes, which we will discuss in the next article of this series and more relevant to adults' health and wellness). Healthy individuals have a balanced and diverse range of microbiota and an intact intestinal barrier, which prevents penetration (euphemistically termed "translocation") and dissemination of bacteria and their mediators and enhances the production of anti-inflammatory cytokines, which contribute to a tolerant immune environment (17).

"Healthy individuals have a balanced and diverse range of microbiota and an intact intestinal barrier, which prevents penetration (euphemistically termed "translocation") and dissemination of bacteria and their mediators and enhances the production of anti-inflammatory cytokines, which contribute to a tolerant immune environment."

FIGURE 4. Host immune responses to the intestinal microbiota. "To maintain intestinal homeostasis, many immune mechanisms interact with gut bacteria in harmony. Through Toll-like receptors (TLRs), goblet cells secrete mucin glycoproteins, plasma cells release IgA, and epithelial cells secrete antimicrobial proteins [AMP]. After migrating to Peyer's patches and mesenteric lymph nodes, where B cells develop into IgA-secreting plasma cells, dendritic cells (DCs) absorb microorganisms. Furthermore, intestinal DCs isolated from *Bacteroides fragilis* polysaccharide A (PSA) induce regulatory T (Treg) cells, which are responsible for producing IL-10. Furthermore, the microbiota composition can be altered by antimicrobial proteins secreted by host cells. M cell; interleukin 10 (IL-10). Macrophages carry out their regular duties after migrating to the digestive tract lamina propria." (Ullah, Creative Commons Attribution License (CC BY)(17)



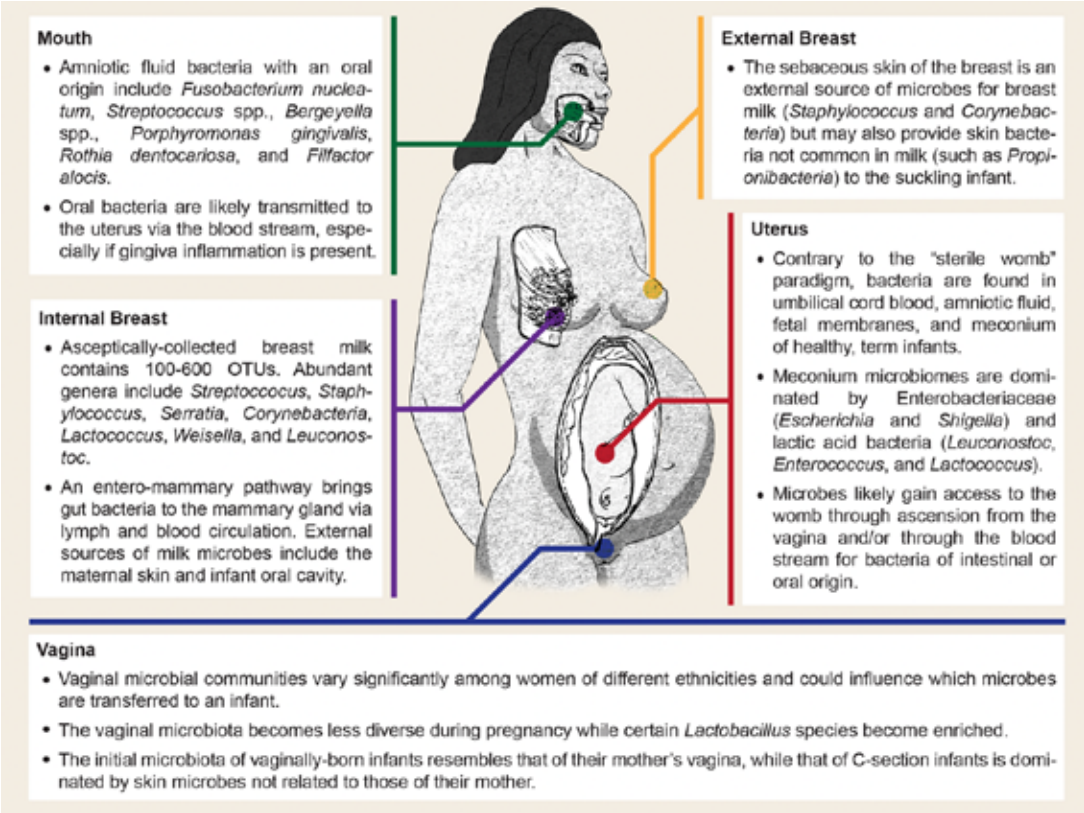
Approximately 70–80% of our entire immune system is in our gut, which makes sense since food intake is our most significant exposure to microorganisms (and other things) that may harm us. The vast majority of this is in the Gut-associated Lymphoid Tissues (GALT), which play a vital role in maintaining our body's tolerance to commensal bacteria. (See Figure 4) GALT is composed of the mesenteric lymph nodes, appendix, isolated lymphoid follicles, Peyer's patches, and crypt patches. M (microfold) cells, often located above Peyer's patches, "sample" the antigens from the intestinal lumen, transporting them into the immune cells below to process and initiate an immune response. Through Pattern Recognition Receptors (such as Toll-like receptors [TLRs] and nucleotide-binding oligomerization domain [NOD] molecules) and epigenetic modulators (such as short-chain fatty acids [SCFAs]), the gut microbiota influences the development of the GALT, activate host defense pathways, and maintain tolerance to commensal bacteria (17). In Type I diabetes, a known autoimmune condition, the GALT (in response to either diet or microbes) appears to be involved in sending inflammatory signals to the pancreatic lymph nodes, which in turn destroys pancreatic β-cells that produce insulin in murine studies (18). Interestingly, since celiac disease is often associated with T1DM, removal of gluten from the diet delayed or reduced the onset of diabetes in a non-obese mouse model (19). (We sure have cured or prevented many diseases in mice and rats!)

Microbial Colonization:

We know that microbial colonization is vital to the gut's developing tolerance to commensal bacteria. Sudo et al. found in 1997 that germ-free mice could not develop tolerance and that reconstituting the germ-free mice with one of the predominant organisms in the infant's gut, *Bifidobacterium infantis*, helped develop tolerance if done during the newborn period but not if introduced in older mice (20).

"GALT is composed of the mesenteric lymph nodes, appendix, isolated lymphoid follicles, Peyer's patches, and crypt patches. M (microfold) cells, often located above Peyer's patches, "sample" the antigens from the intestinal lumen, transporting them into the immune cells below to process and initiate an immune response. Through Pattern Recognition Receptors (such as Toll-like receptors [TLRs] and nucleotide-binding oligomerization domain [NOD] molecules) and epigenetic modulators (such as short-chain fatty acids [SCFAs]), the gut microbiota influences the development of the GALT, activate host defense pathways, and maintain tolerance to commensal bacteria."

Figure 5. "Sources of microbial transmission in humans from mother to child. A cut-away diagram highlights the various internal and external sources of maternal microbial transmission as well as the species that are commonly associated with transfer from those regions. Regions discussed include the oral cavity, the mammary glands, the sebaceous skin surrounding the breast, the vaginal tract, and the intrauterine environment. Illustration by Robert M. Brucker." (Funkhouser, Creative Commons Attribution License (CC BY)(21)



How do we obtain our microbiota? It is widely accepted that microbial colonization of the infant (first discovered by Henri Tissier in 1899) occurs during and after birth and that this method of delivery significantly impacts the development of the microbiota in the infant. (See Figure 5.)

"We know that microbial colonization is vital to the gut's developing tolerance to commensal bacteria. Sudo et al. found in 1997 that germ-free mice could not develop tolerance and that reconstituting the germ-free mice with one of the predominant organisms in the infant's gut, Bifidobacterium infantis, helped develop tolerance if done during the newborn period but not if introduced in older mice."

Vaginal delivery and breastfeeding provide exposure to a wide diversity of bacteria that colonize the infant, first by facultative anaerobes (*Enterobacteriaceae*, streptococci, and staphylococci) (22) and then obligate anaerobes (*Bacteroides*, *Clostridium*, and *Bifidobacterium* spp.). Factors that modify colonization include gestational age, hospitalization, maternal infection/illness, mode of delivery, diet (breastmilk v. formula), sanitation, and antibiotic treatment (both maternal and neonate) (21–23).

"The maternal gut microbiota plays an important role in the maternofetal molecular transfer, thereby affecting fetal development. In rat studies, certain maternal microbiota-derived products (AhR [aryl hydrocarbon receptor] ligands) and IgGs stimulate the proliferation of lymphoid cells, specifically, the innate lymphoid cells type 3 [ILC3], in the pup, which are important for maintaining the gut epithelial barrier and host defense by the production of specific cytokines and secretion of antimicrobial peptides."

In addition, more recent studies looking into potential bacterial transmission through the placenta have found a possible placental microbiota (24) and commensal bacteria in umbilical cord blood (25, 26) and fetal membranes (26, 27) from newborns without signs of infection. Meconium also contains a complex microbiota (25, 28), so the intrauterine environment may not be as sterile as we previously believed, and the mother may be transmitting her microbiota during the intrauterine as well as the intrapartum period. However, other studies that ensured no contamination of these tissues have not found a placental microbiota (29–31). Although the presence of a placental microbiota is still in dispute, the transport of commensal bacterial products via the placenta is accepted. The maternal gut microbiota plays an important role in the maternofetal molecular transfer, thereby affecting fetal development (32). In rat studies, certain maternal microbiota-derived products (AhR [aryl hydrocarbon receptor] ligands) and IgGs stimulate the proliferation of lymphoid cells, specifically, the innate lymphoid cells type 3 [ILC3], in the pup (33), which are important for maintaining the gut epithelial barrier and host defense by the production of specific cytokines and secretion of antimicrobial peptides.

"The gut microbiota of infants are characterized by low diversity and relative dominance of Proteobacteria and Actinobacter and become more diversified with the development of Firmicutes and Bacteroidetes as the infant grows older. By one year of age, the child's microbiota are individually distinct and approach those of adults and, by age 2–5 years, completely correspond to the adult's composition and diversity."

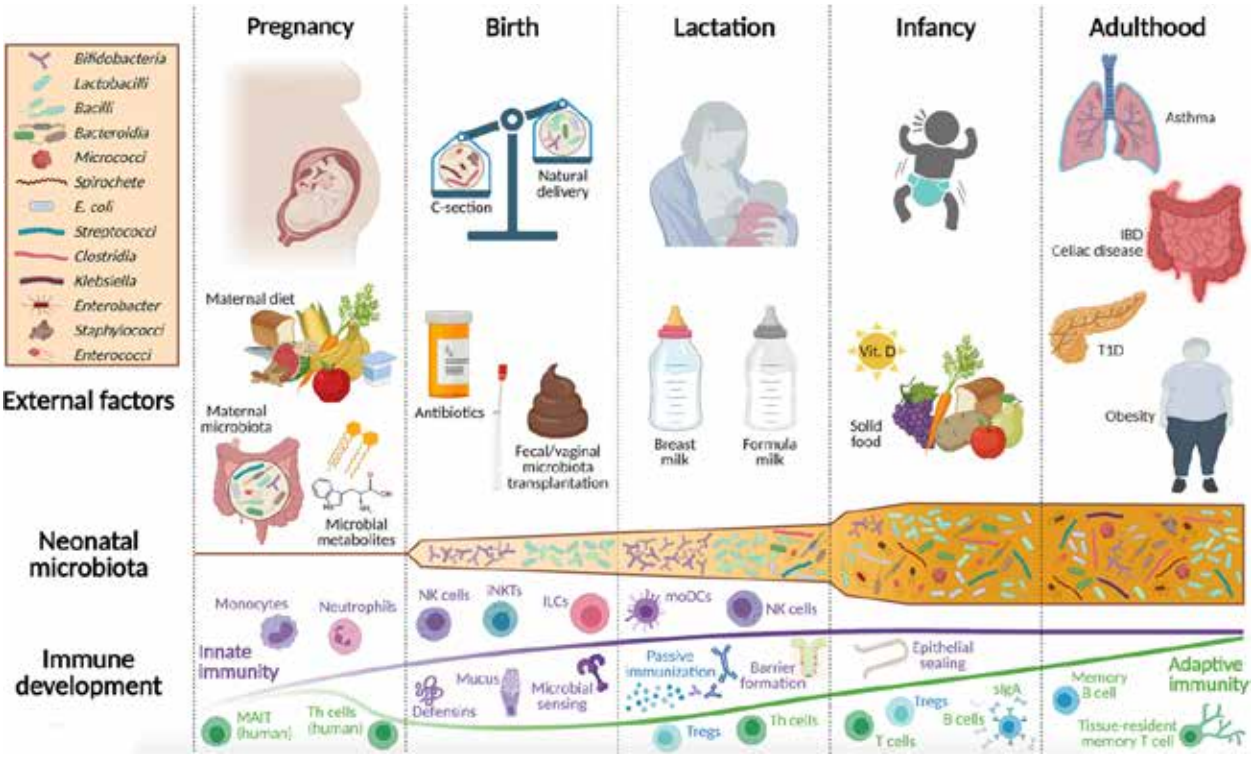
The gut microbiota of infants are characterized by low diversity and relative dominance of Proteobacteria and Actinobacter (34) and become more diversified with the development of Firmicutes and Bacteroidetes as the infant grows older (35–37). By one year of age, the child's microbiota are individually distinct and approach those of adults and, by age 2–5 years, completely correspond to the adult's composition and diversity (34, 38, 39). While the baby is first colonized with the mother's microbiota during pregnancy and vaginal birth, and breastfeeding, as the child grows, their environment becomes more important, and the child's microbiota more closely resembles that of members in the same household and differs from members of other households (40). The first three years of life appear to be the most important period for modulating the microbiota to improve child growth, development, and health. After that, the individual's microbiota is relatively stable but influenced by long-term changes in diet, lifestyle, surgeries, antibiotic exposure, and infections. (Figure 6)

Mode of Delivery:

(Much of the following is taken from Kalbermatter et al.'s excellent review in Frontiers in Immunology, "Maternal Microbiota, Early Life Colonization and Breast Milk Drive Immune Development in the Newborn."[41])

Indeed, one of the most significant factors in the infant's colonization is the delivery mode. Babies born via C/S share about 30% less bacterial species with their mother than those delivered vaginally. Infants delivered by C/S are first colonized with skin

Figure 6." Factors influencing the infant gut microbiota development and the adult and elderly microbiota. Overview of environmental factors shaping the development of the newborn microbiota and mucosal immune system. Throughout pregnancy, fetal immune development is supported by microbial metabolites originating from the maternal microbiota and by dietary compounds. Innate immune cell populations, such as monocytes, ILCs, and neutrophils, belong to this stage's most affected immune cells. Only at birth is the emerging immune system of the newborn confronted with live bacteria and, thus, is still dependent on maternal protection, which is ensured through breastfeeding. Apart from passive immunization via breast milk, neonatal iNKTs, NK cells, ILCs, and the gastrointestinal epithelial barrier protect against invading pathogens and promote the beneficial interplay with the neonatal microbiota. The adaptive immune system in mice develops primarily postnatally, while a component of adaptive immunity is already present in the human fetus. Birth mode, feeding, and the intake of antibiotics are additional factors that shape the early life microbiota and the neonatal immune system. During the subsequent weaning reaction, when solid food is introduced to the infant's diet, a tremendous shift occurs in its intestinal bacterial community composition. Consequently, the microbiota is no longer represented by Bifidobacteria and Lactobacilli but increases in metabolomic diversity, evolving to a more adult-like microbiota established during this early period of life. This period is often also called the window of opportunity since, particularly during this time, external cues profoundly impact life-long health, the evolving microbiota, and the mucosal immune system. IBD, inflammatory bowel disease; sIgA, secretory immunoglobulin A; ILCs, innate lymphoid cells; iNKTs, invariant natural killer T cells; MAIT, mucosal-associated invariant T cells; moDCs, monocyte-derived dendritic cells; NK, natural killer cells; Th cells, T helper cells; Treg, regulatory T cells; T1D, type 1 diabetes." (Kalbermatter, Creative Commons Attribution License (CC BY) (41)

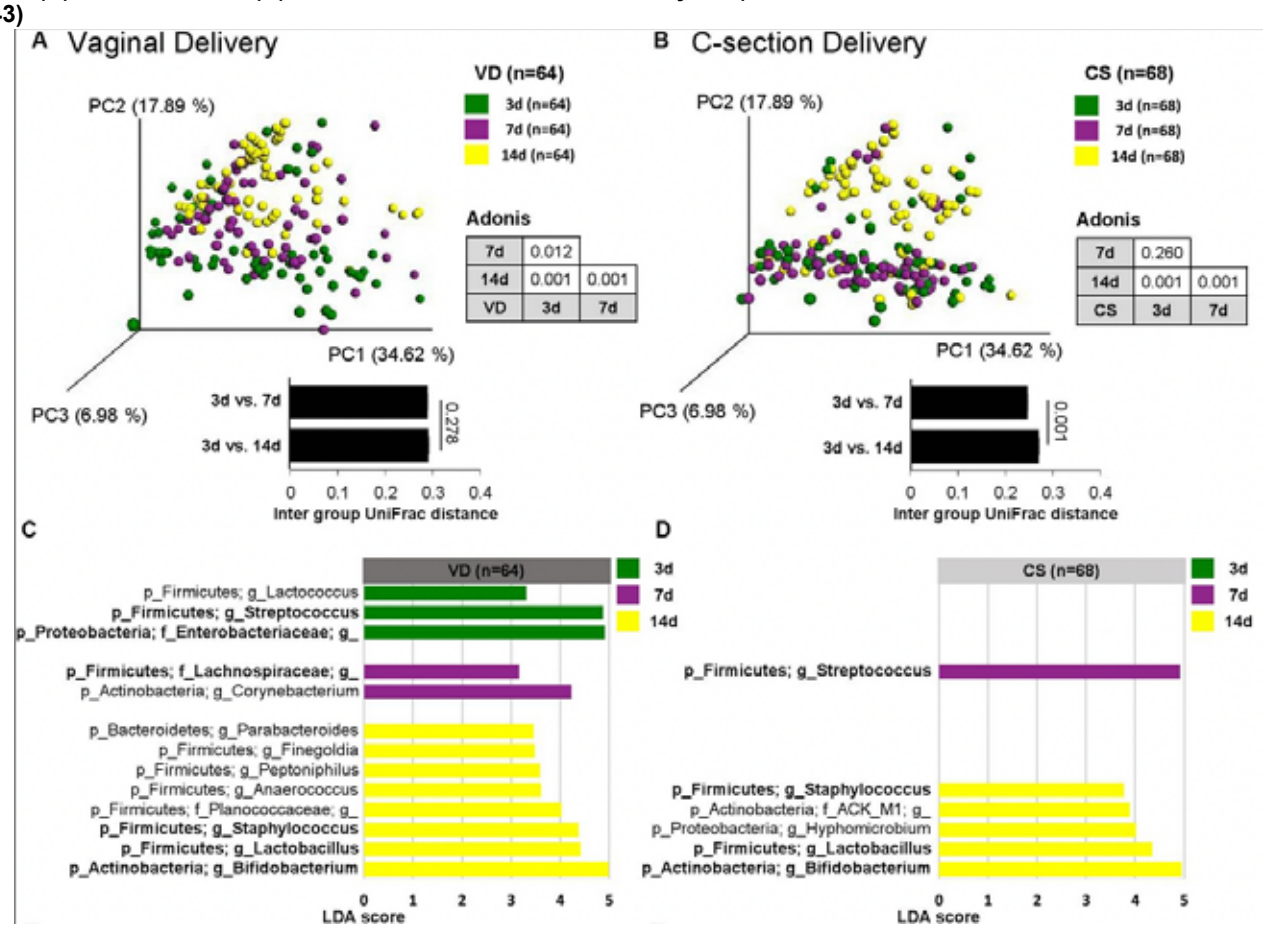


organisms (*Staphylococcus saprophyticus*) or hospital organisms (*Enterobacter faecalis, Enterobacter cloacae, Klebsiella pnumoniae, and Clostridium perfringens*)(42). These strains are opportunistic pathogens and often carry antimicrobial resistance genes. At the phylum level, the microbiota of babies born by C/S are predominantly Firmicutes and Actinobacteria.

As mentioned above, infants born via Cesarian section (C/S) have lower total microbiota diversity in the first days after delivery, as seen in Figure 7 (43). A study by Bäckhed on the microbiota in the first year of life also shows the persistence of the decreased microbiota diversity in infants delivered by C/S, especially in *Bacteroides fragilis* and *Bacteroides thetaiotaomicron*, as well as the decreased and delayed acquisition of various *Bifidobacterium* spp. (37). A study by Jakobssen showed lower abundance and diversity of the Bacteroidetes phylum and a lower Th1 (T helper 1) response during the first two years of life. The delayed or altered colonization of both of these phyla and others is believed to be involved in the development of atopic diseases (44).

"Babies born via C/S share about 30% less bacterial species with their mother than those delivered vaginally. Infants delivered by C/S are first colonized with skin organisms (Staphylococcus saprophyticus) or hospital organisms (Enterobacter faecalis, Enterobacter cloacae, Klebsiella pnumoniae, and Clostridium perfringens)."

Figure 7. "Bacterial structure differences in early gut microbiota according to delivery mode over time. Weighted UniFrac distances were used to evaluate the beta diversity of VD (A) and CS (B) infant gut microbiomes using PCoA and intra-group distance. Adonis was used to test dissimilarity. LEfSe analysis (LDA > 3.0) was used to identify biomarkers between sampling points in VD (C) and CS infants (D)." LDA is Linear Discriminant Analysis. (Kim et al., Creative Commons Attribution License (CC BY))(43)



In one Danish study, over 2.5 million subjects were followed from birth to 40 years of age. Those who were delivered by C/S had a higher risk of developing chronic inflammatory diseases—diabetes, arthritis, celiac disease, or IBD—however, subsequent risks contributing to the development of these conditions could not be eliminated (45). Another study showed that when the C/S infant can recover a microbiota profile similar to vaginally-delivered infants by one year, they do not have an increased incidence of these diseases. However, if, at one year of age, they still retained their C/S microbiota profile, they were more susceptible to childhood asthma and increased risk of allergic sensitization with high IgE (46). Having an older sibling at home also helps the post-C/S infant develop fewer allergies (47) and a rich and diverse microbiota profile (48), though the latter study did not find an effect on the incidence of asthma and eczema.

There appears to be a "window of opportunity" whereby environmental factors can influence host microbiota composition, immune regulation, and disease susceptibility. Scientists noticed the correlation between better hygiene standards in industrialized countries and the increasing incidence of allergic and autoimmune diseases (49), postulating that decreased exposure to a microbial-rich environment may be a possible cause (47)—popularly known as "The Hygiene Hypothesis," though perhaps "The Microbiome Depletion Hypothesis" would be a better term. For example, growing up in a microbial-rich environment, like a farm, prevents the development of allergic asthma (50, 51). The window of opportunity period in humans has not been established but is probably sometime within the first three to five years of life.

"In one Danish study, over 2.5 million subjects were followed from birth to 40 years of age. Those who were delivered by C/S had a higher risk of developing chronic inflammatory diseases—diabetes, arthritis, celiac disease, or IBD—however, subsequent risks contributing to the development of these conditions could not be eliminated. Another study showed that when the C/S infant can recover a microbiota profile similar to vaginally-delivered infants by one year, they do not have an increased incidence of these diseases."

Since the rate of C/S is increasing around the world and allergies also have been increasing, there have been attempts to improve

the microbiota of the C/S infant by transfer from maternal vaginal or fecal sources. Compared with vaginal sources, fecal sources appear to establish the desired microbiota more durably—not surprising since the primary source of microbiota for vaginally-delivered infants is the maternal intestinal flora (46, 52). However, caution must be taken with this approach, as some flora in the mother may be pathogenic, and while her immune system is capable of handling it, the neonate's immature immune system may not be as adept. Studies are ongoing.

"There appears to be a 'window of opportunity' whereby environmental factors can influence host microbiota composition, immune regulation, and disease susceptibility. Scientists noticed the correlation between better hygiene standards in industrialized countries and the increasing incidence of allergic and autoimmune diseases, postulating that decreased exposure to a microbial-rich environment may be a possible cause—popularly known as 'The Hygiene Hypothesis,' though perhaps 'The Microbiome Depletion Hypothesis' would be a better term. For example, growing up in a microbial-rich environment, like a farm, prevents the development of allergic asthma. The window of opportunity period in humans has not been established but is probably sometime within the first three to five years of life."

Another common factor in neonatology that affects the developing microbiota of our patients is the wide use of antibiotics. Neonatal, as well as maternal (often seen in C/Ss and preterm deliveries), antibiotic treatment causes dysbiosis in the newborn microbiota and may be selected for pathogenic and/or drug-resistant organisms. In a study with mice, Niu et al. found that short- (3 days) and long-term (7 days) antibiotics produced microbiota similar to those of post-C/S babies with a predominance of Proteobacteria. After long-term antibiotic therapy, *Enterobacter* and *Enterococcus spp.* could translocate to the spleen and liver. *K. pneumoniae* was then able to colonize the gut and translocate systemically to cause sepsis. Long-term antibiotics also decreased the ILC3 (innate lymphoid cells type 3) population in the lamina propria—which, as mentioned previously, are important for maintaining the gut epithelial barrier and host defense by producing cytokines and secreting antimicrobial peptides—thereby resulting in the neonate's increased susceptibility to infections. Reconstitution with mature microbiota (by gavage) could only partially offset this adverse effect (53). Therefore, we need to be even more judicious about the long-term use of antibiotics in our neonates.

Breastfeeding

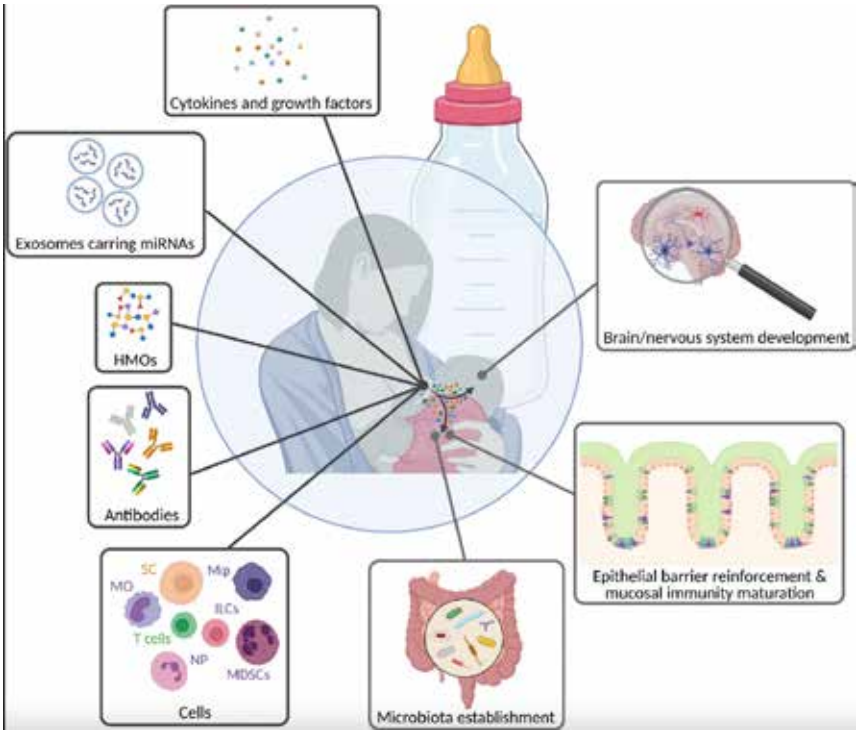
The importance of breast milk for the development of the neonate cannot be overemphasized. Human milk is, of course, the best source of nutrition for our neonatal patients—it has the perfect balance of macronutrients (lipids, proteins, and carbohydrates) as well as hundreds to thousands of micronutrients (54), which are integral to optimal growth and development. Many components of breast milk are not only nutritive but also biologically active and are not available in infant formula. These compounds are not only nutritive but also protect against pathogen- and immune-mediated diseases and promote the maturation of the immune system. (Figure 8)

"In a study with mice, Niu et al. found that short- (3 days) and long-term (7 days) antibiotics produced microbiota similar to those of post-C/S babies with a predominance of Proteobacteria. After long-term antibiotic therapy, Enterobacter and Enterococcus spp. could translocate to the spleen and liver. K. pneumoniae was then able to colonize the gut and translocate systemically to cause sepsis. Long-term antibiotics also decreased the ILC3 (innate lymphoid cells type 3) population in the lamina propria—which, as mentioned previously, are important for maintaining the gut epithelial barrier and host defense by producing cytokines and secreting antimicrobial peptides—thereby resulting in the neonate's increased susceptibility to infections. Reconstitution with mature microbiota (by gavage) could only partially offset this adverse effect."

Human Milk Oligosaccharides:

Human Milk Oligosaccharides (HMOs) are undigestible complex glycans that make up about a third of human breast milk and are vital to the optimal development of the neonate. More than a hundred HMOs have been found in human milk, but mothers do not make all of them. Some are dependent on blood group characteristics. The composition and amount vary between different women and throughout lactation (reviewed by Kunz, 55). Colostrum contains the most HMOs (20–25 g/L), and the oligosaccharide content decreases as lactation progresses (5–20 g/L) but still usually surpasses the content of total milk protein (8

Figure 8. "Breastfeeding mediates the transfer of biologically active molecules from the mother to the infant. Breast milk contains a vast diversity of components, ranging from simple sugars, antibodies, and cells to molecules that directly trigger reactions in target cells and/or tissues, such as cytokines, growth factors, and exosomes. Thereby, milk molecules ensure the infant's well-being by driving innate and adaptive immune maturation and further contributing to its mucosal and nervous system development. HMOs, human milk oligosaccharides; ILCs, innate lymphoid cells; Mj, macrophages; MDSCs, mononuclear-derived suppressor cells; MO, monocytes; NP, neutrophils; SC, stem cells." (Kalbermatter, Creative Commons Attribution License (CC BY) (41)



g/L) and is 100–400x the amount found in cow milk (0.05 g/L)(56)! Cow milk also only has about 40 MOs, and some are identical to HMOs. Not unexpectedly, preterm human milk has more HMOs than term milk (57).

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HMOs contain 3–22 saccharide units per molecule, which are composed of five monosaccharides—glucose, galactose, N-acetylglucosamine, fucose, and sialic acid. All HMOs contain lactose, a disaccharide made up of glucose and galactose, as you may remember from biochemistry. HMOs resist the low pH in the baby's stomach as well as pancreatic and brush border digestive enzymes and arrive intact at the distal ileum and large intestine. Some are absorbed and appear in the urine (58), but some are excreted in the feces, with degradation and processing varying with age (59).

Their functions are myriad. HMOs act as prebiotics to help establish the gut microbiota, including *Bifidobacteria* and *Bacteroides* (60) and especially *B. infantis*, which predominate in the gut of breastfed infants and have numerous beneficial effects on the development of the gut and immune system (61). Prebiotics are compounds that promote the growth of beneficial microorganisms. HMOs protect against necrotizing enterocolitis (NEC) by inhibiting the growth of pathogenic organisms (62), increasing the production of mucin (63), and promoting the maturation of intestinal cells (59). Researchers also found a specific isomer of disialyllacto-N-tetraose (DSLNT), an HMO, to be protective against NEC in a rat model (64). HMOs may also act as receptor decoys for pathogenic bacteria and viruses by binding to them instead of the microbes binding to the intestinal epithelium and causing infections (65–67).

HMOs also promote the maturation of immune cells, enhance immune tolerance (68), and help prevent immune-mediated diseases like T1DM (69). In addition, they may influence brain development and function (70).

There are probably more functions of HMO that we are not aware of yet, and studies are ongoing.

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Proteins and Peptides in Breast Milk:

A wide range of peptides and proteins is found in human milk with diverse functions, including nutrient absorption (amylase, α1-antitrypsin), immune and antimicrobial properties (immunoglobins, lactoferrin, cytokines), and growth-promotion (lactoferrin, epidermal growth factor [EGF]). The most abundant are α-lactalbumin, casein, lysozyme, and sIgA (71, 72).

Maternal IgA prevents NEC by binding to intestinal bacteria (73). In addition to binding pathogenic bacteria in the infant's gut, maternal antibodies may also help limit responses toward commensal organisms by modulating T-cell reactions. A study supporting this found higher activation of T helper cells and increased germinal center B cells in Peyer's Patches and mesenteric lymph nodes in mice born to antibody-deficient mothers. Thus, maternal commensal-specific antibodies in breast milk helped reduce commensal-specific T-cell responses in the baby, promoting mucosal homeostasis (74).

Other proteins in milk also modulate the immune system. Lactoferrin stimulates the proliferation of intestine epithelial cells and decreases pro-inflammatory cytokines in innate immune cells (75, 76). b-defensin 1 promotes the maturation of dendritic cells (77). Another compound called milk fat globule epidermal growth factor VIII (MFGE8), also known as lactadherin, helps prevent NEC by limiting intestinal permeability and reinforcing the barrier function (78). It also promotes an anti-inflammatory gut environment (79).

One of the cytokines in BM is TGF-b, which stimulates mucosal IgA production, inhibits the synthesis of pro-inflammatory cytokines (80), and modifies Natural Killer cells in the mesenteric lymph nodes (81) as well as splenic lymphocyte composition (82), the latter implying a role in systemic immune maturation. Levels of TGF-b correlated inversely with the occurrence of eczema in neonates. Another cytokine, IL-7, correlated with the development of the infant's thymus (83).

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BM also contains EGF, which inhibits goblet cell-associated antigen passages (GAPs)—structures in goblet cells that help pass antigens to underlying dendritic cells—during the early postnatal period, preventing the translocation of gut bacteria and, therefore, sepsis (84). However, the formation of GAPs must occur during the "window of opportunity" before weaning to enable tolerance to commensal gut bacteria (85). Fortuitously, the levels of EGF in BM fall throughout lactation to facilitate this process, which must occur before the "weaning reaction," during which solid food is introduced, and there is a barrage of changes in the microbiota and immune regulation. If this does not occur, then the infant is prone to develop allergies. You can see that BM is important in developing the infant's immune system and promptly choreographing its development.

"One of the cytokines in BM is TGF-β, which stimulates mucosal IgA production, inhibits the synthesis of pro-inflammatory cytokines, and modifies Natural Killer cells in the mesenteric lymph nodes as well as splenic lymphocyte composition, the latter implying a role in systemic immune maturation. Levels of TGF-β correlated inversely with the occurrence of eczema in neonates. Another cytokine, IL-7, correlated with the development of the infant's thymus."

Exosomes/miRNAs (MICRO-RNAs) in BM:

Exosomes are endosome-derived extracellular vesicles, 3–100 nm in size, that circulate in various body fluids and were found in BM in 2007 (86). These are involved in immune-related processes (antigen presentation and immune activation and suppression) as well as intercellular communication by transferring proteins, lipids, and miRNAs. miRNAs are small, noncoding RNA molecules, usually about 22 nucleotides long, which regulate gene expression and protein translation. They play a role in inflammatory responses. Abnormal expression of miRNAs can lead to cell death, autoimmune diseases, or cancer.

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In 2010, miRNAs were discovered in exosomes from BM and colostrum (87, 88). Due to their known influence on the immune system, it was postulated that miRNAs in BM probably have effects on gene expression and immune development and function in the infant. First, they had to prove that exosomes with their miRNAs would survive a passage through the stomach and not get digested, which they did *in vitro*, and that they are absorbed by the intestinal cells (89, 90). A study using pigs detected higher miRNA levels in colostrum than in mature milk, and the serum of the piglets had higher levels of colostrum-derived miRNAs, indicating they were absorbed from the maternally derived miRNAs in BM (91). Another study showed that bovine miRNAs were found in humans after intake of bovine milk (92). However, some studies do not show absorption of particular miRNAs (93). This is a topic of intense research and contention (though—if I may speculate here—since there are many different miRNAs, and they cannot test for them all, and maybe not all are supposed to be absorbed systemically?)

Since exosomes are suspected to be involved in the immune processes of the infant, studies on BM-derived exosomes investigated whether they have a protective effect on the intestinal epithelial cells during an infection. These cells were incubated with H_2O_2, which increases oxidative stress-mediated cell death and produces an inflammatory environment, and exposed to BM-derived exosomes, which had a protective effect by attenuating cell death (94). Another study found that bovine milk exosomes promoted the expression of mucin-related genes in goblet cells, which prevented intestinal injury and reduction of goblet cells in experimentally induced NEC (95). Human milk exosomes also attenuated intestinal damage to neonatal rat cells and protected stem cells from undergoing apoptosis secondary to oxidative stress (96, 97).

"They concluded that exosomes, both intraperitoneal and by gavage, significantly decreased the incidence and severity of NEC and may be a therapeutic intervention in the future."

An interesting study done by Pisano et al. examined the effect of exosomes in premature rats with induced NEC (98). Pups were divided into four groups: 1) breastfed, no induced NEC (N=13); 2) formula-fed, induced NEC, sterile water x1 intra-peritoneally (N=70); 3) formula-fed, induced NEC, exosome x1 intra-peritoneally (N=17); 4) formula-fed, induced NEC, human BM exosome with each feed by gavage (N=42). Pups were sacrificed at 96 hours of life. The incidences of NEC were 0% in the BM-fed, no induced NEC group; 62% in the second group; 29% in the group that underwent induced NEC and received an intraperitoneal infusion of exosomes; and 11.9% in the group that underwent induced NEC and received OG exosomes with feeds. They concluded that exosomes, both intraperitoneal and by gavage, significantly decreased the incidence and severity of NEC and may be a therapeutic intervention in the future.

"The presence of immune cells (neutrophils, macrophages, and lymphocytes) in BM is well-known and probably contributes to the maturation of the innate immune system in the infant. There are also Innate Lymphoid Cells (ILC) in BM...ILC1s and ILC3s protect against bacteria and maintain epithelial homeostasis, while ILC2s defend against parasitic infections at the mucosal surfaces."

Cells Present in BM Cells:

The presence of immune cells (neutrophils, macrophages, and lymphocytes) in BM is well-known and probably contributes to the maturation of the innate immune system in the infant. There are also Innate Lymphoid Cells (ILC) in BM; ILC1s are the most abundant, followed by ILC3s and ILC2s. ILC1s and ILC3s protect against bacteria and maintain epithelial homeostasis, while ILC2s defend against parasitic infections at the mucosal surfaces.

Mucosal-associated invariant T cells (MAIT) and gdT cells are also found in BM (99) and predominantly found in the gut (100). They are probably involved in the development of microbiota and mucosal defense.

"Interestingly, a 2020 study by Zheng et al. found that the macrophage and cytokine profiles in BM change in response to ongoing respiratory infections in the nursing infant, indicating that the composition of BM adapts to the infant's needs to optimize protection of the nursing infant."

Myeloid-derived suppressor cells (MDSCs) have repressing effects on immune cells of the innate and adaptive immune system. BM granulocyte MDSCs may help promote immune tolerance by suppressing neonatal T cell proliferation and Toll-like receptor expression on monocytes, suggesting a role in regulating innate immune response (101). Interestingly, a 2020 study by Zheng et al. found that the macrophage and cytokine profiles in BM change in response to ongoing respiratory infections in the nursing infant (102), indicating that the composition of BM adapts to the infant's needs to optimize protection of the nursing infant. (Formula cannot do that!)

Maternally-derived IL-13-producing cells in BM may help protect the infant from allergies. A decrease in these cells in BM has been associated with an increased incidence of atopic dermatitis in infants (103). It is speculated that maternal IL-13 may inhibit its synthesis by the infant, therefore avoiding the activation of eosinophils and IgE secretion, which are both involved in the pathophysiology of atopy (41).

"BM also contains stem cells, which are more abundant in colostrum than mature milk. A fascinating study in green fluorescing protein-expressing transgenic mice detected BM-derived stem cells in the blood and brain of suckling pups. These stem cells had differentiated into neuronal and glial cells in the pup's brain, indicating a role in the development of the pup's nervous system"

BM also contains stem cells, which are more abundant in colostrum than mature milk. A fascinating study in green fluorescing protein-expressing transgenic mice detected BM-derived stem cells in the blood and brain of suckling pups. These stem cells had differentiated into neuronal and glial cells in the pup's brain, indicating a role in the development of the pup's nervous system (104). (Formula cannot do that yet, either!)

As you can see, there is a vast myriad of bioactive compounds in human BM that formula cannot even come close to at the moment. Perhaps we may be able to use some of these to help prevent or treat diseases like NEC in the future, and perhaps we can incorporate them into formula someday. However, for the moment, in general, BM is still the best (by far!) source of nutrition, and it promotes and develops the optimal immune system, especially for our premature babies. The general public is still uninformed about just how important BM is for infants and for their future health. In light of the increasing incidence of allergies, obesity, and chronic inflammatory diseases, we need to educate our parents and be stronger proponents for BM and, especially, colostrum.

"Developing diverse and tolerant commensals is vital to our babies' short-term and long-term health to minimize chronic inflammatory diseases...and one of the most significant and possibly best ways to accomplish this is to give the neonate mother's colostrum/ BM whenever possible to decrease infections, to help both the gut and systemic immune system develop properly, to help decrease the incidence and severity of NEC, and possibly to optimize brain development."

Conclusion:

Developing diverse and tolerant commensals is vital to our babies' short-term and long-term health to minimize chronic inflammatory diseases. However, many of the things we do for our patients can cause dysbiosis, like C/S delivery, antibiotics, formula feeds, etc., most of which are unavoidable. It is crucial to offset these adverse effects on the microbiota, and one of the most significant and possibly best ways to accomplish this is to give the neonate mother's colostrum/BM whenever possible to decrease infections, to help both the gut and systemic immune system develop properly, to help decrease the incidence and severity of NEC, and possibly to optimize brain development. While studies continue on exosomes and miRNA, which may be added to feeds or formula in the future, hundreds of other micronutrients in BM still have yet to be identified, studied, and understood for their likely beneficial effects on the developing infant. Others are studying probiotics as possible remedies as well for dysbiosis. However, these investigations take many years, often decades, before the benefits are widely acknowledged and accepted, much less implemented at scale. In the meantime, our patients will grow up with the epidemic of asthma, allergies, IBD, and a host of

metabolic problems that we will discuss in the next article, as well as the alarming problem of the loss of diversity of the microbiota in our industrialized society.

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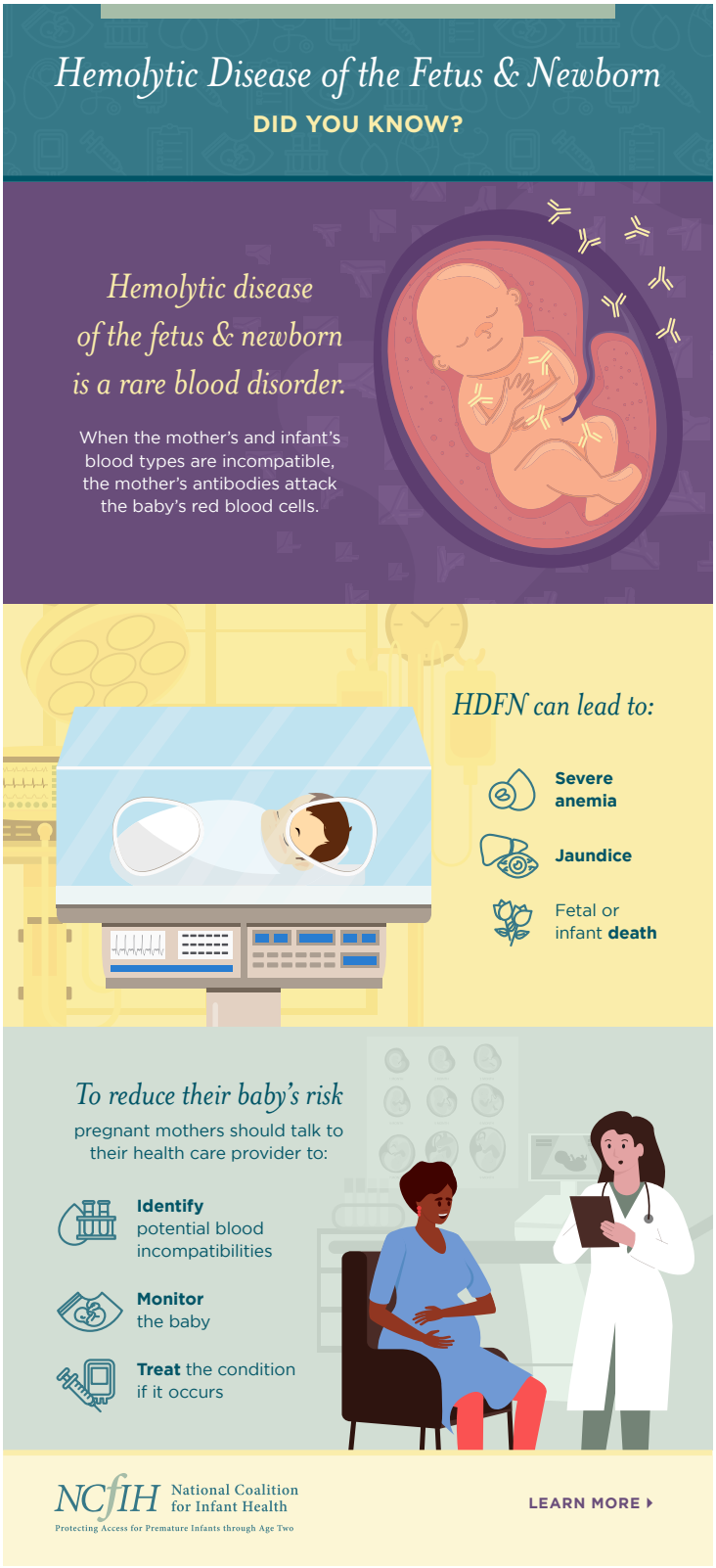
Disclosures: The author has no disclosures.

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The Power of Language: How Empathy Transforms Communication and Care in the NICU

Jessica Daigle, MD, FAAP

The neonatal intensive care unit (NICU) is a world unto itself—often unfamiliar, overwhelming, and emotionally charged for families. As healthcare professionals, our words are more than a means of delivering clinical facts. They are the bridge between intention and trust, between uncertainty and connection. Language, when paired with empathy, has the power to transform care from transactional to relational, and from distressing to healing.

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My perspective on this shifted profoundly when I transitioned from a physician to a NICU parent. After a high-risk pregnancy and nine weeks of hospital bed rest, I delivered my son prematurely at 31 weeks. In those early days, I was not a doctor—I was a mother coping with postpartum healing and confronting deep emotional fear. That lived experience permanently reframed how I view communication in neonatal care.

Language Shapes Experience:

NICU families are often in survival mode—physically recovering, emotionally overwhelmed, and trying to make sense of a new and frightening environment. They are encountering not just new people and procedures but a new language and culture altogether. Studies confirm that parent-provider communication has a significant influence on parental stress, confidence, and emotional well-being, even when clinical outcomes are favorable. (1)

"In those early interactions, we are not just explaining interventions—we are shaping the family's emotional memory of the NICU. The tone we use, the space we hold, and the compassion we show—or do not—become part of their story."

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Empathy Fuels Intention:

Empathy is not about fixing—it is about feeling with. It invites us to wonder, "What might this moment mean to them?" A mother sitting quietly at the bedside might appear disengaged, but perhaps she is afraid to bond, haunted by guilt, or is simply exhausted. Empathy enables us to approach families not just as caregivers, but as fellow human beings.

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Moreover, when empathy fuels our intention, it begins to transform how we communicate. For example, instead of saying, "We've intubated your baby," we might say, "We've placed your baby on a breathing machine to support her lungs as they continue to grow." This minor shift delivers the same clinical message, but with emotional awareness that calms rather than alarms.

Sobrinho Valete et al. argue that empathy is not a soft skill; it is essential to developmentally supportive care and improves outcomes beyond discharge. (2)

Communication Beyond Words:

Every cue we offer—verbal, written, or non-verbal—communicates care or indifference. Eye contact, tone, posture, and timing matter. A nurse saying, "He's stable," without making eye contact while charting sends a very different message than pausing, facing the parent, and saying gently, "He's had a calm night."

Thompson and Lee note that empathy is often perceived more through presence than speech. (3) In practice, this means even our silence can communicate connection when held intentionally.

Likewise, written communication in the chart carries weight. Phrases like "non-compliant mother" reflect judgment rather than curiosity. Documenting that "Mother was unavailable during care time; discussed potential barriers and offered support" shifts the

tone from blame to partnership. With open notes increasingly accessible to families, the language we use can either strengthen or sever trust.

"Thompson and Lee note that empathy is often perceived more through presence than speech. In practice, this means even our silence can communicate connection when held intentionally."

From Transactional to Relational Care:

Many NICU interactions are task-driven—charting vital signs, completing assessments, and updating parents. However, every task is also an opportunity to build trust. Moving from "doing to" families toward "being with" families is at the heart of relational care. When we pause, listen, reflect, and empower, we become partners in the care journey.

Guttmann et al. found that inconsistent communication, even in the context of good clinical care, can lead to emotional distress and breakdowns in trust. (4) This supports the need for intentional, emotionally intelligent communication.

"Guttmann et al. found that inconsistent communication, even in the context of good clinical care, can lead to emotional distress and breakdowns in trust. This supports the need for intentional, emotionally intelligent communication."

The C.A.R.E. Framework:

To operationalize these concepts, I created and use the C.A.R.E. framework:

- C – Connect: Lead with presence and empathy.
- A – Actively Listen: Make space for emotion and questions.
- R – Reflect and Validate: Normalize and affirm what families are feeling.
- E – Empower and Guide: Offer clear next steps and reinforce partnership.

This model was developed to help clinicians shift from automatic, procedural language to communication that centers on emotional safety and connection.

Creating a Culture of Psychological Safety:

Empathetic communication is not sustainable in a culture where staff feel rushed, dismissed, or judged. Psychological safety—the belief that one can speak up without fear—is critical for both providers and families. (5) When staff feel safe, they are more likely to model empathy. When families feel safe, they are more likely to participate in care and express needs.

Kasat et al. showed that even brief empathy training can improve communication quality and staff confidence. (6) We must not only train for empathy—we must create the culture that allows it to flourish.

"Empathetic communication is not sustainable in a culture where staff feel rushed, dismissed, or judged. Psychological safety—the belief that one can speak up without fear—is critical for both providers and families. When staff feel safe, they are more likely to model empathy. When families feel safe, they are more likely to participate in care and express needs."

Conclusion:

Language is not neutral in the NICU. It carries weight, creates meaning, and either fosters healing or deepens harm. When we lead with empathy, communicate with presence, and document with compassion, we transform care. Every word matters—because families will remember not just what we said, but how we made them feel.

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Disclosures: Dr. Daigle is the Founder and CEO of Mom and Me.LLC.

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Multiple Pterygium Syndrome in a Neonate

Erin N. L. Thrasher, MD, Joseph B. Philips, III, MD

"Baby W was born at 37.2 weeks gestation to a 31-year-old gravida 1, para 0 mother via planned cesarean section due to severe fetal growth restriction, less than the 5th percentile, and breech presentation. The pregnancy was complicated by multiple fetal congenital anomalies with concern for arthrogryposis."

Baby W was born at 37.2 weeks gestation to a 31-year-old gravida 1, para 0 mother via planned cesarean section due to severe fetal growth restriction, less than the 5th percentile, and breech presentation. The pregnancy was complicated by multiple fetal congenital anomalies with concern for arthrogryposis. Baby W had numerous detailed anatomy scans throughout pregnancy, which consistently demonstrated bilateral talipes calcaneovalgus (clubfoot), bilateral fixed flexion of the wrists with clenched hands, scoliosis of the lumbar spine, and limited flexion/extension of the upper and lower extremities. A cell-free DNA test resulted in a normal female, and the mother declined amniocentesis. In the third trimester, Baby W demonstrated a growth lag, which ultimately developed into severe fetal growth restriction for which a cesarean section was scheduled.

"Genetic testing included a CGH array and an arthrogryposis panel. The arthrogryposis panel identified a pathogenic variant CHRNG: c.1081_1102del p.(P361Rfs*49), c.459dup, p.V154Sfs*49; indicating an autosomal recessive form of Multiple Pterygium Syndrome."

Physical examination at birth was notable for downward slanting eyes; low-set, posteriorly rotated ears; micrognathia; fixed, bilateral flexion of upper and lower extremities at the knees and elbows with pterygia; bilateral talipes calcaneovalgus; fixed, bilateral flexion of the wrists; and a small sacral dimple. Baby W was admitted to the NICU on non-invasive positive pressure ventilation (NIPPV). After obtaining a sacral ultrasound with concern for a tethered cord, an MRI was performed, which showed dural tethering of the cord posteriorly at the L4 level.

Genetic testing included a CGH array and an arthrogryposis panel. The arthrogryposis panel identified a pathogenic variant CHRNG: c.1081_1102del p.(P361Rfs*49), c.459dup, p.V154Sfs*49; indicating an autosomal recessive form of Multiple Pterygium Syndrome.

"Affected infants present at birth with multiple joint contractures, pterygia (most commonly of the antecubital, popliteal, intercrural, axillary, interdigital, and neck regions), foot deformities, facial dysmorphism, and scoliosis. Case reports describe normal mentality and intelligence."

Multiple Pterygium Syndrome is an autosomal recessive disorder caused by mutations in the CHRNG gene, which encodes the gamma (γ) protein subunit of the acetylcholine receptor (AChR) protein. The AChR protein is located in the membrane of skeletal muscle cells and is essential for signaling between nerve and muscle cells. The inactivation of the neuromuscular junction in utero results in fetal akinesia, characterized by multiple joint contractures and muscle weakness. The γ subunit is present in early fetal life and is replaced during the third trimester to produce the adult AChR protein. Mutations that block all γ subunit production are usually lethal in utero, while those that allow some γ subunit production cause Escobar-type Multiple Pterygium Syndrome. Affected infants present at birth with multiple joint contractures, pterygia (most commonly of the antecubital, popliteal, intercrural, axillary, interdigital, and neck regions), foot deformities, facial dysmorphism, and scoliosis. Case reports describe normal mentality and intelligence.

Baby W is now 6 months old and has a tracheostomy due to chronic respiratory failure secondary to restrictive lung disease and right diaphragmatic eventration. She is tolerating tracheostomy collar trials during the day and still requires ventilator support overnight. She is receiving full feeding volumes through a gastrostomy tube. Photos were obtained and included with parental consent.

Further suggested reading:

1. Carrera-García et al. (2019). CHRNG-related nonlethal multiple pterygium syndrome: Muscle imaging pattern and clinical, histopathological, and molecular genetic findings. American journal of medical genetics. Part A, 179(6), 915–



Figure 1. Photo demonstrating downward slanting eyes, low-set and posteriorly rotated ears, micrognathia, contractures of upper extremities with clenched fists.



Figure 2. Photo demonstrating talipes calcaneovalgus and contracture of the left lower extremity with pterygium of the popliteal region.

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

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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 guidlines limit their access to RSV preventative treatment, increasing these babies' risk.

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We Are We So Often the Last to Know?

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 type of problem is rampant in the world of consumer goods. From directions and labels with microscopic fonts to electronics with black fronts and faint grey labels (a pox on their houses!), it is evident that end users were an afterthought, if given any thought at all."

I have an induction cooktop (which I love, get one!). The cooktop is black, and the capacitive touch virtual "buttons" for all its functions are grey. It works well, except for one notable exception: those "buttons". When clean, the virtual buttons are easily seen; when slightly less clean, not so much. Impossible in fact! I am constantly asking myself, "Who designed this thing?!". Simply having back-lit the virtual buttons would have eliminated the problem, so why was this not incorporated into the design? (On the other hand, were this so, it might never be cleaned!)

This type of problem is rampant in the world of consumer goods. From directions and labels with microscopic fonts to electronics with black fronts and faint grey labels (a pox on their houses!), it is evident that end users were an afterthought, if given any thought at all.

In 1965, Ralph Nader's damning indictment of automobile manufacturers, "Unsafe at Any Speed" (1), was published. The book is primarily credited with the rapid advancement of automobile design and safety. Chapter 2 of the book dealt with automatic transmissions. For the most part, only those at least as old as the writer can recall any other gear selector layout than "P R N D (L,1,2,3, etc)" (**P**ark, **R**everse, **N**eutral, **D**rive), but its adoption was only mandated by the U.S. Department of Transportation in 1971 (2). While already largely standardised by this time, it was not legislatively mandated. Several manufacturers utilised different layouts, the most notorious of which was "P N D R" (**P**ark, **N**eutral, **D**rive, **R**everse). Anyone unfamiliar with one of these vehicles, and used to rapidly pulling down the shift lever to the "D" position, could very easily shift into reverse instead of drive. In this situation, stomping on the accelerator could be lethal to themselves and/or others.

The importance of this standardisation was recently (and tragically) demonstrated when actor Anton Yelchin (of Star Trek) was crushed by his JEEP and killed. A "confusing shifter design" led him to believe he had placed the vehicle in park when, in fact, he had not. Consequently, over 1 million vehicles were recalled to have software installed that would automatically place the vehicle in park as soon as the driver's door was opened (2).

"Engineers have made possible almost every aspect of modern life, including the tools used in medicine to diagnose, test, and treat patients. Outside the world of medicine, numerous examples of the gravity of engineering error exist. Medicine has not been spared the consequences of faulty engineering."

Engineers have made possible almost every aspect of modern life, including the tools used in medicine to diagnose, test, and treat patients. Outside the world of medicine, numerous examples of the gravity of engineering error exist. Medicine has not been spared the consequences of faulty engineering.

In 1985, Atomic Energy Canada introduced a new radiology oncology treatment machine -- a medical linear accelerator called the "Therac-25". The machine was computer-controlled and considered state-of-the-art. Software engineering was then a relatively new field, and it was not long before faulty software used in the Therac-25 resulted in a tragic outcome. An unclear error code explanation in the user manual resulted in severe and fatal radiation energy overexposure in 4 patients (possibly more) and severe injury in 2 more (3). It was not until 1987 (the last accident

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occurring in January of that year) that a *fifth* corrective action plan finally addressed the problem (4). Notably, the previous machine, the Therac-20, had the same faulty code. That machine had mechanical mechanisms to prevent patient overdosing, unlike the Therac-25, which relied solely on software (4).

The most recent and egregious example of disaster produced by faulty software is the Boeing 737-MAX Maneuvering Characteristics Augmentation System (MCAS). In this case, those responsible for making final decisions at Boeing deemed the changes to the new plane (including the aforementioned software) to be minor enough that additional pilot training was not required. Unfamiliar with the MCAS function, pilots were unsure how to respond when the software malfunctioned. In this case, the cost of failing to involve end users in changes deemed "insignificant" was far greater than four lives… 346, to be exact. This documentary (5) gives a detailed explanation (sign-in may be required, contains ads).

The NICU is particularly vulnerable to being excluded from consultations, whether with device manufacturers, financial officers, or support services. The nature of our population makes many devices used elsewhere in the hospital unsuitable for use in the NICU. What follows are a few examples.

"Several new ventilators have been introduced recently, which either lack features or stray from what clinicians may expect in their design. Without mentioning specific models, I find 2 of note."

Devices:

Several new ventilators have been introduced recently, which either lack features or stray from what clinicians may expect in their design. Without mentioning specific models, I find 2 of note.

One machine lacks a "manual inspiration" function. When a baby has a desaturation and/or bradycardic episode, it is common practice to administer a few manual breaths to nudge them out of it. Without this function, a bedside caregiver must either manually stimulate the baby or even resort to manually ventilating them. Stimulation usually stops these episodes, but is neurologically and developmentally much less friendly than manual breaths. As a side note, when manual breaths are available, I recommend setting them at 5 cmH_2O above PEEP with conventional or jet ventilation, or mean airway pressure with high frequency oscillation. This pressure can consistently be increased, if necessary, but the lower pressure affords a degree of lung protection.

Another machine lacks an FiO_2 boost function. This increases the oxygen level by a set amount for a set period. Why is this important? While having one-to-one nurse-to-patient ratios may be ideal, particularly for the extremely premature infant, budget and staffing realities often do not allow for this. When a baby desaturates, FiO_2 is often manually increased, particularly if manual breaths are not effective. If this occurs while caring for another baby, the increased oxygen setting may remain in effect for far longer than the desaturation episode. Not having assignments adjacent to each other compounds this problem. It is all too common to discover that a baby has had an SpO_2 of 100%, and whose FiO_2 has been increased for 10 or more minutes. A baby who ordinarily saturates 100% in an FiO_2 of 0.21 will have the SpO_2 high limit alarm set at 100%; thus, no alarm will sound. This has potentially injurious consequences.

Along the lines of the "PRND" example, with one exception, all the ventilators I have used in my career have the inspiratory limb of the circuit connected to the ventilator on the side closest to the patient, i.e., on the right. Changing this orientation increases the chance of having the inspiratory and expiratory limbs reversed. While newer humidifiers will eventually catch this error and alarm, it has not always been the case. While on the topic of ventilator connections, it would make sense to have inspiratory and expiratory connections with different, standardised diameters.

"Corporate procurement policies may also conflict with the needs of the NICU. IV pumps are a good example. Pumps used for adult patients may not allow for dosing volumes low enough for premature infants, thus requiring concentrations to be decreased and volumes delivered to be increased."

Corporate procurement policies may also conflict with the needs of the NICU. IV pumps are a good example. Pumps used for adult patients may not allow for dosing volumes low enough for premature infants, thus requiring concentrations to be decreased and volumes delivered to be increased. In a larger baby, this may not be a problem, but with a micro or nano-prem, it comes at the expense of total fluid intake and also introduces a potential source of dosing error. Precision is expensive, but a bargain compared to the cost of a catastrophic dosing error.

Systemic Factors:

Laboratory equipment and policy can also negatively impact our patient population. Increasing the volume of blood required for testing from 0.25 mL to 0.5 mL may seem insignificant, but given the number of tests performed from a minimal circulating blood volume, it may increase the need for transfusion(s) that might otherwise be avoided.

Similarly, requiring a test to be repeated before abnormal results are released is not helpful. In a world aiming to reduce blood draws and tests, blood was likely drawn because an abnormal result was *expected.* Delaying the receipt of the results may delay treatment, and anyone who has dealt with a baby whose perfusion is rapidly deteriorating knows how difficult that blood may have been to get, let alone a second sample. In my opinion, those far from the bedside should not decide whether a result is awry or not. One notable exception is a potassium level far outside the

normal range; in such cases, the consequences of inappropriate treatment outweigh the additional time required to repeat the test.

Money:

Point-of-care testing devices are another instance of a "penny-wise, pound-foolish" budgetary priority. Yes, they are more costly than the equivalent laboratory-run tests, but the difference in time required to obtain results may be critical, particularly when it comes to blood gases in the critical first 72 hours. A result from blood drawn 30 minutes ago may not reflect a baby's current status. Additionally, the benefit of requiring a lower volume is not taken into consideration.

" The time required to transfer a patient to level two units north of the city was also scrutinised. The consultants asked why it took so long since, outside peak travel times, the return trip should not take much more than 2 hours. They failed to take into account the time required for the handover report, bed and staff availability at the receiving hospital, availability of our staff for transport, and the availability of our non-acute transport service."

The NICU is a proverbial money pit, and when cost savings are sought, it is a prime target for reductions. Achieving desired savings is not a simple task! Consultants tasked with finding savings in the unit where I am employed pounced on a few areas. One of them was the cost of different syringes. The syringes in question were those used for oral feeding, mandated for safety reasons. The time required to transfer a patient to level two units north of the city was also scrutinised. The consultants asked why it took so long since, outside peak travel times, the return trip should not take much more than 2 hours. They failed to take into account the time required for the handover report, bed and staff availability at the receiving hospital, availability of our staff for transport, and the availability of our non-acute transport service. (Aside, a common joke is that Toronto is an hour away from Toronto – we have the worst traffic in North America. Yes, worse than LA!) Ultimately, there were few savings to be found.

I am incredibly grateful for the numerous advances in medicine that engineers have brought to us. In the development of advances, they should not decide for us what is needed, and certainly without consultation. To coin a phrase, "stay in your own lane"! (Or at least signal before changing lanes!)

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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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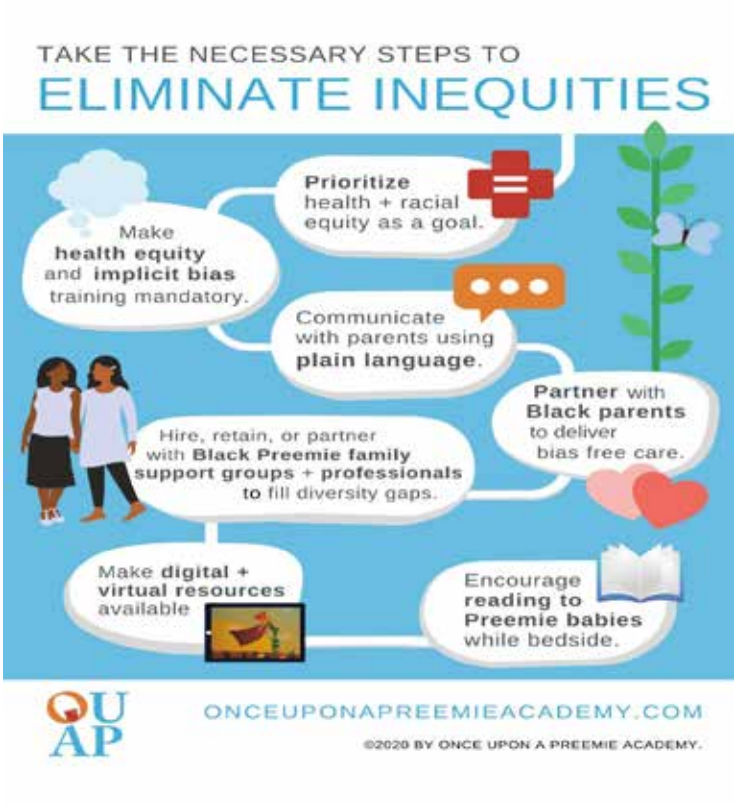
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NICuriosities: The Curious Case of Disappearing Pleural Effusions and Persistent Polycythemia

Shaina Khan Lodhi, MD

"The NICU team was notified of a mother scheduled for induction at 39 weeks' gestation due to bilateral fetal pleural effusions identified on prenatal imaging."

Presentation:

The NICU team was notified of a mother scheduled for induction at 39 weeks' gestation due to bilateral fetal pleural effusions identified on prenatal imaging.

Maternal History:

The mother was a 30-year-old G3P2 with a past medical history of chronic hypertension and migraines, and a prior pregnancy complicated by intrauterine growth restriction. Her current pregnancy had been largely unremarkable:

- First-trimester screening and 12-week nuchal translucency were normal.
- Noninvasive prenatal testing (NIPT) indicated a low-risk male fetus.
- The anatomy scan at 20 weeks and the growth scan at 28 weeks were both within normal limits.

At 36 weeks' gestation, bilateral small fetal pleural effusions were noted, more prominent on the right. No other signs of hydrops were present— there were no ascites, pericardial effusion, or skin edema, and the middle cerebral artery doppler was normal. The mother denied any febrile illness during the pregnancy. CMV and Parvovirus serologies, as well as a repeat antibody screen, were negative. At 37- and 38-weeks gestation, pleural effusion was again seen, more notably on the right. No obvious etiology could be determined, and congenital chylothorax was suspected. The case was reviewed with the Neonatology and Maternal-Fetal Medicine teams, and a plan was developed for induction of labor at 39 weeks' gestation. At the time of delivery, the mother was taking magnesium oxide and acetaminophen as needed for migraines, in addition to prenatal vitamins.

Delivery Course:

Labor was induced at 39 weeks' gestation. Prenatal laboratory testing was only significant for Group B Streptococcus (GBS) positivity. Due to a penicillin allergy, she was treated with Vancomycin, initiated 10 hours prior to delivery. An epidural was placed, and IV Pitocin was started. She remained normotensive,

"At 36 weeks' gestation, bilateral small fetal pleural effusions were noted, more prominent on the right. No other signs of hydrops were present— there were no ascites, pericardial effusion, or skin edema, and the middle cerebral artery doppler was normal."

and laboratory testing was not concerning for HELLP syndrome. The baby had category 1 fetal heart tracing. There was a spontaneous rupture of membranes with clear amniotic fluid. The baby was delivered via vaginal delivery at 39 weeks and 1 day. The amniotic fluid was lightly meconium-stained at the time of delivery.

Neonatal Resuscitation and Initial Assessment:

Delayed cord clamping was performed for 60 seconds. The baby cried spontaneously. He was dried, warmed, and stimulated. He required blow-by oxygen for 5 minutes for desaturations. APGAR scores were 7 and 9 at 1 and 5 minutes, respectively.

On initial assessment, birth weight was 3160 grams (35th percentile). Length and head circumference were appropriate for gestational age. The initial physical exam was only notable for a small caput, head molding, and edema over the face and eyelids. Vital signs were normal, and he was breathing comfortably in room air. Breath sounds were normal. The remainder of the exam was unremarkable.

Hospital Course:

The infant was admitted to the NICU in room air. Chest X-ray and lung ultrasound showed no evidence of pleural effusions. He was started on ad lib oral feeds. Given maternal GBS positivity with inadequate intrapartum prophylaxis, a complete blood count (CBC) was ordered at 12 and 36 hours of life. Blood culture was not drawn, and he was monitored without the use of empirical antibiotics. A chromosomal microarray was sent due to the presence of pleural effusions in utero. Echocardiography was only notable for a PDA, which was appropriate for the first day of life.

The initial CBC at 12 hours of life showed polycythemia, with a hemoglobin (Hb) level of>24 g/dL and a hematocrit (Hct) of 71.4%. There was mild thrombocytopenia with a platelet count of 98 x10^3/µL. The baby's oral feeds were gradually increased. The next CBC at 36 hours of life showed persistent polycythemia with Hb >24 g/dL and Hct 71.0%. He was given a normal saline bolus and started

	Latest Reference Range & Units	12 hours	36 hours	2 days	3 days	4 days	4 days	5 days	6 days	7 days	8 days	9 days	9 days	14 days
WBC	9.0 - 13.0 10*3/µL	**25.7 (H)**	**14.5 (H)**	11.0	9.8	**8.8 (L)**	**8.8 (L)**	**8.7 (L)**	10.8	9.4	**7.4 (L)**	**6.5 (L)**	**5.3 (L)**	**6.1 (L)**
RBC	4.50 - 5.90 10*6/µL	**6.59 (H)**	**6.60 (H)**	5.67	Pend	**5.97 (H)**	5.88	5.76	5.56	5.62	5.10	5.87	5.66	4.94
Hgb	14.0 - 20.0 g/dL	**>24.0 (HH)**	**>24.0 (HH)**	**21.2 (H)**	**22.2 (HH)**	**22.1 (HH)**	**21.6 (H)**	**21.7 (H)**	**21.3 (H)**	**20.6 (H)**	18.5	**21.3 (H)**	**20.5 (H)**	18.0
Hct	42.0 - 60.0 %	**71.4 (HH)**	**71.0 (HH)**	**60.9 (H)**	**64.0 (HH)**	**63.5 (HH)**	**62.4 (HH)**	**61.2 (H)**	59.5	59.5	54.5	**61.6 (H)**	59.2	50.7
MCV	100.0 - 112.0 fL	108.3	107.7	107.5	107.5	106.4	106.1	106.3	106.9	105.8	106.7	105.0	104.6	102.7
MCH	33.0 - 41.0 pg	36.8	37.1	37.3	37.2	37.0	36.8	37.6	38.3	36.6	36.2	36.3	36.2	36.4
MCHC	30.0 - 35.0 g/dL	34.0	34.5	34.7	34.6	34.8	34.7	**35.4 (H)**	**35.8 (H)**	34.6	34.0	34.6	34.6	**35.5 (H)**
RDW	11.8 - 14.6 %	**18.4 (H)**	**18.4 (H)**	**18.7 (H)**	Pend	**17.8 (H)**	**17.6 (H)**	**18.0 (H)**	**17.2 (H)**	**17.1 (H)**	**17.6 (H)**	**17.1 (H)**	**17.2 (H)**	**16.5 (H)**
Plts	147 - 409 10*3/µL	**98 (L)**	**120 (L)**	**116 (L)**	Pend	**95 (L)** (C)	**101 (L)**	**131 (L)**	**102 (L)**	**134 (L)**	**137 (L)**	**116 (L)**	**140 (L)**	**106 (L)**
MPV	7.4 - 10.4 fL	8.4	7.7	7.9	**10.6 (H)**	8.1	9.5	8.6	8.8	9.7	9.6	8.8	9.0	9.2

(HH): Data is critically high
(H): Data is abnormally high
(L): Data is abnormally low
(C): Corrected

on intravenous fluids at 100 mL/kg/day, in addition to his feeds. The Hct trended down to 60.9% the next morning, and therefore, the intravenous fluid rate was decreased. However, the Hct increased again the following day to 64.0% so intravenous fluids were again increased to 100 ml/kg/day. Over the next few days, the Hct remained between 61% and 64%. Throughout this time, platelet counts remained stable between 98 and 131 x10^3/µL.

"Pediatric hematology/oncology was consulted for persistent polycythemia, and they recommended sending genetic testing for the JAK2 mutation."

Pediatric hematology/oncology was consulted for persistent polycythemia, and they recommended sending genetic testing for the JAK2 mutation.

With ongoing intravenous hydration and increased oral intake, the Hct gradually declined over the next few days. Intravenous fluids were slowly reduced and then stopped. A CBC drawn 18 hours after being off intravenous fluids showed Hct 59%. The infant was discharged with instructions to follow up with the pediatrician and to repeat the CBC in one week. Follow-up testing showed continued improvement in the hematocrit.

Diagnosis:

At a week of life, once the eyelid edema resolved, the baby was noted to have subtle dysmorphic features, including epicanthal folds and widely spaced eyes. A detailed examination showed normally positioned ears, normal tone, and no evidence of single palmar crease or sandal gap deformity. The medical team discussed the possibility of trisomy 21 given the presence of subtle facial features, pleural effusions, and polycythemia. However, other hallmark physical findings were absent, and NIPT had a low risk for trisomy 21. A karyotype was sent to aid in the diagnosis.

Genetic testing resulted a few days after the baby was discharged. Karyotyping showed an additional chromosome 21 in 6 of 20 cells (30%). The chromosomal microarray revealed a gain of chromosome 21 in approximately 40% of the sample. These results were consistent with the diagnosis of mosaic trisomy 21. JAK2 mutations were not detected.

Discussion:

This case presents an infant with mosaic trisomy 21 who had bilateral fetal pleural effusions noted late in pregnancy, with spontaneous resolution. Fetal pleural effusions are observed in approximately 1% of fetuses with Trisomy 21, and many present as a late-onset finding in the second or third trimester. (1,2) Proposed mechanisms for pleural effusion in trisomy 21 include lymphatic dysplasia, transient abnormal myelopoiesis, and alveolar hypoplasia. (1) Other chromosomal anomalies —such as Turner syndrome and Trisomy 18— have also been associated with pleural effusions. (1) Fetal pleural effusions in trisomy 21 have been associated with a broad range of outcomes — from spontaneous resolution to severe complications such as hydrops fetalis or perinatal death. (3)

Polycythemia is a common finding in newborns with Trisomy 21, occurring in approximately 8–64% of cases, and typically resolves spontaneously. (4–7) One hematologic condition uniquely associated with this population is transient abnormal myelopoiesis (TAM), also known as transient myeloproliferative disorder (TMD). TAM occurs almost exclusively in neonates with trisomy 21.

(4,5,7) Although TAM typically resolves spontaneously within the first three months of life, affected individuals have an elevated risk (10–30%) of developing leukemia later in childhood. (4,5,7)

In this case, the diagnosis of mosaic trisomy 21 was delayed, as the clinical features can be subtler when mosaicism is present. The phenotypic expression of trisomy 21 varies depending on the proportion of trisomic cells. (8) Little is known about the pathogenesis of the phenotype in individuals with trisomy 21 mosaicism and Down syndrome. The primary goal of this study was to identify factors contributing to the observed phenotypic variation by evaluating 107 individuals having trisomy 21 mosaicism. To investigate a potential "threshold" effect due to trisomic imbalance, lymphocyte and buccal mucosa nuclei were scored using FISH. Overall, buccal cells showed a significantly higher frequency of trisomy than lymphocytes ($P < 0.0001$ Additionally, trisomy 21 was not suspected on prenatal screening as the first-trimester screening was normal and NIPT was low-risk. First-trimester screening has a high detection rate of approximately 82% to 87% for Down syndrome. (7) Similarly, NIPT is considered highly sensitive, with reported detection rates exceeding 90% for trisomy 21. (9,10) To assess the correlation between Z-scores of positive noninvasive prenatal testing (NIPT However, false-negative results have been documented in cases of mosaic trisomy 21. (11,12) Non-invasive prenatal testing (NIPT) detects aneuploidies by measuring differences in the amount of DNA fragments from specific chromosomes. In trisomy 21, for example, there is a measurable increase in chromosome 21 fragments. However, in cases of mosaicism, this difference may be minimal, potentially leading to a false-negative result.(13)

"This case highlights the diagnostic challenges of mosaic trisomy 21, particularly when prenatal screening is unrevealing and clinical features are subtle. It emphasizes the importance of ongoing clinical vigilance and pursuing postnatal evaluation in atypical presentations."

This case highlights the diagnostic challenges of mosaic trisomy 21, particularly when prenatal screening is unrevealing and clinical features are subtle. It emphasizes the importance of ongoing clinical vigilance and pursuing postnatal evaluation in atypical presentations.

Clinical pearls:

- Fetal pleural effusions can be associated with trisomy 21, Turner syndrome, and trisomy 18, and may develop later in pregnancy.
- Phenotypic features of mosaic trisomy 21 are variable and may be subtle or incomplete, leading to delayed diagnosis.
- NIPT may not detect mosaic trisomy 21 due to the low levels of trisomic cells, which increases the risk of false-negative results.

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Disclosures: *The author has no disclosures*

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Pioneer Profile – Lula Olga Lubchenco, MD

Joseph B. Philips, III, M.D., FAAP



Source: https://www.cogreatwomen.org/project/dr-lula-o-lubchenco-josephson/

Dr. Lula Lubchenco was born to an American mother and a Russian father. (1) Her mother was the first woman to graduate from the now-defunct North Carolina Medical College. She was practicing in South Carolina when she met her husband, an agronomist, who was studying cotton farming. They moved to Russia, where Lula was born prematurely (or perhaps small for gestational age, as she would later speculate) in 1915. The Lubchenco family fled Russia in 1917 during the Bolshevik Revolution and returned to the family farm in South Carolina. However, they abandoned the farm in 1930 with the onset of the Great Depression and the destruction of the cotton crop by the boll weevil and moved to Colorado. After high school, Lula attended Colorado College and then the University of Colorado School of Medicine, from which she graduated in 1939. Dr. Lubchenco served a one-year rotating internship at Colorado General Hospital before moving to Strong Memorial Hospital in Rochester, New York, for pediatric training. She then returned to Colorado for further training and, after a year in private practice, joined the faculty of the University of Colorado School of Medicine in 1943. In 1947, she was appointed as the first Medical Director of the Premature Infant Center, a position she held for the next 30 years.

"In 1947, she was appointed as the first Medical Director of the Premature Infant Center, a position she held for the next 30 years."

Among her earliest publications was an article detailing the methods of care used in the Premature Infant Center, (2) and another co-written with the Chairman of Obstetrics and Gynecology advocated for joint responsibilities between the two specialties "Mothers and babies as well as doctors and nurses benefit when the specialists in each field join in teaching and planning." (3) Dr. Lubchenco encountered an alarming circumstance shortly after opening a new state-of-the-art premature nursery. Eight of the first 12 infants treated in the new nursery were blinded by what was then called retrolental fibroplasia (RLF). (1) She eventually narrowed the cause down to excess use of oxygen well before it was fully recognized. I was unable to find any publications on this topic; however, I find the cited reference convincing.

"Dr. Lubchenco encountered an alarming circumstance shortly after opening a new state-of-the-art premature nursery. Eight of the first 12 infants treated in the new nursery were blinded by what was then called retrolental fibroplasia (RLF). She eventually narrowed the cause down to excess use of oxygen well before it was fully recognized."

Dr. Lubchenco's most important contributions to our field are her seminal publications on intrauterine growth. Before her landmark studies, it was widely assumed that all babies weighing less than 2,500 grams at birth were premature. This all changed in 1963 with the release of the first of several reports assessing the adequacy of fetal growth. (4) Using data from 5,635 liveborn Caucasian infants with reliable gestational ages, Lubchenco and

"Using data from 5,635 liveborn Caucasian infants with reliable gestational ages, Lubchenco and colleagues plotted the adequacy of intrauterine growth versus gestational age and plotted percentiles. This ultimately led to the coining of the terms small for gestational age (SGA) for those less than the 10th percentile for their gestational age, appropriate for gestational age (AGA) for those between the 10th and 90th percentiles, and large for gestational age (LGA) for those above the 90th percentile."

colleagues plotted the adequacy of intrauterine growth versus gestational age and plotted percentiles. This ultimately led to the coining of the terms small for gestational age (SGA) for those less than the 10th percentile for their gestational age, appropriate for gestational age (AGA) for those between the 10th and 90th percentiles, and large for gestational age (LGA) for those above the 90th percentile. Interestingly, the authors noted that the mean birth weight of infants born at 40 weeks' gestation in their cohort was somewhat lower than in other reports and speculated that altitude might have been a factor.

"Dr. Lawrence then went on to advocate for daycare centers near schools where adolescent mothers could participate in the care of their children and learn parenting skills to improve on the well-documented poorer outcomes of such infants."

This key report was followed by an equally important one plotting length and head circumference in a similar manner. (5) These concepts were solidified in a 1967 paper coauthored by the equally legendary Frederick Battaglia entitled "A practical classification of newborn infants by weight and gestational age." (6) This study formally introduced the terms SGA, AGA, and LGA and linked the adequacy of intrauterine growth to the risk of death based

Figure 1. The "Lulagram" defines both adequacy of intrauterine growth and risk of mortality. (6)

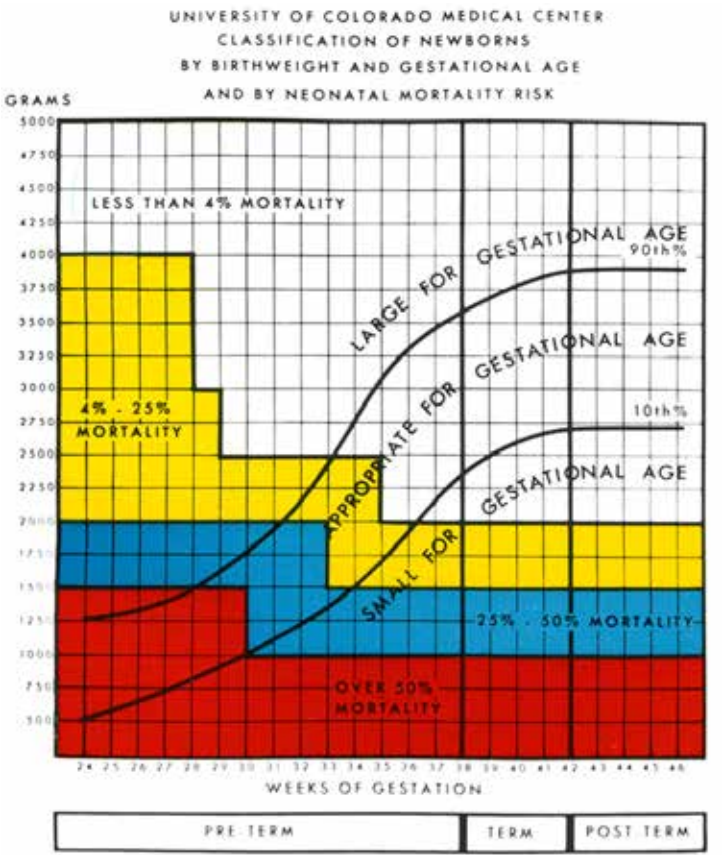
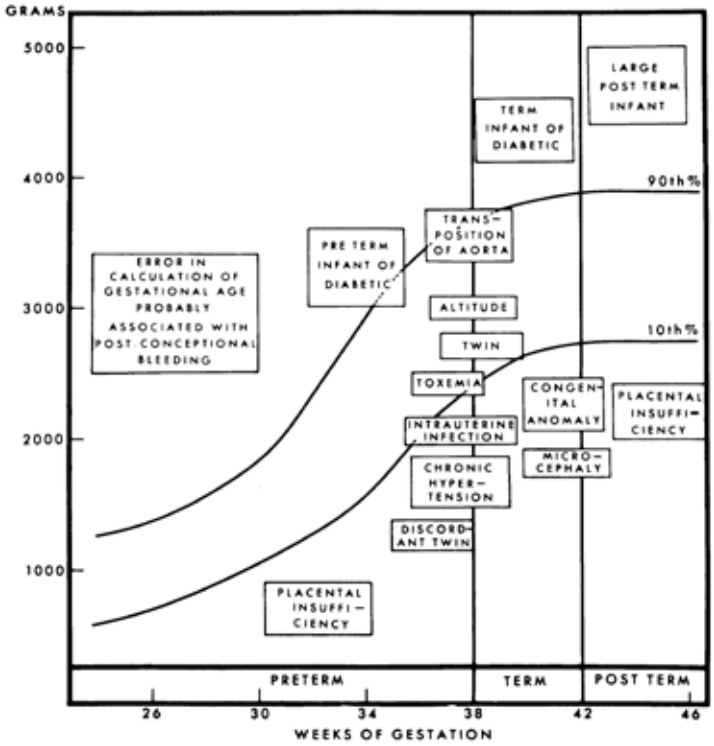
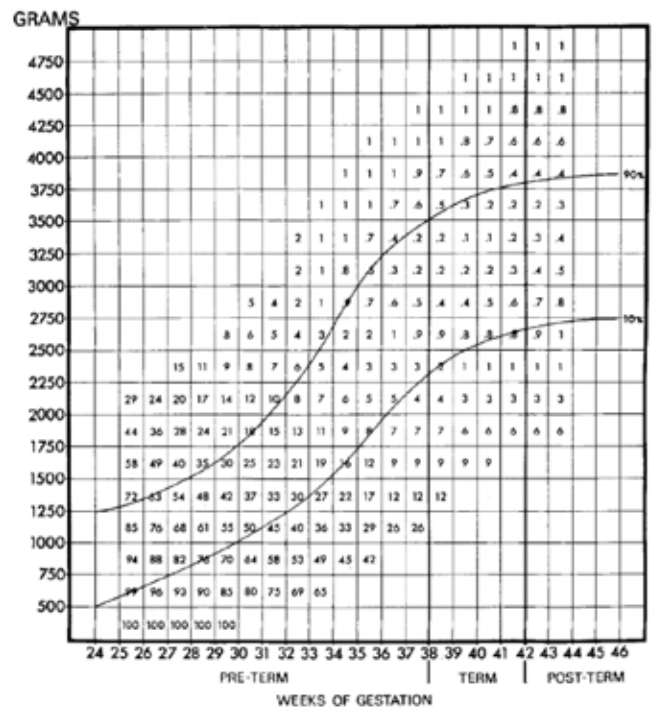


Figure 2. Effects of Various Conditions on Fetal Growth. (7)



on classification into these categories (Figure 1). A subsequent publication reported on the effects of various conditions, such as diabetes, twinning, trisomies, and other genetic disorders, on the adequacy of fetal growth (Figure 2). (7) A further study showed that hypoglycemia is more common in SGA infants and preterm LGA infants than in those who are AGA. (8) More granular mortality rates based on the adequacy of fetal growth followed

Figure 3. Interpolated mortality rates by birthweight and gestational age. (9)



shortly thereafter (Figure 3). (9) A final report presented growth charts for boys and girls from birth to 18 years of age. (10)

"A final report presented growth charts for boys and girls from birth to 18 years of age."

Dr. Lu, as she was affectionately known, was also a pioneer in follow-up. Her first report compared the growth of infants with and without RLF, showing that those with RLF were smaller to begin with but exhibited catch-up growth as they neared term. (11) She reported on the sequelae of premature birth in 94 surviving infants with birthweights ≤ 1,500 grams at approximately ten years of age born between July 1, 1947, and July 1, 1950, and found a high rate of "visual defects primarily due to retrolental fibroplasia, brain damage, retarded growth, and social and emotional problems." (12) Children included in the former study were added to a group born up until July 1, 1953. During that time, oxygen use was curtailed. (13) There was a lower rate of blindness from RLF, but the rate of neurodevelopmental handicap was unchanged. The authors noted that caloric intake in the first week of life was very low for all infants and speculated that this might have been a factor. A further study using a subset of this cohort showed that both low birthweight and low birthweight percentile at birth were risk factors for moderate to severe handicap. (14) A later study of a cohort born in the early to mid-1960s showed improved outcomes overall, which were attributed to the use of intravenous fluids, but still showed the same increases in risk of handicap associated with prematurity and the adequacy of intrauterine growth. (15) A pair of studies were among the first to suggest that outcomes are better for very low birthweight infants born in a tertiary center with a newborn intensive care unit and for infants transferred in utero or postnatally to a tertiary center. (16, 17)

"Denver, Colorado is nicknamed the Mile High City because its altitude is exactly one mile above sea level. Although the percentage of oxygen in the atmosphere remains the same, the lower partial pressure of oxygen makes the air in Denver roughly the equivalent of breathing 17.2% oxygen... Thus, the incidence of polycythemia and hyperviscosity is elevated in children born at altitude."

Denver, Colorado is nicknamed the Mile High City because its altitude is exactly one mile above sea level. Although the percentage of oxygen in the atmosphere remains the same, the lower partial pressure of oxygen makes the air in Denver roughly the equivalent of breathing 17.2% oxygen. This results in lower oxygen saturation levels in the fetus, who then compensates by producing erythropoietin, which in turn results in higher hemoglobin and red blood cell counts in the fetus and newborn. Thus, the incidence of polycythemia and hyperviscosity is elevated in children born at altitude. Dr Lubchenco was therefore ideally positioned to study this phenomenon. Her group's first study, entitled "Thick Blood Syndrome," reported a 5% incidence of hyperviscosity and documented short-term outcomes in 20 infants, half of whom received partial exchange transfusions with plasma to lower the viscosity of their blood. (18) Transfused infants were reported to have less lethargy after treatment and improved neurologic examinations at follow-up 2–3 weeks later, hinting at decreased incidence and severity of neurologic sequelae later on. Follow-up of these infants at 8 months showed a high rate of neurologic problems in both groups, leading the authors to question the value of the intervention. (19) A subsequent study again showed a 5% incidence of hyperviscosity and that this condition was more common in SGA and LGA term and post-term infants when compared to AGA infants. (20)

"A larger randomized, controlled trial of partial exchange transfusion, including 93 infants, found a reduction in the overall rate of neurologic conditions and fine motor abnormalities in the exchanged group. However, again, the authors questioned whether longer-term outcomes would be affected. A companion publication to this trial noted a higher rate of necrotizing entero-colitis, a relatively rare occurrence in term infants, in the exchanged group, raising a cautionary flag over this procedure."

A larger randomized, controlled trial of partial exchange transfusion, including 93 infants, found a reduction in the overall rate of neurologic conditions and fine motor abnormalities in the exchanged group. However, again, the authors questioned whether longer-term outcomes would be affected. (21) A companion publication to this trial noted a higher rate of necrotizing enterocolitis, a relatively rare occurrence in term infants, in the exchanged group, raising a cautionary flag over this procedure. (22) A further study matched 111 infants with hyperviscosity to 110 controls and found a much higher rate of neurologic sequelae in the affected infants, and that partial exchange transfusion had little effect on outcome. (23) Forty-nine infants with hyperviscosity, roughly half of whom had partial exchange transfusions, were assessed at 7 years of age and matched with 40 controls. (24) Children who had hyperviscosity had a higher rate of minor impairments, and there was no difference between those who had partial exchanges and those who did not. A Cochrane systematic review has since confirmed that partial exchange transfusion has little to no effect

on long-term outcomes, but it does increase the risk of necrotizing enterocolitis. (25) The implication is therefore that most or even all of the neurologic injury in infants with hyperviscosity occurs in utero and that postnatal interventions therefore have little to no impact in long term outcomes. Dr. Lubchenco along with Dr. Virginia Black published a comprehensive review of what was known about neonatal polycythemia and hyperviscosity in 1982. (26)

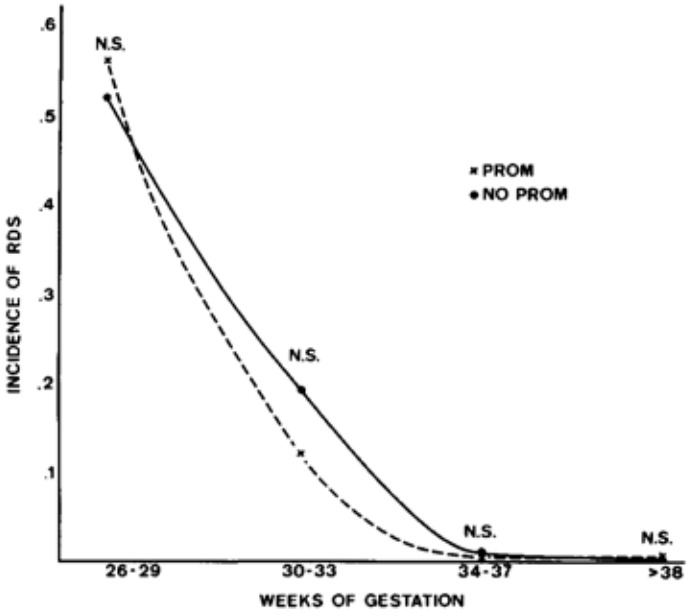
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As with all neonatologists of her era, Dr. Lubchenco was interested in the pathogenesis of respiratory distress syndrome (RDS). The hyaline membranes associated with RDS were known to contain fibrin, so she turned her attention to the coagulation and fibrinolytic systems. She described lower fibrinolytic activity in premature infants compared to term infants and showed that those with RDS had even lower activity than those without RDS. (27) Subsequent reports documented hypercoagulability in infants with RDS and described a trial of heparin therapy to attempt to reduce the frequency of RDS and death therefrom. (28, 29) Heparinization did not affect the rate of RDS or death. Another study refuted the hypothesis that premature rupture of the membranes was associated with a lower rate of RDS, nor was mortality reduced (Figure 4). (30) Another early study aimed at improving the survival of infants with RDS by providing 20% glucose water enterally also failed to show a reduction in mortality. (31)

Further studies investigated urinary excretion of various substances, including amino acids, and described patterns of electrolyte and nitrogen balance in premature infants. (32–34) Another report described spontaneous pneumothorax and noted that it was more common in premature infants. (35) Dr. Lubchenco was opposed to routine circumcision except for religious purposes (36) and advocated for what she called self-regulatory feeding, which we now call feeding on demand, in vigorous premature infants. (37, 38)

Dr. Lula Lubchenco was married to Carl Josephson, a Denver internist, and they had four children, the last of whom had Down syndrome. (1) She became a lifelong advocate for Down syndrome individuals and helped found the Denver Adult Down Syndrome

Figure 4. Lack of effect of premature rupture of membranes on the rate of RDS.(30)



Clinic. Her daughter, Gretchen, became a spokesperson for Down syndrome and traveled extensively, both nationally and internationally. (39) Dr. Lubchenco was honored with the Apgar Award from the Section on Neonatal-Perinatal Medicine of the American Academy of Pediatrics in 1982. The Premature Infant Center was renamed in her honor. Her work on the adequacy of fetal growth forever changed how we look at babies at birth.

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Disclosures: The author has no disclosures.

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Acknowledgements:

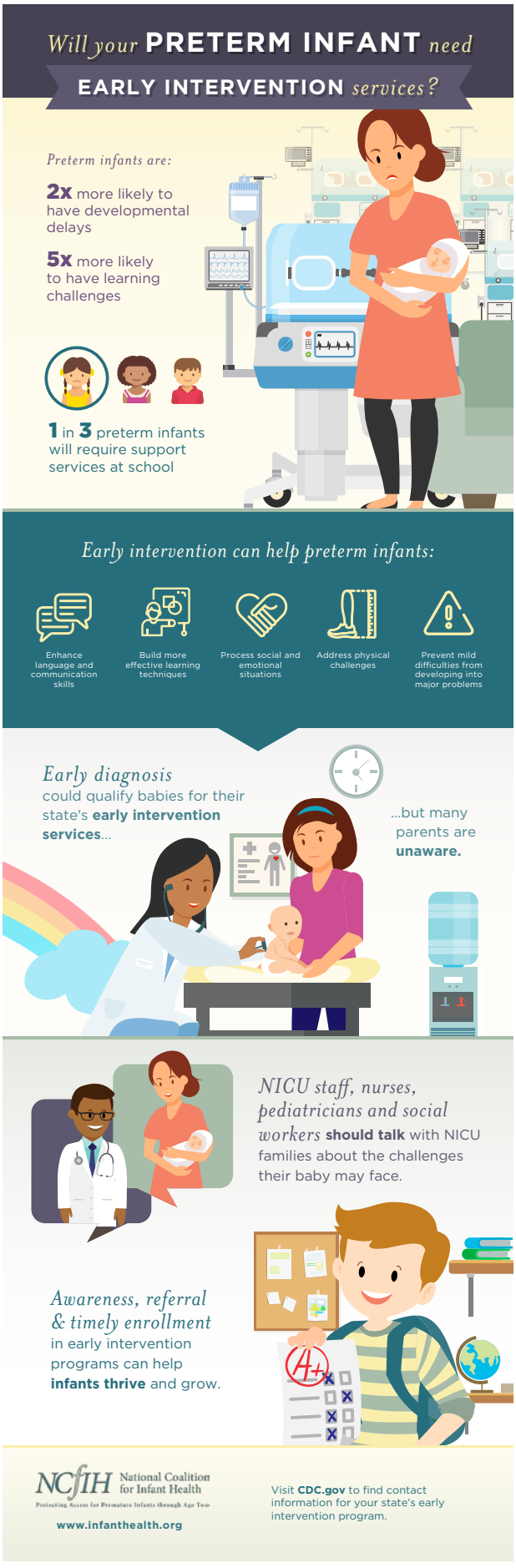
I thank Ms. Lauren McInnis, BA, MA, for her invaluable assistance in obtaining many of the cited manuscripts and arranging the references.

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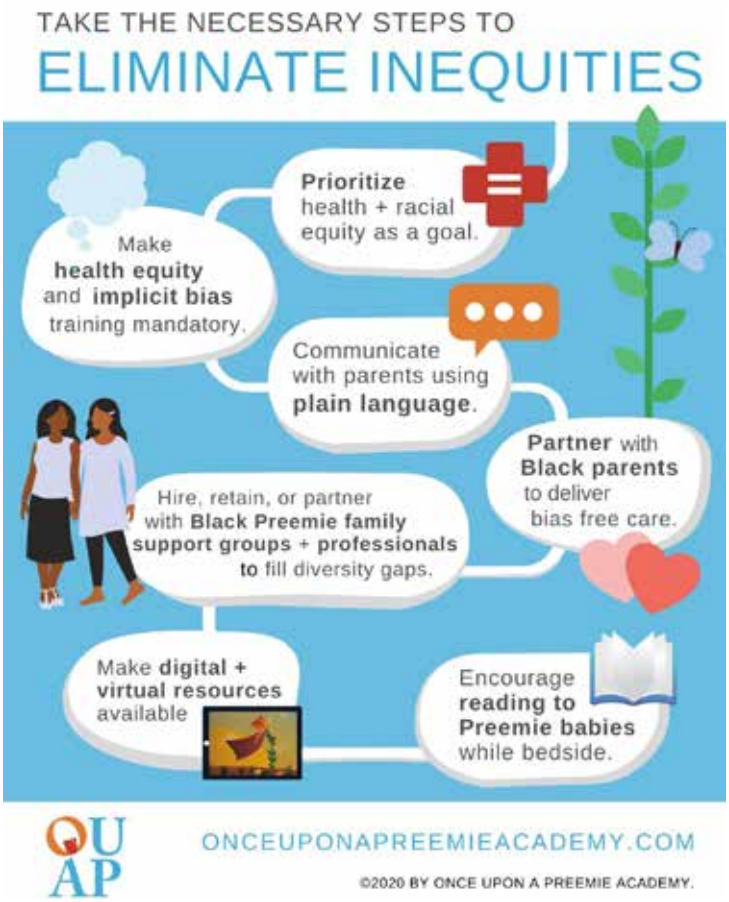


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Kangaroo Mother Care for Neonatal Abstinence Syndrome: A Mother's Feedback

Raouth R. Kostandy, PhD, MSN, RN, CKC.

"Neonatal Abstinence Syndrome (NAS) is a withdrawal syndrome that affects neonates exposed to different substances/drugs in the womb shortly after birth. Continued opioid and other substance crises led to the high rates of NAS. It is estimated that the rates of NAS have increased fivefold between 2010 and 2017."

Abstract:

Neonatal Abstinence Syndrome (NAS) is a withdrawal syndrome that affects neonates exposed to different substances/drugs in the womb shortly after birth. Continued opioid and other substance crises led to the high rates of NAS. It is estimated that the rates of NAS have increased fivefold between 2010 and 2017. Neonates with NAS experience various neurological and Physiological symptoms such as irritability, excessive crying, tremors, poor sleep, poor feeding, vomiting, diarrhea, poor weight gain, and developmental delays. NAS management is very costly to the health system as neonates require a longer hospital stay, admission to Neonatal Intensive Care Units (NICU), and multilayered resources throughout their lives. A holistic care approach has been recommended as the best way to manage NAS, focusing on non-pharmacological interventions that involve parents and caregivers as the first line of treatment. Many non-pharmacological interventions are used in clinical settings, such as swaddling, rocking, room-in, Eat-Sleep-Console (ESC), and Kangaroo Mother Care (KMC). This paper presents one mother's feedback on her experience of holding her neonate in the KMC position for a one-and-a-half-hour session. The mother reported that she had a positive experience, witnessed a change in her neonate's behavior that prompted her to hold her neonate in KMC at different times outside the study timeline. More research evidence is needed on the effect of KMC in managing NAS.

Keywords: *Neonatal Abstinence Syndrome, non-pharmacological interventions, and Kangaroo Mother Care*.

Introduction:

Neonatal Abstinence Syndrome (NAS) is defined as a withdrawal syndrome that is experienced by neonates who have been exposed to certain substances, primarily opioids, during pregnancy. As the effects of these substances abruptly cease at birth, neonates experience multisystem withdrawal symptoms. These symptoms appear within the first few days after birth and can include hyperactivity of the central and autonomic nervous systems, gastrointestinal distress, irritability, and other signs of withdrawal (1). By 2023, healthcare providers continued to observe elevated incidents of NAS, particularly considering compounded issues such as polysubstance use and systemic gaps in maternal-neonatal healthcare services (2). A holistic approach to the mother-neonate dyad should be incorporated to improve both the mother's and the neonate's care. Non-pharmacological interventions are recommended as the first line of NAS management (3). One of these non-pharmacological interventions is Kangaroo Mother Care (KMC). KMC is an intervention that offers numerous benefits for both mother and neonate. The purpose of this paper is to provide one mother's feedback on her experience with KMC during the care of her neonate, who was diagnosed with NAS.

Review of Literature:

Neonatal Abstinence Syndrome (NAS):

NAS is a general term used for neonates who have been exposed to opioid and non-opioid substances during pregnancy, and it occurs as a result of prenatal exposure to opioids, leading to withdrawal symptoms in neonates shortly after birth. More recently, this syndrome has been called Neonatal Opioid Withdrawal Syndrome (NOWS) by federal agencies. The NOWS term is explicitly used for the opioid exposed neonates. However, these two terms are used interchangeably. Statistics on NAS underscore the ongoing public health issue in the United States, particularly due to its correlation with the opioid epidemic. From 2000 to 2017, the incidence of NAS escalated significantly, with a notable increase from 1.2 to 7.3 cases per 1,000 live births, illustrating a grave trend over the years (4). The increase in NAS diagnoses is evident across various regions and demographics. However, it has disproportionately affected specific populations, leading states like West Virginia to report extraordinarily high rates, with NAS incidence reaching 50.6 per 1,000 live births (5). Thus, it requires tailored interventions to ensure optimal care, taking into account the available financial resources.

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The long-term financial implications of NAS are pronounced, with a quarter of affected neonates requiring extensive resources in neonatal intensive care units, thus intensifying the burden on healthcare systems (2). The economic burdens associated with NAS are significant. A systematic review indicated that the financial costs related to NAS hospitalizations increased to approximately $572.7 million by 2016, marking a significant rise from previous years (6). The extended length of hospital stays for neonates diagnosed with NAS, averaging around 16-26 days depending on the severity of symptoms, further underscores the urgent need for effective management strategies.

NAS is characterized by a range of withdrawal symptoms that can vary widely in onset, severity, and duration depending on the drug/substance used, length of use, combination of substances, etc. (1, 2). These symptoms include various neurological and physiological symptoms. Neurological symptoms include irritability, high-pitched cry, tremors, seizures, and hypertonia (1, 2). Physiological symptoms include temperature instability, yawning, nasal congestion, tachycardia, apnea, and gastrointestinal disturbances such as vomiting, diarrhea, poor feeding, and weight loss (1, 7). These symptoms significantly impact the neonate's health and can lead to developmental delays (1). Mothers who have just given birth and are not well themselves face hardships in taking good care of their sick neonates, who require more attention and patience due to these withdrawal symptoms. Both mother and neonate require compassionate care. Non-pharmacological interventions can be the needed solution.

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Use of non-pharm interventions:

The literature to support specific nonpharmacologic approaches is sparse; however, evolving evidence suggests that effective nonpharmacologic care that engages the mother is an essential foundation to the care of a neonate with opioid exposure (8). The use of non-pharmacologic interventions is becoming an essential element and a focus of care (9). Non-pharmacologic care that is individualized should be applied from birth for all neonates with substance exposure, and continued throughout hospitalization and after discharge, regardless of the need for pharmacologic interventions. Engaging caregivers, especially mothers, in non-pharmacologic care promotes bonding and can improve outcomes. Starting with education about the neonate-specific signs of NAS and helping the family interpret what triggers these signs in the neonate, as well as how to manage them. Clinical manifestations of NAS, such as irritability, uncontrolled movements, and fragmented sleep, can be challenging for the mother. Providing support to the mother as she responds to these clinical features is important. Mothers frequently experience overwhelming feelings of guilt and anxiety in response to the dysregulated neurobehaviors associated with NAS (2). Thus, involving the mother in providing non-pharmacologic interventions can help her overcome the feeling of guilt. Non-pharmacological treatment may include a variety of supportive care approaches, and these should be modified to meet each neonate's specific needs.

"Swaddling, gentle handling, demand feeding, and stimulus reduction are examples of non-pharmacologic interventions used in managing NAS (10). Breastfeeding is another recommended intervention. Current research supports that breastfeeding can lead to decreased severity of NAS symptoms, a delayed onset of withdrawal, and reduced likelihood of requiring pharmacological treatment (11-12)."

Swaddling, gentle handling, demand feeding, and stimulus reduction are examples of non-pharmacologic interventions used in managing NAS (10). Breastfeeding is another recommended intervention. Current research supports that breastfeeding can lead to decreased severity of NAS symptoms, a delayed onset of withdrawal, and reduced likelihood of requiring pharmacological treatment (11-12). The mechanism behind breastfeeding's effectiveness in managing NAS could lie in the nutritional and comforting properties of breast milk and the caregiver relationship established during breastfeeding. Guidelines from organizations, such as the Academy of Breastfeeding Medicine, recommend breastfeeding as the first-line approach for managing NAS, except in contraindicated circumstances, due to its benefits in improving clinical outcomes (3,11,12). Furthermore, innovative care strategies that incorporate breastfeeding, such as rooming-in and skin-to-skin contact, enhance their effectiveness in managing NAS. These strategies are linked to reduced lengths of hospitalization and medication use, as they create a supportive environment for both the mother and infant during recovery (13-

14). Eat-Sleep-Console (ESC) and Kangaroo Mother Care (KMC) are two other non-pharmacologic interventions that can be highly effective in managing NAS.

Eat-Sleep-Console:

The ESC model originated at Yale-New Haven Children's Hospital to simplify the assessment and care process for neonates with NAS. The key components of the ESC intervention are three primary criteria: the neonate's ability to eat adequately, sleep well, and be easily consoled (15). The ESC approach prioritizes functional capacity and comfort, enabling providers to assess how well the neonate can thrive without over-relying on medications (15, 16). The ESC method operates on the principle that if a neonate can eat, sleep, and be consoled effectively, they may not require intensive pharmacotherapy, thus reducing the likelihood of prolonged hospital stays. Research indicates that this method can lead to enhanced outcomes, with findings suggesting that neonates managed using the ESC approach experience shorter lengths of hospitalization and decreased need for opioid therapy (17). Additionally, reducing the length of hospital stay and readmission rates can result in significant financial savings for hospitals (17). The implementation of the ESC intervention has gained traction in various healthcare settings, highlighting its potential for broader application in hospitals treating neonates with NAS and emphasizing family-centered care practices that involve parents actively in the infant's care (18, 19). A key aspect of implementing the ESC intervention aligns with the growing body of evidence supporting the need for holistic management of NAS and the focus on the mother-neonate dyad. When mothers were not present to provide care for their neonates after discharge from the hospital, the neonates did not experience the full benefits (15). Amin et al. (2023) reported no significant differences between the ESC and control neonates in terms of length of stay and pharmacological therapy. The authors suggested that these findings may be due to the absence of parents' presence, as they found no parents or caregivers present in 41% of the 4-hour period examined. ESC intervention promotes the inclusion of other non-pharmacologic approaches such as rooming-in and KMC (15). However, there is a lack of standardization in the use of such impactful interventions.

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Kangaroo Mother Care:

KMC is a method of care that involves skin-to-skin contact between the neonate and the mother. In KMC, the neonate is held upright against the mother's chest, allowing for warm, secure contact that significantly supports the neonate's physiological stability and emotional well-being. This intervention promotes several critical benefits, including thermoregulation, breathing, weight gain, sleep, behavioral state organization, breastfeeding, and bonding. In addition, less crying and irritability (20, 21). The interaction fostered by KMC contributes not only to the physical health of the neonate but also to psychological and social benefits for the mother-neonate dyad (20, 22).

KMC is associated with improved sleep patterns in neonates and mothers. Studies have shown that neonates receiving KMC exhibit more stable sleep durations and improved sleep quality (20), and mothers experience better sleep quality, increased sleep time, and enhanced mental health (23). Stability and high-quality sleep are crucial in managing NAS. In KMC, the neonate lies in a comfortable position, listening to their mother's heartbeat, rocked by her gentle chest movements, held tightly by her hands, and enjoying her scent, which creates a perfect environment that mimics the womb, producing a state of neonatal relaxation (24). The soothing nature of KMC leads to substantial reductions in the duration of crying and irritability among neonates. Neonates receiving KMC exhibit decreased crying episodes compared to those in conventional care, a benefit attributed to the calming effects of skin-to-skin contact (24, 25). The nurturing environment created by KMC helps in managing the emotional and physiological distress associated with NAS. In addition, KMC facilitates breastfeeding readiness, initiation, and success, which is particularly beneficial for neonates experiencing NAS. Neonates held in KMC can establish a better latch and breastfeeding rhythm, contributing to improved nutrition and hydration necessary for recovery (26, 27). NAS neonates experience weight loss and poor feeding. KMC enhances the neonate's ability to learn breastfeeding cues, leading to increased rates of breastfeeding, which is beneficial for weight gain. In summary, KMC can play a crucial role in managing NAS, positively influencing sleep, feeding behaviors, and emotional stability, thereby providing a multifaceted approach that enhances neonatal health outcomes while also promoting maternal confidence in caregiving.

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A Mother's Feedback:

A full-term neonate was diagnosed with NAS by the end of the second day of life. The neonate suffered from irritability, crying,

lack of sleep, diarrhea, and has not been feeding well. On the third day, the mother approached and asked if she would participate in an IRB-approved study about the KMC effect on NAS, conducted by the site principal investigator, a nurse practitioner. Mother and neonate met the study eligibility criteria. For the study, neonates were included if they were a product of an uneventful and spontaneous vaginal delivery or planned caesarean section, gestational age 37-42 weeks, birth weight of 2,500 grams or more, 5-minute Apgar score of at least 7, judged clinically healthy, and had a confirmed diagnosis of NAS. Neonates were excluded if they had evidence of congenital abnormalities or medical complications. Mothers were included if they agreed to provide KMC and were excluded if there were medical or non-medical reasons that prevented them from being in contact with their neonate. The mother agreed to participate and held her neonate skin-to-skin and chest-to-chest between feedings. This session lasted for 1.5 hours. The next day, the site principal investigator visited the mother to check on her and the neonate. The mother stated that her baby had changed since the KMC session. She said that her baby was quieter, cried less, slept longer, and fed better. The mother said, "he is a different baby." She also stated that, due to the change she witnessed in her baby's behavior, she asked the night nurse to help her hold her baby again in the KMC position. She had another KMC session with her baby that evening, which lasted more than an hour. The mother said that she will continue to hold her baby skin-to-skin.

"Non-pharmacological interventions are extremely useful in the management of NAS, and they are considered the first line of treatment. When non-pharmacological interventions are used correctly and consistently, the need to use pharmacological treatments decreases."

Implications for Practice:

Non-pharmacological interventions are extremely useful in the management of NAS, and they are considered the first line of treatment. When non-pharmacological interventions are used correctly and consistently, the need to use pharmacological treatments decreases. Thus, lower length of stay and better neonatal outcomes were achieved. Nurses are the healthcare team members who provide and implement these non-pharmacological interventions. As one of these non-pharmacological interventions, KMC has documented evidence of its effects on optimizing neonatal behaviors, including improved sleep and decreased irritability. KMC improves breastfeeding and mother-neonate attachment. Nurses need to use all that they have in their care arsenal to ensure they provide optimal care to their patients. Nurses also educate, encourage, and empower mothers to participate in their neonates' care. Thus, they can make a lasting impact on these neonates' lives.

Future Suggestions:

More research is needed to thoroughly investigate the effects of KMC, as part of the routine care, on NAS management. More standardized care protocols are needed, and their effectiveness must be verified through various research studies. There is a need for continuous nurse education and training programs to keep nurses updated on the standards of care. Utilizing advanced strategies in education and training, such as Artificial Intelligence (AI), can be beneficial as it helps personalize these educational and training programs.

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Disclosures: *The authors have no disclosures*

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Appeal to the FDA for Pragmatic, Efficient Evaluation of Bifidobacterium longum ssp. infantis for NEC Prevention

Brian Scottoline, M.D., Ph.D.

"This is a pragmatic path to accelerate the generation of robust safety and efficacy data necessary to potentially bring probiotics back to our patients as a drug, complying with the FDA's guidance."

Dear Colleagues,

Summary:

I am asking you to sign an online appeal urging the US FDA to allow a B. *infantis* strain—one that was effective in VLBW NEC incidence reduction in my unit at Oregon Health & Science University (OHSU) (Tobias et al, 2022)—to proceed directly to a Phase III trial. (1) This is a pragmatic path to accelerate the generation of robust safety and efficacy data necessary to potentially bring probiotics back to our patients as a drug, complying with the FDA's guidance.

"In 2022, OHSU reported a greater than fourfold reduction in NEC incidence (p<0.001) in VLBW infants after initiating administration of Bifidobacterium longum ssp. infantis (B. infantis) in the Journal of Pediatrics (Tobias et al. 2022)."

The Details:

In 2022, OHSU reported a greater than fourfold reduction in NEC incidence (p<0.001) in VLBW infants after initiating administration of *Bifidobacterium longum* ssp. *infantis* (*B. infantis*) in the *Journal of Pediatrics* (Tobias et al. 2022). (1) This effect continued for the five years OHSU gave *B. infantis* to VLBW infants. A second publication in the *Journal of Perinatology* also indicated a 10-fold reduction in NEC incidence associated with *B. infantis* (Sohn et al. 2024). (2)

We were not alone in administering probiotics to preterm infants; by 2023, 30-40% of US NICUs were using probiotics to prevent necrotizing enterocolitis (NEC) (Wala et al. 2024; Hanna et al., 2024). (3, 4) Approximately half of these units reported using a probiotic containing *B. infantis* as either a single strain or part of a multi-strain blend (Wala et al. 2024). (3)

"Since OHSU discontinued using probiotics in September 2023, our NICU has experienced a significant increase in NEC incidence back to pre-probiotic levels (p < 0.001). This crossover observation has been submitted for peer-reviewed publication (Selesner et al. submitted) and will be available on bioRxiv."

As many are aware, in September 2023, the United States Food and Drug Administration (FDA) issued an advisory letter (5) to US NICUs, advising against the use of probiotics (live bacterial products) in preterm infants without Investigational New Drug (IND) status, following reports of probiotic-associated bacteremia. This letter effectively stopped the use of probiotics in NICUs in the US (FDA workshop). (6) Since OHSU discontinued using probiotics in September 2023, our NICU has experienced a significant **increase in NEC** incidence back to pre-probiotic levels (p < 0.001). This crossover observation has been submitted for peer-reviewed publication (Selesner et al. submitted) and will be available on bioRxiv.

The potential of *B. infantis* as a live bacterial product for preventing NEC has motivated a multi-member group, including me, to find a pathway for formal evaluation of *B. infantis* as a means to prevent NEC. The FDA letter makes it clear that any probiotic used in preterm infants must follow a formal IND path to assess safety and efficacy. As such, we have been working on an IND application and trial design to evaluate *B. infantis* as a drug. This work aligns with appeals by the SoNPM and the NEC Society to the FDA to prioritize the timely and efficient evaluation of probiotics as a potential therapeutic for preventing NEC.

The FDA's concerns regarding probiotic-associated sepsis are well-founded and deserve formal evaluation in a large trial. However, the typical drug development path, which starts with a Phase I trial enrolling a few dozen patients, is ill-suited to evaluate risk in a meaningful way in this population. This is particularly true for rare safety signals such as probiotic-associated sepsis, which is estimated to occur in approximately 1.4 per 1,000 VLBW patients given probiotics (Alshaikh et al. 2025). (7)

Given the experience with hundreds of thousands of doses of *B. infantis* administered to VLBW infants as a single-strain live

bacterial product, and an even larger number of doses with *B. infantis* as part of a mixture of other strains, it seems prudent to proceed directly to a large-scale trial. Only a Phase III trial enrolling 1,000+ patients will be scaled to adequately asses the safety and efficacy of *B. infantis* in a rigorous, prospective, and transparent manner, Given the published data in support of the potential for a probiotic to reduce NEC incidence, and with our own experience as a guiding light, there is no time to waste on uninformative steps.

"Is B. infantis the best possible candidate? Difficult to know without testing. What I do think—and hope to have conveyed to you—is that it is a very strong candidate for testing as a drug, particularly in light of the FDA advisory. I am choosing not to settle for the current state where no live bacteria product may be used to prevent NEC in preterm infants, when NEC continues to claim the lives of babies every day."

Is *B. infantis* the best possible candidate? Difficult to know without testing. What I do think—and hope to have conveyed to you—is that it is a very strong candidate for testing as a drug, particularly in light of the FDA advisory. I am choosing not to settle for the current state where no live bacteria product may be used to prevent NEC in preterm infants, when NEC continues to claim the lives of babies *every day*.

I have no financial stake in this effort. What I do have, and share with you, is a deep and abiding loathing of NEC, its effects on patients, families, and NICUs, and a conviction that FDA evaluation of probiotic efficacy and safety in preterm infants must be accelerated.

If you are supportive of an efficient FDA evaluation process that is detailed, safe, and informative, I urge you to join me in supporting this online appeal.

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Thank you,

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The Indirect Impact of **RSV**

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

OVERVIEW



RSV impacts not only infants and young children, but also entire families.

The National Coalition for Infant Health and the Alliance for Patient Access sought to examine the multifaceted burden that RSV places on families and to identify potential policy solutions.

Two surveys were conducted, one of parents who had at least one child contract RSV and one of health care providers who treat infants and children with RSV.

Both surveys were conducted with YouGov, a global public opinion and data company. Parents and providers were recruited from a pool of pre-selected respondents to ensure they met the survey's requirements. Participants received an honorarium.

RSV PARENT SURVEY

340 parents who had at least 1 child sick with RSV



67% of parents said their child was hospitalized for RSV

RSV HEALTH CARE PROVIDER SURVEY

175 health care providers across various pediatric and neonatal subspecialties



67% worked in an outpatient facility

33% worked in a hospital

RESULTS

FINANCIAL BURDEN

More than ⅔ of parents said the costs of RSV posed a financial burden or financial crisis.

7% of parents said they were fired as a result of caring for their child with RSV.

32% of parents reported losing potential income while their child had RSV.

EMOTIONAL BURDEN

68% of parents said watching their child suffer affected their mental health.

69% of parents felt guilty that they could not do more to prevent their child's RSV.

When parents found out there was no treatment for RSV, only supportive care:

- **48%** felt angry
- **46%** felt helpless

SOCIAL BURDEN

43% of parents had never heard of RSV before finding out their child was sick.

54% of parents had to rely on family and friends for sibling care, transportation and other responsibilities.

42% of parents said they struggled to care for their other children when one faced RSV.

RESULTS

PARENT EDUCATION & AWARENESS

86% of providers said they include RSV education as part of routine care.

99% of providers agreed that parents need more information about RSV.

TREATMENT CHALLENGES

Nearly ⅓ of providers have been reluctant to test for RSV because no treatment exists.

48% of providers said it was difficult to decide whether to send an infant or child with RSV to the emergency room.

92% agreed that if an immunization were available, it should be added to the Vaccines for Children program's list of pediatric vaccines.

MISCONCEPTIONS

A majority of providers (60%) explained that around 50% or more of the babies they see hospitalized for RSV were born healthy, despite many people thinking severe RSV only impacts premature infants or those with preexisting conditions.

CONCLUSION

Both surveys highlighted that the burden of RSV extends well beyond its physical symptoms.

The virus may lead to:

- **Long-lasting health challenges** for babies and young children
- **Financial, social and emotional burdens** for families
- **Frustration for providers,** who lack a cure or viable preventive interventions

This burden is not experienced by the few. Most infants and children contract RSV by the time they are two, and challenges that accompany RSV may impact anyone who has been affected.

Moving forward, the many burdens of RSV demonstrate the need for:

- **More RSV education**
- **Research and innovation** for preventive interventions
- **Access to prevention and treatment** for all babies and children

The challenges caused by RSV can reach far and wide, and its indirect impacts often leave families struggling.

infanthealth.org

Peer Reviewed

Legacy in Action: Coaching Future Leaders Through Apprenticeship

Rody Azar, MHA, RRT-NPS

"If you are ready to transform your leadership legacy by raising apprentices, not just subordinates, read on to discover how to build, guide, and sustain the next generation of leaders."

Abstract:

Effective leadership in today's dynamic environments rests not simply on experience, but on intentional coaching and apprenticeship. This article explores how coaching emerging leaders through structured apprenticeship models foster transferable skills, organizational continuity, and leadership identity. Drawing on scholarly research in leadership education, youth development, and coaching theory, it outlines actionable strategies for embedding coaching-as-apprenticeship within professional settings. Case studies and frameworks highlight how critical reflection, mentor-guided practice, and identity formation synergize to elevate both individual and organizational performance.

Closing teaser: If you are ready to transform your leadership legacy by raising apprentices, not just subordinates, read on to discover how to build, guide, and sustain the next generation of leaders.

Introduction: The Leadership Gap and the Coaching Imperative

Organizations often struggle with leadership continuity, not because of a shortage of talent, but due to the lack of developmental pathways for emerging leaders. Traditional training is often episodic, outcome-focused, and disconnected from real-world work. In contrast, apprenticeship-style coaching integrates on-the-job practice, guided reflection, and mentor scaffolding, offering a more durable model for leadership development. This approach recognizes that leadership is not merely a set of competencies, but a mindset and identity forged over time. The urgency to shift from transactional leadership development to transformational apprenticeship-based coaching is underscored by the increasing volatility of organizational environments, where agile and empathetic leadership is critical. Coaching emerging leaders through apprenticeship enables them to learn by doing, internalize the organization's values, and develop the confidence necessary to lead effectively in complex situations.

Coaching Young Leaders: Foundations and Key Benefits:

Research increasingly supports the idea that coaching has a disproportionate impact when targeted at younger or less experienced leaders. Not only do these individuals exhibit higher growth trajectories in leadership identity and self-efficacy, but they also tend to show increased engagement and retention. Coaching becomes a vehicle for establishing positive habits, fostering psychological safety, and creating alignment with core organizational values at the earliest stages of one's leadership journey. Coaching supports the holistic development of young leaders, improving both their technical capabilities and their emotional intelligence. Moreover, when coaching is introduced early, it becomes embedded in their leadership DNA, making them more likely to coach others in the future. This creates a ripple effect of development, where coaching becomes not just a practice but a cultural norm. Organizations that invest in coaching young talent are investing in a long-term, sustainable leadership pipeline.

Apprenticeship as a Leadership Model:

Unlike ad hoc mentorship, apprenticeships are structured to emulate expert-apprentice learning paradigms found in fields such as medicine or skilled trades. These involve a deliberate, phased progression: observation, participation, leadership with supervision, and finally autonomous execution. Apprenticeships in leadership also emphasize the social construction of leadership identity. Through cycles of feedback and reflective inquiry, the emerging leader gradually integrates personal values with professional expectations. This model positions leadership as an evolving identity, not a static role. Apprenticeship also enables learning from lived experience rather than abstract instruction, reinforcing the importance of real-world exposure, feedback loops, and relationship-based development. It fosters humility in the coach and curiosity in the apprentice, setting the stage for deep trust and mutual growth. Apprenticeships elevate leadership development from sporadic training to an intentional journey of transformation.

"Apprenticeships in leadership also emphasize the social construction of leadership identity. Through cycles of feedback and reflective inquiry, the emerging leader gradually integrates personal values with professional expectations."

Shared and Super-Leadership: **Enabling Young Leaders:**

Shared leadership refers to distributing leadership responsibilities across roles rather than concentrating them in a single position. When younger leaders are empowered to co-lead projects, they not only gain experience but also receive validation as future in-

fluencers. This approach builds confidence, fosters innovation, and enhances team collaboration. Super-leadership, defined by the ability to help others lead themselves, offers another powerful coaching mindset. Rather than creating dependents, leaders cultivate autonomy, encouraging apprentices to develop their own leadership identities and decision-making capabilities. Super-leaders invest in unlocking the potential within others by fostering critical thinking, self-direction, and ownership. These frameworks challenge traditional hierarchical models, favoring instead a collaborative environment where every team member is seen as capable of contributing leadership value. By doing so, organizations not only enhance their leadership capabilities but also foster cultures of empowerment and resilience.

Designing a Coaching-Apprenticeship Program:

Building a coaching-apprenticeship program begins with intentional matching; coaches should be trained not only in their disciplines but also in delivering feedback and reflective questioning. Programs should incorporate a phased structure with clear goals per stage, shadowing opportunities, and assigned leadership responsibilities. Embedding reflection points, journaling, peer discussions, or coach debriefs, creates a feedback-rich environment that accelerates development and reinforces critical thinking. Designing such a program also entails aligning the apprenticeship with the organization's strategy. What leadership behaviors and mindsets are most critical for your future? These should be embedded in coaching conversations, project assignments, and developmental goals. Regular check-ins, performance reviews, and cross-functional exposure can enhance the apprentice's understanding of broader business operations. Moreover, integrating the program into HR and L&D systems ensures sustainability, scalability, and accountability.

"Building a coaching-apprenticeship program begins with intentional matching; coaches should be trained not only in their disciplines but also in delivering feedback and reflective questioning."

Case Examples & Research Evidence:

Data from academic institutions and corporations demonstrate measurable improvements in leadership capability, confidence, and identity when coaching and apprenticeship programs are implemented in tandem. One study found that undergraduates who received leadership coaching outperformed their peers in self-evaluation, initiative-taking, and communication. Similarly, organizations that pair junior executives with seasoned leaders on real-world projects report greater succession readiness and improved cultural continuity. For instance, a healthcare system implemented a year-long leadership apprenticeship for high-potential clinical managers, resulting in a 25% increase in internal promotions and significantly reduced turnover. These examples underscore the power of experiential learning and the trust it fosters between generations. The most impactful programs are those that strike a balance between structure and flexibility, allowing apprentices to stretch while remaining supported. The case for apprenticeship is not just anecdotal; it is data-driven and results-proven.

"Effective metrics include observable behavior changes, feedback from peers and supervisors, and progression into formal leadership roles. Making coaching part of job expectations, and distributing time in calendars and budgets, signals organizational commitment and reinforces its strategic value."

Overcoming Challenges in Coaching Apprentices:

Leaders struggle to find time for coaching or mistakenly default to giving directives. An effective apprenticeship requires a shift in mindset: from command to inquiry, from short-term results to long-term development. Another challenge is the temptation to clone oneself—coaches must resist imposing their exact styles. Instead, they should encourage apprentices to explore and refine their voices, emphasizing authenticity and self-discovery over replication. Leaders must also learn to relinquish control, allowing apprentices to make mistakes, learn, and recover. For the apprentice, imposter syndrome and fear of failure can hinder growth, coaches must be adept at building psychological safety and modeling vulnerability. Lastly, organizational structures must support this effort; when performance metrics favor only short-term outcomes, coaching can be deprioritized. Addressing these challenges requires intention, effective communication, and a commitment across all leadership levels.

Measuring Success and Institutionalizing the Practice:

To sustain apprenticeship models, organizations must define clear metrics of success and integrate coaching into their leadership pipelines. Effective metrics include observable behavior changes, feedback from peers and supervisors, and progression into formal

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leadership roles. Making coaching part of job expectations, and distributing time in calendars and budgets, signals organizational commitment and reinforces its strategic value. Institutionalizing the practice also requires training and support for coaches. Not everyone is naturally equipped to coach; it must be seen as a skill to be developed. Recognition and reward systems can further encourage participation and excellence. Over time, the goal is to normalize coaching-as-apprenticeship as a cultural standard, not a temporary initiative. When embedded deeply, it becomes self-perpetuating: today's apprentices become tomorrow's coaches.

"Coaching young leaders through an apprenticeship approach creates multiplier effects, developing not only leadership skills but also leadership identity, confidence, and organizational continuity."

Action Plan - Six-Month Coaching Apprenticeship Template:

Month	Activity
1	Identify apprentice and coach pair; set mutual goals. Clarify expectations and agree on communication rhythm.
2	Shadowing senior leader in meetings, decision-making, and interpersonal scenarios. Focus on observation and questioning.
34	Apprentice leads small initiatives or portions of projects under supervision. Provide real-time feedback and adjust tasks as needed.
5	Deep reflection session: discussing key learnings, identify growth areas, and recalibrate developmental objectives.
6	Final project debrief: summarize progress, co-create a personal leadership vision statement, and develop a transition roadmap.

This plan is not a rigid template but a guide for phased development. Each month's focus allows for a gradual transition from observation to ownership. Coaches facilitate experiences while ensuring support and reflection. By the end of six months, apprentices should not only demonstrate enhanced skills but also articulate a personal leadership philosophy shaped by feedback and experience.

Conclusion:

Coaching young leaders through an apprenticeship approach creates multiplier effects, developing not only leadership skills but also leadership identity, confidence, and organizational continuity. This shifting paradigm, from managing tasks to growing people, challenges leaders to measure legacy by who they raise, not just what they achieve. Investing in apprenticeship coaching today helps ensure stronger, more adaptive organizations tomorrow. By embracing apprenticeship as a strategic imperative, leaders cultivate a lasting impact, one that extends far beyond their tenure and shapes the trajectory of future generations.

More importantly, the coaching-as-apprenticeship model restores a human-centric ethos to leadership development. It recognizes the power of relationships, trust, and long-term investment in others. It transforms organizations into learning communities, where leaders are not only accountable for business outcomes but also for building capacity in others. The impact ripples outward, from individual apprentices to teams, departments, and entire institutions.

Every seasoned leader has the opportunity —and the responsibility —to create space for others to grow. Leadership, at its best, is not a destination but a legacy to be passed down. Moreover, that legacy is measured not only in profit margins and productivity metrics, but in the readiness, values, and courage of those who follow. Coaching future leaders as apprentices ensures that the mission and values we lead with today endure and evolve through those we mentor tomorrow.

Challenge question: As a leader, are you merely managing today's results, or are you actively shaping tomorrow's leaders through intentional apprenticeship?

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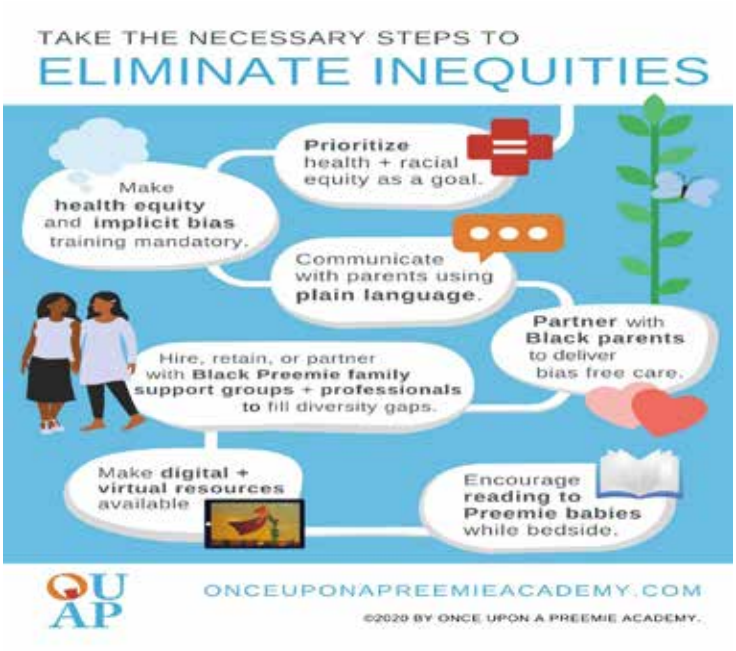
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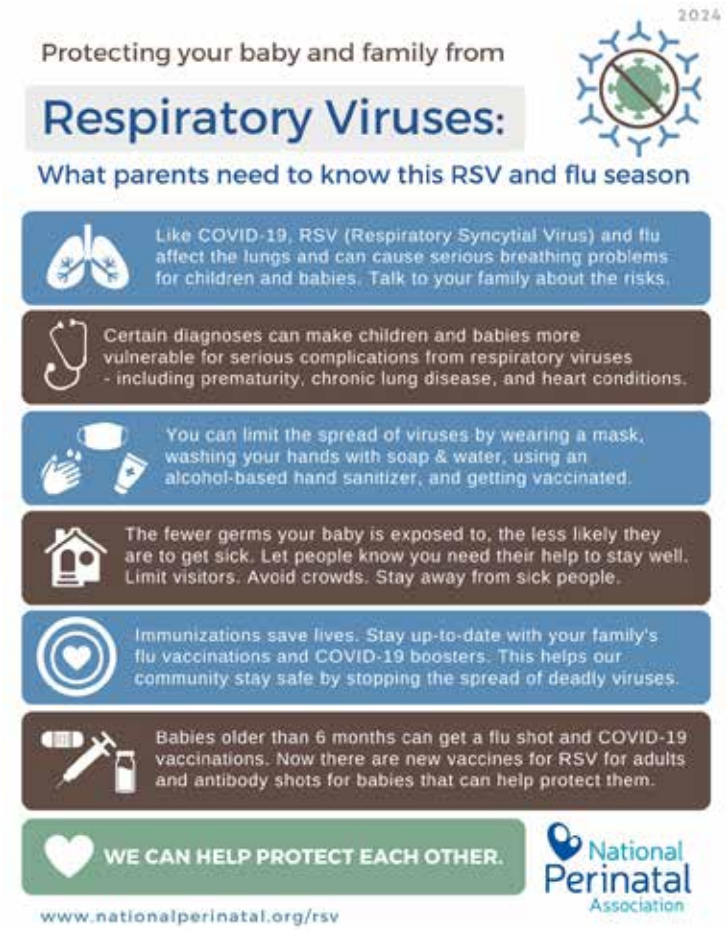
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Rody Azar Bio:

With over 20 years of leadership experience, Rody has a proven track record of driving results and developing high-performance teams. A staunch believer in fostering strong, trusting relationships, he advocates for servant leadership and is passionate about nurturing talent and human asset development. Rody emphasizes the importance of effective people leadership in guiding teams to deliver exceptional results. He has successfully promoted leaders into key mid-management and senior roles, significantly contributing to organizational success and enhancing shareholder value.

Currently, Rody serves as the Vice President of Sales and Clinical at a leading medical device manufacturing company in Orange County, CA. He is also an Organizational Leadership Coach and a faculty member in clinical education. As a proud member of the American College of Healthcare Executives (ACHE) and the American Association for Respiratory Care (AARC), he remains committed to advancing healthcare leadership and education.



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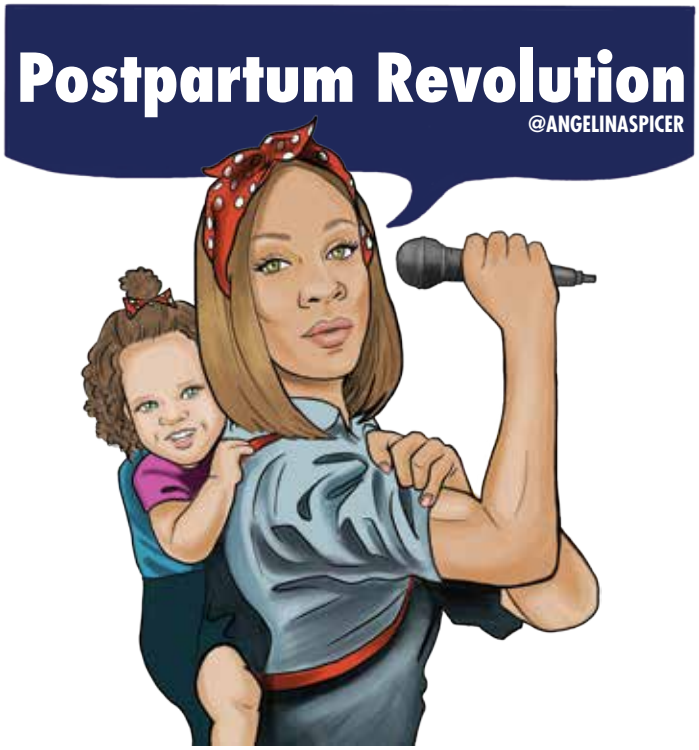
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Ethics and Wellness: Disregarding the Evidence — Physician Retention, a Priority at What Cost?

Mitchell Goldstein, MD, MBA, CML, T. Allen Merritt, MD, MHA

"In our academic neonatal practices, we continually seek the best path for our patients' futures and strive to improve our outcomes. We work hard to achieve this by developing best practices, securing grants, conducting research, and writing manuscripts. Outside influences affect our goal-setting when we see our colleagues leaving for other, better-paying positions."

In our academic neonatal practices, we continually seek the best path for our patients' futures and strive to improve our outcomes. We work hard to achieve this by developing best practices, securing grants, conducting research, and writing manuscripts. Outside influences affect our goal-setting when we see our colleagues leaving for other, better-paying positions. It is challenging to adapt when the metric for success changes, especially when it is modified to meet the requirements of those who are not necessarily as committed or devoted to the group's academic betterment. Decreasing the requirement for success or the benchmark for achievement does not advance academics. Higher pay may incentivize individuals to remain in the group and avoid seeking better-paying, clinical-only positions. However, not requiring an academic standard beyond clinical practice is not the best path. (1-3)

Various philosophical tools have been used to assess the value of improving the situation for group members. Those who initiate the improvement may view this as a Pareto efficiency improvement, where no one is worse off as a result of a change in contract or expectation. A Pareto-optimal outcome occurs when no further improvements are feasible. (4) However, diminishing the reward structure for those who have already achieved it and rewarding everyone else does not feel good for those who have given their all. By analogy, if four hungry people sit down to enjoy a pizza, by Pareto improvement, if one person gets half a pizza, two people get a quarter of a pizza, and one person gets no pizza, it is still an "improvement" for the aggregate. Arguably, the Pareto efficiency improvement outcome is in the eyes of the evaluator, not the one affected by the slight.

"Various philosophical tools have been used to assess the value of improving the situation for group members. Those who initiate the improvement may view this as a Pareto efficiency improvement, where no one is worse off as a result of a change in contract or expectation."

Kaldor-Hicks efficiency occurs when most people in the group experience an improvement in their situation, but some may not see any improvement or may even be worse off. Using the previous example, the person who receives no pizza also pays for the meal. In these circumstances, there is a real risk that those who achieve or dedicate an inordinate amount of time or effort to the academic work product will be undervalued by a global improvement in pay designed to improve physician retention. That is rewarding those who have not contributed to the academic performance and are at risk of leaving due to the allure of a higher-paying clinical-only position. True academics may suffer because the new metric no longer compensates for their efforts or values their abilities. Furthermore, they may perceive that they are being punished because their historical efforts to elevate the group's academic reputation may not be valued in the new metric. (5-7)

"Kaldor-Hicks efficiency occurs when most people in the group experience an improvement in their situation, but some may not see any improvement or may even be worse off."

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"In these circumstances, there is a real risk that those who achieve or dedicate an inordinate amount of time or effort to the academic work product will be undervalued by a global improvement in pay designed to improve physician retention. That is rewarding those who have not contributed to the academic performance and are at risk of leaving due to the allure of a higher-paying clinical-only position."

Worse still, other rules can be changed. There can be a considerable difference between clinical services at different sites. Important considerations in the work environment can be diminished as insignificant. Parity between different clinical sites can be disregarded in the name of retention. (8) Metrics can be wholly redefined to favor a particular service line. Cognitive dissonance reigns when dissimilar work efforts are equated. When the relative value of the work product is diminished only at one clinical site, it is easy to see how Pareto efficiency can be in name only. (9, 10)

"These devoted academicians may have spent years doing everything they could to improve the academic value statement of group team members. This effort is ghosted and devalued by 'improvements' intended to retain without acknowledging the value academics bring."

In essence, while a Pareto optimal outcome is theoretically possible by focusing primarily on improving remuneration, Kaldor-Hicks efficiency is more likely; individuals will suffer, especially those striving to advance the academic prowess of the group. These devoted academicians may have spent years doing everything they could to improve the academic value statement of group team members. This effort is ghosted and devalued by "improvements" intended to retain without acknowledging the value academics bring. Leaving out those who are trying to serve in a mentor role or a role that advances the academic reputation of the group will invariably result in a group with no interest in advancing the state of the art and no mentors who can help them reach the next level. (5, 7, 8, 10)

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Disclosures: The authors have no disclosures

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INFANT AND FAMILY-CENTERED DEVELOPMENTAL CARE (IFCDC)

STANDARDS AND SAMPLE RECOMMENDATIONS FOR INFANTS IN THE INTENSIVE CARE UNIT

SYSTEMS THINKING IN COMPLEX ADAPTIVE SYSTEMS

- Are the baby and family central to the mission, values, environment, practice & care delivery of IFCDC in the unit?
- Are the parents of each baby fully integrated into the team and treated as essential partners in decision-making and care of the infant?
- What are the strategies and measurements used to improve and sustain IFCDC in the unit?

POSITIONING & TOUCH FOR THE NEWBORN

- Are the positioning plans therapeutic and individualized, given the care needs and development of the baby?
- Are the positioning and touch guidelines continually reviewed by the team, including the parents, and adapted to meet the changing comfort needs of the baby?

SLEEP AND AROUSAL INTERVENTIONS FOR THE NEWBORN

- Can the team confidently describe the "voice" or behavioral communication of the baby?
- Are the baby's unique patterns of rest, sleep, and activity documented by the team and protected in the plan of care?

SKIN-TO-SKIN CONTACT WITH INTIMATE FAMILY MEMBERS

- Is the practice of skin-to-skin contact supported and adjusted to the comfort needs of each baby, parent, & family member?
- Are the parents & family members supported to interact with the baby to calm, soothe, & connect?

REDUCING AND MANAGING PAIN AND STRESS IN NEWBORNS AND FAMILIES

- Are parents supported to be present and interactive during stressful procedures to provide non-pharmacologic comfort measures for the baby?
- Are there sufficient specialty professionals to support the wellbeing of the team, including parents, families, and staff? Examples include mental health, social, cultural, & spiritual specialists.

MANAGEMENT OF FEEDING, EATING AND NUTRITION DELIVERY

- Are the desires of the m/other central to the feeding plan? Is this consistently reflected in documentation with input of the m/other?
- Does the feeding management plan demonstrate a feeding & nutrition continuum from in-hospital care through the transition to home & home care?

WANT TO KNOW MORE ABOUT THE STANDARDS AND RECOMMENDATIONS?
VISIT: HTTPS://NICUDESIGN.ND.EDU/NICU-CARE-STANDARDS/

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Procedural Pain Management in Full-Term Newborns: An Innovative Nurse Intervention

Raouth R. Kostandy, PhD, MSN, RN, CKC.

"All healthy full-term newborns face multiple painful procedures immediately after birth. This is part of the routine care provided. Full-term newborns are capable of feeling and responding to pain as their cortical and subcortical networks' structural and functional development occurs during the gestational period."

Abstract:

All healthy full-term newborns face multiple painful procedures immediately after birth. This is part of the routine care provided. Full-term newborns are capable of feeling and responding to pain as their cortical and subcortical networks' structural and functional development occurs during the gestational period. Unmanaged and repeated pain can lead to negative consequences. Crying, altered behavioral states, increased heart rate, and decreased oxygen saturation levels are examples of the documented short-term pain responses. To manage these painful procedures, non-pharmacological interventions are recommended. Nurses implement these non-pharmacological interventions as part of the care for newborns. Thus, nurses play a special role in the care of these newborns at this sensitive period of life. Although these established non-pharmacological interventions may not be used due to different reasons, nurses can be innovative and develop interventions that work for their patients and themselves. This report aims to describe one innovative nurse's intervention that she developed and practiced with all newborns she cared for.

Keywords: *Full-term newborns, painful procedures, and nurse interventions.*

Introduction:

As part of their routine care, healthy full-term newborns are exposed to painful procedures. These include injections, heel-sticks, routine screenings, and circumcision (1). Although most of these interventions seem to be mild, painful procedures, they cause severe enough pain that newborns exhibit pain responses. These pain responses range from behavioral responses, such as grimacing and crying, to altered behavioral states, as well as physical responses, including increased heart rate, respiratory rate, and decreased oxygen saturation levels (2). In addition, these painful procedures occur shortly after birth at a "sensitive period" in the newborn's life, which can lead to long-term effects if not managed effectively. To manage these painful procedures, non-pharmacological interventions are mainly used. It is the nurse's responsibility to consistently use effective interventions to provide optimal pain management to these vulnerable newborns. Thus, the purpose of this article is to describe one nurse's innovative intervention to manage newborns' clustered procedural pain.

"To manage these painful procedures, non-pharmacological interventions are mainly used. It is the nurse's responsibility to consistently use effective interventions to provide optimal pain management to these vulnerable newborns."

Literature Review:

Routine painful procedures are a part of the very early lives of healthy newborns (3,4,5). Although these procedures are conducted to ensure a healthy start for the newborn and are recommended by various agencies, such as the American Academy of Pediatrics (6), they can be painful and stressful (1). These painful procedures include injections for Vitamin K and immunizations; heel-sticks for newborn screen (NBS), bilirubin testing, and blood sugar testing; and hearing, sight, and Critical Congenital Heart Defect [CCHD] testing. In addition, male newborns get circumcised within 48 hours after birth if their parents request. Full-term newborns can recognize and respond to painful procedures because the pain connectome forms early in gestation (7). Short-term pain responses encompass a range of physiological changes, behavioral expressions, and neuroendocrine alterations. Physiologically, newborns exhibit a range of immediate reactions when subjected to painful stimuli. Painful procedures lead to rapid increases in heart rate, a decrease in peripheral oxygen saturation (SpO2), and other autonomic changes, such as sweating, particularly in term newborns (8). In addition, these interactions underscore the complex neurobiological processes activated in response to pain, including changes in metabolic rate that can exacerbate injury by leading to increased oxygen consumption, delayed wound healing, and heightened risk of infection (9,10). Such physiological changes suggest that pain responses are closely tied to the newborn's overall stability and health, as described by Waxman et al. (2016), who noted that acute pain responses in newborns can be measured through cardiovascular indices. Behaviorally, pain in newborns is often indicated by nonverbal cues, including crying,

grimacing, or changes in sleep patterns (11,12). That is why the assessment of pain in newborns often relies on scales that measure these behavioral responses, which have been validated through clinical observations. Neuroendocrinologically, the activation of the stress response pathway occurs alongside these physiological and behavioral responses. Melchior et al. (2021) outlined how painful stimuli can lead to the immediate activation of the hypothalamic-pituitary-adrenal (HPA) axis, resulting in the secretion of stress hormones, such as cortisol, which can have lasting effects on both the pain response systems and overall brain development. Furthermore, research has suggested that repetitive painful exposures in the neonatal period could modify the neurodevelopmental trajectory, influencing pain reactivity and immune system responses over time (6,14). Understanding the implications of these painful experiences is critical, as early-life exposure to pain can lead to altered pain sensitivity and adverse neurodevelopmental outcomes later in life.

"Understanding the implications of these painful experiences is critical, as early-life exposure to pain can lead to altered pain sensitivity and adverse neurodevelopmental outcomes later in life"

The concept of a "sensitive period" in a newborn's life refers to specific developmental windows during which certain experiences or exposures can have profound and lasting effects on the newborn's development. These periods are characterized by heightened neural plasticity (5), making newborns more susceptible to experiencing long-term effects of painful procedures. Valeri et al. (2016) reported that exposure to multiple painful procedures during the neonatal period altered school-aged children's venipuncture self-rated pain. Thus, it is imperative to use effective non-pharmacological pain management interventions. The safety and efficacy of many non-pharmacological interventions have been established (4). Examples of such non-pharmacological interventions include Kangaroo Mother Care, breastfeeding, sucrose, non-nutritive sucking, and breast milk. Most of the painful procedures that newborns are exposed to are performed by nurses through their daily care of these newborns. Thus, nurses play a crucial role in recognizing and managing painful procedures.

The Intervention:

The following is the step-by-step procedure that one innovative nurse developed and practiced with all newborns under her care during their clustered painful procedures. The clustered painful procedures included a heel stick for newborn screening (NBS), a bilirubin check (if necessary), and a Hepatitis B vaccine injection. All newborns were healthy full-term on the mother-baby unit in an urban hospital. This nurse always performed the heel stick first because she stated that all newborns cry when they get the injection. Thus, by keeping the more painful procedure last, she avoids prolonged pain periods and enhances recovery after these clustered painful procedures.

"The following is the step-by-step procedure that one innovative nurse developed and practiced with all newborns under her care during their clustered painful procedures. The clustered painful procedures included a heel stick for newborn screening (NBS), a bilirubin check (if necessary), and a Hepatitis B vaccine injection."

1. The nurse begins by providing the mother with information on the procedures that will be performed and explaining what she will do.
2. Take the newborn to the nursery in their crib. Mothers can be present if they choose. Some mothers choose to stay in their rooms to rest or shower.
3. Place the newborn in a dim, quiet room of the nursery.
4. Then, the nurse wraps the newborn tightly in two warm blankets, keeping one foot easily accessible. The usual practice used in this clinical setting is to select the opposite foot from which the Vitamin K injection was given.
5. Then she wraps a warm pad around the heel, which she will use to obtain the blood sampling to encourage more blood flow to the heel. Then, cover that foot loosely.
6. She raises the head of the crib about 30 degrees to allow more blood to flow to the heel.
7. The nurse leaves the newborn undisturbed for about five to ten minutes to allow them to relax.
8. After that time, she exposes the heel (not the whole leg to keep the newborn warm), removes the warm pad, and lances the heel to collect the needed blood.
9. Blood collection includes NBS, bilirubin, and glucose check (if needed).
10. Then she wraps the heel with gauze.
11. Next, she uncovered the newborn's thigh to give the Hepatitis B vaccine injection.
12. She wipes the skin with an alcohol swab, gives the shot, and applies a bandage if needed.
13. Then, cover the leg back and lower the head of the crib.
14. After the procedure is completed, the nurse returns the newborn to the mother's room and addresses any questions the mother may have.

Practice Implications and Recommendations:

This innovative nurse developed and practiced this intervention to provide the best care for the newborns under her care. Sometimes, mothers are not available to provide KMC, and to this nurse, this is the second-best intervention she has found to help manage the newborn's pain. She stated that using pacifiers only or with a sweetener was not helpful, as newborns usually drop them when they start crying. She had to keep putting the pacifier back into the newborn's mouth, which was not practical most of the time due to her hands being occupied with blood sampling and injection procedures. This nurse always wraps newborns in two warm blankets. Gray et al. (2015) reported that newborns who were only wearing a diaper, placed under a warmer, and given 1 mL of 24% sucrose solution two minutes before receiving a Hepatitis B vaccine injection experienced 50% less crying and grimacing than newborns who received sucrose only. The heart rate increased in both groups; however, the sucrose-only newborns had a significantly higher heart rate. Sucrose-only newborns' heart rate increased about 20 beats per minute, but the sucrose plus warmer newborns' heart rate increased about 11 beats per minute. This could explain the calming behaviors that newborns displayed during the clustered pain procedures. This author witnessed eight newborns undergoing this intervention; they were calmer and cried less than other newborns on the same unit who did not receive this intervention.

"Nurses are perfectly positioned to provide the optimal care for these newborns. Nurses are present from the moment a newborn takes their first breath until discharge; they are there during this sensitive period of human life. They are also there to teach and educate the mother on all aspects of care for their newborn. Thus, nurses should be encouraged to develop appropriate care practices that will advance the care for their patients."

Nurses are perfectly positioned to provide the optimal care for these newborns. Nurses are present from the moment a newborn takes their first breath until discharge; they are there during this sensitive period of human life. They are also there to teach and educate the mother on all aspects of care for their newborn. Thus, nurses should be encouraged to develop appropriate care practices that will advance the care for their patients. Nurse managers can support bedside nurses by having open communication and listening to nurses' feedback and suggestions. Additionally, I advocate for nursing education and training, particularly in the use of non-pharmacological interventions for pain management. Although non-pharmacological interventions are highly recommended for procedural pain management, they are not consistently utilized (16,17). Hospital administration should acknowledge and recognize nurses for their innovations. Administrators can develop policies that enable nurses to share their skills and practices with other nurses and healthcare team members across the institution, as well as on a national or international level, through presentations at various conferences. New nurse interventions must be validated through research studies to document their efficacy and dissemination for use on a large scale.

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Disclosures: *The authors have no disclosures*

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Brilliant! Dr. Bell bridges the journey from grief to growth. This is classic wisdom on healing from our heartbreaks and ultimately enjoying a fulfilling life.

– Christine Theard, M.D.

Post-Traumatic Thriving

The Art, Science, & Stories of Resilience



Randall Bell, Ph.D.

First Candle: Darryl's Story Is Why The ISPID Conference Matters – Come Be Seen, Heard, and Held

Alison Jacobson

first candle

Saving babies. Supporting families.

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

"June is National Safety Month, and it is the perfect time to share a few key tips to help keep babies safe while they sleep. At First Candle, we understand how overwhelming all the advice can be, so we keep it simple: safe sleep saves lives."

Darryl Hano's world changed the day his daughter was born — and again the day she died.

In this moving video, Darryl opens his heart about the devastating loss of his baby and why he is speaking out now. His story is raw, honest, and full of love — and it is just one of many you will hear during the 2025 International Conference on Stillbirth, SIDS, SUID/SUDI & SUDC (ISPID), hosted virtually October 8 – 10 by First Candle.

Click on the image below to watch Darryl's video, or paste the link in your browser.

https://vimeo.com/1088110739

"We are here to help make safe sleep simple. These small changes can make a huge difference—and give you peace of mind while your baby rests."

Why attend?

- **Be together with researchers, professionals, advocates, and parents**
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- **Join from anywhere in the world**
- **"Chat with a Researcher": Real-time conversations with leading experts**
- **Three days of virtual programming — no travel or time off required**
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- **Parents: A deeply meaningful Memorial Service to honor your baby's life**

Featured Parent Sessions:

- *From Grief to Action: A Parent's Guide to Advocacy, Impact, and Creating a Legacy*



- *Debunking Myths on Grief*
- *Creative Outlets for Coping*
- *Strong and Silent? Exploring Fathers' Grief and Healing After Loss*
- *Living in the Shadow, Shining in the Light: Siblings Share Their Stories …and more.*

Register today HERE and be part of a global movement for research, healing, and remembrance.

Darryl's story is one of love, pain, and a sense of purpose. If you see yourself in it, know someone who does, or simply need a space where your grief is understood, we invite you to join us.

Disclosure: *The author is the Executive Director and Chief Executive Officer of First Candle, a Connecticut-based not-for-profit 501(c3) corporation.*

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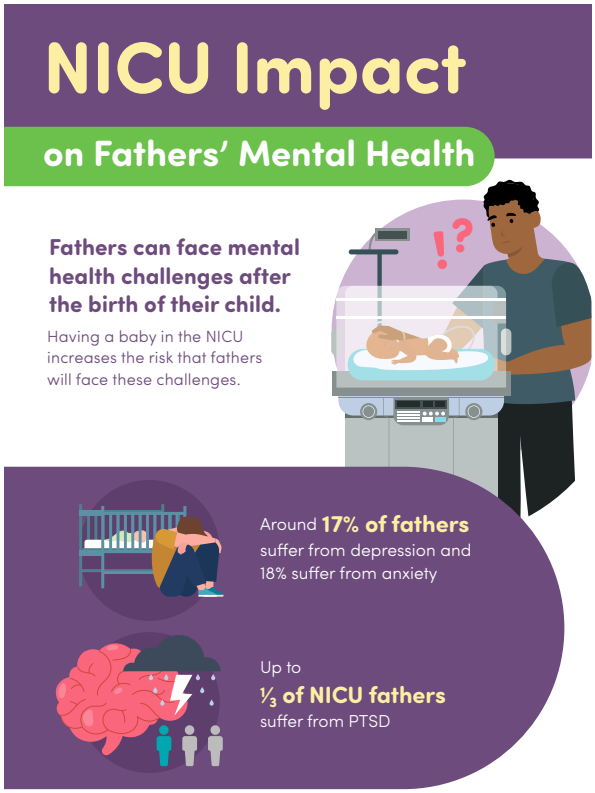
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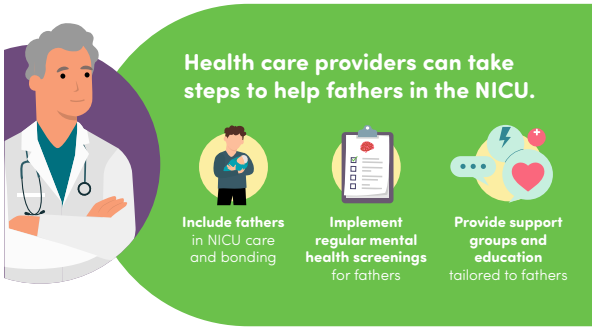
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About First Candle:

First Candle, based in New Canaan, CT, is a 501c (3) committed to eliminating Sudden Unexpected Infant Death while providing bereavement support for families who have suffered a loss. Sudden Unexpected Infant Death (SUID), which includes SIDS and Accidental Suffocation and Strangulation in Bed (ASSB), remains the leading cause of death for babies one month to one year of age, resulting in 3,700 infant deaths nationwide per year. It is also the host of the 2025 International Society for the Study and Prevention of Perinatal and Infant Death (ISPID) Conference in Houston from October 7 – 10.









Maternal Vaccines:

WHAT YOU NEED TO KNOW

CDC-Recommended Vaccines for Pregnant Women

	COVID	FLU	RSV	TDAP
Does it protect baby?	+	+	+	+
Does it protect mother?	+	+		
Is there an immunization for baby after birth?			+	

Vaccines given to pregnant women **are safe and effective.**

Maternal vaccines help the body create antibodies that can be passed to your baby and help protect them when they are born.

Talk with your health care provider to learn more about protecting yourself and your baby.

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NATIONAL COALITION for Infant Health

Telehealth in the NICU

The thoughtful use of telehealth technology can improve care and minimize the risks of exposure to COVID-19.

- Consult with specialists.
- Move family education and resources online.
- Use technology to help parents bond with their babies when they can't be bedside.
- Provide parents lactation support.
- Facilitate shared decision-making.
- Screen for perinatal mood and anxiety disorders (PMADs).
- Support case management.

The move to telehealth services can compound inequities and disparities. Assess each family's technology skills and needs - including the need to use their preferred language.

My Perinatal Network and My NICU Network are products of a collaboration between National Perinatal Association (NPA) and NICU Parent Network (NPN).

myNICUnetwork.org

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Advancing Neonatal-Perinatal Care: July Update: Your More-Than-Monthly #SONPM date

Clara H. Song, MD, FAAP

"Your more-than-monthly update from SONPM to keep us all connected and informed!"



1 – SONPM Member Shout-Out

We're thrilled to recognize **Sheri Nemerofsky, MD** from *Albert Einstein / The Children's Hospital at Montefiore*! Dr. Nemerofsky is a neonatal intensivist, a national leader in newborn coding, and the newly appointed **Chair of the** **AAP Committee on Coding and Nomenclature (COCN)**. Congratulations, Sheri!

2 – AAP Leadership Conference: Your Voice Matters!

The **AAP Leadership Conference** is right around the corner, and **online comments are open until July 18**. This is where AAP Leadership votes on the annual Top 10 Resolutions, which will be recognized by the AAP Board.

SONPM has one official vote per resolution—so make yours count!

Our section sponsored **Resolutions #1, #61, and #62** (with TECaN leadership).

How to Review & Comment:

- All **2025 Resolutions** are now posted on the **Leadership Conference website**.
- Members can comment online from **June 30 to July 18**.
- New to Webex? Instructions for registering, downloading, and participating are available. You can also request a practice session by contacting **Jonathan Faletti** at jfaletti@aap.org or 630-626-6752.

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3 – Webinar Highlight: "Are Children Small Adults?"

SONPM WiN and **FLEXpeds** co-hosted a June 2025 webinar with **Drs. Satyan Lakshminrusimha** and **Robin Steinhorn** comparing adult vs. pediatric productivity.

Key takeaway:

"Ultimately, payor reform will be needed to sustain growth in subspecialty compensation." — Robin & Satyan

Watch the recording

4 – Post-Webinar Reading

Pediatric Subspecialty and Research Workforce in the US: Is it Time for an Emergency Federal Transfusion?

5 – Medicaid Advocacy Podcast

Referenced in the above webinar: a must-listen conversation with our SONPM advocacy leader **Dr. Shetal Shah (@NICUbatman)**
#319 – Medicaid at a Crossroads: What Neonatologists Need to Know

6 – ICYMI: Resuscitation Guidelines

From the AAP & AHA: *Considerations on the Use of Neonatal and Pediatric Resuscitation Guidelines for Hospitalized Neonates and Infants*
Read here

7 – HRSA Pediatric Specialty Loan Repayment Program Update

Big news for fellows: **HRSA** has clarified eligibility requirements!

- Research hours do **not** count toward the required 144 clinical hours/month.
- Fellows can extend their service to meet the requirements.
- Many fellows not on a research track are now eligible—**apply now!**

Clarification secured by the AMSPDC Pediatric Workforce Initiative (as of 7/9/25).

8 – SONPM Recognition Committee Contest

Help us honor newly retired neonatal intensivists!
Design a **retirement recognition medal** and submit your entry by **August 1** to lilylou@mindspring.com.

9 – 2025 SONPM Awardees & NCE Preview

📅 **September 27, Denver, CO** – **SONPM h-Program at NCE**
Theme: *Neonatal Pain: Management and Effects on the Developing Brain*

Awards:

- **Virginia Apgar Award** – Dr. Satyan Lakshminrusimha (UC Davis)
- **Avroy Fanaroff Education Award** – Dr. Heather French (CHOP)
- **Maria Delivoria-Papadopoulos Landmark Award** – Dr. Rich Molteni (University of Washington, Joint Commission)
- **Pioneer Award** – Dr. Jeffrey Perlman (Cornell University)

Membership Supports:

- Travel grants for top 10 trainee abstracts
- Marshall Klaus Research Awards & other grants
- Young Investigator Awards

Payment Parity Focus 2024–2026

Our current SONPM advocacy goal—**fair payment for neonatology services**—is directly aligned with the **AAP Payment Transformation Agenda**:

Fair payment ➞ improved salary/FTE ratio ➞ better staffing ➞ less burnout ➞ stronger workforce ➞ sustainable profession.

♡ **Until next time, your SONPM Executive Committee is here for you!**

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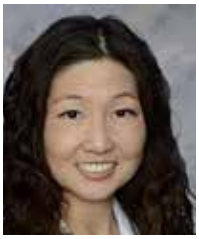
With warm regards,

Clara H. Song, MD, FAAP

Disclosures: No conflicts noted

NT

Corresponding Author



Clara H. Song, MD, FAAP
Neonatal Intensivist, Southern California Permanente Medical Group
Chair Elect, Communication & Digital Media Chair; Women In Neonatology Steering Committee, All Pathways group Co-Chair: District IX California Chapter 4 Council Representative,
Chair, American Academy of Pediatrics, Section on Neonatal-Perinatal Medicine
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HELP US HONOR A LIFETIME OF DEDICATION TO NEONATOLOGY

SONPM Design Contest

- We are starting a new program to recognize retiring neonatologists who have had career-long impacts
- Honorees will be recognized at the Workshop on Neonatal-Perinatal Practice Strategies, showcased in the Neonatology Hall of Honor (Itasca headquarters), honored at a reception and presented with a medal
- Your design can be featured on our career medal!
  - Submit designs in pdf format
  - Front and back designs can be submitted
  - Send to lilylou@mindspring.com, subject line: "Neonatology Career Medal"
  - Deadline: August 1, 2025



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Call for Nominations!

Section on Neonatal-Perinatal Medicine Executive Committee: District Representatives from Districts III, VI, and IX

One of the most significant opportunities to engage with the Section on Neonatal-Perinatal Medicine (SONPM) is to serve on the SONPM Executive Committee (EC). The EC consists of one representative from each of the 10 AAP Districts, in addition to chair, chair-elect, past-chair, of-counsel advisor, and AAP section manager (currently Jim Couto). District representatives serve 3-year terms, and are eligible to serve a second term.

District representatives to the EC are responsible for representing all neonatologists working in their AAP districts. The district representative is a liaison between district neonatologists and the SONPM, providing members direct input into SONPM and conveying section activities and opportunities back to the members. More specifically, responsibilities of EC members include the following:

Within executive committee and SONPM broadly:

1. Attend two **required** EC meetings annually, at Scottsdale spring workshop and at NCE;
2. Attend the full SONPM program at Scottsdale spring workshop and NCE meetings annually;
3. Participate in periodic virtual SONPM EC meetings (generally once or twice per month);
4. Review and score abstract submissions to NCE and review poster and oral presentations at NCE meeting, including scoring for SONPM Young Investigator Award;
5. Suggest and select annual SONPM honorary lecturers, including the Cone, Merenstein, Butterfield and Silverman speakers;
6. Solicit and review nominations for annual SONPM awards, including the Apgar, Education, Landmark and Pioneer awards, and select awardees;
7. Participate in planning and execution of national meetings, including section program at NCE, Scottsdale conference, and NeoPREP;
8. Review applications and determine awardees for the Section Strategic Grant Program, currently offered every two years;
9. Review and provide feedback on AAP policy statements, clinical reports, and guidelines as they pertain to newborn care;
10. Participate in and support AAP and SONPM advocacy efforts, including AAP Days of Action;
11. Participate in section committees, groups, and task forces based on interest and need;
12. Participate in SONPM strategic leadership, including implementation of goals of strategic plan; and
13. Participate in SONPM administration, including maintenance and updating of section manual of operations and section budget planning.

Within district:

1. Solicit updates from district members for inclusion in section newsletter twice annually;
2. Allocate annual SONPM district grants by soliciting and evaluating grant proposals;
3. Provide regular updates to district members on relevant aspects of section activities;
4. Provide regular updates to section on district activities and needs of district members;
5. Actively participate in district activities, including attendance at regional conferences; and
6. Encourage AAP and SONPM membership from representative's district, including trainees.

The core executive committee is a productive group! Participation on the executive committee does require a commitment of time and effort, but it is a highly rewarding experience.

Letters to the Editor

Letter to the Editor: "Retinopathy of Prematurity—Targeting Hypoxic and Redox Signaling Pathways"

Dear Editor,

"Retinopathy of Prematurity—Targeting Hypoxic and Redox Signaling Pathways" by Zhang et al (2024) is a review of the pathophysiological mechanisms of retinopathy of prematurity (ROP) as well as its current and novel therapeutic options. ROP is a proliferative vascular eye disease of the retina that may result in permanent vision loss if left untreated. ROP is often seen in infants born prematurely, particularly those who are very preterm (VPT) and very low birth weight (VLBW). Given the advancements in neonatal screening and improved survival among VPT and VLBW infants, there is an increased incidence, making it an important area of research for both neonatology and ophthalmology. The article provides a comprehensive look at the signaling pathways, thereby providing a nuanced understanding of ROP progression and treatment targets.

"Given the advancements in neonatal screening and improved survival among VPT and VLBW infants, there is an increased incidence, making it an important area of research for both neonatology and ophthalmology. The article provides a comprehensive look at the signaling pathways, thereby providing a nuanced understanding of ROP progression and treatment targets."

While the authors compellingly describe the redox signaling in ROP and emerging potentially therapeutic molecular targets, future work should include data or discussion on how the pathways influence disease severity or treatment response in order to enhance their applicability. For example, Vitamins C and E are touched upon in the context of antioxidant therapy; however, the clinical correlation is limited. It does not provide an in-depth analysis of the current clinical applications, dosing, or long-term outcomes related to vitamin therapy in ROP management. Furthermore, the focus of the article was more pathophysiological, but it would have been beneficial to have a greater discussion of the potential impacts of the proposed therapeutics on retinal structure, given that retinal detachment is a classified stage of ROP. Retinal scarring and fibrous proliferation are known to cause traction on the retina, which increases the lifetime risk of tractional retinal detachment. Therefore, discussion on the length of follow-up would directly tie in with long-term outcomes.

"Furthermore, the focus of the article was more pathophysiological, but it would have been beneficial to have a greater discussion of the potential impacts of the proposed therapeutics on retinal structure, given that retinal detachment is a classified stage of ROP. Retinal scarring and fibrous proliferation are known to cause traction on the retina, which increases the lifetime risk of tractional retinal detachment. Therefore, discussion on the length of follow-up would directly tie in with long-term outcomes."

The article does mention that long-term use of anti-VEGF therapy is unclear. This is a fair statement; however, further discussion of what past studies have shown would provide a more comprehensive look at the clinical outcomes of VEGF. Furthermore, there was limited discussion on how the modulation of hypoxic and redox pathways may impact long-term visual outcomes in infants with ROP. Given that ROP affects a very vulnerable population, i.e., preterm infants, long-term safety and efficacy should be an essential consideration. In particular, exploring visual development from childhood to adolescence would provide a better understanding of the potential of these mentioned therapeutics.

"Furthermore, there was limited discussion on how the modulation of hypoxic and redox pathways may impact long-term visual outcomes in infants with ROP. Given that ROP affects a very vulnerable population, i.e., preterm infants, long-term safety and efficacy should be an essential consideration. In particular, exploring visual development from childhood to adolescence would provide a better understanding of the potential of these mentioned therapeutics."

In conclusion, this review provides a valuable foundation for understanding the redox and hypoxic pathways involved in ROP and introduces promising directions for therapeutic development.

However, a greater emphasis on clinical correlation, long-term outcomes, and interdisciplinary integration would enhance its translational relevance. As research in this area progresses, bridging molecular mechanisms with patient-centered outcomes will be essential. I commend the authors for their contribution and encourage continued exploration of these complex, clinically impactful pathways.

Best Regards,

Aelita Petrosyan

OMS III

Western University

References:

1. Zhang L, Buonfiglio F, Fieß A, Pfeiffer N, Gericke A. Retinopathy of Prematurity-Targeting Hypoxic and Redox Signaling Pathways. Antioxidants (Basel). 2024;13(2):148. Published 2024 January 25. doi:10.3390/antiox13020148

2. Fierson WM. Retinopathy of prematurity: Treatment and prognosis. UpToDate. Waltham, MA: UpToDate Inc. Accessed April 21, 2025. https://www.uptodate.com/contents/retinopathy-of-prematurity-rop-treatment-and-prognosis

Editor's Response

I thank Aelita Petrosyan for her careful and constructive review of "Retinopathy of Prematurity—Targeting Hypoxic and Redox Signaling Pathways" by Zhang et al. Your comments thoughtfully highlight both the strengths of the review and the opportunities to strengthen its translational impact.

We agree that Zhang and colleagues have presented a comprehensive and well-structured synthesis of the molecular underpinnings of ROP, particularly in the context of hypoxic and redox signaling. Their work adds valuable clarity to a pathophysiological landscape that is often discussed in fragmented detail. Your emphasis on the importance of linking these mechanistic insights to measurable clinical outcomes is well-taken, especially for a condition that affects such a vulnerable patient population.

The points raised regarding the role of antioxidant therapies, such as vitamins C and E, underscore the need for a deeper integration of current clinical trial data, including considerations of dosing, timing, and the complex balance between benefit and risk in preterm infants. Similarly, your call for more discussion of the structural consequences of advanced ROP—such as scarring, fibrous proliferation, and tractional retinal detachment—reminds us that therapeutic efficacy must be evaluated not only by halting neovascularization but also by preserving long-term retinal integrity and visual function.

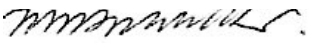
Your observations about anti-VEGF therapy echo ongoing debates in both neonatology and ophthalmology regarding durability, safety, and neurodevelopmental impact. A richer exploration of the existing literature on these long-term outcomes would indeed complement the authors' mechanistic focus, as would consideration of visual development trajectories from infancy through adolescence.

We especially appreciate your concluding point on the necessity of bridging molecular mechanisms with patient-centered outcomes. Future work in this area will benefit from multidisciplinary collaboration, bringing together molecular scientists, neonatologists, pediatric ophthalmologists, and long-term follow-up specialists, to ensure that emerging therapies are not only biologically sound but also clinically meaningful throughout the lifespan.

I thank you for your thoughtful engagement with this topic and for advancing the dialogue on how to translate mechanistic insight into lasting improvements in care for preterm infants at risk of ROP.

With the most profound respect and encouragement,

Sincerely,



Mitchell Goldstein, MD, MBA, CML

Editor in Chief

NEONATOLOGY TODAY

Loma Linda Publishing Company

A Delaware "not for profit" 501(c) 3 Corporation.

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© 2006-2025 by Neonatology Today ISSN: 1932-7137 (online)

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Erratum (Neonatology Today June, 2025)

Dr. Hopkins interview with Dr. Modanlou has several corrections.

They are:

1. Sydenham Children's Hospital in London

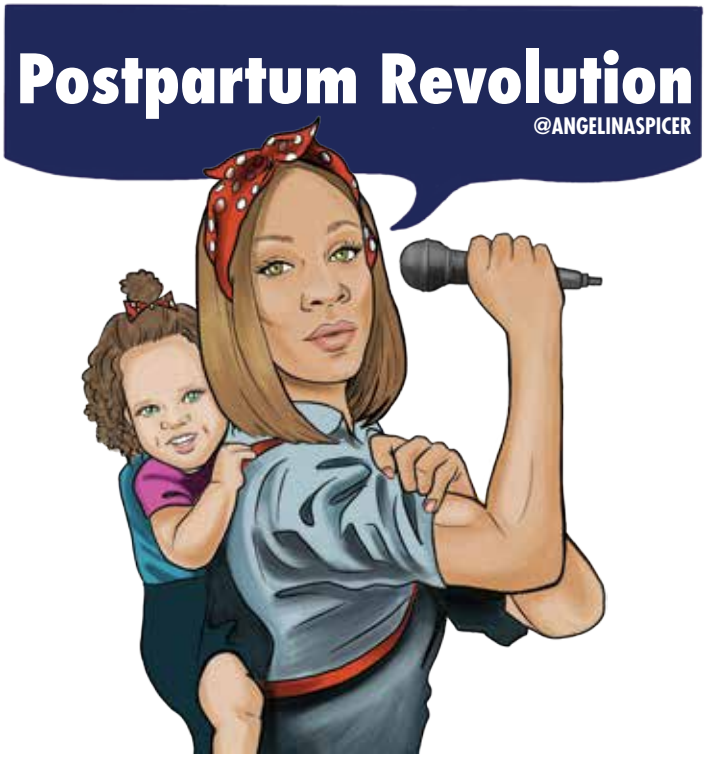
2. Green Journal of "Obstetrics and Gynecology"

3. Dr. Quilligan, Then the Chairman, Department of OB/GYN at USC

4. Dr. Hon (Edward Hon). The pioneer in developing Electronic Fetal Monitoring

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

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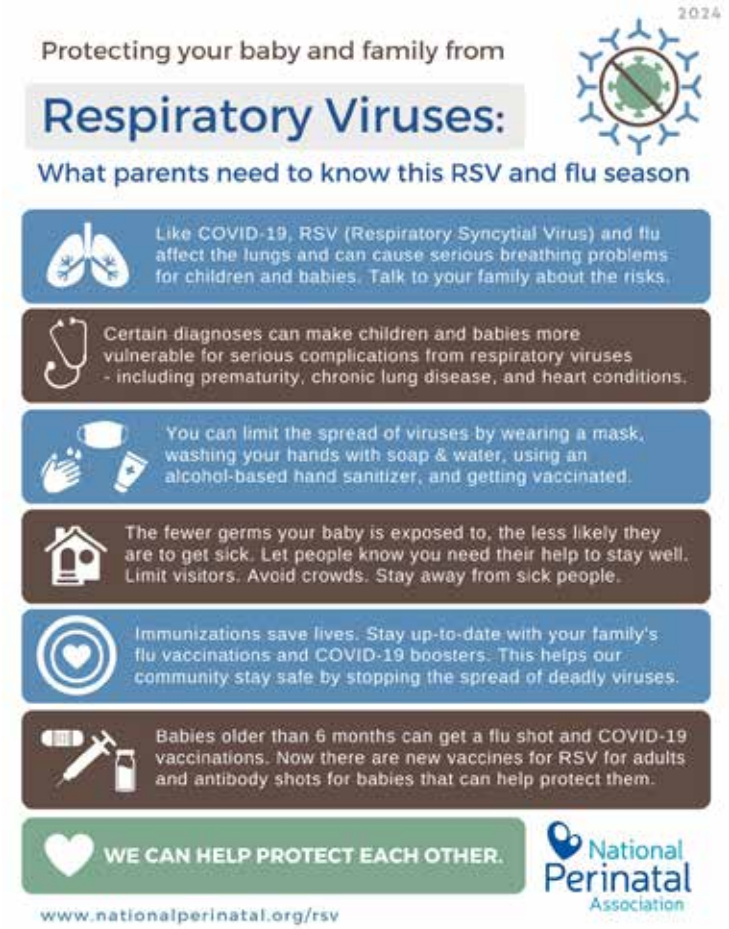
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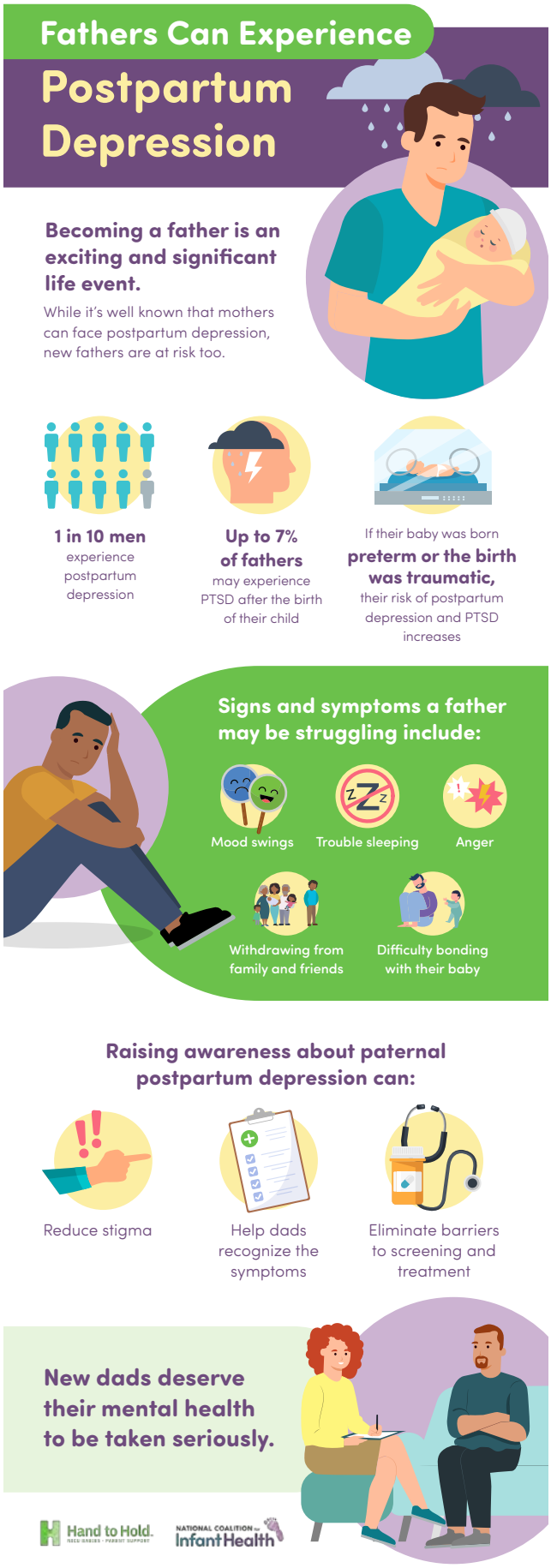
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Gravens by Design: Healthcare Decarbonization, Health Equity, the NICU and You! What Should We Know? What Can We Do?

Troy Savage, Christina Vernon Sanborn

1 Abstract:

The World Health Organization has named climate change as the greatest threat to public health. In the United States, the healthcare sector accounts for 8.5% of greenhouse gas (GHG) emissions. Neonatal Intensive Care Units (NICUs) and the patients and families who rely on their medical interventions and overall guidance are uniquely impacted by climate change. So, what should NICU professionals know, and what should NICU professionals do? NICU clinicians and designers should recognize that healthcare contributes to climate change, which in turn worsens health issues, especially for vulnerable groups affected by social determinants of health. NICU professionals are well-positioned to understand and influence health equity, having participated in related efforts. Insights gained from addressing health equity can inform strategies for approaching climate change. Individuals should advocate within their organization for climate-forward policies and can counsel patients on climate-forward behavior, implementing education programs where possible. NICUs can transition to reusable surgical gowns and linens safely.

Additionally, NICU professionals should advocate for decarbonized building systems whenever new construction or renovations are proposed. Hospitals should advocate for integrating sustainability into their operations and culture. Decarbonization plans should be developed and implemented to reduce climate impacts. Healthcare systems should strive to decarbonize their operations and also consider influencing their supply chain. The NICU has a unique opportunity to make a difference.

"The World Health Organization has named climate change as the greatest threat to public health. In the United States, the healthcare sector accounts for 8.5% of greenhouse gas (GHG) emissions."

2 Introduction:

Our most difficult and stressful challenges all end up at the hospital, and especially in the Neonatal Intensive Care Unit. NICU professionals, such as neonatologists, nurses, therapists, administrators, environmental services staff, and facilities staff, intimately know the details of their most challenging cases. The impact on families is profound. (1–3). Families do not want others to experience what they have experienced.

Nevertheless, climate change exacerbates health challenges and may ultimately lead to increased NICU admissions (4, 5), This represents a vicious cycle: providing NICU care produces carbon emissions that lead to environmental harm, which in turn increases NICU admissions. The implications are clear. The NICU must deliver excellent care while reducing its environmental footprint. NICUs, in particular, have a moral imperative and an opportunity to minimize carbon and other environmental impacts. To achieve this goal, what should neonatologists know, and how can they help?

This paper provides an informational overview, citing literature on the climate crisis, the role of healthcare, and the role of the NICU in contributing to the crisis. It briefly considers health equity as a model for both how societal challenges impact the NICU and how NICUs have responded to address these challenges. Then it identifies some practical ways NICUs can reduce their impact on climate change while buttressing the resilience of the patients and families they serve.

3 What You Should Know

3.1 Humans Impact Climate Change

The scientific foundation of climate change is unequivocal. The Intergovernmental Panel on Climate Change (IPCC), in its Sixth Assessment Report (6) confirmed that human activity—primarily the combustion of fossil fuels and deforestation—is responsible for the observed rise in global average temperatures since the pre-industrial era. The Earth's surface has already warmed by 1.1°C, with current trajectories placing the planet on track to exceed 1.5°C of warming within the next two decades unless emissions are drastically curtailed (6).

This warming is driving a cascade of systemic changes, including the increasing frequency and severity of heatwaves, wildfires, droughts, storms, and floods; rising sea levels and coastal erosion; ocean acidification; and biodiversity loss. The climate system's destabilization is not only an environmental phenomenon—it has become a structural determinant of human health.

"The climate system's destabilization is not only an environmental phenomenon—it has become a structural determinant of human health."

The IPCC warns that without immediate and drastic reductions in GHG emissions, the world is likely to exceed 2°C of warming by mid-century, a threshold associated with widespread agricultural collapse, mass displacement, and infrastructure failure (6). For healthcare systems, this future portends interrupted services, overwhelmed emergency rooms, supply shortages, and soaring demand for mental health and infectious disease care. Thus,

climate action is foundational to public health preparedness and systems resilience.

"The IPCC warns that without immediate and drastic reductions in GHG emissions, the world is likely to exceed 2°C of warming by mid-century, a threshold associated with widespread agricultural collapse, mass displacement, and infrastructure failure. For healthcare systems, this future portends interrupted services, overwhelmed emergency rooms, supply shortages, and soaring demand for mental health and infectious disease care. Thus, climate action is foundational to public health preparedness and systems resilience."

3.2 Climate Change Impacts Health

From the standpoint of healthcare, climate change poses a comprehensive threat to public health, affecting every organ system, population, and location. The World Health Organization (WHO) has called it "the single biggest health threat facing humanity" (7). Key health impacts include heat-related illnesses and deaths (8), vector-borne diseases, including malaria, dengue, Lyme disease, and West Nile virus (8), respiratory conditions: from exposure to fine particulate matter (PM2.5), increasing asthma exacerbations, COPD flare-ups, and cardiovascular morbidity (9). Climate change poses significant risks to agriculture in a world where 2 billion people lack essential micronutrients (10). Climate-related trauma, such as displacement, economic instability, and environmental grief, can increase anxiety, depression, PTSD, and substance use disorders (11), as well as food and water insecurity. These mental health impacts fall most heavily on low-income groups, communities of color, Indigenous peoples, children, and the elderly, who already face structural barriers to healthcare.

3.3 Climate Change Particularly Impacts Neonatal and Perinatal Health

Children are among the most vulnerable populations to the health effects of climate change. They are not only physically more susceptible to environmental hazards since they breathe more air and consume more food and water per kilogram of body weight than adults, but also developmentally dependent on the stability of ecological, social, and healthcare systems. Furthermore, exposures during critical developmental windows, particularly in utero and during the neonatal period, can have lifelong implications for respiratory health, neurodevelopment, immune function, and cardiovascular risk (12). A systematic review found that maternal exposure to extreme heat is associated with a statistically significant increased risk of adverse pregnancy outcomes (13). Particulate matter (especially PM2.5) from traffic, fossil fuels, and increasingly wildfires, which are more common due to a changing climate, is associated with increased risk of low birth weight and preterm birth (14).

"Children are among the most vulnerable populations to the health effects of climate change. They are not only physically more susceptible to environmental hazards since they breathe more air and consume more food and water per kilogram of body weight than adults, but also developmentally dependent on the stability of ecological, social, and healthcare systems. Furthermore, exposures during critical developmental windows, particularly in utero and during the neonatal period, can have lifelong implications for respiratory health, neurodevelopment, immune function, and cardiovascular risk"

3.4 Climate Change puts demands on NICU Operations.

The climate crisis also poses increasing operational and ethical challenges to neonatal intensive care units (NICUs). Facilities themselves are vulnerable to climate disruptions, including flooding, wildfires, supply chain interruptions, and power outages. Clinicians must now consider climate resilience as a core function of the NICU. This includes investments in redundant power systems, emergency planning for neonatal transport, and sustainable design to ensure uninterrupted care delivery.

The carbon footprint of neonatal care, caused by single-use plastics, energy-heavy incubators, and anesthetic gases, prompts questions about how NICUs can cut emissions while ensuring safety.

"The carbon footprint of neonatal care, caused by single-use plastics, energy-heavy incubators, and anesthetic gases, prompts questions about how NICUs can cut emissions while ensuring safety."

3.5 Structural/Social Determinants of Health impact NICU Admissions and NICU outcomes

Structural and social determinants of health (SDOH) significantly

influence neonatal outcomes, especially in NICUs, where medical vulnerability intersects with systemic inequities. Social determinants of health include access to and quality of education, healthcare, neighborhood and built environment, social and community context, and economic stability (15). Recent studies offer strong empirical evidence linking race, socioeconomic status, geography, and language to disparities in NICU experiences and clinical outcomes (16–19). Addressing these determinants is crucial not only for equity but for clinical excellence in neonatal care.

"Infants born into poverty, homelessness, or marginalized communities face a triple threat: they are more exposed to environmental risks, less likely to access high-quality healthcare, and more affected by systemic racism. For example, historically redlined neighborhoods in US cities are more likely to be heat islands, characterized by fewer green spaces and higher rates of air pollution, which correlates with higher rates of chronic disease.

3.6 Climate Change Intensifies the Inequitable Impact of Social Determinants of Health

Climate change exacerbates the social determinants of health that already affect children. Infants born into poverty, homelessness, or marginalized communities face a triple threat: they are more exposed to environmental risks, less likely to access high-quality healthcare, and more affected by systemic racism. For example, historically redlined neighborhoods in US cities are more likely to be heat islands, characterized by fewer green spaces and higher rates of air pollution, which correlates with higher rates of chronic disease (20).

Indigenous children face disproportionate health risks from water insecurity, wildfire displacement, and food system collapse (21). Worldwide, children in the Global South will bear the most significant disease burden despite contributing the least to the climate crisis (9).

For neonatologists, these inequities are not abstract. They show up in disparities in preterm birth rates, NICU admissions, and developmental outcomes, trends that will worsen without targeted intervention.

3.7 Healthcare is a major contributor to Greenhouse Gas Emissions (GHG)

While healthcare systems are at the frontlines of climate impact, they are also major contributors to the crisis. Globally, healthcare is responsible for 4.4% of net GHG emissions (22). In the United States, the sector emits roughly 8.5% of national emissions, making it one of the largest institutional sources of pollution (23).

"For neonatologists, these inequities are not abstract. They show up in disparities in preterm birth rates, NICU admissions, and developmental outcomes, trends that will worsen without targeted intervention."

Emissions arise from energy use, high-impact anesthetic gases such as desflurane and nitrous oxide, pharmaceutical and medical supply chains, patient transportation, waste incineration, and water consumption.

3.8 Thus, the Act of Delivering Healthcare Can Cause Harm

Critically, these emissions pose a contradiction to the sector's mission: the act of delivering care can simultaneously cause harm through environmental degradation. As such, climate mitigation must be reframed as a core component of healthcare quality, safety, and ethics.

3.9 Organizations can make a difference despite changing national-level policies.

In this context, a diverse array of actors, including healthcare organizations, nonprofits, local, provincial/state, and national governments, as well as international organizations, have mobilized in response. While the role of nations is important, climate action happens at the provincial/state, local, organizational, and even individual levels. At the time of this writing, several changes to United States federal policy were made. The Office of Climate Change and Health Equity was disbanded by executive order, eliminating one of the few federal bodies explicitly focused on climate equity in healthcare. Additionally, NIH climate and health research funding was paused or eliminated. Even during times of changing federal policy, other actors, including health care organizations, can continue to make progress.

"While the role of nations is important, climate action happens at the provincial/state, local, organizational, and even individual levels."

3.10 Healthcare Systems Have Made or Maintained Commitments to Decarbonize

In 2025, the Health Sector CARES Pledge (Climate Action, Resilience, and Equity Solutions) was introduced to replace a repealed US Health and Human Services Health Sector Pledge. The CARES pledge invites hospitals and health systems to publicly commit to a 50% reduction in Scope 1 and 2 emissions by 2030, complete Scope 3 emissions inventories within one year, and embed climate resilience and equity into their operations (22).

Within months of its release, more than 60 systems, including CommonSpirit Health, Providence, and NYC Health + Hospitals, had signed on.

Additionally, the National Academy of Medicine (NAM) has continued to push for sector-wide decarbonization.

"The CARES pledge invites hospitals and health systems to publicly commit to a 50% reduction in Scope 1 and 2 emissions by 2030, complete Scope 3 emissions inventories within one year, and embed climate resilience and equity into their operations. Within months of its release, more than 60 systems, including CommonSpirit Health, Providence, and NYC Health + Hospitals, had signed on."

3.11 It is possible to Decarbonize Building Emissions.

Building utility decarbonization is possible, and several hospitals are making significant progress in their plans to decarbonize. Decarbonizing building and utility emissions involves three fundamental steps: 1. Reduce the consumption of electricity as much as possible; 2. Switch your systems (for example, heating, sterilizers, kitchen equipment, etc.) to run on electricity instead of fossil systems (natural gas, steam, etc.); and 3. Procure electricity from renewable sources. When you have electrified emissions and procured your electricity from renewable sources, you have effectively decarbonized. Reducing energy as a first step enables you to decrease the amount of energy that needs to be electrified, thereby lowering costs.

"Decarbonizing building and utility emissions involves three fundamental steps: 1. Reduce the consumption of electricity as much as possible; 2. Switch your systems (for example, heating, sterilizers, kitchen equipment, etc.) to run on electricity instead of fossil systems (natural gas, steam, etc.); and 3. Procure electricity from renewable sources."

On the electricity production side, onsite- or offsite-owned zero-carbon energy (such as solar) reduces purchases of emissions from dirty sources. Organizations can enter contracts to procure renewable energy. Within renewable energy purchasing, there is a concept called additionality. Additionality refers to renewable energy contracts where the purchase results in an increase in the total amount of renewable energy. For example, a contract to purchase renewable electricity from an existing hydroelectric power plant is not additional, since the energy would be placed on the grid regardless of whether you made the purchase or not. An investment in a new wind farm would be additional, since the new wind farm would not exist without purchase. By purchasing additional renewable energy, you are actually reducing greenhouse gas emissions.

Decarbonizing existing facilities can be challenging, but there are resources available to support the process. The Guidebook for Decarbonizing Healthcare (www.decarbhealthcare.com) provides helpful information. For new buildings, the ASHRAE/ASHE Decarbonizing Hospital Buildings Guidebook (24) provides a detailed guide focused on the design, construction, and operation of new hospital buildings and major renovations. This guidebook includes a treatment of embodied carbon—the carbon associated with a building's construction (as opposed to operation), which is helpful.

The healthcare industry is focused on decarbonization, and there are practical guides available to help achieve this goal.

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4 What Can "You" Do?

4.1 Be Motivated by NICU-led Health Equity Work

You should also be aware of the progress made in thinking on NICU, health equity, and population health, as NICU professionals have played a unique role in this space.

The Neonatal Intensive Care Unit (NICU) plays a pivotal yet often underrecognized role in shaping population health trajectories. Traditionally viewed as acute care settings, NICUs are now being reimagined as launchpads for long-term developmental, so-

cial, and community health outcomes. Bold new ideas in design further this trend (25). A growing body of literature supports the integration of NICU care with broader public health models to address disparities and promote lifelong well-being. Several studies stand out.

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Population-based NICU care models have been developed to redesign follow-up programs for children at risk of falling through safety nets (26). For example, Litt et al. (26) propose a *Life Course Health Development* (LCHD) framework that emphasizes the importance of early experiences in shaping long-term outcomes. Their model encourages NICUs to coordinate care that extends beyond survival, integrating follow-up services, community engagement, and policy reform. The theoretical strength of this model lies in its comprehensive approach to public health through individualized care for neonates (27).

Equity audits, culturally competent care, and social supports are being developed to mitigate the compounded effects of racial and socioeconomic inequities on neurodevelopmental outcomes post-NICU (28). Neonatologists are proposing new models of neonatal follow-up that emphasize family and child function (29). For example, leveraging existing staff, a NICU raised the level of social risk screening coupled with referral to resources in the NICU, with effective results (30).

Moreover, the familiar Vermont Oxford Network Potentially Better Practices for Follow Through are a key acknowledgement of the idea that "As neonatal care providers, we play critical roles in the lives of small and sick newborns and their families and therefore are uniquely positioned to address social determinants of health. Our responsibility to infants and families extends beyond the walls of the hospital or clinic. We must follow through. Follow-through is different from the more typical neonatal practice of 'follow-up.' It is a comprehensive approach that begins before birth and continues into childhood. Health professionals, families, and communities must partner to meet the social as well as medical needs of infants and families to achieve health equity" (31).

These efforts are highly relevant for two reasons. First, climate change will exacerbate health equity challenges. The forward-thinking NICU will therefore need to be even more diligent about addressing social determinants of health and disparities, even to maintain its current level of outcomes. NICU professionals should be aware of this and the ways that colleagues have effectively done this work. Second, NICUs have uniquely developed systems to address complex problems that involve both upstream and downstream factors, for which it may initially seem that the NICU has little to no control. This type of thinking and action provides important lessons and motivation as NICUs strategize to impact decarbonization.

"Although their personal choices might seem modest in scale, the cumulative effect across a large workforce and patient population can be profound. For instance, clinicians can make deliberate choices to avoid low-value care, such as ordering unnecessary diagnostic tests or procedures, which then not only reduces patient harm but also curbs resource waste and emissions. Similarly, choosing digital over printed materials, avoiding overuse of disposables, and advocating for reusable equipment where safe are all everyday actions that help reduce waste streams."

4.2 At the Individual Level: Empowering Climate-Conscious Healthcare Workers

Individual healthcare workers and patients are often the first points of contact in the climate-health interface. Although their personal choices might seem modest in scale, the cumulative effect across a large workforce and patient population can be profound. For instance, clinicians can make deliberate choices to avoid low-value care, such as ordering unnecessary diagnostic tests or procedures, which then not only reduces patient harm but also curbs resource waste and emissions. Similarly, choosing digital over printed materials, avoiding overuse of disposables, and advocating for reusable equipment where safe are all everyday actions that help reduce waste streams.

Clinicians also influence clinical practice. By counseling patients on climate-resilient behaviors, such as adopting plant-based diets, quitting smoking, and using active transportation like walking or biking, they can advance both individual health and climate goals. Hospitals like Kaiser Permanente have adopted this ethos, offering incentives for green commuting, including subsidized transit passes, bike facilities, and carpooling programs.

Education is essential. Frontline providers who are informed about the health effects of climate change are better equipped to communicate with patients and colleagues, thereby reinforcing a culture of climate literacy and sustainable practices—these actions, while individual, are essential building blocks for larger systemic change.

Neonatologists are uniquely positioned to advance climate-respon-

sive care. Their roles span clinical advocacy, research, systems improvement, and public health engagement. NICU professionals should collaborate with hospital leadership to reduce waste, switch to lower-impact equipment, and improve energy efficiency. Other actionable steps include implementing clinical screening for climate-related risk factors: housing instability, exposure to air pollution, maternal heat stress, and advocacy for policies that reduce air pollution, expand maternal protections during heatwaves, and strengthen infrastructure for birth centers and NICUs.

Additionally, NICU professionals can lend their voices to interdisciplinary coalitions that recognize child health as a core pillar of climate justice. Their authority, rooted in science and ethics, can shape public discourse and health policy.

"The NICU represents one of the most resource-intensive settings within a hospital. Infants in NICUs often require continuous monitoring, temperature control, oxygen therapy, and sterile environments, all of which demand energy and generate waste. Nevertheless, even here, there are viable strategies for reducing environmental impact without compromising safety."

4.3 At the NICU Level: Greening High-Intensity Care Without Compromising Safety

The NICU represents one of the most resource-intensive settings within a hospital. Infants in NICUs often require continuous monitoring, temperature control, oxygen therapy, and sterile environments, all of which demand energy and generate waste. Nevertheless, even here, there are viable strategies for reducing environmental impact without compromising safety.

NICUs can rethink single-use items. Many NICUs have historically relied heavily on disposable gowns, linens, and medical tools to ensure sterility. However, studies suggest that switching to reusable surgical gowns offers both environmental and financial benefits (32).

NICU professionals should insist that major renovation or new construction projects are designed to use zero operational carbon. The NICU should enthusiastically support any hospital decarbonization efforts. This includes supporting energy reduction projects. NICUs rely on constant power to support incubators, ventilators, and monitors. Retrofitting these spaces with LED lighting, motion-sensor controls, and energy-efficient HVAC systems can lead to substantial energy savings.

Additionally, better waste segregation can reduce the overclassification of waste as "regulated medical waste," which is often incinerated and carries a carbon footprint several times greater than general waste (33).

Finally, NICUs may consider approaches to manage the use of oxygen and anesthetic gases, especially during surgeries involving neonates. Choosing lower-impact anesthetic agents and using them judiciously not only reduces GHG emissions but also protects staff from exposure.

"At the hospital level, climate mitigation must become a central tenet of operational planning. Hospitals are significant consumers of energy, water, and materials, and they generate substantial waste, including high GHG emissions from anesthetic gases and sterilization processes."

4.4 At the Hospital Level: Embedding Sustainability in Operations and Culture

At the hospital level, climate mitigation must become a central tenet of operational planning. Hospitals are significant consumers of energy, water, and materials, and they generate substantial waste, including high GHG emissions from anesthetic gases and sterilization processes.

A critical area for action is the operating room, which can account for 30% or more of hospital waste. Hospitals like Hackensack University Medical Center have implemented successful initiatives to eliminate the use of desflurane, a potent anesthetic with a global warming potential more than 2,500 times that of carbon dioxide. By switching to sevoflurane or total intravenous anesthesia, they significantly reduced emissions without compromising patient care (34).

Food services represent another high-impact area. Hospitals serve millions of meals each year, and most of these meals traditionally rely on carbon-intensive meat and dairy products. Transitioning toward plant-forward menus, sourcing food locally, and implementing food waste diversion programs, such as composting and donating excess food, can significantly reduce a hospital's environmental impact. Several institutions working with Health Care Without Harm have reported cost savings and improved patient satisfaction with healthier, sustainable meals (35).

Additionally, investing in green building standards, such as LEED certification, for new construction or retrofitting existing infrastructure with high-performance HVAC systems, water recycling systems, and smart building automation can generate long-term savings and enhance resilience. Hospitals like the Cleveland Clinic have reduced their emissions by 20–30% between 2010 and 2020 with a plan to continue improving energy and waste performance.

These changes often require a cultural shift. Hospitals must empower a "green team" of clinicians, facilities managers, and executives to drive change, track metrics, and communicate progress regularly to staff and the community.

"Additionally, investing in green building standards, such as LEED certification, for new construction or retrofitting existing infrastructure with high-performance HVAC systems, water recycling systems, and smart building automation can generate long-term savings and enhance resilience. Hospitals like the Cleveland Clinic have reduced their emissions by 20–30% between 2010 and 2020..."

4.5 At the Health System Level: Leading Climate Action Through Policy and Partnerships

At the top of the pyramid, health systems have the unique capacity to shape supply chains, influence public policy, and lead national or global climate action. They can develop system-wide sustainability roadmaps that set science-based targets for emissions reductions and embed climate goals into governance structures.

Large health systems, such as Kaiser Permanente in the US, have achieved carbon neutrality through investments in renewable energy, the elimination of coal-based power contracts, sustainable procurement practices, and aggressive energy efficiency efforts. Their model proves that decarbonization is achievable at scale with proper leadership and investment.

"At the top of the pyramid, health systems have the unique capacity to shape supply chains, influence public policy, and lead national or global climate action. They can develop system-wide sustainability roadmaps that set science-based targets for emissions reductions and embed climate goals into governance structures."

On a broader level, health systems can influence their entire supply chain by prioritizing vendors that meet environmental, social, and governance (ESG) criteria. Given that the majority of healthcare's emissions are Scope 3 (indirect) emissions from supply chains, procurement reform is one of the most powerful levers available (36).

Finally, resilient infrastructure planning is essential. Hospitals now require climate-resilient infrastructure, microgrids, and emergency plans to ensure they remain operational during floods, wildfires, and extreme heat events.

Organizations that act decisively can not only reduce their environmental footprint but also improve population health, lower costs, and build long-term resilience. Every part of the healthcare system is essential in the move toward climate-smart care.

5 Conclusion:

Climate change is a threat to public health, impacting children and neonates all around the world, making them more likely to end up in the NICU and more likely to have adverse long-term outcomes. Likewise, climate change will augment health inequities. Like all areas of hospitals, NICUs contribute significantly to greenhouse gas emissions. There is an imperative for NICUs to have a positive impact on the climate. Fortunately, this is possible. By leveraging their unique voice and in-depth understanding of complex problems, NICU professionals can advocate for policies and projects that significantly reduce the carbon footprint of operating the NICU, thereby continuing to save babies and families.

Select Key Resources:

The following are select key resources to be used to promote and execute building decarbonization:

- National Academy of Medicine Key Actions to Reduce Greenhouse Gas Emissions: https://nam.edu/product/key-actions-to-reduce-greenhouse-gas-emissions-by-u-s-hospitals-and-health-systems/
- National Academy of Medicine Clinical Journey Map: https://nam.edu/clinicaljourneymap/stage-one/#actions
- Decarb:Healthcare: https://www.decarbhealthcare.com/
- ASHRAE/ASHE Decarbonizing Hospital Buildings Guidebook: https://www.ashe.org/sustainability/decarbonizing-hospital-guidebook

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Disclosures: *The authors have no disclosures*

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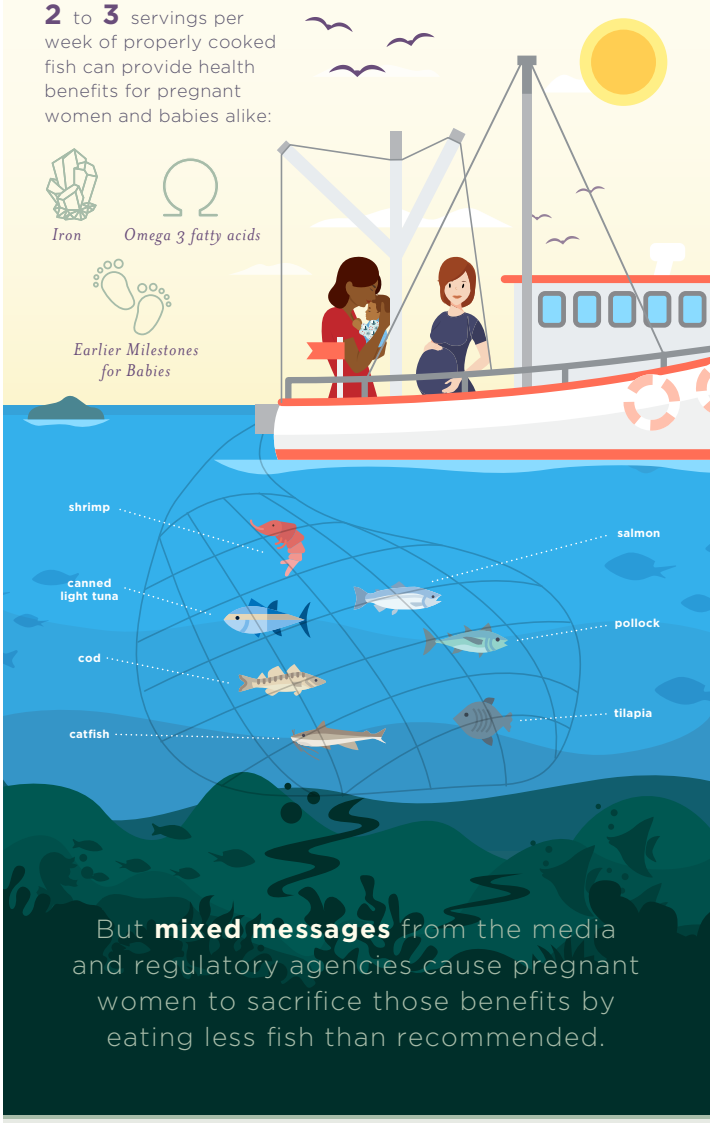
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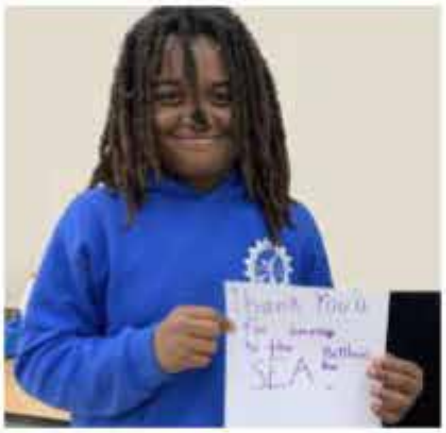


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1 semester	$540
1 year	$1,080
Middle School	$3,240

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The Village Son



A Life's Journey

Iranian village to a university professor in the United States of America in this memoir. As a boy, his unruly behavior was sedated by scholastic challenges as a remedy. At age twelve, he left home for junior high school in a provincial capital. At first, a lack of self-esteem led him to stumble, but he soon found the courage to tackle his subjects with vigor. He became more curious about the world around him and began to yearn for a new life despite his financial limitations. Against all odds, he became one of the top students in Iran and earned a scholarship to study medicine in Europe. Even though he was culturally and socially naïve by European standards, an Italian family in Rome helped him thrive. The author never shied away from the challenges of learning Italian, and the generosity of Italy and its people became part and parcel of his formative years. By the time he left for the United States of America, he knew he could accomplish whatever he imagined.

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COVID-19

FREE RESOURCES for your NICU

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- Bonding with Your Baby
- Caregivers Need Care Too

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KEEP PATIENTS UP-TO-DATE WITH CHANGES IN POLICIES SO THEY KNOW WHAT TO EXPECT. LISTEN TO THEIR CONCERNS.





Provide culturally-informed and respectful care.

TELL PARENTS HOW YOU WILL KEEP THEM AND THEIR BABIES SAFE DURING THEIR NICU STAY.





Use technology like video chat apps to include family members who can't visit the NICU.

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and

National Perinatal Association
NICU Parent Network

My Perinatal Network and My NICU Network are products of a collaboration between NPA and NPN.

2024

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 the 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 broader insurance coverage for both vaccination and palivizumab prophylaxis so more babies can be protected



Use your best clinical judgement



when prescribing RSV prophylaxis

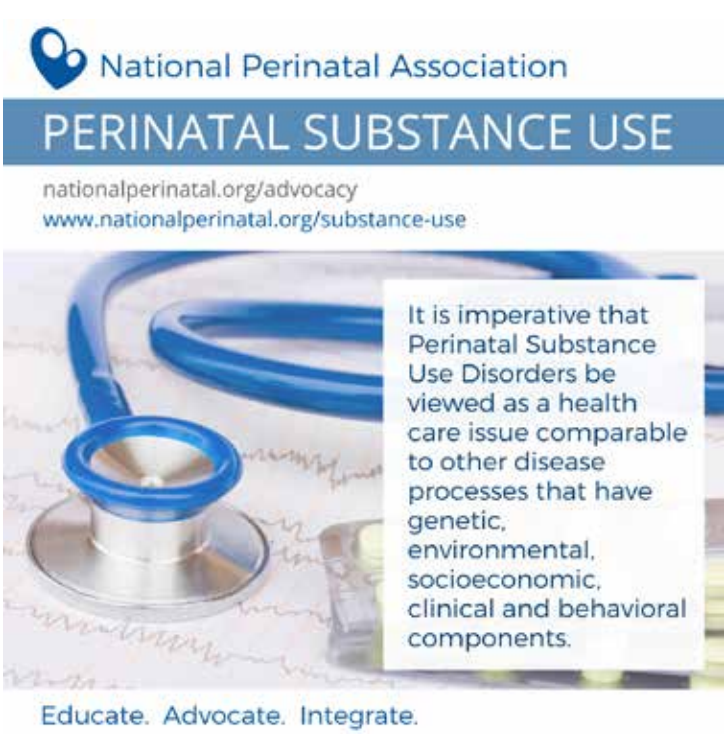
Tell insurers what families need



and provide the supporting evidence

National Perinatal Association

www.nationalperinatal.org/rsv



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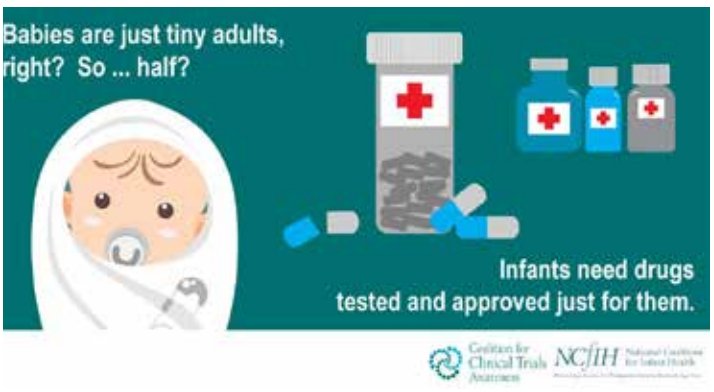
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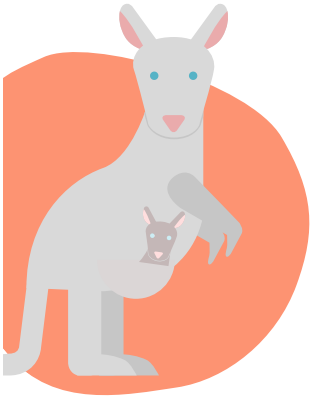






SUPPORTING KANGAROO CARE

SKIN-TO-SKIN CARE DURING COVID-19



GET INFORMED ABOUT THE RISKS + BENEFITS

work with your medical team to create a plan

GET CLEAN

WASH YOUR HANDS, ARMS, and CHEST

with soap and water for 20+ seconds. Dry well.





PUT ON FRESH CLOTHES

change into a clean gown or shirt.

IF COVID-19 + WEAR A MASK

and ask others to hold your baby when you can't be there



National Perinatal Association

nicuparentnetwork.org

NPN NICU PARENT NETWORK

nationalperinatal.org/skin-to-skin

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Health Equity Resources and Strategies



+ Dalia Feltman, MD, MA, FAAP
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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.

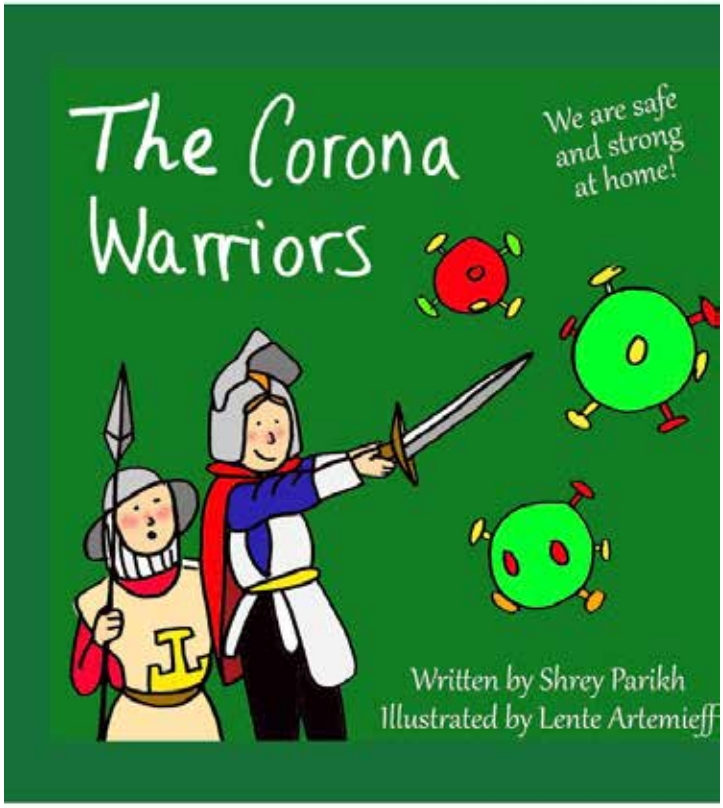
They have produced a personal video entitled "*Why we should all know about RSV*" about Simone van Wyck, a mother who lost her son due to RSV. The video is available at www.rsvgold.com/awareness and can also be watched using the QR code on this page. Please share the video with your colleagues, family,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

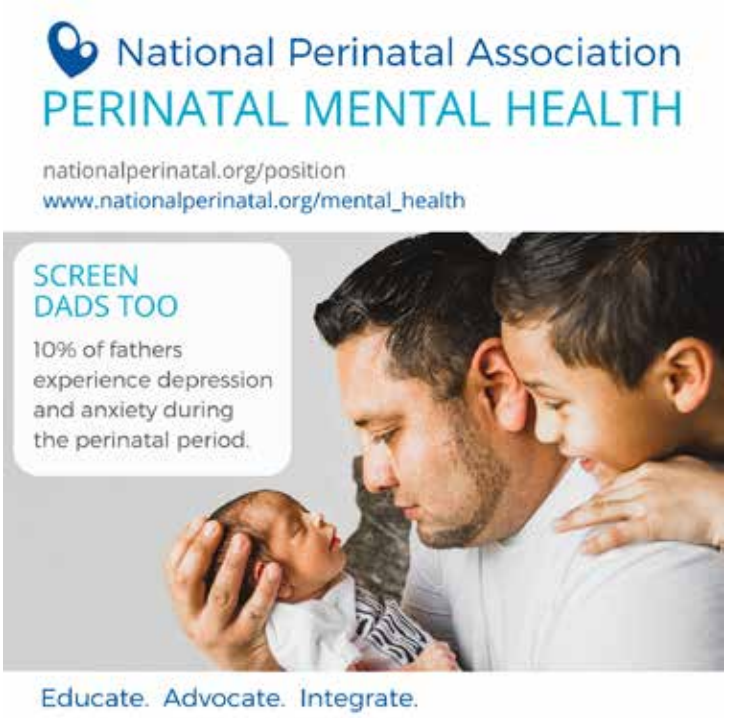


RSV GOLD

A Global Mortality Database for Children with RSV Infection

The RSV awareness video was produced in collaboration with the Bill & Melinda Gates Foundation



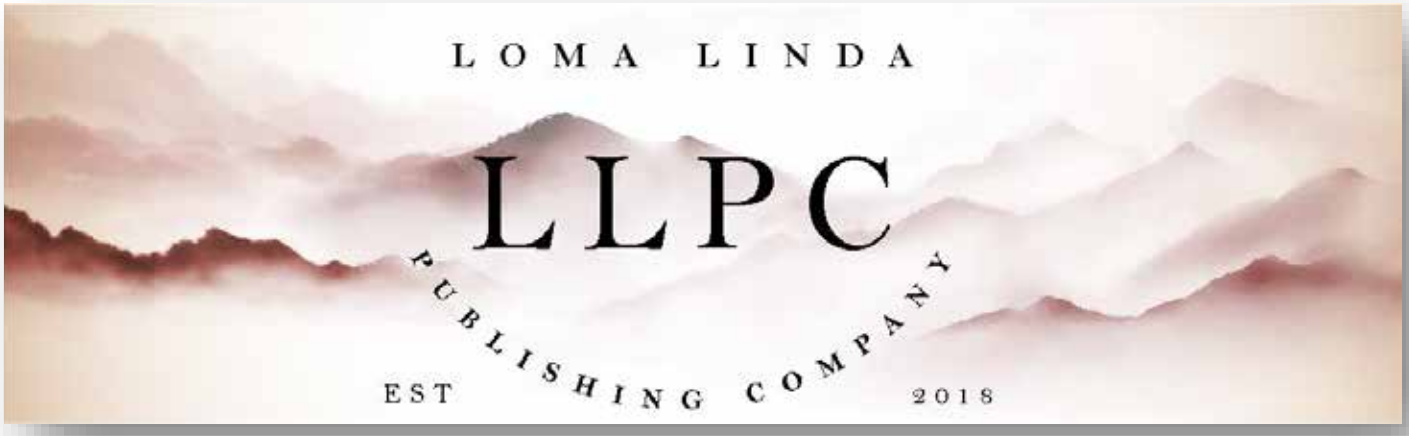


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Thirteen-year-old Emily Rose Shane was tragically murdered on April 3, 2010 on Pacific Coast Highway in Malibu, CA. Our foundation exists to honor her memory.

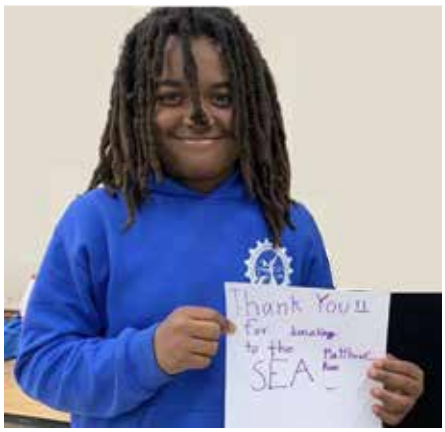


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National Coalition for Infant Health: Infant Health Matters: Pneumococcal Disease

Joseph Domachowske, MD

NATIONAL COALITION for Infant Health

The National Coalition for Infant Health is a collaborative of more than 200 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.

"Immunizations are the safest and most effective tools against pneumococcal disease. The risk of being unvaccinated far outweighs the risk of a vaccine."

"Newborns benefit early on from some protection passed down from their mother, but these antibodies are gone after two to three months, leaving them susceptible. With each vaccine dose, infants gain better protection against infection."

Steering Committee

The National Coalition for Infant Health is supported by a volunteer steering committee, all of whom contribute significantly to lives of premature infants through work and parenting. Steering committee members represent national nonprofits, academic institutions, and parent organizations, and they provide leadership as well as help to mobilize partners in the field of prematurity.

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INFANT HEALTH **MATTERS**

Pneumococcal **Disease**

Joseph Domachowske, MD



Immunizations are the safest and most effective tools against pneumococcal disease. The risk of being unvaccinated far outweighs the risk of a vaccine.

Q: What is pneumococcal disease and how does it affect infants?

Pneumococcal disease is an infection caused by a bacteria called Streptococcus pneumoniae which has over 100 different strains.

The bacteria can live harmlessly in the throat, but during times of stress or when the immune system is vulnerable, it can cause mild symptoms or severe infection by invading the ears, sinuses, or lungs or by entering the bloodstream where it can travel to other sites including the brain.

It is the most common cause of bacteremia, bacterial pneumonia and bacterial meningitis, each of which all have the potential to result in life-threatening complications.



Q: What tools are available to protect infants from pneumococcal disease?

Tools such as pneumococcal conjugate vaccines are safe and effective at preventing pneumococcal disease. Vaccinations produce an immune response that not only protects the vaccinated individual but also those around them by preventing the spread of bacteria.

Babies receive the vaccine in a four-dose series starting at 6-8 weeks, then at four months and six months with a booster dose between 12 and 15 months.

These vaccines have been around for 24 years and have greatly reduced the infection rates of pneumococcal disease wherever they are used worldwide.

Q: Why is continued vaccination important to protect infants?

Around a decade after the first pneumococcal conjugate vaccine became available, there was around a 90% decrease in invasive infection.

Vaccinations reduce the chance that someone is infected or carries the bacteria and infects others.

When both infection and carrier rates decrease, communities benefit from herd immunity.



The best way to protect infants is to vaccinate and ensure the completion of all four doses of the vaccine series on time.

Q: When are children most vulnerable to pneumococcal disease?

Children are most vulnerable during their first year of life because their immune system is still developing.

Newborns benefit early on from some protection passed down from their mother, but these antibodies are gone after two to three months, leaving them susceptible. With each vaccine dose, infants gain better protection against infection.

Certain genetic factors can increase the risk for severe disease, including chronic kidney or liver disease, diabetes and immune deficiency. Native Alaskans and American Indians also have higher rates of severe disease in their communities.

Q: How do we best protect infants from pneumococcal disease?

The best way to protect infants is to vaccinate and ensure the completion of all four doses of the vaccine series on time.

Since there is a time range for the booster dose, I routinely give it at 12 months to boost immunity at the earliest time possible. Many toddlers fail to receive their fourth booster dose leaving them without the maximum protection from the disease.

Also, severe influenza can increase the risk of severe pneumococcal disease in infants, so receiving a flu vaccine can also help reduce pneumococcal disease.

Q: What are the differences in the available vaccinations?

All three pneumococcal vaccine formulations are effective, and all three have very favorable safety profiles, but the three available vaccines are not exactly the same. While some versions of the vaccine protect against more strains, it does not always mean better protection. The vaccines protect against different strains of the bacteria, so providers must look at infection data to decide which vaccine offers the best protection for their patients.

NATIONAL COALITION for Infant Health

The National Coalition for Infant Health is a collaborative of professional, clinical, community and family support organizations.

The coalition focuses on education and advocacy promoting patient-centered care for all infants–whether born preterm or full term–and their families.

infanthealth.org

Disclosures: The author has no relevant disclosures.

NT

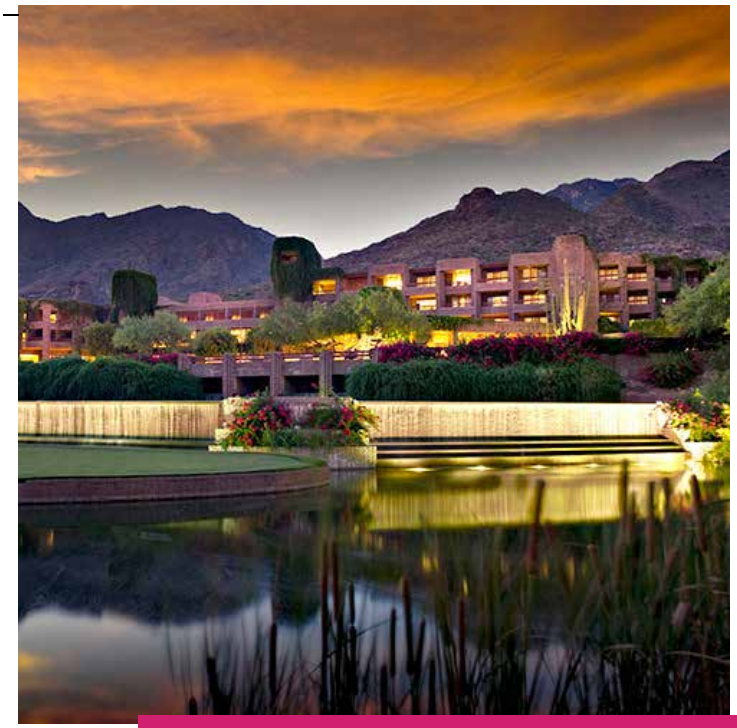
National Coalition for Infant Health Values (SANE)

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.

Equity. 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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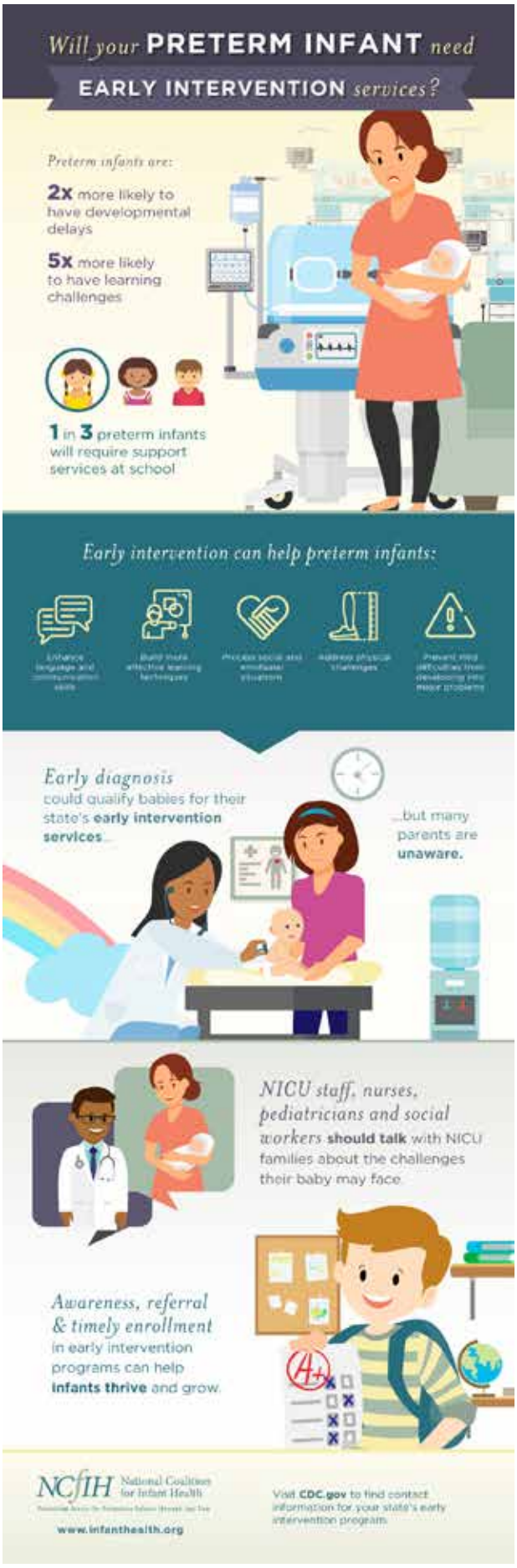
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2026 WORKSHOP ON NEONATAL-PERINATAL PRACTICE STRATEGIES

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Tucson, AZ


Will your PRETERM INFANT need
EARLY INTERVENTION services?
Preterm infants are:
2x more likely to have developmental delays
5x more likely to have learning challenges
1 in 3 preterm infants will require support services at school
Early intervention can help preterm infants:
Early diagnosis could qualify babies for their state's early intervention services...but many parents are unaware.
NICU staff, nurses, pediatricians and social workers should talk with NICU families about the challenges their baby may face.
Awareness, referral & timely enrollment in early intervention programs can help infants thrive and grow.
NCIH National Coalition for Infant Health
www.infanthealth.org
Visit CDC.gov to find contact information for your state's early intervention program.


WHY INFANTS NEED THE
Vitamin K Shot
Newborn babies need vitamin K to help with proper blood clotting and protect them from vitamin K deficiency bleeding.
This type of bleeding is dangerous and can lead to:
Internal bleeding, including in the brain and other organs
Brain damage
Death
One out of every five babies with vitamin K deficiency bleeding dies.
Babies don't get vitamin K from their moms before they are born.
But vitamin K deficiency bleeding is easily preventable with a shot at birth.
Newborns who do not get a vitamin K shot are 81 times more likely to develop severe bleeding.
The vitamin K shot is:
Safe and effective
Routinely given to newborns
Recommended by the American Academy of Pediatrics
Not a vaccine
Protect infants from life-threatening bleeding with a vitamin K shot at birth.
National Coalition for Infant Health

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 Medications for Opioid Use Disorder (MOUD) 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.

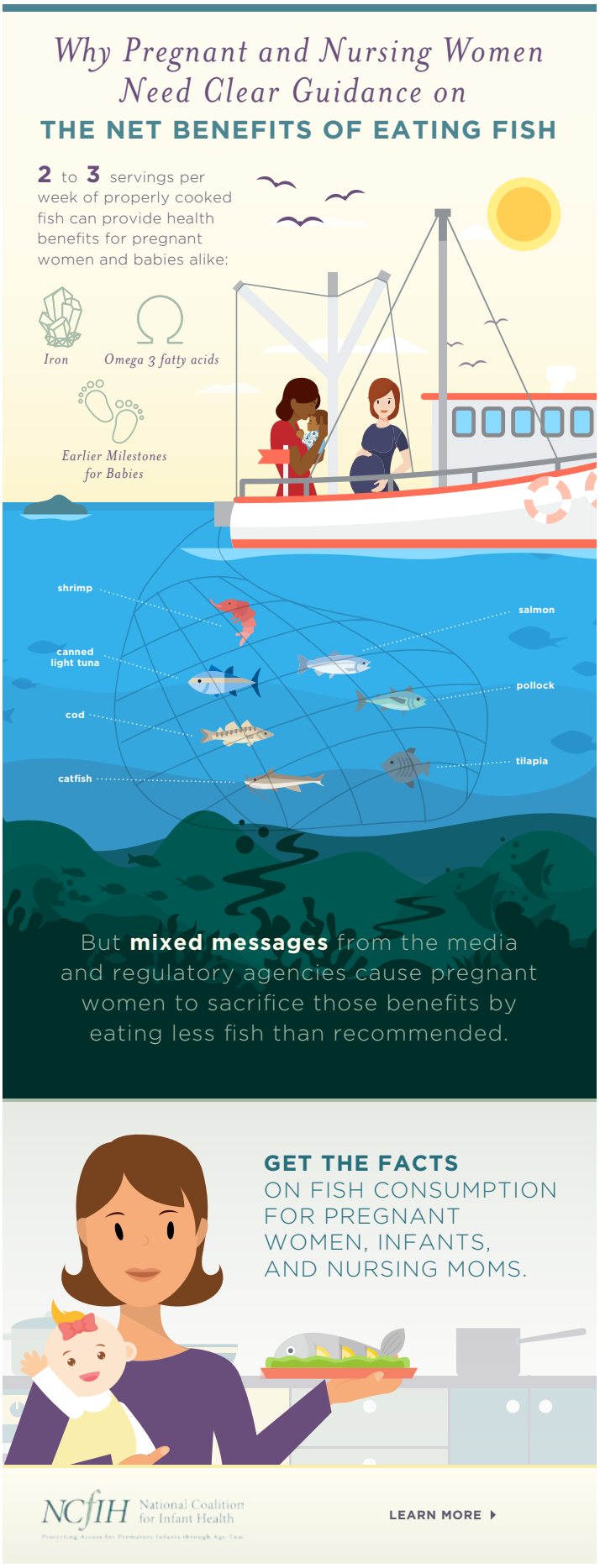
- Eat healthy and take your prenatal vitamins
- Find the right balance of rest and exercise
- Surround yourself with people who care

Your Health Matters

Academy of Perinatal Harm Reduction

National Perinatal Association

www.perinatalharmreduction.org | www.nationalperinatal.org



SHARED DECISION-MAKING PROTECTS MOTHERS + INFANTS DURING COVID-19

KEEPING MOTHERS + INFANTS TOGETHER

Means balancing the risks of...

- HORIZONTAL INFECTION
- SEPARATION AND TRAUMA





EVIDENCE

We encourage families and clinicians to remain diligent in learning **up-to-date evidence**.

PARTNERSHIP

What is the best for this unique dyad?

SHARED DECISION-MAKING

- **S** EEK PARTICIPATION
- **H** ELP EXPLORE OPTIONS
- **A** SSESS PREFERENCES
- **R** EACH A DECISION
- **E** VALUATE THE DECISION





TRAUMA-INFORMED

Both parents and providers are confronting significant...

- FEAR
- GRIEF
- UNCERTAINTY

LONGITUDINAL DATA

We need to understand more about outcomes for mothers and infants exposed to COVID-19, with special attention to:

- MENTAL HEALTH
- POSTPARTUM CARE DELIVERY



NEW DATA EMERGE DAILY. NANN AND NPA ENCOURAGE PERINATAL CARE PROVIDERS TO ENGAGE IN CANDID CONVERSATIONS WITH PREGNANT PARENTS PRIOR TO DELIVERY REGARDING RISKS, BENEFITS, LIMITATIONS, AND REALISTIC EXPECTATIONS.

Partnering for patient-centered care when it matters most.

nann.org nationalperinatal.org

National Association of Neonatal Nurses

National Perinatal Association

Fragile Infant Forums for Integration of the IFCDC Standards: The Significance and Modifiability of Sleep and Arousal Development in Early Life

Amy L. Salisbury, PhD, APRN, PMH-CNS, BC, FAAN, Tiara Bolden, BSN, RN, TIP, Maria Mooney, MPH



Sleep is a dynamic system that is both shaped by maturational processes and contributes to lifelong health and neurodevelopmental trajectories. Although sleep is a silent and often undervalued biological necessity, its quality and absence reverberate with significant consequences**.** In the neonatal intensive care unit (NICU), where preterm and critically ill infants face constant environmental disruption, sleep is a fundamental neurodevelopmental process requiring protection and intentional support. Both emerging and existing evidence consistently support the need to prioritize and promote adequate and developmentally appropriate sleep-state organization throughout each developmental phase.

"In the neonatal intensive care unit (NICU), where preterm and critically ill infants face constant environmental disruption, sleep is a fundamental neurodevelopmental process requiring protection and intentional support."

To address this need, the Infant and Family Centered Developmental Care **(**IFCDC) standards for best practices in the NICU (https://nicudesign.nd.edu/nicu-care-standards/ifcdc--recommendations-for-best-practice-to-support-sleep-and-arousal/) incorporate evidence-based practices to support babies and their families in achieving optimal sleep and arousal patterns. (1) The Sleep & Arousal standards have been previously described, with suggested actions highlighted. (2) Briefly, they include: 1) Promote developmentally appropriate sleep-wake states and cycles for every baby, 2) Provide education for clinical providers and families to assess and document infant sleep and wake states, 3) Provide modifications to the physical environment and caregiving routines to optimize infants' sleep and arousal patterns, and 4) Prepare families for the transition home through adequate guidance on safe sleep practices and best practices at home to support optimal sleep development. This article provides an overview of the current evidence that informed these standards, including the significance of sleep and behavioral states to lifelong health, and how environmental factors and caretaking can influence their developmental course.

"This article provides an overview of the current evidence that informed these standards, including the significance of sleep and behavioral states to lifelong health, and how environmental factors and caretaking can influence their developmental course."

Why is it important to promote sleep and arousal states in the NICU and beyond?

Sleep and arousal development

Behavioral state development is a dynamic process that reflects changes in brain structure, function, and metabolic activity occurring from the earliest embryonic days onward. The maturation of behavioral states is further shaped later in gestation by maternal inputs, including circadian rhythms, which are regulated by light-responsive signaling in the maternal suprachiasmatic nucleus and mediated through circulating and placental hormones. (3, 4)

The emergence of sleep and wake states and their rhythms begins in utero as a fluid interplay between evolving spontaneous and reflexive movement patterns and brain synapse connectivity, which can be observed in utero using ultrasound and other measurement devices under both typical and atypical conditions. (5–7) The earliest discernible embryonic movements occur by the seventh gestational week and are seemingly reflexive. (8, 9) Movement patterns expand to include the full repertoire of fetal

behaviors by the end of the 15th gestational week, encompassing spontaneous movements of the limbs and head, as well as reflexive or involuntary movements such as fetal eye movements, breathing movements, hiccups, stretches, and startles. (8, 10, 11) Fetal movements are nearly continuous and seemingly random as the second trimester begins, with increasing occurrences and durations of quiescent periods helping to organize behaviors into measurable rest-activity cycles by the end of the second trimester (27 weeks). (12–16) The formation of rest-activity patterns is coincident with mid-gestation maturation of brain inhibitory networks. (17) The spontaneous and cyclical fetal movements become increasingly coincident with fetal eye movements and heart rate acceleration patterns by 32 weeks of gestation and form the basis of defined fetal behavioral states of fetal active and quiet sleep states. (18–22) Organized fetal behavioral states are routinely observed by 36 weeks' gestational age, when periods of arousal (high spontaneous motor activity with high heart rate variability) have been described between sleep periods. (22) During late gestation, the fetus spends most of its time in sleep states, predominantly fetal active sleep, with brief periods of quiet sleep and arousal-type patterns. The Figure demonstrates the emergence of state organization in the fetal and newborn period.

The experience of movement patterns, rhythms, and coincident physiological changes inherent in sleep is necessary for optimal brain development. (23) The developmental pattern of spontaneous movements reflects dynamic changes as the brain's white matter matures and the experience of movement is incorporated into the brain's increasingly complex neural networks. As gestation progresses, fetal sleep and brain development are also shaped by uterine and extrauterine environmental inputs as well as maternal circadian physiology and behaviors. (24, 25) In animal studies, the absence of these typical experiences leads to alterations in brain development. (26) In human studies, when the typical fetal experience-dependent brain development is cut short by preterm birth or disrupted by maternal illness, the development of sleep and other behavioral states is also altered.

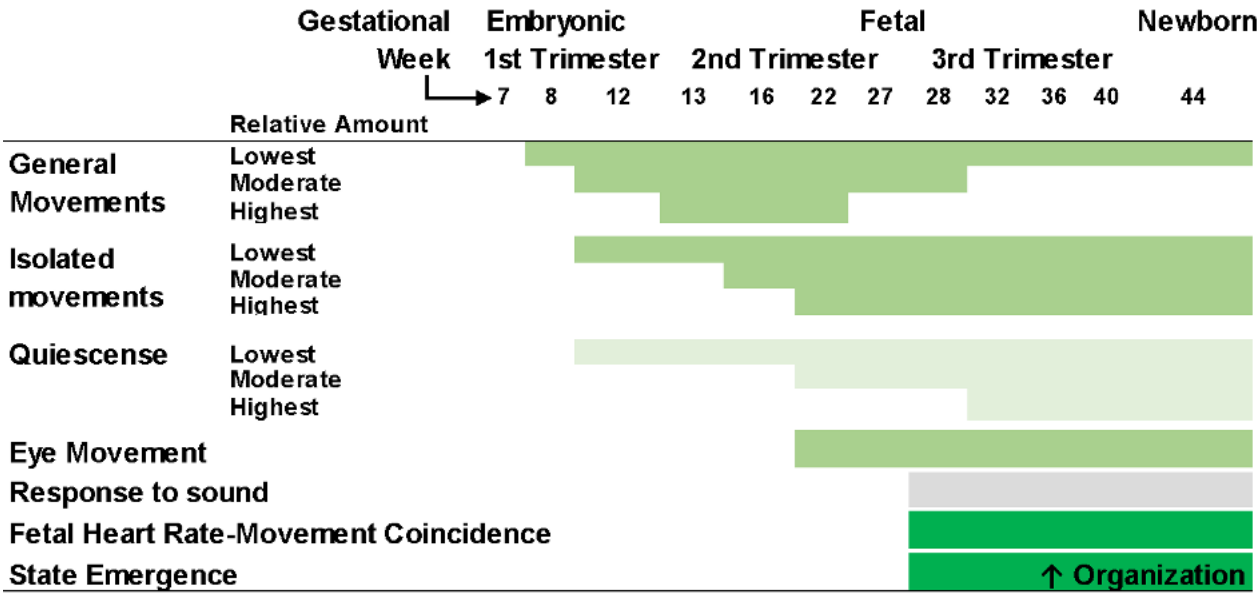
"The experience of movement patterns, rhythms, and coincident physiological changes inherent in sleep is necessary for optimal brain development."

Essentials of sleep for newborn neurodevelopment

Both the quantity and quality of sleep are essential for supporting the optimal growth and development of preterm and term babies. (27–29) Sleep duration and cycling of sleep states support neuroplasticity by enhancing the production of neural structures critical to forming and refining brain circuitry. (25) In older children and adults, findings consistently link sleep fragmentation (short duration sleep and loss of adequate sleep state cyclicity) to poorer cognitive and functional outcomes, as well as other health metrics. (30, 31) Individual studies have shown that disrupted sleep duration or poor sleep state cyclicity in infancy predict varying problems with later neurodevelopmental outcomes. (32, 33) These findings are supported by studies reporting that less fragmented sleep is related to higher cognitive, verbal, or attention scores in infants, toddlers, and school-aged children. (34) However, the predictive nature of early infant sleep to later developmental outcomes is less clear based on findings from systematic reviews of this literature. (35, 36) The lack of consistency in findings from early infancy to later ages may be due to the higher degree of brain plasticity at this developmental age as well as the significant individual differences in state expression. (37)

The collective evidence suggests that the presence, stability, and cycling of sleep-wake states are key indicators of intrinsic brain development, exhibit individual consistency over time, and may predict future neurodevelopment. The high variability in outcomes from early sleep disruption suggests a vast opportunity to support long-term optimal health. Since sleep and arousal

Figure. Fetal movement development and state emergence over gestation



states are influenced by environmental factors such as the NICU environment, light, caregiving, and feeding (38–40), it is crucial to understand and observe infant sleep patterns to best support them and promote optimal health and development. (38, 39, 41–43)

"The collective evidence suggests that the presence, stability, and cycling of sleep-wake states are key indicators of intrinsic brain development, exhibit individual consistency over time, and may predict future neurodevelopment."

Observing Infant Sleep and Wake States

Behavioral observation to determine sleep states

Behavioral states are visually observable throughout early infancy. Validated criteria for identifying arousal states in both preterm and term infants have been established using direct observation and physiologic measures. (44–52) Combining behavioral indicators—such as rapid eye movements, facial expressions, and gross motor activity—with physiological markers, including respiratory patterns and heart rate variability, provides a structured framework for assessing sleep and arousal states. This approach can be integrated into routine assessments by NICU staff and parents.

Advancing technologies are improving the options for the automated evaluation of infant sleep states in the NICU. (53, 54) However, sleep states and their quality can be visually observed in real time if these technologies are not available. The early categorization of sleep states in immature infants can be challenging, resulting in a general lack of agreement on the categorization of early infant sleep states. However, there is a consensus on which behavioral signs determine the sleep and wake state of the infant and on the two central sleep states: Active Sleep (a precursor to Rapid Eye Movement or REM sleep) or Quiet Sleep (a precursor to Non-REM sleep).

An infant in Active Sleep typically has their eyes closed, with intermittent eye movements visible through the eyelids. However, these movements can be challenging to observe in real time. When time-lapse video recordings of infant sleep are used, they can exaggerate eye movements to demonstrate their presence in Active Sleep and their absence in Quiet Sleep. (50) As the name of the state implies, infants in Active Sleep are periodically active, with intermittent limb movements accompanied by facial twitching, smiles, and occasional vocalizations or fussing. Irregular respiratory patterns and increased heart rate variability are observed as the cardiorespiratory system responds to changes in movement and rest.

Sleep state transitions

Generally, changes from one state to another should proceed in an expectant order based on frequently observed cyclical patterns. These typical patterns have been firmly established in older infants through adulthood, when polysomnographic measures can be reliably used to determine mature sleep stages. For most of us, a night of sleep is typically initiated by perceived drowsiness, followed by a period of non-REM sleep that is divided into lighter and deeper sleep stages, before proceeding to bouts of REM sleep. The cycling between non-REM and REM sleep then proceeds throughout the night, with increasing durations of REM sleep and decreasing durations and occurrences of deep non-REM sleep. Young infants also typically transition from higher arousal, active wake states into drowsy states before falling asleep. However, unlike older infants and adults, newborn infants move from waking states into sleep through Active Sleep (REM Sleep).

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As the name of the state implies, infants in Active Sleep are periodically active, with intermittent limb movements accompanied by facial twitching, smiles, and occasional vocalizations or fussing. There is an observable irregular respiratory pattern and higher heart rate variability. Short periods of higher activity and full-body movements can also be observed, and may appear as if the infant is starting to awaken. Indeed, the infant may transition to a wake state or continue in Active Sleep. If the infant remains asleep, they will eventually enter quiet sleep, a quiescent state characterized by the absence of full-body, eye, and facial movements. Respirations become more regular and slower; there may be very brief and infrequent hand movements or startles. Parents observing this state often worry that the infant is not breathing due to the shallow nature of the chest and abdominal movements, as well as a generally paler skin tone. If they proceed to touch the infant or make loud sounds, the infant will likely startle while in Quiet Sleep.

The transition from Active to Quiet Sleep, or vice versa, does not always occur immediately. Often, behaviors of both states can be observed simultaneously as one or the other state emerges. Although this transition has been defined as "indeterminant" by some researchers, others refer to it as a "transitional state" or "intermittent state" due to data showing individual consistency and predictability in this state pattern. (44, 48) Therefore, it may be important to document when a transitional Active-Quiet sleep states are observed, as extensive time spent in transitional states relative to sleep states is less optimal. (55)

Quiet Sleep typically does not last as long as active sleep in the preterm or newborn infant, and the infant usually transitions back to Active Sleep before proceeding to a more prolonged period of activity, indicating a sleep-wake transition before waking. Infants in a wake state usually have their eyes open. However, very young infants, especially in bright light, may keep their eyes closed even when awake. Once awake, the infant may be in one of

three states, ranging from the lowest to the highest arousal: quiet awake, active awake (which includes movement and fussing), or crying. Importantly, infants in quiet wakefulness are more likely to be alert and most ready for social interaction and feeding.

Supporting Sleep State Organization

Sleep organization in the young infant

Sleep-state organization refers to the presence of age-appropriate amounts of each sleep state and the ability to transition smoothly between sleep and wakefulness. Distinct sleep states and the transitions between them play essential roles in infant growth and development, particularly in supporting brain maturation and long-term health. It is clear from the available evidence that sleep duration alone is insufficient to support optimal neurodevelopment; it must also include organization and quality.

The stages of sleep each have specific roles in brain development and thus are optimally expressed in developmentally appropriate ways. Active Sleep is the predominant state during fetal gestation and remains prominent through early infancy. Emerging research highlights the vital neurodevelopmental significance of active sleep**.** Current studies suggest that Active Sleep plays a key role in synaptic pruning and maintenance, processes that are essential for healthy, long-term brain development. (56) This growing body of work underscores the importance of the high proportion of active sleep in preterm and newborn infants. (57) Periods of active sleep are often disrupted by stressful yet necessary procedures (e.g., skin-breaking interventions such as blood draws) in the NICU. These disturbances could reduce the developmental and neuroprotective benefits associated with active sleep. (58)

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Quiet Sleep gradually increases in both proportion and duration with advancing gestational age and postnatal development, including in infants born very preterm. (59, 60) Quiet sleep is vital to brain network connectivity and synaptic formations. (38, 61, 62) The increase in Quiet Sleep proportions during development occurs in conjunction with increasing brain network connectivity and growth hormone levels, highlighting its importance at specific developmental periods. (60)

Some studies have found that preterm infants who spent a disproportionately higher amount of time in quiet sleep and a lower amount in active sleep demonstrated lower cognitive and motor outcomes after six months of age compared to those with more typical distributions of sleep states. (29, 32) Conversely, evidence also suggests that more rapid maturation of both quiet and active sleep is associated with more favorable growth trajectories in later infancy. (63) Current evidence is insufficient to suggest promoting one sleep state over another or intentionally modifying sleep patterns during the early preterm or term periods. Instead, the existing literature emphasizes the importance of supporting developmentally appropriate sleep states and sleep cyclicity through adequate and protected sleep opportunities.

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Evidence on factors that promote or inhibit sleep and wake states

Infant behavioral states reflect the developmental maturation of cortical and subcortical brain activation, as well as the synchronization of circadian circuitry with external factors, such as light and feeding. (24, 64, 65) Therefore, the development of behavioral states should be preserved and protected. To do this, we need to understand the factors that can help or hinder these efforts and ensure that clinicians and parents are aware of the current evidence supporting this advice.

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Collective evidence (see the Table for a summary of the following suggestions) indicates that procedures and feeding routines should be timed to allow for at least 60–120 minutes of uninterrupted sleep, providing adequate time for sleep state cycling to occur. Handling or interacting with infants while they are in a quiet, awake state is the preferred state. However, if handling preterm infants while asleep must occur, there is some evidence that handling infants in Quiet Sleep rather than Active Sleep may be beneficial, as preterm babies desaturate more frequently when

Table: Summary of evidence-based guidelines to promote infant sleep and arousal states as reflected in the IFCDC Standards

1. Promote and protect infant sleep and arousal states
    a. Ensure adequate time for complete sleep cycles of both Active and Quiet Sleep (preferably 120-minute bouts of undisturbed time)
    b. Assess and document the infants' sleep and arousal states to ensure adequate time is spent in both Active Sleep and Quiet Sleep. Document the baby's sleep and wake states, cyclicity, disruptions, and observe for trends or changes that may signal illness or unmet need.
    c. Assess infant sleep and arousal states before care and interactions, assess duration of sleep, presence of states, and readiness for interaction
2. Provide Interprofessional education on sleep and arousal and the importance of sleep for neuroprotection.
3. Educate Families about sleep and arousal development, and how to observe behavior and physiology patterns to guide care
4. Prepare families for the transition home and how to establish healthy sleep patterns early in the process.

handled during Active Sleep compared to handling in Quiet Sleep or wake states. (66) If the infant needs to be awakened, it should ideally happen during a sleep-wake arousal period or when the infant is already awake.

The type of holding (e.g., in arms vs. skin-to-skin), duration of contact, positioning, and activities while in contact (e.g., parental/caregiver singing vs. sleeping) all may impact infant sleep state organization. (67, 68) There is evidence that immediate skin-to-skin holding supports more stable infant temperatures (69) and cardiorespiratory stability. (70) There is also some evidence suggesting that early and frequent skin-to-skin holding may impact Quiet Sleep, although the findings are not consistent. (71, 72) More evidence is needed on the sensory characteristics and timing of parental interventions, such as skin-to-skin contact, singing/reading, touch and holding, and the impact on infant sleep. (29)

"The type of holding (e.g., in arms vs. skin-to-skin), duration of contact, positioning, and activities while in contact (e.g., parental/caregiver singing vs. sleeping) all may impact infant sleep state organization. "

Data suggests that sound levels greater than 45 dB disrupt sleep and physiology (for reference, 40 dB is found in a quiet library). In a recent meta-analysis, the effects of dB over 45 included fragmented sleep, less quiet sleep, changes in heart rate and heart rate variability, and heightened arousal. (73–76) The average NICU sound levels often range between 50 dB (similar to the sound of moderate rain) and 80 dB (similar to the level of a hair dryer). Sound level changes as small as 5–10 dB can increase awakenings by a factor of three. (77) Therefore, a sound level at or below 45 dB is recommended for the NICU environment.

In a recent scoping review (78), Kok et al. reported that continuous bright light exposure in preterm infants is associated with increased stress signs, decreased sleep duration, and delayed entrainment of circadian rhythms, in contrast to infants exposed to cycled light (e.g., 12 hours of light, 12 hours of dark). Those exposed to cycled light showed higher amounts of quiet sleep duration, higher total sleep duration, and increased entrainment of circadian rhythms, which in turn led to increased daytime arousal and nighttime sleep duration. Infants also showed improved growth and a reduction in infections. Overall, early exposure to cycled light shows a benefit to sleep maturation and weight gain in most studies. (79, 80)

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Preparing parents and caregivers for the transition home

Parents who experience a NICU stay with their infants often express heightened stress, anxiety, and sleep disruption (81, 82), leading to disturbed parental sleep in the newborn period. Typical disruptions are often caused by short infant sleep periods

during the night or excessive crying. Strategies to help parents understand their infants' sleep needs may also improve their sleep quality and decrease associated risks for parental depression or anxiety during this time. (83–85)

Preterm infants are particularly at a heightened risk of Sudden Unexpected Infant Death (SUID) as well as sleep disruptions, including sleep onset delay, night waking, and daytime sleepiness. (86) Families transitioning from hospital to home benefit from targeted education that addresses safe sleep environments (87–89), the typical trajectory of sleep-wake cycles, and the promotion of optimal sleep patterns. This knowledge may support improved caregiving practices in both hospital and home settings, reducing sleep problems and enhancing later outcomes. Safe sleep practices modeled during the NICU stay increased the likelihood that families would adopt these practices following discharge. (90–92) The American Academy of Pediatrics (AAP) Safe Sleep Recommendations include guidelines for NICUs to only use supine sleeping positions at all gestational ages unless the infant requires a prone position for respiratory support. (93) The prone positioning strategies frequently used in the NICU for preterm infants are often necessary for medical stability. Still, they are not suitable for home use, and parents might continue these practices at home if not educated otherwise. (94) Greater success in using safe sleep practices post-discharge was found after allowing sufficient time for families to observe, model, and practice safe sleep behaviors before discharge. (90–92)

"Families transitioning from hospital to home benefit from targeted education that addresses safe sleep environments, the typical trajectory of sleep-wake cycles, and the promotion of optimal sleep patterns. This knowledge may support improved caregiving practices in both hospital and home settings, reducing sleep problems and enhancing later outcomes."

There is no single method of parenting that promotes healthy sleep habits exclusively supported by scientific evidence. Specific parenting practices for supporting infant sleep are often debated, as preferences and beliefs vary widely, especially among parents who may be influenced by cultural, familial, or other factors in their choices regarding sleep location and practices. However, two main factors have mounting evidence of their importance, even in infancy, to improve immediate and long-term sleep habits in infants and children, and should be considered for their appropriateness for families transitioning home.

First, establishing consistent sleep-wake routines in early infancy has been associated with improved infant sleep-wake organization and state-regulation outcomes. (95, 96) More consistent and adaptive bedtime routines were related to earlier bedtimes and longer sleep durations. (97) Thus, consistent, positive bedtime routines help to shape sleep behavior in infants and children.

"First, establishing consistent sleep-wake routines in early infancy has been associated with improved infant sleep-wake organization and state-regulation outcomes. More consistent and adaptive bedtime routines were related to earlier bedtimes and longer sleep durations."

The second practice consistently related to improved infant and child sleep is placing the infant in their bed or sleeping location while they are drowsy but awake. (98, 99) It is hypothesized that infants who enter sleep from an awake state in their nighttime sleeping location are less likely to require parental intervention during routine arousals between sleep bouts and will return to sleep on their own, thereby increasing sleep duration and sleep-wake cyclicity. (45) Recent data suggests that minimized need for parental responsiveness during nighttime sleep is key to successful infant sleep habits. (100)

Conclusion:

The evidence presented in this paper summarizes the literature that informed the IFCDC standards on sleep and arousal to support optimal state development and organization. Ideally, the standards provide evidence for promoting and protecting infant sleep and arousal states through caregiving practices, assessment, and documentation. Providing education to both providers and parents on sleep state development is critical to achieving these goals. Parent education should also include information on healthy sleep habits at home, such as safe sleep practices.

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Disclosures: The authors have no relevant disclosures.

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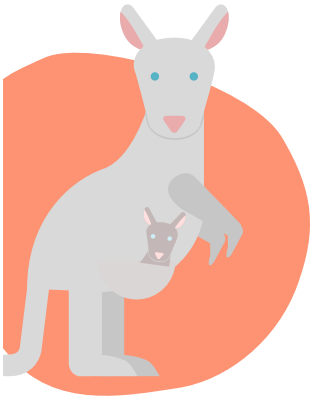
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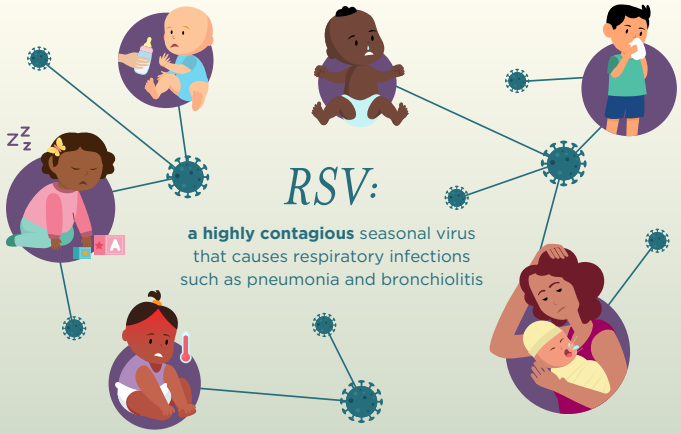
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Respiratory Syncytial Virus

DID YOU KNOW?



RSV:

a highly contagious seasonal virus that causes respiratory infections such as pneumonia and bronchiolitis

Infants under age 1

RSV is the **leading cause** of hospitalization



16x more likely to get RSV than the flu





Kids under age 5 experience



500,000 emergency room visits for RSV each year



57,000 hospitalizations for RSV each year

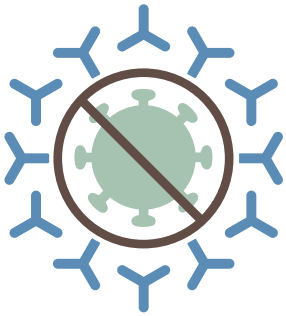
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Protecting your baby and family from

Respiratory Viruses:



What parents need to know this RSV and flu season

Like COVID-19, RSV (Respiratory Syncytial Virus) and flu affect the lungs and can cause serious breathing problems for children and babies. Talk to your family about the risks.

Certain diagnoses can make children and babies more vulnerable for serious complications from respiratory viruses - including prematurity, chronic lung disease, and heart conditions.

You can limit the spread of viruses by wearing a mask, washing your hands with soap & water, using an alcohol-based hand sanitizer, and getting vaccinated.

The fewer germs your baby is exposed to, the less likely they are to get sick. Let people know you need their help to stay well. Limit visitors. Avoid crowds. Stay away from sick people.

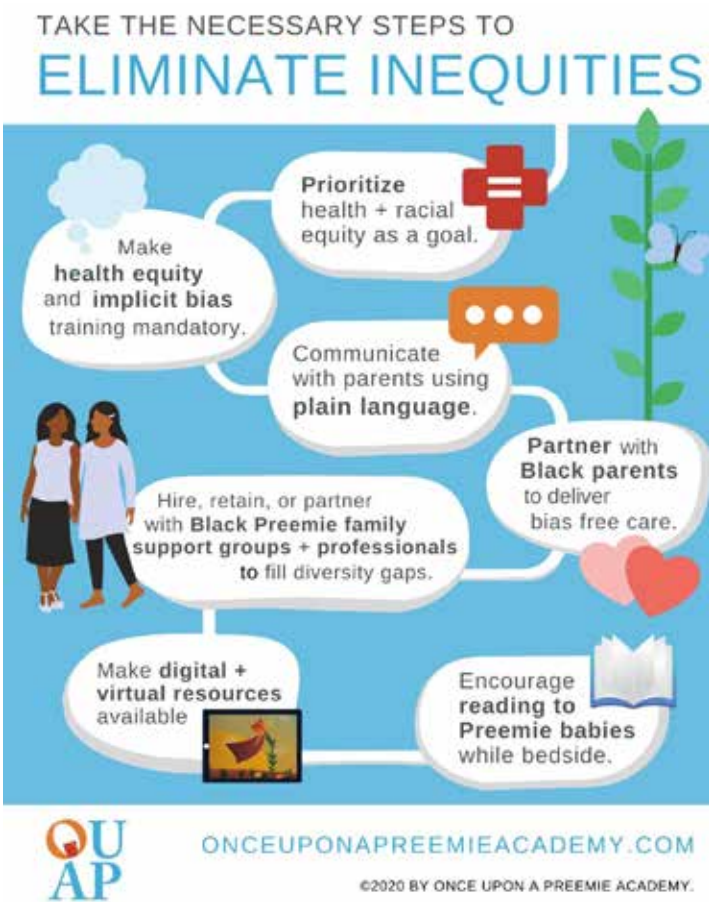
Immunizations save lives. Stay up-to-date with your family's flu vaccinations and COVID-19 boosters. This helps our community stay safe by stopping the spread of deadly viruses.

Babies older than 6 months can get a flu shot and COVID-19 vaccinations. There is no vaccine for RSV, but monthly antibody shots during RSV season can help protect them.

WE CAN HELP PROTECT EACH OTHER.

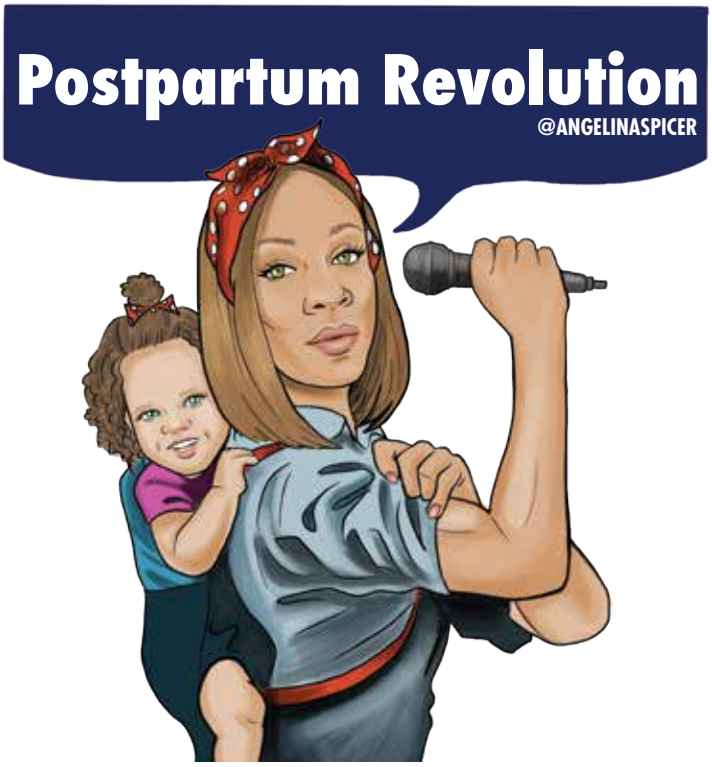
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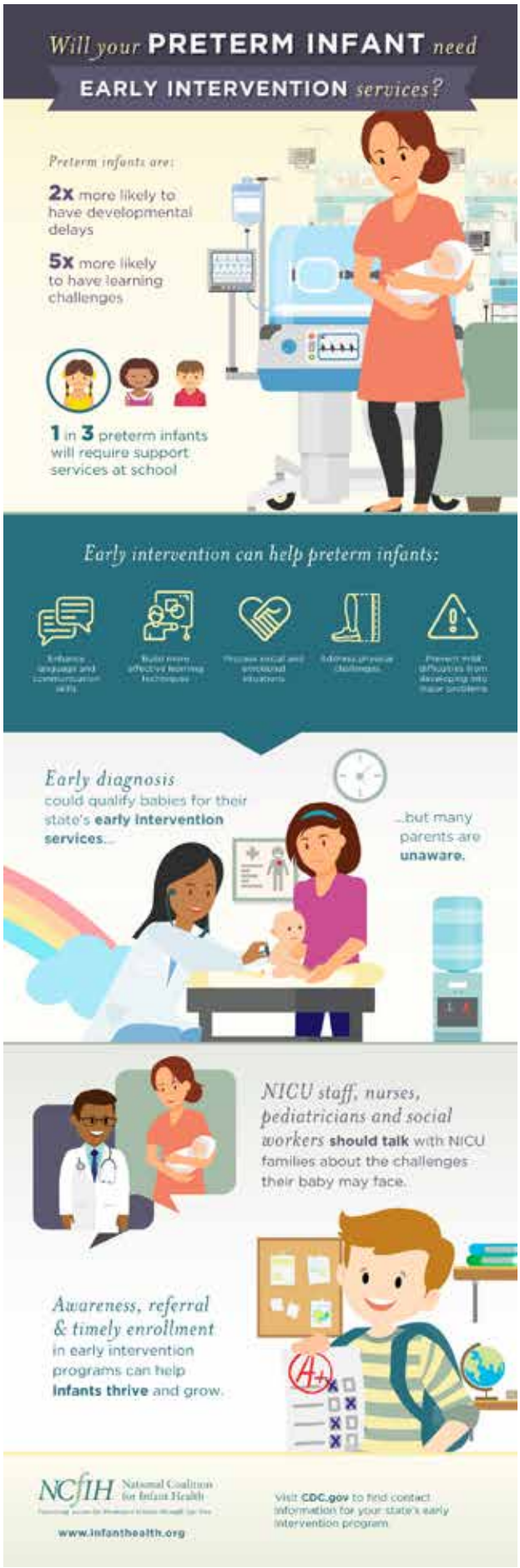
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As we indicated last month, we look forward to a number of new features as well.

1. An online submission portal: Submitting a manuscript online will be easier than before. Rather than submitting by email, we will have a devoted online submission portal that will have the ability to handle any size manuscript and any number of graphics and other support files. We will have an online tracking system that will make it easier to track manuscripts in terms of where they are in the review process.
2. Reviewers will be able to review the manuscript online. This portal will shorten the time from receipt of review to getting feedback to the submitting authors.
3. An archive search will be available for journals older than 2012.
4. A new section called news and views will enable the submission of commentary on publications from other journals or news sources. We anticipate that this will be available as soon as the site completes the beta phase
5. Sponsors will be able to sign up directly on the website and submit content for both the digital and PDF issues of Neonatology Today.

Neonatology Today will continue to promote our Academic True Open Model (ATOM), never a charge to publish and never a charge to subscribe.

If there are any questions about the new website, please email Dr. Chou directly at:

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Hemolytic Disease of the Fetus & Newborn

DID YOU KNOW?

Hemolytic disease of the fetus & newborn is a rare blood disorder.

When the mother's and infant's blood types are incompatible, the mother's antibodies attack the baby's red blood cells.





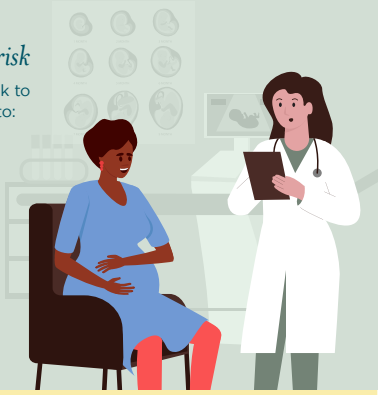
HDFN can lead to:

- **Severe anemia**
- **Jaundice**
- Fetal or infant **death**

To reduce their baby's risk

pregnant mothers should talk to their health care provider to:

- **Identify** potential blood incompatibilities
- **Monitor** the baby
- **Treat** the condition if it occurs



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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 guidlines limit their access to RSV preventative treatment, increasing these babies' risk.

AfPA Alliance for Patient Access

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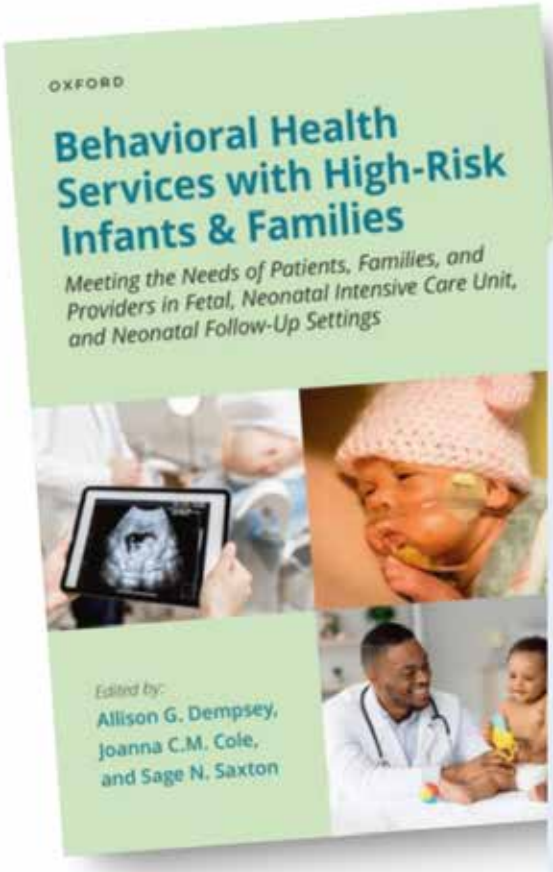
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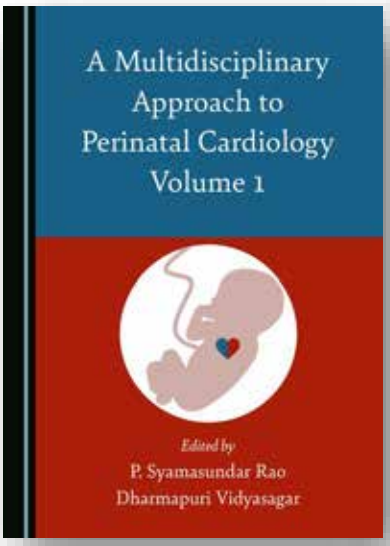
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A Multidisciplinary Approach to Perinatal Cardiology *Volume 1*

Edited by P. Syamasundar Rao and Dharmapuri Vidyasagar



Hardback

ISBN-13:
978-1-5275-6722-1

ISBN-10:
1-5275-6722-2

Date of Publication:
24/04/2021

Pages / Size:
794 / A5

Price:
£99.99

Book Description

Recent developments in diagnostic and therapeutic aspects of cardiac and neonatal issues have advanced the care of the newborn. To achieve excellence in cardiac care, however, close interaction and collaboration of the pediatric cardiologists with neonatologists, pediatricians, general/family practitioners (who care for children), anesthesiologists, cardiac surgeons, pediatric cardiac intensivists, and other subspecialty pediatricians is mandatory. This book provides the reader with up-to-date evidence-based information in three major areas of neonatology and prenatal and neonatal cardiology. First, it provides an overview of advances in the disciplines of neonatology, prenatal and neonatal cardiology, and neonatal cardiac surgery in making early diagnosis and offering treatment options. Secondly, it presents a multidisciplinary approach to managing infants with congenital heart defects. Finally, it provides evidence-based therapeutic approaches to successfully treat the fetus and the newborn with important neonatal issues and congenital cardiac lesions. This first volume specifically explores issues related to perinatal circulation, the fetus, ethics, changes in oxygen saturations at birth, and pulse oximetry screening, diagnosis, and management.

About the Editors

Dr P. Syamasundar Rao, MD, DCH, FAAP, FACC, FSCAI, is Professor of Pediatrics and Medicine and Emeritus Chief of Pediatric Cardiology at the University of Texas-Houston Medical School. He received his medical degree from Andhra Medical College, India, and subsequently received post-graduate training both in India and the USA before joining the faculty at the Medical College of Georgia, USA, in 1972. He has also served as Chairman of Pediatrics at King Faisal Specialist Hospital and Research Center, Saudi Arabia, and Professor and Director of the Division of Pediatric Cardiology at the University of Wisconsin and St. Louis University, USA. He has authored 400 papers, 16 books and 150 book chapters, and is a recipient of numerous honors and awards.

Dr Dharmapuri Vidyasagar, MD, MSc, FAAP, FCCM, PhD (Hon), is currently Professor Emeritus in Pediatrics at the University of Illinois, Chicago, where he served as Professor of Pediatrics for four decades. He is a graduate of Osmania Medical College, India. He has published over 250 papers and authored several books with a focus on prematurity, neonatal pulmonary diseases and neonatal ventilation. His goal is to reduce neonatal mortality in the USA and around the world, and he has received multiple awards and honors including the Ellis Island Award.

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About the Program

- **WHO SHOULD TAKE THE PROGRAM?** This program is designed for both office and hospital staff in all disciplines that interact with pregnant patients and their families. A key focus is recognizing risk factors for perinatal mood and anxiety disorders, and mitigating their impact through provision of trauma-informed care.

- **WHY TAKE THE PROGRAM?** Families will benefit when staff have improved skills, through enhanced parental resilience and better mental health, and improved parent-baby bonding leading to better developmental outcomes for babies. Benefits to staff include improved skills in communicating with patients; improved teamwork, engagement and staff morale; reduced burnout, and reduced staff turnover.

- **HOW DOES THE PROGRAM ACHIEVE ITS GOALS?** Program content is representative of best practices, engaging and story-driven, resource-rich, and developed by a unique interprofessional collaboration of obstetric and neonatal professionals and patients. The program presents practical tips and an abundance of clinical information that together provide solutions to the emotional needs of expectant and new parents.

- **HOW WAS THE PROGRAM DEVELOPED?** This program was developed through collaboration among three organizations: a multidisciplinary group of professionals from the National Perinatal Association and Patient + Family Care, and parents from the NICU Parent Network. The six courses represent the different stages of pregnancy (antepartum, intrapartum, postpartum), as well as perinatal mood and anxiety disorders, communication techniques, and staff support.

Program Objectives

- Describe principles of trauma-informed care as standards underlying all communication during provision of maternity care in both inpatient and outpatient settings.
- Identify risk factors, signs, and symptoms of perinatal mood and anxiety disorders; describe treatment options.
- Define ways to support pregnant patients with high-risk conditions during the antepartum period.
- Describe obstetric violence, including ways that providers may contribute to a patient's experience of maternity care as being traumatic; equally describe ways providers can mitigate obstetric trauma.
- Describe the importance of providing psychosocial support to women and their families in times of pregnancy loss and fetal and infant death.
- Define the Fourth Trimester, and identify the key areas for providing psychosocial support to women during the postpartum period.
- Identify signs and symptoms of burnout as well as their ill effects, and describe both individual and systemic methods for reducing burnout in maternity care staff.

Continuing education credits will be provided for physicians, clinic and bedside nurses, social workers, psychologists, and licensed marriage and family therapists. CEUs will be provided by Perinatal Advisory Council: Leadership, Advocacy, and Consultation.

PROGRAM CONTENT



COMMUNICATION SKILLS CEUs offered: 1

Learn principles of trauma-informed care, use of universal precautions, how to support LGBTQ patients, obtaining informed consent, engaging in joint decision-making, delivering bad news, dealing with challenging patients.

Faculty: Amina White, MD, MA, Clinical Associate Professor, Department of OB/Gyn, University of North Carolina, Chapel Hill, NC; Sue Hall, MD, MSW, FAAP, St. John's Regional Medical Center, Oxnard, CA; Karen Saxer, CNM, MSN, University of North Carolina Maternal-Fetal Medicine, UNC Women's Hospital, Chapel Hill, NC; Tracy Pella, Co-Founder & President, Connected Forever, Tecumseh, NE.



PERINATAL MOOD AND ANXIETY DISORDERS CEUs offered: 1

Identify risk factors for and differential diagnosis of PMADs (perinatal mood and anxiety disorders), particularly perinatal depression and/or anxiety and posttraumatic stress syndrome. Learn the adverse effects of maternal depression on infant and child development, and the importance of screening for and treating PMADs.

Faculty: Linda Baker, PsyD, psychologist at Unstuck Therapy, LLC, Denver, CO; Sue Hall, MD, MSW, FAAP, neonatologist at St. John's Regional Medical Center, Oxnard, CA; Angela Davids, Founder of Keep 'Em Cookin', Baltimore, MD; Brittany Boet, Founder of Bryce's NICU Project, San Antonio, TX.



PROVIDING ANTEPARTUM SUPPORT CEUs offered: 1

Identify psychosocial challenges facing high risk OB patients, and define how to provide support for them, whether they are inpatient or outpatient. Recognize when palliative care is a reasonable option to present to pregnant patients and their families.

Faculty: Amina White, MD, MA, Clinical Associate Professor, Department of OB/Gyn, University of North Carolina, Chapel Hill, NC; Sue Hall, MD, MSW, FAAP, neonatologist at St. John's Regional Medical Center, Oxnard, CA; Angela Davids, Founder of Keep 'Em Cookin', Baltimore, MD; Erin Thatcher, BA, Founder and Executive Director of The PPROM Foundation, Denver, CO.



PROVIDING INTRAPARTUM SUPPORT CEUs offered: 1

Describe how to manage patient expectations for labor and delivery including pain management; identify examples of obstetric violence, including identification of provider factors that may increase patients' experience of trauma; learn how to mitigate patients' trauma, and how to provide support during the process of labor and delivery.

Faculty: Sara Detlefs, MD, Fellow in Maternal-Fetal Medicine, Baylor College of Medicine, Houston, TX; Jerry Ballas, MD, MPH, Associate Clinical Professor, UCSD Health System, Maternal-Fetal Medicine, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California at San Diego, San Diego, CA; MaryLou Martin, MSN, RNC-NIC, CKC, Women's and Children's Services Nurse Educator, McLeod Regional Medical Center, McLeod, SC; Claire Hartman, RN, IBCLC, Labor & Delivery, University of North Carolina Hospital, Chapel Hill, NC; Crystal Duffy, Author of Twin To Twin (from High Risk Pregnancy to Happy Family), and NICU Parent Advisor, Houston, TX; Erin Thatcher, Founder and Executive Director of The PPROM Foundation, Denver, CO.



PROVIDING POSTPARTUM SUPPORT CEUs offered: 1

Define the 4th Trimester and the importance of follow-up especially for high risk and minority patients, learn to recognize risk factors for traumatic birth experience and how to discuss patients' experiences postpartum; describe the application of trauma-informed care during this period, including support for patients who are breastfeeding and those whose babies don't get to go home with them.

Faculty: Amanda Brown, CNM, University of North Carolina Hospital, Chapel Hill, NC; ; Sue Hall, MD, MSW, FAAP, neonatologist at St. John's Regional Medical Center, Oxnard, CA; Crystal Duffy, Author of Twin To Twin (from High Risk Pregnancy to Happy Family), and NICU Parent Advisor, Houston, TX.



SUPPORTING STAFF AS THEY SUPPORT FAMILIES CEUs offered: 1

Define burnout and compassion fatigue; identify the risks of secondary traumatic stress syndrome to obstetric staff; describe adverse impacts of bullying among staff; identify the importance of both work-life balance and staff support.

Faculty: Cheryl Milford, EdS, Consulting NICU and Developmental Psychologist, Director of Development, National Perinatal Association, Huntington Beach, CA; Sue Hall, MD, MSW, FAAP, neonatologist at St. John's Regional Medical Center, Oxnard, CA; Erin Thatcher, BA, Founder and Executive Director, The PPROM Foundation, Denver, CO

Cost

- RNs: $10/CEU; $60 for the full program
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- Although PACLAC cannot award CEs for certified nurse midwives, they can submit certificates to their own professional organization to request credit. $35/CEU; $210 for the full program

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Faculty

Linda Baker, PsyD
Psychologist at Unstuck Therapy, LLC, Denver, CO.

Jerasimos (Jerry) Ballas, MD, MPH
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  - If you elect to take more than one course and pay in advance, there will be no cancellations or refunds after payment has been made unless a written request is sent to help@myperinatalnetwork.com and individually approved.
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  - After we are in possession of a signed contract by an authorized agent of the hospital and the program fees have been paid, a 50% refund of the amount paid will be given if we are in receipt of a written request to cancel at least 14 (fourteen) days prior to the scheduled start date for your hospital's online program.
  - Refunds will not be given for staff members who neglect to start the program. Also, no refunds for those who start the program, but do not complete all 6 courses within the time frame allotted.

For Physicians: This activity has been planned and implemented in accordance with the Institute for Medical Quality and the California Medical Association's CME Accreditation Standards (IMQ/CMA) through the Joint Providership of the Perinatal Advisory Council: Leadership, Advocacy and Consultation (PAC/LAC) and the National Perinatal Association. PAC/LAC is accredited by the Institute for Medical Quality/California Medical Association (IMQ/CMA) to provide continuing education for physicians. PAC/LAC takes responsibility for the content, quality and scientific integrity of this CME activity. PAC/LAC designates this activity for a maximum of 6 *AMA PRA Category 1 Credit(s)TM*. Physicians should only claim credit commensurate with the extent of their participation in the activity. This credit may also be applied to the *CMA Certification in Continuing Medical Education*.

For Nurses: The Perinatal Advisory Council: Leadership, Advocacy and Consultation (PAC/LAC) is an approved provider by the California Board of Registered Nursing Provider CEP 5862. When taken as a whole, this program is approved for 7 contact hours of continuing education credit.

For CAMFT: Perinatal Advisory Council: Leadership, Advocacy, and Consultation (PAC/LAC) is approved by the California Association of Marriage and Family Therapists to sponsor continuing education for LMFTs and LCSWs. CE Provider #128542. PAC/LAC maintains responsibility for the program and its content. Program meets the qualifications for 6 hours of continuing education credit for LMFTs and LCSWs as required by the California Board of Behavioral Sciences. You can reach us at help@myperinatalnetwork.org.

SHARED DECISION-MAKING PROTECTS MOTHERS + INFANTS DURING COVID-19

KEEPING MOTHERS + INFANTS TOGETHER

Means balancing the risks of...

- **HORIZONTAL INFECTION**
- **SEPARATION AND TRAUMA**





EVIDENCE

We encourage families and clinicians to remain diligent in learning **up-to-date evidence**.

PARTNERSHIP

What is the best for this unique dyad?

SHARED DECISION-MAKING

- **S** EEK PARTICIPATION
- **H** ELP EXPLORE OPTIONS
- **A** SSESS PREFERENCES
- **R** EACH A DECISION
- **E** VALUATE THE DECISION





TRAUMA-INFORMED

Both parents and providers are confronting significant...

- **FEAR**
- **GRIEF**
- **UNCERTAINTY**

LONGITUDINAL DATA

We need to understand more about outcomes for mothers and infants exposed to COVID-19, with special attention to:

- **MENTAL HEALTH**
- **POSTPARTUM CARE DELIVERY**



NEW DATA EMERGE DAILY. NANN AND NPA ENCOURAGE PERINATAL CARE PROVIDERS TO ENGAGE IN CANDID CONVERSATIONS WITH PREGNANT PARENTS PRIOR TO DELIVERY REGARDING RISKS, BENEFITS, LIMITATIONS, AND REALISTIC EXPECTATIONS.

Partnering for patient-centered care when it matters most.

nann.org nationalperinatal.org

National Association of Neonatal Nurses

National Perinatal Association

FREE ONLINE EDUCATION

Coping with COVID-19





A viral pandemic

A racial pandemic within a viral pandemic









Will mental illness be the next inevitable pandemic?

WWW.MYNICUNETWORK.ORG

and

National Perinatal Association
NICU Parent Network

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Alliance for Patient Access: Legislation Targets Maternal Care Gaps in Medicaid Program

Josie Cooper

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.

A new bill in Congress could reshape maternal care for women across the country.

"The HEALTH for MOM Act would fund state efforts to build more coordinated, accessible, and responsive care for pregnant and postpartum women who are insured through Medicaid programs. With one of the highest maternal mortality rates in the developed world — 80% of which are preventable- the United States faces an urgent need for action."

The HEALTH for MOM Act would fund state efforts to build more coordinated, accessible, and responsive care for pregnant and postpartum women who are insured through Medicaid programs. With one of the highest maternal mortality rates in the developed world — 80% of which are preventable- the United States faces an urgent need for action.

Support for States to Reach Underserved Communities



The federal and state governments jointly fund Medicaid to provide healthcare for low-income individuals, pregnant women, and young children.

While Medicaid covers nearly half of all births, policymakers recognize that the program could improve the way it provides prenatal and postpartum services. For many women, particularly those in rural areas, fragmented care contributes to dangerous delays and missed diagnoses.

"While Medicaid covers nearly half of all births, policymakers recognize that the program could improve the way it provides prenatal and postpartum services. For many women, particularly those in rural areas, fragmented care contributes to dangerous delays and missed diagnoses."

By promoting flexibility and innovation, the HEALTH for MOM Act would enable state and local providers to tailor care to the specific needs of prenatal and postpartum mothers in their communities.

For populations with limited access to routine care, support may include telehealth services or transportation assistance to a clinic. In diverse communities, implementing culturally responsive care models may be a higher priority. Regardless of location, investments like these can be a lifeline for pregnant women and new mothers during a beautiful but often challenging period.

Medical Homes Make a Difference

Despite the country's abundance, too many mothers die from conditions that could have been prevented with timely, coordinated care. From postpartum hemorrhage to hypertension and eclampsia, the risks are well-known, but care remains fragmented.

"By supporting state-led efforts to meet local needs, the HEALTH for MOM Act aims to improve outcomes for expectant and new mothers on Medicaid by enhancing access to maternity services in ways that meet local needs. This legislation can reduce maternal risk, save lives, and strengthen families; it's worth supporting."

To reverse this reality, the new bill would also support states' efforts to establish maternal health homes that offer comprehensive maternity services, preventive care, and health screenings with a focus on continuity and coordination. Individualized care planning and support for follow-up are correlated with fewer emergency department visits and better long-term outcomes.

By supporting state-led efforts to meet local needs, the HEALTH for MOM Act aims to improve outcomes for expectant and new mothers on Medicaid by enhancing access to maternity services in ways that meet local needs. This legislation can reduce maternal risk, save lives, and strengthen families; it's worth supporting.

References:

1. https://pressley.house.gov/2025/05/12/pressley-nunn-underwood-reintroduce-bill-to- expand-access-to-maternal-healthcare/
2. https://www.aha.org/fact-sheets/2025-02-07-fact-sheet-medicaid

Social Suggestions:

- The HEALTH for MOM Act helps states offer better coordinated care for pregnant and postpartum women on Medicaid.
- Pregnancy is hard enough. The HEALTH for MOM Act aims to help pregnant and postpartum moms with improved access to services that can keep them healthy and strong.
- The HEALTH for MOM Act invests in locally directed innovations that could save lives.
- The HEALTH for MOM Act supports coordinated, community-based care for pregnant women.
- More access. Better outcomes. Fewer emergencies. That is the point of the HEALTH for MOM Act.

Disclosure: Josie Cooper is the Executive Director of the Alliance for Patient Access. This article was also published at healthpolicytoday.org.

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Immunizing Yourself Against **COVID-19**

COVID-19 vaccines have been shown to:

- Lessen the severity of symptoms[1]
- Reduce disease transmission[3]
- Reduce risk of mortality[2]
- Make communities healthier and safer[4]

Understanding the Options

COVID-19 vaccines are available for children, adolescents and adults. There are 3 types to choose from.

mRNA VACCINES

New to market, but research has been ongoing since the 1990s.

HOW THEY WORK: **Instruct cells to make COVID-like proteins that trigger the immune system to fight the virus.**

PROTEIN SUBUNIT VACCINES

Used for three decades against the flu, whooping cough and hepatitis B.

Deliver harmless versions of the COVID protein that train the immune system to fight the virus.

VECTOR VACCINES

Used for decades against chickenpox, malaria and tuberculosis.

Use a modified virus, such as a common cold, to teach the body to fight off COVID.

COVID vaccines are recommended for everyone ages 6 months and older, and boosters for everyone ages 5 years and older, if eligible.[5]

Safe and Sound

COVID vaccines have been:

- **Thoroughly tested** through multi-phase trials with tens of thousands of participants[6]
- **Proven safe and effective** for adults as well as children[7]
- **Vetted and approved** by the US FDA and EMA and endorsed by the WHO[8-10]

Get Your Jab

Vaccines are available at your:

- **Doctor's office**
- **Neighborhood pharmacy**
- **Community health center**



Talk to your **health care provider** or **pharmacist** about which vaccine is right for you.

1. https://www.mayoclinic.org/diseases-conditions/coronavirus/symptoms-causes/syc-20479963
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8782520/
3. https://www.nejm.org/doi/full/10.1056/nejmc2107717
4. https://royalsocietypublishing.org/doi/full/10.1098/rsif.2020.0683
5. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
6. https://doh.wa.gov/emergencies/covid-19/vaccine-information/safety-and-effectiveness
7. https://doh.wa.gov/emergencies/covid-19/vaccine-information/safety-and-effectiveness
8. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
9. https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-authorised
10. http://www.bccdc.ca/Health-Info-Site/Documents/COVID-19_vaccine/WHO-EUA-qualified-covid-vaccines.pdf

GAfPA Global Alliance for Patient Access

NCPA NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

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- Evidence-Based

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Still a **Preemie?**

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.

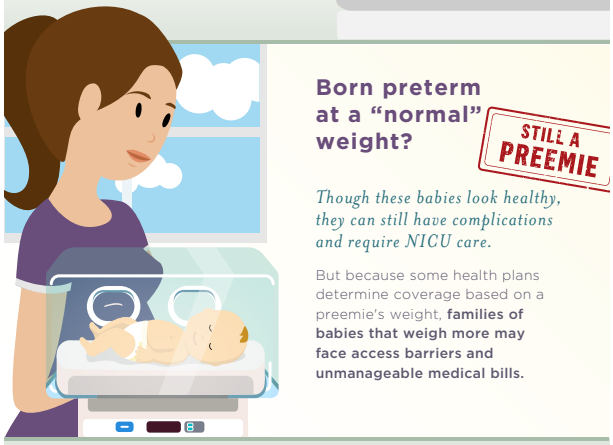
Born between 34 and 36 weeks' gestation?

STILL A PREEMIE

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 PREEMIE

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

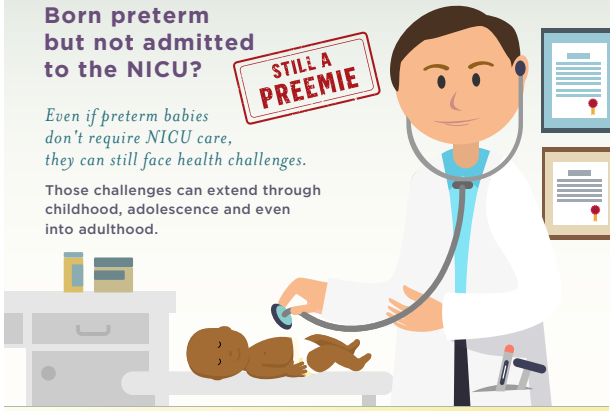
But because some health plans determine coverage based on a preemie's weight, **families of babies that weigh more may face access barriers and unmanageable medical bills.**

Born preterm but not admitted to the NICU?

STILL A PREEMIE

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

- Will spend weeks in the hospital
- Will have lifelong health problems
- Are disadvantaged from birth

All Preemies

- Face health risks
- Deserve appropriate health coverage
- Need access to proper health care

NCfIH National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

www.infanthealth.org

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

iCAN July Newsletter: The Summit Edit Pushing the Bounds of Youth-Driven Patient Centricity An Organization Propelling Change

Abby Clark

iCAN International Children's Advisory Network

Get involved today and Join the iCAN Parent Council!

"iCAN, the International Children's Advisory Network, is the premier global pediatric platform working to empower the patient voice in healthcare, driven by youth for youth. As a worldwide network of 40+ KIDS (Kids Impacting Disease through Science) advisory groups that spans four continents (as well as virtually), iCAN's dedicated youth member groups work in unison to provide a voice for children and families in medicine, research, science, and innovation."

iCAN, the International Children's Advisory Network, is the premier global pediatric platform working to empower the patient voice in healthcare, driven by youth for youth. As a worldwide network of 40+ KIDS (Kids Impacting Disease through Science) advisory groups that spans four continents (as well as virtually), iCAN's dedicated youth member groups work in unison to provide a voice for children and families in medicine, research, science, and innovation. To foster greater global understanding about the importance of the pediatric patient and caregiver voice in healthcare, clinical trials, and research, iCAN's young people continue to drive incredible change in the global health landscape.

"iCAN celebrates the understanding that all patients, even the youngest, have valuable insights into improving the healthcare experience. All children, regardless of their location, are welcome to participate in iCAN's programming. iCAN also supports young adults, as well as the voices of parents and siblings. We continue to be an ecosystem of schools, children's hospitals, academia, and other like-minded non-profits."

On average, our youth are between the ages of eight and eighteen years old, most of whom are living with chronic, rare, and complicated diagnoses; although, not all of iCAN's youth members have a medical diagnosis or medical condition. iCAN celebrates the understanding that all patients, even the youngest, have valuable insights into improving the healthcare experience. All children, regardless of their location, are welcome to participate in iCAN's programming. iCAN also supports young adults, as well as the voices of parents and siblings. We continue to be an ecosystem of schools, children's hospitals, academia, and other like-minded non-profits.

Our mission is to ensure that youth are placed in positions where their voices are heard and make a difference in pediatric healthcare through interactions with industry professionals, presenting





original research at conferences, innovating new solutions, and sharing their stories. iCAN continues to empower the pediatric patient voice through community partnerships with organizations such as the FDA, the Everylife Foundation for Rare Diseases, the PFMD, MRCT, iSPI, and the AAP.

Whether you are a patient, family member, friend, healthcare professional, or simply an individual looking to make a difference, you are welcome to visit our website at www.icanresearch.org to explore our mission, programs, and initiatives. Join us today in ensuring that every child's voice is enshrined in the effort to improve healthcare for all pediatric patients.

"As the sun sets on the 2025 iCAN Summit (hosted in Montreal, Canada, from July 14-18), we want to take some time to reflect on the incredible strides made in empowering pediatric patients. During the week of July, the voices and insights of youth and families resonated throughout the global healthcare community."

The 2025 iCAN Summit: A Youth-Led Movement

As the sun sets on the 2025 iCAN Summit (hosted in Montreal, Canada, from July 14-18), we want to take some time to reflect on the incredible strides made in empowering pediatric patients. During the week of July, the voices and insights of youth and families resonated throughout the global healthcare community.

Communities from all over the world came together to exchange ideas, foster cross-cultural connections, and identify lessons learned to propel healthcare advocacy into a new light.

This year, which marks eleven years since the inaugural Summit, iCAN is proud to say that what once started as a small group of passionate individuals and a dream has grown into an event that has brought together representation from 11 countries, spanning four continents, and an overall attendance of over 170 members. The 2025 iCAN Summit challenges the traditional inclusion of patients in healthcare by ensuring that youth are not only involved in the creation process but also lead the charge. Thank you to our families and caregivers, our industry friends (researchers, clinicians, and healthcare innovators), community partners, and our youth and young people for guiding iCAN through another Summit of incredible change. Through your involvement, you have transformed the Summit as well as the healthcare landscape itself, ensuring that the perspectives of children are even more central to the Summit's core mission.

Day One Summit Highlights:

- We kicked the Summit off with a strong start, celebrating the incredible work the iCAN community has accomplished throughout the year. We completed over 20 feedback projects from January to June, changing pediatric patient-facing products for the betterment of future patients. iCAN youth and families have spoken out around the world, such as at FDA workshops, and created incredible service projects, including the iCAN "Coloring for Change" coloring book. They have also grown the chapter program to 46 global chapters.
- Aaron Horowitz from Empath Labs shared an incredible real-world example of how iCAN youth have made a tangible impact in the world of pediatrics through his process of designing with iCAN youth to improve the clinical trial experience. He took us through what is possible when young people are given a seat at the table shaping solutions made for them.
- Youth members continued to be engaged and educated in the process of patient-centricity in healthcare through BioCryst's standout session, "From Molecule to Medicine to Me: Using Your Voice in Drug Development," and researcher Kathy Malas's session, "Let's Co-Create an Education Tool: Design Thinking in Action."

Day Two Summit Highlights:

- The topic of the day was digital data! Industry leaders, Pfizer and Eli Lilly, came to our youth with the goal of better understanding how digital data collection can be best adapted to users, and what better way to understand what changes to



enact than by gleaning insights from the youth themselves?

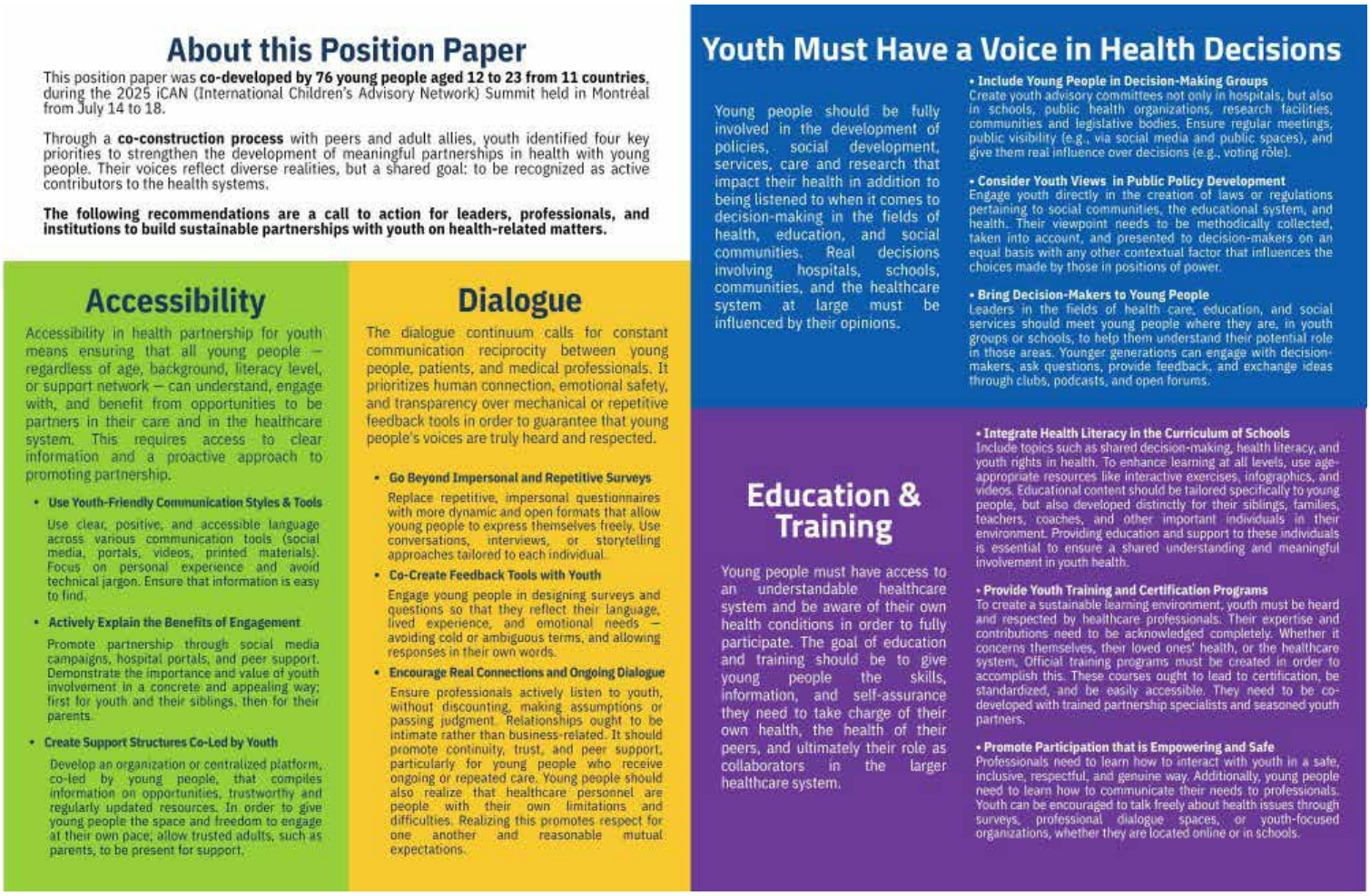
- iCAN's first poster session of the Summit showcased the standout work that iCAN chapters have done throughout the year. KIDS Mexico City blew the room out of the water by describing their research on improving the experience of the APAC, a non-profit based in Mexico City, and its programs. In their own words, "the results of the survey allow us not only to identify advancement in the empowerment of children and teenagers in decision making in matters which affect their health but also evidence a significant gap between the country's legal framework and its application in real-life clinical contexts."

- Wrapping up day two, Dr. Sharon Smith, from Children's Connecticut Hospital and KIDS Connecticut Chapter Leader, led the group in an exercise where the youth played the role of doctors. Taking the attendees through the steps of a diagnosis, Dr.Smith was able to illustrate the deductive process of symptom identification, to disease configuration, to eventual diagnosis, providing our youth with greater insight into how their conditions may have been diagnosed, giving them a greater understanding of the "mystery" of what is sometimes a diagnosis odyssey.

Day Three Summit Highlights:

- Both iCAN Youth and Parents had the opportunity to attend a mental health session tailored for them! PhD Candidate, Brandon Benchimol-Elkaim, led the youth attendees in exploring practical tools for dealing with stressors and anxieties that come with living with a medical condition, while Dr. Marie-Eve Buldoc, Assistant Professor of Occupational





Therapy at McGill University, engaged our adult attendees in themes of understanding, empowering, and connecting parental mental health.

- Representatives from Georgia Tech's Design for Planet Impact team wowed the room with their innovative product designs, which can be manufactured at a low cost to support underserved communities. They shared many incredible projects before delving into their work on "Team Fuzzy," a project aimed at creating a stuffed toy to help children through traumatic experiences. Our youth were able to get creative and come up with their versions of comfort toys that would help manage personal stress during hospitalizations or other healthcare traumas.

"Together with his chapter leader, his story was shared in both English and Spanish, demonstrating iCAN's commitment to linguistic and cultural inclusivity. His powerful message of how kids with disabilities can have a powerful voice and impact set the tone for the incredible last day of the 2025 iCAN Summit."

Day Four + Day 5 Summit Highlights:

- We kicked off the last full day of the Summit by sharing an incredible story from Gael, a KIDS Mexico City Youth member. Together with his chapter leader, his story was shared in both English and Spanish, demonstrating iCAN's commitment to linguistic and cultural inclusivity. His powerful message of how kids with disabilities can have a powerful voice and impact set the tone for the incredible last day of the 2025 iCAN Summit.

- Our youth had the opportunity to explore various roles in healthcare through our in-person "Ask the Experts: Careers in Healthcare" panel. iCAN youth were able to learn from and ask questions to experts in the med-tech space, including clinical scientists, nurses, advocates, clinical researchers, healthcare educators, and psychologists. We know that our youth are the future of healthcare—and by sharing the breadth of roles in healthcare, iCAN youth are poised to create lasting change in the years to come.

- Finally, our youth presented their Activity of the Week project: A youth-driven *International Position Paper on Youth Partnership in Healthcare.* Throughout the week, our youth, led by host Chapter Leader Catherine Wilhelmy, drafted a position paper focusing on the accessibility of healthcare for youth, the importance of keeping the youth voice at the forefront in healthcare decisions, and the need for healthcare education and training for youth. First presented to the whole conference, select youth leaders then presented the position paper (in both French and English) at the Summit's closing press conference and to Lesley Hill, Montreal Director of

Youth Protection.

International Position Paper on Youth Partnership in Healthcare

Connecting with Future Changemakers: Sabina Schmidt Goldstein-Becerra Meets with CHOC Mi4 Interns:

At the beginning of July, Sabina, Executive Director of the International Children's Advisory Network (iCAN), joined a virtual session with high school students in the CHOC Mi4 Summer Internship Program to share how young people are helping shape the future of healthcare.

She spoke about iCAN's global network of youth, families, and community partners who work together to make pediatric healthcare more inclusive and patient-centric. From contributing to research design to advising on clinical trials and product development, young people are playing a fundamental role, and doing it now.

"What stood out most was not just the thoughtful questions the interns asked, but also the evident enthusiasm they showed for getting involved. Several students inquired about establishing their iCAN chapters at their schools. Some had ideas for local projects and were already thinking about how to connect with others who share their passion for making a difference."

What stood out most was not just the thoughtful questions the interns asked, but also the evident enthusiasm they showed for getting involved. Several students inquired about establishing their iCAN chapters at their schools. Some had ideas for local projects and were already thinking about how to connect with others who share their passion for making a difference.

"It was great to see how quickly they connected with the idea that they don't need to wait to lead," Sabina said. "They already have the interest, the lived experience, and the drive."

While the meeting was virtual, the momentum felt very real. For many of the interns, this was not just an informational session; it was the beginning of something they could take with them into their schools and communities.

To learn more about how to get involved or start a chapter, visit icanresearch.org.

Looking Ahead: How Youth are Transforming the World of Healthcare Advocacy this Summer and Beyond:

- **Ask the Experts:**
  - Ask the Experts is a monthly webinar series hosted by iCAN to connect our young people to changemakers and experts in health. By engaging directly with these healthcare transformers, our youth can learn about topics they are interested in, explore careers, and discover additional ways to engage in the broad world of healthcare.
  - Mark your calendars - iCAN invites you to another installment of Ask the Experts on August 16 with our Irish chapter, KIDS RAiN CRAG! Click Here to Register.
  - Stay tuned for more updates and chances to connect with experts like our KIDS RAiN CRAG youth members!
  - Want to be part of our next *Ask the Experts* Session? Please reach out to sabina@icanresearch.org.
- **Pen Pal Project:**
  - Spearheaded by our POLPEDNET KIDS Chapter based in Poland, this brand-new initiative invites iCAN youth from all over the world to connect in shared experience and new friendships!



NEONATOLOGY TODAY is interested in publishing manuscripts from Neonatologists, Fellows, NNPs and those involved in caring for neonates on case studies, research results, hospital news, meeting announcements, and other pertinent topics.

Please submit your manuscript to: LomaLindaPublishingCompany@gmail.com

The 2026 iCAN Summit

Our annual Summit serves as a transformative platform for innovation, compassion, and collaboration in pediatric healthcare. The shifting landscape in the current healthcare industry has made an in-person Summit for 2026 uncertain. The lasting impact of this annual event on the youth who attend, the iCAN Network, and the broader healthcare community as a whole cannot be measured. Together, we continue to make a tangible and meaningful impact on pediatric healthcare. By giving every child a seat at the table through discussion and co-creation, both current and future pediatric patients are empowered and transformed. We invite you to be part of this life-changing event by contributing in three meaningful ways:

1. Sponsor the 2026 Summit: Your sponsorship will play a vital role in ensuring a transformative experience for all attendees.

2. Sponsor a Child to Attend: Your sponsorship directly impacts a child's life by granting them the opportunity to attend the Summit. Your support will cover travel, accommodation, and participation, offering them a world of learning and empowerment. Together, we are shaping a brighter future for pediatric healthcare. Your contribution, big or small—makes a significant difference in prioritizing the patient voice and driving positive change. Your generosity and dedication are deeply valued. Let us unite to create a summit experience that empowers the pediatric community for years to come.

3. Contribute to the GoFundMe for the iCAN 2026 Summit: We want our next Summit to be in person—and we can only do that with your support! Our goal is to raise $200,000 by December 1, 2025. Please share or donate to our GoFundMe:

   - https://gofund.me/525439b3
   - www.icanresearch.org

"Sponsor a Child to Attend: Your sponsorship directly impacts a child's life by granting them the opportunity to attend the Summit. Your support will cover travel, accommodation, and participation, offering them a world of learning and empowerment. Together, we are shaping a brighter future for pediatric healthcare. Your contribution, big or small—makes a significant difference in prioritizing the patient voice and driving positive change."

Let us work together to make our 2026 Summit even bigger by bringing more kids to share their voices! To contribute to the funding for next year's Summit, please click here to sponsor or make a donation.

Disclosures: *There are no reported disclosures*

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by Gavrieli

Murad

RESTAURANT
GREEN STREET

WHEEL FUN
RENTALS

gorjana

USS Midway
MUSEUM

AMERICA'S LIVING
SYMBOL OF FREEDOM

KINGS ICE

California
BOTANIC GARDEN

Betty Up

Raising
Cane's
CHICKEN FINGERS

BATTLESHIP
IOWA
LOS ANGELES

NEW WEST SYMPHONY
MICHAEL CHRISTIE | Music Director

PHILHARMONIC
SOCIETY
presents

NEWPORT
LANDING

THE MISSION INN FOUNDATION
RIVERSIDE
VISITOR CENTER + MUSEUM

Fiesta Village
Family Fun Park

WILLOW
THEATRICUM · BOTANICUM

CPH
CORONADO
PLAYHOUSE

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RESTAURANTS

THE HUNTINGTON

Hollywood
WAX MUSEUM

SANTA
MONICA
PLAYHOUSE

SANTA ANITA
PARK

Go Kart World

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RISTORANTE

DOMENICO'S
RESTAURANT

ENJOY DELIGHT. YOU DESERVE IT.

Brent's

CHIPOTLE
MEXICAN GRILL

Panera
BREAD

Caroline Arnold, Author

BARK
BOX

PETERSEN
AUTOMOTIVE MUSEUM

Want to Strengthen your NICU's Safe Sleep Efforts?

LET'S TALK IN THE NICU: PREPARING FAMILIES FOR SAFE SLEEP AT HOME

HOW CAN ONE CONVERSATION CHANGE EVERYTHING?

Let's Talk Community Chats are now in the NICU—bringing culturally responsive, judgment-free safe sleep and breastfeeding education directly to families before discharge.

Led by **community peers trained by First Candle** and adhering to AAP Guidelines, these sessions empower NICU parents with knowledge, support, and resources to help protect their most vulnerable babies.



Learn how you can bring Let's Talk to your NICU.

Email alison@firstcandle.org for more information

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LET'S TALK
Community Chats
IN THE NICU

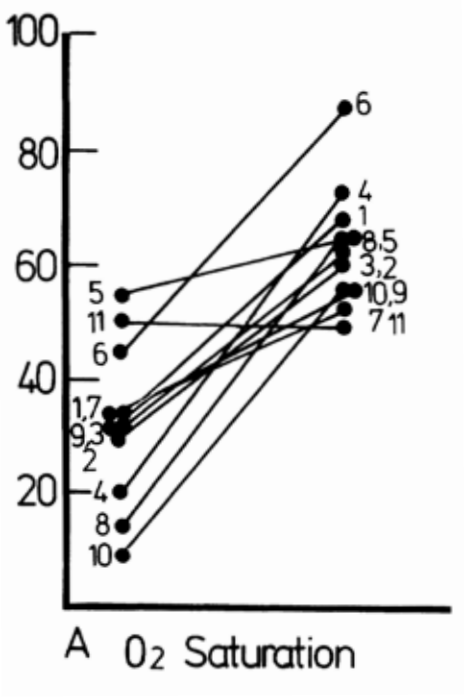


Historical Perspective: Prostaglandin E_1

Joseph B. Philips, III, MD, FAAP

I had only been at UAB for a few weeks in the summer of 1980, starting my academic career as an Assistant Professor, when I was summoned to the office of Dr. John W. Kirklin, a world-renowned cardiovascular surgeon. Dr. Kirklin began his career at The Mayo Clinic, where he perfected the heart-lung bypass machine and pioneered open heart surgery, often for congenital heart defects. (1) He was recruited to UAB in 1966, where he continued his innovative work. He was a living legend, and I had no idea why he wanted to meet with me, a fledgling junior faculty member. The reason became clear after we exchanged pleasantries. He said something like "I understand you've been working with prostaglandins." This was true. During my fellowship, I worked in the laboratory of Dr. Sidney Cassin studying the effects of various eicosanoids on the pulmonary circulation of exteriorized fetal goats. (2, 3) Prostaglandin E_1 (PGE_1) had recently been shown to reopen or maintain patency of the ductus arteriosus in animal models (4, 5) and infants with ductal-dependent pulmonary or systemic blood flow (Figure 1). (6–9) "I want this drug here now," said Dr. Kirklin, "This is my associate, Dr. Eugene Blackstone, who will help you get Investigational New Drug approval from the Food and Drug Administration." Dr. Blackstone, who went on to a distinguished career as well, assisted with the paperwork, and in fairly short order, we had the drug in hand, nearly a full year before its approval by the FDA in July 1981.

Figure 1. Changes in oxygen saturation with PGE1 infusion. (9) Patient 11 was 99 days old when treated and therefore would not be expected to respond.



It is hard to describe the profound impact this miracle drug had at the time. Echocardiography was in its infancy (pun intended) and was not very helpful in establishing an anatomic diagnosis.

"Prostaglandin E_1 (PGE_1) had recently been shown to reopen or maintain patency of the ductus arteriosus in animal models and infants with ductal-dependent pulmonary or systemic blood flow. 'I want this drug here now,' said Dr. Kirklin, 'This is my associate, Dr. Eugene Blackstone, who will help you get Investigational New Drug approval from the Food and Drug Administration.' ...and in fairly short order, we had the drug in hand, nearly a full year before its approval by the FDA in July 1981."

Routine fetal ultrasounds were years in the future, and there was no screening for congenital heart disease in the newborn nursery. Pulse oximetry devices were in the early stages of development and were not yet part of clinical care. So, unless an infant were visibly cyanotic or had an evil-sounding heart murmur, she would be discharged, only to return within a few days to the emergency department, often late at night. Her presentation would be either profound cyanosis or extreme pallor as a result of ductal constriction shutting off blood flow to the lungs or body, depending on the lesion. In either situation, severe metabolic acidosis and hemodynamic instability would occur. I vividly recall how we would obsess over the physical findings, chest radiograph, EKG, and laboratory data, trying to guess the correct diagnosis. The baby would then be taken to the cardiac catheterization laboratory, where a hastily convened team would establish an anatomic diagnosis. If he survived this, he would then be taken to the operating room, where an equally urgently assembled team would

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perform emergency surgery on an infant in awful overall condition. As you can imagine, the results were often not good.

PGE_1 changed all of that. It was wonderful to behold. Within hours of starting an infusion, the baby would be pink, and we could begin the process of correcting all of the metabolic abnormalities, provided the child had not gone too far down the path towards irreversible organ damage. Acid-base status was restored, electrolytes were normalized, and renal function returned, allowing the infant to proceed to the operating room during the day in optimal condition with a rested surgical team. Results improved dramatically.

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Nowadays, the previous scenario is uncommon. Many ductal-dependent congenital heart lesions are detected prenatally so that delivery can occur in a tertiary setting, and the drug can be started soon after birth to maintain ductal patency. Many other lesions are detected prior to discharge by oxygen saturation monitoring and an overall higher index of suspicion for such issues. Bedside real-time echocardiography can, in most cases, establish a definitive diagnosis, and PGE_1 therapy can be initiated before circulatory deterioration occurs. So, while the effects of PGE_1 administration may not be as dramatic as in the past, it remains one of the most potent and effective drugs in our therapeutic tool kit. Babies with ductal-dependent congenital heart disease are well served by Prostaglandin E_1.

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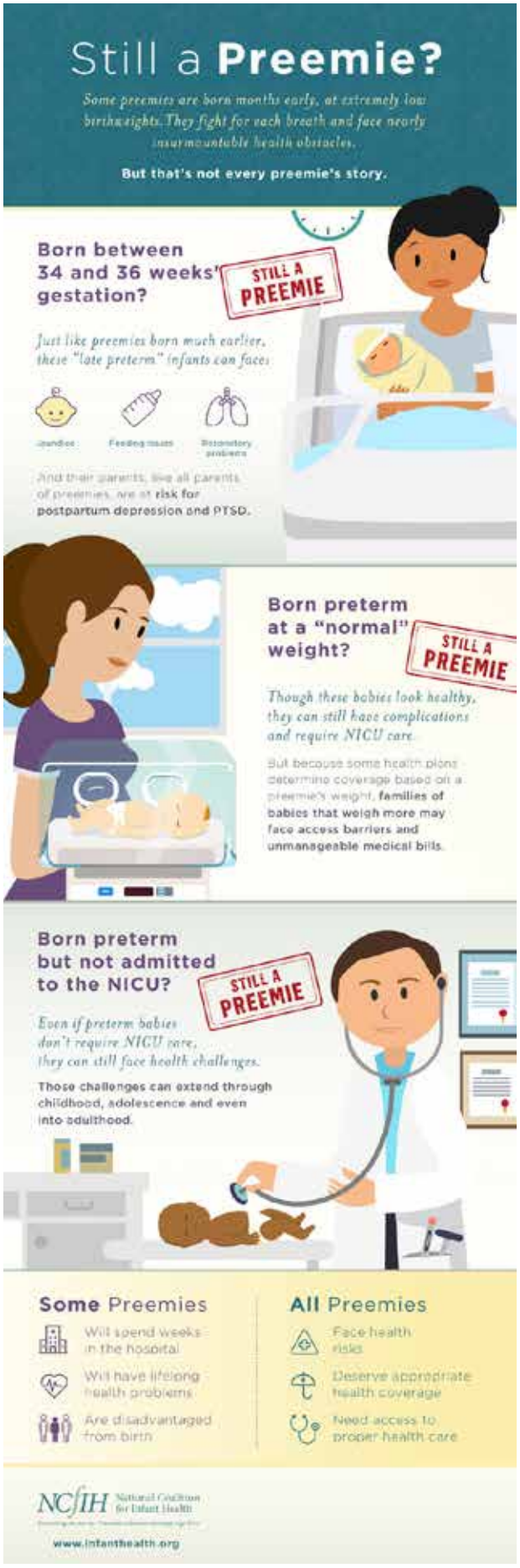
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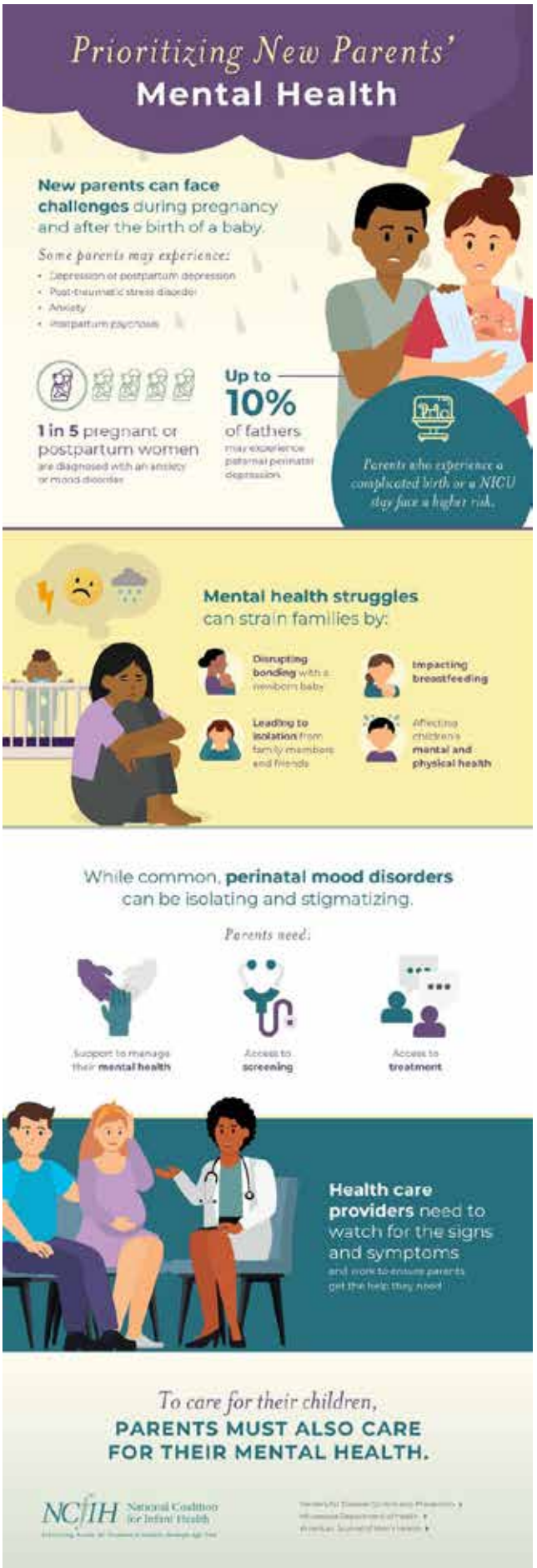
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Still a Preemie?
Some preemies are born months early, at extremely low birthweights. They fight for each breath and face nearly insurmountable health obstacles.
But that's not every preemie's story.
Born between 34 and 36 weeks' gestation?
STILL A PREEMIE
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 PREEMIE
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 PREEMIE
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
Will spend weeks in the hospital
Will have lifelong health problems
Are disadvantaged from birth
All Preemies
Face health risks
Deserve appropriate health coverage
Need access to proper health care
NCIIH National Coalition for Infant Health
www.infanthealth.org


Prioritizing New Parents' Mental Health
New parents can face challenges during pregnancy and after the birth of a baby.
Some parents may experience:
Depression or postpartum depression
Post-traumatic stress disorder
Anxiety
Postpartum psychosis
1 in 5 pregnant or postpartum women are diagnosed with an anxiety or mood disorder
Up to 10% of fathers may experience paternal perinatal depression
Parents who experience a complicated birth or a NICU stay face a higher risk.
Mental health struggles can strain families by:
Disrupting bonding with a newborn baby
Impacting breastfeeding
Leading to isolation from family members and friends
Affecting children's mental and physical health
While common, perinatal mood disorders can be isolating and stigmatizing.
Parents need:
Support to manage their mental health
Access to screening
Access to treatment
Health care providers need to watch for the signs and symptoms and work to ensure parents get the help they need
To care for their children,
PARENTS MUST ALSO CARE FOR THEIR MENTAL HEALTH.
NCIIH National Coalition for Infant Health

Join iCAN's Virtual Focus Group!



We warmly welcome all individuals within the age ranges of 8-10 and 12-18, including those with:

- Learning disabilities (example: dyslexia)
- Speech or language disabilities (examples: stuttering, understanding others, hearing)
- Physical disabilities (examples: epilepsy, cystic fibrosis)
- Autism Spectrum Disorder (ASD) or Attention-Deficit/Hyperactivity Disorder (ADHD)

Every voice counts!

It's a one-minute survey to see if you qualify for a one-hour focus group to be scheduled at a later date.

Survey Link: bit.ly/icanxkismet

Fill out the recruitment survey now and let your voice be heard! Together, we can make a real difference in pediatric healthcare!

iCAN
International Children's Advisory Network

Education.
Anytime, Anywhere.

Academy of Neonatal Care



The Academy of Neonatal Care serves to educate Respiratory Therapists, Nurses, and Doctors in current and best practices in Neonatal ICU care. We prepare RT's new to NICU to fully function as a bedside NICU RT. Our goal is to enrich NICU care at all levels. Beginner to Advanced Practice, there is something for you at:

www.AcademyofNeonatalCare.org.

Keeping Your Baby Safe
from respiratory infections

RSV
COVID-19
colds
flu

How to protect your little ones from germs and viruses

This year is an especially dangerous cold and flu season - especially for vulnerable infants and children. Fortunately, there are proven protective measures that we can take to stay healthy.

Here's what you can do...

Wash Your Hands

- This is the single, most important thing you can do to stop the spread of viruses.
- Use soap.
- Wash for more than 20 seconds.
- Use alcohol-based sanitizers.



Limit Contact with Others



- Stay home when you can.
- Stay 6 feet apart when out.
- Wear a face mask when out.
- Change your clothes when you get home.
- Tell others what you're doing to stay safe.

Provide Protective Immunity

- Hold your baby skin-to-skin.
- Give them your breast milk.
- Stay current with your family's immunizations.



Take Care of Yourself

- Stay connected with your family and friends.
- Drink more water and eat healthy foods.
- Seek mental health support.
- Sleep when you can.



Get Immunized

Vaccinations save lives. Protecting your baby from COVID-19, flu and pertussis lowers their risks for complications from respiratory infections.



WARNING

Never Put a Mask on Your Baby

- Because babies have smaller airways, a mask makes it hard for them to breathe.
- Masks pose a risk of strangulation and suffocation.
- A baby can't remove their mask if they're suffocating.



If you feel sick or are positive for COVID-19

- Wash with soap and water and put on fresh clothes before holding or feeding your baby.
- Wear a mask to help stop the virus from spreading.
- Watch out for symptoms like fever, confusion, or trouble breathing.
- Ask for help caring for your baby and yourself while you recover.



We can help protect each other.
www.nationalperinatal.org/rsv

National Perinatal Association

PROTECT YOUR FAMILY FROM
RESPIRATORY VIRUSES

flu | coronavirus | pertussis | RSV



WASH YOUR HANDS
often with soap and warm water.

GET VACCINATED
for flu and pertussis. Ask about protective injections for RSV.





COVER COUGHS AND SNEEZES.
Sneeze and cough into your elbow.

USE AN ALCOHOL-BASED HAND SANITIZER.





STAY AWAY FROM SICK PEOPLE
Avoid crowds. Protect vulnerable babies and children.

National Perinatal Association

www.nationalperinatal.org

FREE RESOURCES FOR YOUR NICU

Coping During COVID-19

Targeted interventions to improve the mental health of parents, infants, families, and providers

BONDING WITH YOUR BABY



HELPING CHILDREN AND FAMILIES COPE

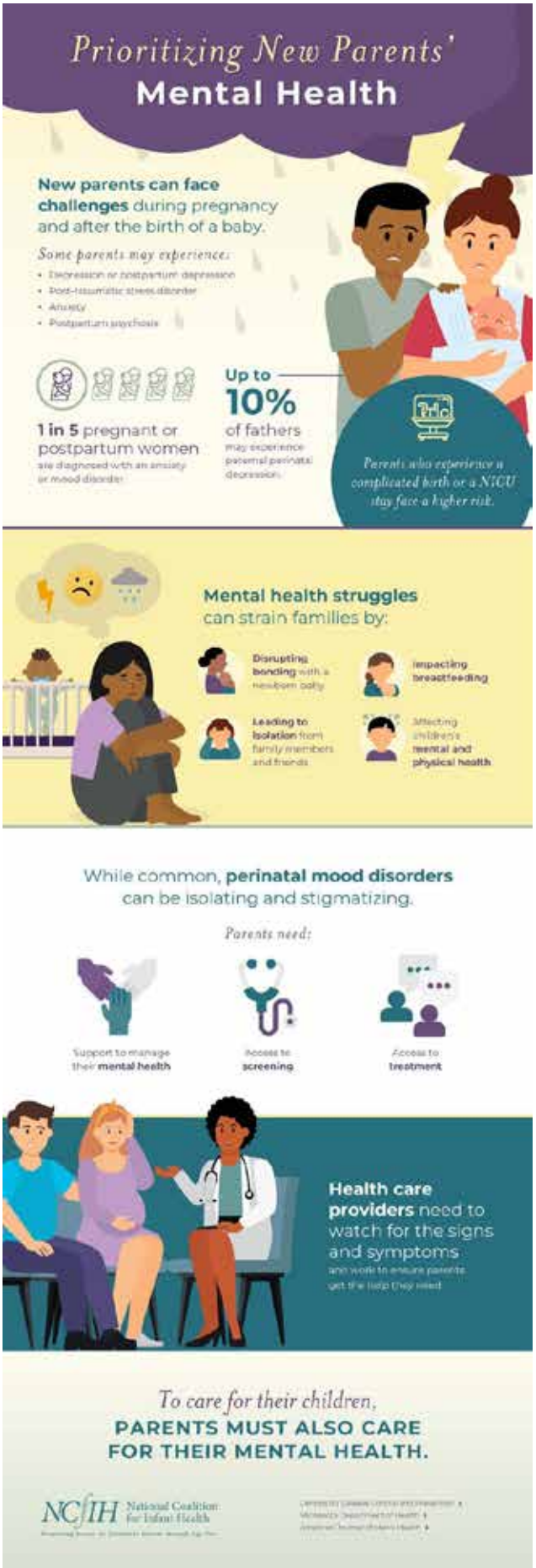


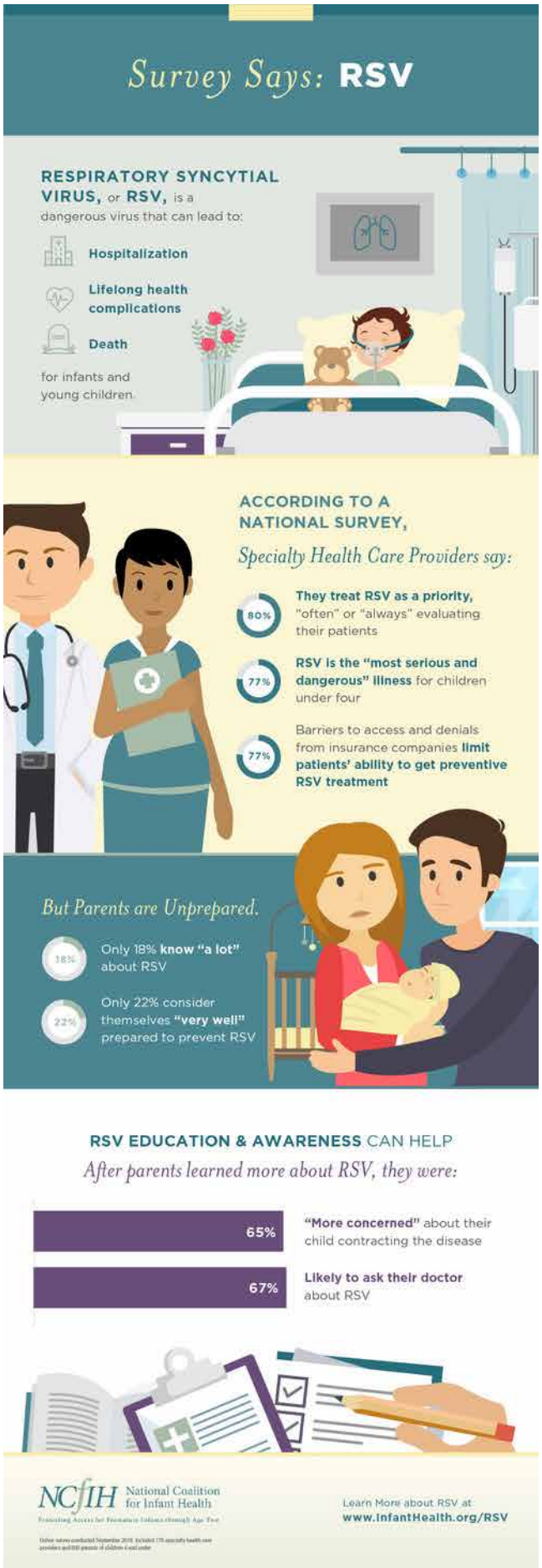
CAREGIVERS NEED CARE TOO



National Network of NICU Psychologists

nationalperinatal.org/psychologists


Prioritizing New Parents' Mental Health
New parents can face challenges during pregnancy and after the birth of a baby.
Some parents may experience:
Depression or postpartum depression
Post-traumatic stress disorder
Anxiety
Postpartum psychosis
1 in 5 pregnant or postpartum women are diagnosed with an anxiety or mood disorder
Up to 10% of fathers may experience paternal perinatal depression
Parents who experience a complicated birth or a NICU stay face a higher risk.
Mental health struggles can strain families by:
Disrupting bonding with a newborn baby
Impacting breastfeeding
Leading to isolation from family members and friends
Affecting children's mental and physical health
While common, perinatal mood disorders can be isolating and stigmatizing.
Parents need:
Support to manage their mental health
Access to screening
Access to treatment
Health care providers need to watch for the signs and symptoms and work to ensure parents get the help they need
To care for their children,
PARENTS MUST ALSO CARE FOR THEIR MENTAL HEALTH.
NCIH National Coalition for Infant Health


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
NCIH National Coalition for Infant Health
Learn More about RSV at www.InfantHealth.org/RSV

Allegations of Obstetrical Malpractice and the Daubert Challenge: What is in an Acronym

Barry S. Schifrin, MD, Maureen Sims, MD

To bring a medical malpractice case to trial requires considerable preparatory effort, including interviewing potential plaintiffs, obtaining and reviewing medical records, identifying experts, taking depositions, attending settlement conferences, and assessing the veracity of the individuals on both sides. The road to the courtroom where justice will hopefully prevail is often torturous and expensive. In the decision to pursue the trial, the expert witnesses and their theories must be vetted. In the area where the allegation involves obstetrical negligence as the prevenance of a compromised or handicapped child, challenges to expert opinions are not infrequent.

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These challenges are referred to as either a Daubert or Frye challenge, depending on the state where the trial is held. The objective is to bar an expert witness for one side or the other from offering testimony in Court on the premise that the anticipated opinion is not supported by reliable scientific enquiry. The challenge may come either before or during the trial.

The Daubert Standard **originates from the 1993 Supreme Court case** *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, which established criteria for admitting all forms of expert testimony in federal courts by underscoring the role of the trial judge as a "gatekeeper" to ensure the reliability and relevance of any expert testimony.

These standards **include:**

1. Can the theory or technique be tested?
2. Has it been subjected to peer review and publication?
3. Is there a known or potential error rate?
4. Are there standards controlling the technique's operation?
5. Is the theory generally accepted in the relevant scientific community?
6. The proponent of the expert testimony must demonstrate its admissibility by a preponderance of the evidence.
7. The expert's opinion must reflect a reliable application of principles and methods to the facts of the case.

Judges use these key criteria of the Daubert Standard *as a guide (no single test is dispositive)* in assessing whether the anticipated testimony is scientifically grounded with valid reasoning and acceptable methodology. Subsequent amendments reinforcing the judge's gatekeeping role, further ensuring that expert testimony is both relevant and reliable, emphasized that:

"The Daubert Standard poses potentially significant issues for expert witnesses: They must affirmatively demonstrate that their methods are scientifically valid and applicable to the case. Daubert hearings, which either side may demand, can be conducted to assess the admissibility of expert testimony either before or during trial."

The Daubert Standard poses potentially significant issues for expert witnesses: They must affirmatively demonstrate that their methods are scientifically valid and applicable to the case. Daubert hearings, which either side may demand, can be conducted to assess the admissibility of expert testimony either before or during trial. Unless appealed, the judge's decision that the expected scientific testimony fails to meet the Daubert criteria can result in the exclusion of critical expert testimony, leading to the dismissal of the case.

To familiarize the reader with the Daubert process, we present a brief case history, the allegations of negligence following the outcome of the case, and then the Court's deliberations in dealing with a Daubert challenge by the defense.

Case History:

The patient is a 27-year-old, married Caucasian primigravida who is 5 feet 3 ½ inches tall and weighs 198 pounds at the outset of her pregnancy. By term, she will have gained 22 pounds. She is Rh-negative. Her family history is significant for diabetes. She had an uneventful prenatal course, with her due date confirmed by several ultrasound examinations.

At 39.3 weeks' gestation, she arrives on L&D at about 0800, complaining of the loss of fluid around 0600 and feeling contractions since about 0700. She is placed on the monitor, which shows a normal, reactive fetal heart rate (FHR) pattern with a baseline of 140 bpm, normal variability, and absent decelerations, despite rather frequent contractions. The patient is normotensive and afebrile. On examination, the cervix is dilated 4 cm., 80% effaced with the vertex at -2 station *4/80/-2). At 1045, following epidural placement, the BP drops to 87/50. At 1115, there is artificial rupture of membranes (AROM) revealing "thin" meconium-stained amniotic

fluid; the cervical exam is "unchanged.", At 1520, the cervix is now 7/100/0, and the position of the fetal head is occiput posterior (OP) – a malposition of the fetal head often associated with prolonged labor, fetal distress, and operative delivery, both cesarean section and operative vaginal delivery (vacuum or forceps). Uterine contractions are said to be 1.5-4 minutes apart, lasting 60-90 seconds. with occasional coupling." Because of the limitation of oxygen availability to the fetus during contractions, the coupling of contractions, by interfering with fetal recovery from the previous contraction, represents excessive uterine activity. To better evaluate uterine contractions, an intrauterine pressure catheter (IUPC) is placed.

"Due to the presence of meconium-stained fluid and decelerations, an amnioinfusion was initiated at 1600 with the introduction of 300cc of saline into the uterus. This is followed by a maintenance infusion of 150cc/hr. The fluid is introduced into the uterine cavity in an attempt to moderate decelerations presumably related to umbilical cord compression and incidentally to dilute any meconium present."

Due to the presence of meconium-stained fluid and decelerations, an amnioinfusion was initiated at 1600 with the introduction of 300cc of saline into the uterus. This is followed by a maintenance infusion of 150cc/hr. The fluid is introduced into the uterine cavity in an attempt to moderate decelerations presumably related to umbilical cord compression and incidentally to dilute any meconium present. Immediately following, Pitocin is started and will be increased 4 times within 2 ½ hours. At 1715, the patient complains of perineal pressure, and the epidural infusion is increased. Internal exam reveals that the cervix is not yet fully dilated, and there has been no progress in descent of the fetal head, which remains in a malposition – OP.

"What follows in the FHR tracing is over 3 hours of intermittent loss of tracing, artifact, and insertion of maternal heart rate (MHR) recording. What tracing reveals is a further rise in baseline FHR to 170-180 bpm, accompanied by diminished / absent variability and decelerations. Despite the problematic findings and the dropout of the signal, no fetal scalp electrode was ever applied to provide a more reliable recording."

At 1800, there has been no progress in dilatation of the cervix or descent of the fetal head. Contractions are coming every 1-2 minutes; the FHR pattern is considered "reassuring" despite decelerations and numerous dropouts of the recording. At 1830, despite the persistent rim of cervix, the "patient pushed 3 times". This action provoked a prolonged deceleration that evolved to a higher fetal baseline rate of 150 bpm and diminished variability. Irrespective, Pitocin was increased further. At 1900, the obstetrician found the cervix to be fully dilated with the vertex in LOP position at 0 to +1 station. At 1945, the patient's legs were in stirrups, and she began pushing. What follows in the FHR tracing is over 3 hours of intermittent loss of tracing, artifact, and insertion of maternal heart rate (MHR) recording. What tracing reveals is a further rise in baseline FHR to 170-180 bpm, accompanied by diminished / absent variability and decelerations. Despite the problematic findings and the dropout of the signal, no fetal scalp electrode was ever applied to provide a more reliable recording.

The Pitocin is decreased to 5 mU/min, and another bolus of anesthetic is administered via epidural.. At 2150, "decelerations with pushing" continue with the patient complaining that she is "very tired with pushing". Nevertheless, she is "encouraged to push another ½ hour then re-evaluate". At that time, the patient states she is tiring and unable to push any longer, and very uncomfortable, and at 2245, another epidural bolus is administered.

"During this time, the fetus suffered increasing distress and, much more probable than not, had suffered a hypoxic-ischemic, neurologic injury as reflected in the changes in the FHR tracing - even prior to the efforts to deliver the fetus vaginally."

At 2300, the decision has been made to apply the vacuum extractor. At that time, there had been no progress in descent of the fetal head despite frequent contractions and compulsive maternal pushing (an arrest of descent of a malpositioned fetal head. In addition, there is obvious caput and molding about the fetal head as would be expected from so long an unproductive labor, and six hours had elapsed from the time that the patient was almost fully dilated to the decision to attempt vacuum delivery. During this time, the fetus suffered increasing distress and, much more probable than not, had suffered a hypoxic-ischemic, neurologic injury as reflected in the changes in the FHR tracing - even prior to the efforts to deliver the fetus vaginally.

In response to the efforts with the vacuum, the FHR is "down to 90s." The vacuum device is removed, and contrary to customary clinical guidelines that discourage the sequential use of instruments for operative delivery, forceps are applied in an attempt to rotate the fetal head to an occiput anterior (OA) position. Ultimately, the fetal head is delivered, precipitating a "mild shoulder dystocia, easily reduced with McRoberts and suprapubic pressure". According to the neonatologist, the delivery is "difficult and complicated". The mother sustains a 4th-degree vaginal laceration. Estimated blood loss is 300 cc.

Neonatal Course:

At birth, the male infant weighed over 4200 grams (LGA) and received Apgar scores of 1, 3, 5, 6, and 7 at 1, 2, 5, 10, and 15 min-

utes. The baby is cyanotic and hypotonic with decreased reflexes. Positive pressure ventilation is administered for 30 seconds; the baby is then intubated and positive pressure is applied for an additional minute. The vocal cords are viewed with no meconium noted, but the skin is meconium-stained. A peripheral IV is started, and a normal saline bolus is given. The baby is re-intubated with a larger tube, and by 5 minutes, it finally began to pink up, and tone and reflexes improved. The baby is taken to the NICU at 24 minutes of age, where he is placed on a ventilator, and he remains until the next day.

The physical exam reveals a large posterior caput, molding, and bruising. The tone is initially diminished, then increased. He is 55 cm long, and his head circumference is 37 cm. The pH of the cord is 7.28 and 7.31. Initial hematocrit is 49.7% with 191K platelets and 22.5 WBCs. Blood cultures are negative. Liver function indicators are elevated, and the baby has oliguria for the first 48 hours.

"Seizures begin at 4.5 hours of age, requiring phenobarbital and Dilantin to control. Initial EEG reveals seizure activity. Maintenance phenobarbital is ultimately discontinued, and there are no subsequent seizures. On 5/4 at 9 days, the EEG is normal."

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At two days of age, a head ultrasound (HUS) is normal. A CT scan on the same day reveals small amounts of tentorial and posterior interhemispheric blood, as well as marked caput succedaneum. The baby is diagnosed with hypoxic ischemic encephalopathy (HIE – despite the lack of acidemia in cord gases). He is discharged home on DOL 11. The neurological exam is within normal limits at discharge, and he is breastfeeding well.

On follow-up, the child has severe CP.

The Lawsuit:

A lawsuit is filed alleging obstetrical malpractice, with the following particulars.

The fetus has suffered an acute, hypoxic-ischemic, traumatic cerebral injury during the prolonged 2nd stage of labor. The condition of the fetus at the outset of labor is normal. Throughout labor, there were numerous failures to safeguard the mother and fetus; these included,

- Failure to properly assess the feasibility of safe vaginal delivery
- Failure to properly manage the Pitocin
- Failure to properly recognize and respond to excessive uterine contractions.
- Failure to properly recognize and timely respond to abnormalities of the fetal heart rate pattern.
- Failure to timely insert a fetal scalp electrode for an interpretable FHR tracing.
- Failure to properly follow guidelines for the use of a vacuum
- Failure to properly follow safe guidelines for the use of forceps
- Failure to obtain proper informed consent from the patient.
- Failure to perform a timely cesarean section.

"As described above, the neuroradiological findings are entirely consistent with partial, prolonged hypoxic-ischemic (HI) injury developing in conjunction with severely abnormal FHR tracing with instances of excessive uterine activity even prior to the insertion of the IUPC. With the advent of the IUPC, an additional feature of increased uterine tone was present."

As described above, the neuroradiological findings are entirely consistent with partial, prolonged hypoxic-ischemic (HI) injury developing in conjunction with severely abnormal FHR tracing with instances of excessive uterine activity even prior to the insertion of the IUPC. With the advent of the IUPC, an additional feature of increased uterine tone was present. The course of labor, especially the protracted 2nd stage, with a failure of the head to descend despite the uterine activity and maternal pushing. Had delivery occurred at or shortly before about 2200, it is medically probable that this baby would have been healthy without any significant neurologic injury.

The initial defense response to these allegations, even before the trial, was a Daubert challenge seeking to cast doubt on the underlying validity of the notion that the fetus may suffer neurological injury as a result of the mechanical effects of labor and delivery – a mechanism referred to as "cranial compression ischemic encephalopathy" or "CCIE". Should this challenge succeed, the plaintiffs would be barred from proceeding with their case. The strategic point of the defense was the lack of severe umbilical acidosis at the time of the delivery despite the repeated diagnosis of hypoxic-ischemic encephalopathy (HIE).

What follows are the judge's abbreviated remarks in response to the Daubert challenge by the defendants.

Background:

This is a medical malpractice action involving a 16-year-old plaintiff alleges that the Defendants committed medical malpractice at the time of his birth and that, as a result, he suffers from brain damage and lifelong disabilities.

Plaintiff's Pediatric Neurology expert opines that his brain injury was caused primarily by trauma in the last two hours or so before his birth as a consequence of several additive factors, including malposition of the fetal head, traumatic instrumented delivery with both vacuum extractor and forceps. Other contributing trau-

matic factors were excessive uterine activity and a prolonged second stage of labor.

Plaintiff's MFM (Maternal-Fetal Medicine) expert notes that CCIE refers to a type of hypoxic ischemic encephalopathy ("HIE") or injury. "HIE is a (widely accepted) descriptive label for injuries that include the mechanical forces of labor. The use of the term CCIE attempts to focus specifically on this long-recognized mechanism of injury".

Defendants request that the Court prohibit any evidence or testimony concerning CCIE, arguing that the medical community as a whole, and specifically the American Congress of Obstetricians and Gynecologists ("ACOG"), has not recognized it as a medical theory, and that other courts have rejected the theory.

For the plaintiffs to defeat the challenge, the judge must pass on the acceptability of the experts and their testimony. (Indeed, it is the judge's prerogative to decide the acceptability of the witness in the case before him.) A witness may testify as an expert if all of the following apply

"For the plaintiffs to defeat the challenge, the judge must pass on the acceptability of the experts and their testimony. (Indeed, it is the judge's prerogative to decide the acceptability of the witness in the case before him.) A witness may testify as an expert if all of the following apply"

(A) The testimony relates to matters beyond the knowledge or experience possessed by lay persons or dispels a misconception common among lay persons.

While Defendants dispute the reliability of CCIE, they do not dispute the reliability of the diagnosis of HIE. However, Defendants claim that the diagnosis of HIE in this case "did not meet the criteria for such diagnosis (because the umbilical pH at delivery was "normal")."

Ruling: The Plaintiff witnesses are qualified as experts by specialized knowledge, skill, experience, training, and education regarding the subject matter of the testimony;

(B) The testimony is reliable only if all of the following apply

a. The theory upon which the theory is based is objectively verifiable or is validly derived from widely accepted knowledge, facts, or principles;

b. The design of experiments that reliably implement the theory;

c. The particular experiments in support of the theory were conducted in a way that would yield an accurate result.

"Because even a qualified expert is capable of rendering scientifically unreliable testimony, it is imperative for a trial court, as gatekeeper, to examine the principles and methodology that underlie an expert's opinion."

"Factors to consider when determining the reliability of scientific evidence are:

(1) whether the theory or technique has been tested,

(2) whether it has been subjected to peer review,

(3) whether there is a known or potential rate of error, and

(4) whether the methodology has gained general acceptance."

The focus is on the principles and methodology, not on the conclusions.

The CCIE Causation Theory:

The notion of mechanical trauma causing injury to the fetal brain has been an accepted notion throughout the specialties of obstetrics, pediatrics, and pathology for centuries, whether this is a result of obstetrical forceps, obstetrical vacuum extractor, and/or by excessive forces resulting in molding and impaired circulation (ischemia) to the fetal brain sufficient to overwhelm compensatory responses. (1-16)

"The notion of mechanical trauma causing injury to the fetal brain has been an accepted notion throughout the specialties of obstetrics, pediatrics, and pathology for centuries, whether this is a result of obstetrical forceps, obstetrical vacuum extractor, and/or by excessive forces resulting in molding and impaired circulation (ischemia) to the fetal brain sufficient to overwhelm compensatory responses. (1-16)"

Furthermore, multiple state trial court orders and opinions addressing the issue have consistently allowed testimony and evidence regarding CCIE.

Defendants rely heavily on a recent opinion of a Court of Appeals from another state, which upholds a ban on CCIE testimony (specifically), rather than on the principles involved.

Analysis:

Whether the theory or technique has been tested

Experimental studies in sheep were conducted to investigate the effects of fetal head compression on heart rate, metabolism, and function (8) showed "[c]ompression of the fetal head by an externally applied force caused severe cerebral ischemia due to a marked reduction in cerebral blood flow." Based on observations, "on the human fetal EEG recordings during contractions and neonatal EEG recordings after forceps delivery were analogous to changes in the EEG noted during head compression in the sheep fetus." (4)

Ruling: Here, Plaintiffs' experts proffer sufficient literature

to support the theory that pressure to the fetal head can produce injury.

Whether it has been subjected to peer review

Defendants argue that CCIE has never been the subject matter of any peer-reviewed articles, journals, or publications. Plaintiffs again offered abundant peer-reviewed literature supporting the principles behind the CCIE theory.

Ruling: "The Court finds that the principles underlying the CCIE theory have been subject to peer review.

Whether there is a known potential rate of error

Plaintiffs do not dispute that there is no known potential rate of error. However, this is not fatal to the theory, as none of the four factors "is dispositive of the inquiry/"

Whether the methodology has gained general acceptance

"[S]cientific opinions need not enjoy 'general acceptance' in the relevant scientific community in order to satisfy the reliability requirement of Daubert. Furthermore, there need not be a consensus in the scientific community regarding the expert's actual opinion or conclusion. The credibility of the conclusion and the relative weight it should enjoy are determinations left to the trier of fact."

"Therefore, its opinion is not entirely unbiased, as it is concerned with the effect CCIE has on the cost of medical services, rather than just the scientific principles behind the theory. Furthermore, universal agreement within the scientific community is not a prerequisite for admissibility under Daubert. Moreover, even one of Defendant's experts admitted that he agreed with the underlying principles behind the theory."

Defendants rely heavily on the American College of Obstetricians and Gynecologists' ("ACOG") opinion in arguing that CCIE has not gained general acceptance, expressed through a previously filed amicus brief. The ACOG is a non-profit membership organization composed of women's healthcare physicians. It indicates in its brief that "[t]he quality of evidence proffered and admitted as 'medical science' in professional liability litigation can significantly influence ACOG's members' medical practices *and the cost and availability of medical services*." (Emphasis added.) Therefore, its opinion is not entirely unbiased, as it is concerned with the effect CCIE has on the cost of medical services, rather than just the scientific principles behind the theory. Furthermore, universal agreement within the scientific community is not a prerequisite for admissibility under Daubert. Moreover, even one of Defendant's experts admitted that he agreed with the underlying principles behind the theory.

Ruling: The Court finds that, based on the articles Plaintiffs provided, the CCIE theory has gained general acceptance. Further, even if it has not, that does not, alone, preclude its admissibility.

Conclusion:

"[T]he reliability requirement of Daubert should not be used to exclude all evidence of questionable reliability, nor should a court exclude such evidence simply because the evidence is confusing." "[T]he 'ultimate touchstone is helpfulness to the trier of fact, and with regard to reliability, helpfulness turns on whether the expert's technique or principle [is] sufficiently reliable so that it will aid the jury in reaching accurate results.'" The Court is in agreement with the other courts cited above. The opinion relied upon by Defendants did not apply the same factors considered by our state courts. Furthermore, it is not binding on the courts of this state. Having reviewed the material supplied by the parties, the Court finds that Plaintiffs have presented sufficient evidence to support the reliability of the CCIE theory.

The Motion *In Limine* to Exclude Plaintiffs' CCIE Causation Theory is hereby DENIED. IT IS SO ORDERED.

Following the results of the Daubert challenge, the defense settled the case. (14-16)

As stated by the judge in dismissing the Daubert challenge, the principles behind CCIE have prevailed in this and numerous other lawsuits. (There is no limit to the number of times the defense can bring the challenge.) However, despite the absence of any compelling rebuttal to the clinical and experimental data supporting cranial compression in the pathway to fetal neurological injury, or its begrudging acceptance by authoritative sources, (15) and even by one of the defense witnesses in this case, there is yet no "official" acceptance of this often-preventable mechanism of fetal neurological injury.

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Disclosures: *There are no reported disclosures*

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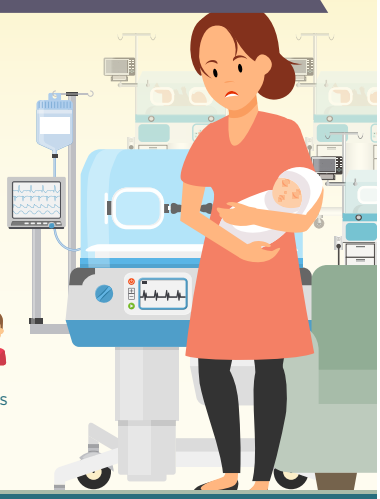
Preterm infants are:

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



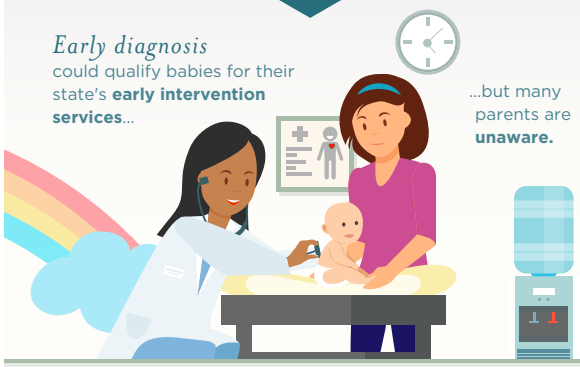
Early intervention can help preterm infants:

- 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.



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

NCFIH National Coalition for Infant Health

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



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

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



Sin embargo, sólo el 15% recibe tratamiento[1]

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



La salud de la madre

El sueño, la alimentación y el comportamiento del bebé a medida que crece[2]

La capacidad para cuidar de un bebé y sus hermanos

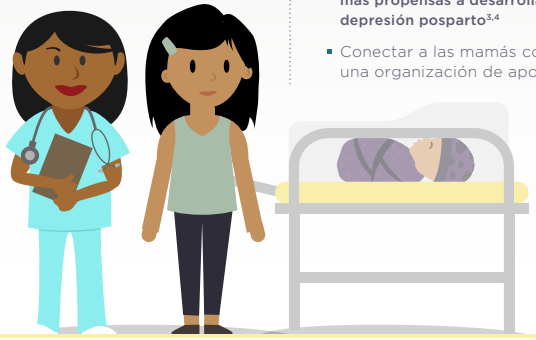
PARA AYUDAR **A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSPARTO**

LOS ENCARGADOS DE FORMULAR POLÍTICAS PUEDEN:

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

LOS HOSPITALES PUEDEN:

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



NCFIH National Coalition for Infant Health

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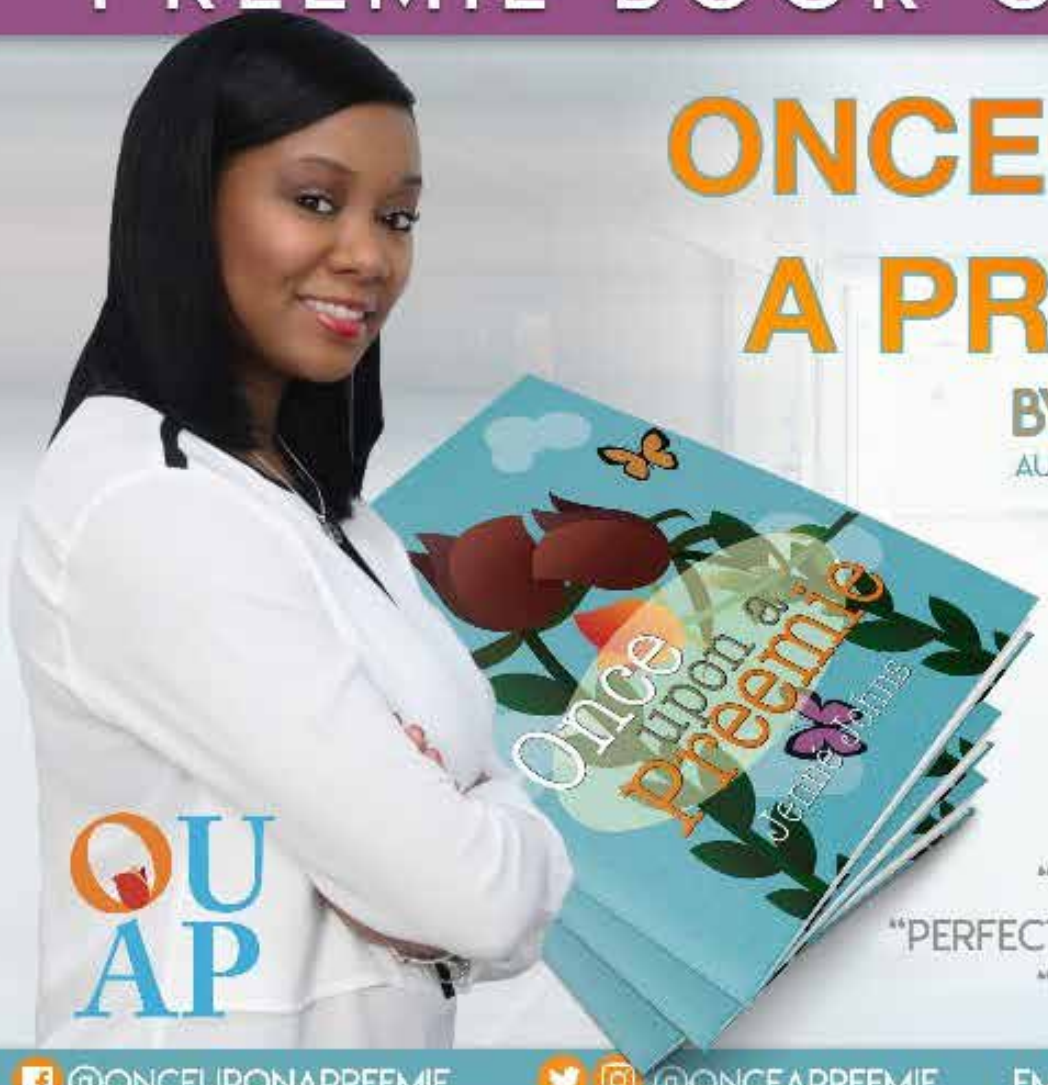
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AAP, medical societies creating flu, RSV, COVID vaccine guidance for fall

NEWS PROVIDED BY

American Academy of Pediatrics

By Melissa Jenco

Study: **AAP, medical societies creating flu, RSV, COVID vaccine guidance for fall**

Current as of July 25, 2025

The AAP is collaborating with external partners and convening a work group of medical societies in sharing approaches for developing evidence-based clinical guidance on influenza, respiratory syncytial virus (RSV) and COVID-19 vaccines for the fall. The effort comes as federal health officials make unscientific changes to vaccine policies.

Creating independent guidance "preserves the process of integrating the best available science into vaccine recommendations," said Nita Mohanty, M.D., M.S., FAAP, senior vice president of Child Health Finance and Quality. "The AAP has always guided pediatricians on vaccinations, and it has always led with science. This role is not new to us."

The AAP has published its own immunization guidance for more than 90 years and worked with the Centers for Disease Control and Prevention (CDC) and others in recent decades to harmonize recommendations when possible. However, Health and Human Services Secretary Robert F. Kennedy Jr. recently replaced CDC Advisory Committee on Immunization Practices (ACIP) members with people who have espoused anti-vaccine viewpoints. He also unilaterally removed COVID-19 vaccines from the routine recommendations for healthy children and pregnant people, sparking a lawsuit from the AAP and other medical groups.

In the wake of these moves, the AAP is collaborating with other medical groups, each offering transparency into their approach to providing science-based guidance for the respective populations served. Each society will oversee recommendations for the upcoming respiratory virus season for specific populations with a goal to develop recommendations by the end of August.

The AAP's guidance for children will include its annual influenza statement releasing July 28 which will address FluMist nasal spray for at-home use, while the RSV guidance will incorporate the new monoclonal antibody clesrovimab for infants. The AAP Committee on Infectious Diseases (COID) consulted with a new advisory group of experts Friday as it crafted COVID guidance. As with all clinical guidance developed by the AAP, conflicts of interest are carefully managed, and recommendations are informed by review of relevant scientific data and are ultimately approved by the Board.

"We want pediatricians to know that vaccine guidance will continue to follow a process that is informed by science, based on thorough analysis of the available data and is in the best interest of child health," Dr. Mohanty said. "We are making every effort to ensure the guidance is available in a timely fashion for the upcoming respiratory virus season."

The AAP has also been talking with payers to ensure the societies' recommendations will be covered by insurance and has gotten positive feedback, according to Dr. Mohanty.

"We continue to consider the practical implementation of immunization guidance in clinical care," said COID Chair Sean T. O'Leary, M.D., M.P.H., FAAP. "For now, we are specifically focused on recommendations for the upcoming respiratory season. We are preparing, though, to address any further actions by ACIP that are not based in science."

Professional societies are also collaborating with the Vaccine Integrity Project (VIP), which is supported by the University of Minnesota's Center for Infectious Disease Research and Policy (CIDRAP) through a philanthropic gift. The initiative is "dedicated to safeguarding vaccine use in the U.S. so that it remains grounded in the best available science, free from external influence, and focused on optimizing protection of individuals, families, and communities against vaccine-preventable diseases," according to its website.

"This project acknowledges the unfortunate reality that the system that we've relied on to make vaccine recommendations and to review safety and effectiveness data faces threats," CIDRAP Director Michael T. Osterholm, Ph.D., M.P.H., said in a statement.

The VIP is reviewing scientific data on vaccines and will share an evidence brief with the medical societies for utilization as they craft their guidance. The VIP will also convene meetings where societies will share their respective vaccine recommendations. While the groups are collaborating, they will not vote on each other's recommendations. Dr. Mohanty said it is not intended to be a "shadow ACIP."

"The ACIP has historically provided a critical public health function, and the desired state is for it to be reconstituted in its original structure," she said.

In the meantime, the AAP is staying apprised of several additional efforts in the medical community to make other independent vaccine recommendations.

"We won't lend our name or our expertise to a system that is being politicized at the expense of children's health," AAP President Susan J. Kressly, M.D., FAAP, said in June. "But we're not stepping back, we're stepping up. The AAP will continue to publish our own immunization schedule just as we always have, developed by experts, guided by science, trusted by pediatricians and families across the country."

CDC confirms worst year for measles since 1992

NEWS PROVIDED BY

American Academy of Pediatrics

By Sean Stangland

Study: **CDC confirms worst year for measles since 1992**

Current as of July 9, 2025

The Centers for Disease Control and Prevention (CDC) confirmed on Wednesday that the U.S. has seen more measles cases this year than any other entire year since 1992.

As of Tuesday, 1,288 measles cases had been reported to the CDC in 2025, passing the 33-year high of 1,274 in 2019. Johns Hopkins University's Center for Outbreak Response Innovation reported last week that milestone had been surpassed as of July 4.

The 2019 case count was the highest since 1992 when 2,126 cases were reported.

Twenty-seven measles outbreaks, defined as three or more related cases, account for 88% (1,130) of confirmed cases this year, the CDC reported. Sixteen outbreaks were reported in 2024.

The AAP recommends ensuring patients are covered with a two-dose measles, mumps and rubella (MMR) vaccination series. Under routine recommendations, the doses are given at ages 12-15 months and 4-6 years. One dose of MMR is 93% effective against measles, and two doses are 97% effective.

Unvaccinated people or people whose vaccination status is unknown account for 92% of this year's cases, according to the CDC.

Measles cases have been reported to the CDC by 39 jurisdictions: Alaska, Arkansas, Arizona, California, Colorado, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Missouri, Montana, Nebraska, New Jersey, New Mexico, New York City, New York State, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington and Wyoming.

AAP suing HHS over vaccine policy 'because we believe children deserve better'

NEWS PROVIDED BY

American Academy of Pediatrics

By Melissa Jenco

Study: **AAP suing HHS over vaccine policy 'because we believe children deserve better'**

Current as of July 7, 2025

The AAP and other leading medical groups are suing Health and Human Services (HHS) Secretary Robert F. Kennedy Jr. for making unilateral, unscientific changes to federal vaccine policy they say are an "assault on science, public health and evidence-based medicine."

AAP President Susan J. Kressly, M.D., FAAP, said the administration's actions are jeopardizing the success of the country's immunization system, a "cornerstone of U.S. public health."

"The American Academy of Pediatrics isn't standing by. We're stepping up," she said. "We're taking legal action because we believe children deserve better."

In the lawsuit filed Monday in U.S. District Court for the District of Massachusetts, the AAP, American College of Physicians, American Public Health Association, Infectious Disease Society of America (IDSA), Massachusetts Public Health Alliance, Society for Maternal-Fetal Medicine and a pregnant woman said Kennedy violated federal law when he unilaterally changed COVID-19 vaccine recommendations, without scientific evidence, for children and people who are pregnant. The lawsuit also describes the secretary's actions as outside established, scientifically credible practice when he abruptly fired 17 members of the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) and replaced them with multiple people who have espoused anti-vaccine viewpoints.

"This wasn't just sidelining science," Dr. Kressly said. "It's an attack on the very foundation of how we protect families and children's health. And the consequences could be dangerous."

In taking these steps, Kennedy ignored scientific evidence, failed to adhere to key steps in the federal rulemaking process and failed to ensure balanced viewpoints on ACIP, according to the lawsuit. In addition, the secretary blocked CDC communications, delayed or canceled meetings of CDC and Food and Drug Administration (FDA) vaccine advisers and announced studies to investigate non-existent links between vaccines and autism, the lawsuit says.

The medical groups are asking a judge to halt Kennedy's changes to COVID-19 vaccine policy.

"We will not stand by while a single federal official unilaterally and effectively strips Americans of their choice to vaccinate with actions that thoroughly disregard overwhelming scientific evidence and decades of established federal processes," said IDSA President Tina Tan, M.D., FIDSA., FPIDS, FAAP.

Kennedy's newly appointed vaccine advisers have stated that they plan to review the child and adolescent immunization schedules, which Dr. Kressly said is alarming.

"These decisions are founded in fear and not evidence, and will make our children and communities more vulnerable to infectious diseases like measles, whooping cough and influenza," she said.

"As we pursue action to restore science to U.S. vaccination policy, AAP will continue to provide the science-based, trusted recommendations that every American deserves."

This is not the first time the AAP has sued the federal government and it has done so regardless of political party. In 1983, the AAP and other medical groups sued HHS over a rule related to life-sustaining treatment for infants with critical illness or disabilities. The AAP sued the FDA in 2016

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and 2018. The first lawsuit was for delaying implementation of graphic warnings for cigarettes and the second was for delaying a review of e-cigarettes and cigars.

AAP: Federal spending cuts 'devastating' to lifeline programs for children

NEWS PROVIDED BY

American Academy of Pediatrics

By Steve Schering

Study: **AAP: Federal spending cuts 'devastating' to lifeline programs for children**

Current as of July 3, 2025

Significant cuts to Medicaid and a childhood nutrition program threaten "the health care system for all children," AAP President Susan J. Kressly, M.D., FAAP, said Thursday.

AAP leaders say the spending bill passed by the Senate and House of Representatives cuts about $1 trillion from Medicaid and will harm children, families and communities. President Donald J. Trump is expected to sign the bill into law Friday.

"The budget reconciliation bill that is now on its way to becoming law fails our country's children and families," Dr. Kressly said. "Instead of supporting the health of our communities, this legislation makes devastating cuts to lifeline programs and places the health care system for all children at risk. This bill will mean more children will not have enough to eat and fewer children will have access to the health care they need to thrive."

Medicaid and the Children's Health Insurance Program (CHIP) provide health care coverage for more than 37 million children. The programs serve as lifelines for families with low incomes, those in rural areas, those with disabilities and those with chronic health conditions. The cuts threaten the viability of pediatric practices, children's hospitals and rural health care providers.

The legislation also makes cuts to the Supplemental Nutrition Assistance Program (SNAP), which serves around 20 million children. Nearly one in five households with children experience food insecurity. SNAP reduces the prevalence of food insecurity by as much as 30%.

The AAP has been vocal throughout the budget reconciliation process, briefing senators and congressional staff on the importance of protecting Medicaid, CHIP and SNAP, writing letters to Congress, participating in press events, leading multi-stakeholder coalitions to educate policymakers and working alongside other leading medical organizations. The issue also was the focus of the AAP's 2025 Advocacy Conference, where nearly 400 pediatricians met with congressional offices.

"Pediatricians strongly opposed this legislation and spoke up on behalf of the communities and families we serve—meeting with hundreds of congressional offices, sending thousands of letters to Congress and making countless calls urging lawmakers to protect child health," Dr. Kressly said.

AAP chapters in every state and the District of Columbia have played key roles in educating and advocating to state and federal policymakers. Chapters wrote letters to governors, worked with coalitions to raise awareness about the impacts of these policies on child health and advocated to their members of Congress. They also held and participated in press events, clinic visits, town halls and other events with policymakers.

The Academy has issued several press statements at critical moments in the process, including this statement earlier this week upon Senate passage expressing its strong opposition to the bill. The AAP's position has also been amplified on its social media platforms, including two videos featuring Dr. Kressly, along with other physician group leaders speaking out about the need to protect Medicaid.

Individual pediatricians have also been weighing in extensively across the country. AAP members have sent over 7,000 letters to Capitol Hill and published numerous op-eds in their state and local news outlets.

In addition to Medicaid, CHIP and SNAP, the AAP has been advocating to protect other crucial programs impacted by the legislation like the Child Tax Credit and clean energy tax credits. In light of provisions impacting immigrant families, the AAP also has stressed the importance of protecting children from detention and family separation. The AAP will be closely tracking this bill's implementation and sharing information with pediatricians and AAP chapters.

"While we are dismayed by the passage of this harmful legislation, we will continue to boldly speak up for our patients and our profession, working alongside our partners and brave families to emphasize the power and urgency of investing in child health," Dr. Kressly said.

Global childhood vaccination coverage holds steady, yet over 14 million infants remain unvaccinated – WHO, UNICEF

NEWS PROVIDED BY

World Health Organization

By Sara Alhattab

Study: **Global childhood vaccination coverage holds steady, yet over 14 million infants remain unvaccinated – WHO, UNICEF**

Current as of July 15, 2025

In 2024, 89% of infants globally – about 115 million – received at least one dose of the diphtheria, tetanus and pertussis (DTP)-containing vaccine, and 85% – roughly 109 million – completed all three doses, according to new national immunization coverage data released today by the World Health Organization (WHO) and UNICEF.

Compared to 2023, around 171 000 more children received at least one vaccine, and one million more completed the full three-dose DTP series. While the gains are modest, they signal continued progress by countries working to protect children, even amid growing challenges.

Still, nearly 20 million infants missed at least one dose of DTP-containing vaccine last year, including 14.3 million "zero-dose" children who never received a single dose of any vaccine. That's 4 million more than the 2024 target needed to stay on track with Immunization Agenda 2030 goals,

and 1.4 million more than in 2019, the baseline year for measuring progress.

"Vaccines save lives, allowing individuals, families, communities, economies and nations to flourish," said Dr Tedros Adhanom Ghebreyesus, WHO Director-General. "It's encouraging to see a continued increase in the number of children being vaccinated, although we still have a lot of work to do. Drastic cuts in aid, coupled with misinformation about the safety of vaccines, threaten to unwind decades of progress. WHO remains committed to working with our partners to support countries to develop local solutions and increase domestic investment to reach all children with the lifesaving power of vaccines."

Children often remain un- or under-vaccinated due to a combination of factors, such as limited access to immunization services, disrupted supply, conflict and instability, or misinformation about vaccines.

Access to vaccines remains deeply unequal

Data from 195 countries show that 131 countries have consistently reached at least 90% of children with the first dose of DTP vaccine since 2019, but there has been no significant movement in expanding this group. Among the countries that reached less than 90% in 2019, only 17 managed to increase their coverage rates in the past five years. Meanwhile, in 47 countries, progress is stalling or worsening. This includes 22 countries that achieved and surpassed the 90% target in 2019 but have since declined.

The data shows conflict and humanitarian crises can quickly erode vaccination progress. A quarter of the world's infants live in just 26 countries affected by fragility, conflict, or humanitarian crises, yet they make up half of all unvaccinated children globally. Concerningly, in half of these countries the number of unvaccinated children has expanded rapidly from 3.6 million in 2019 to 5.4 million in 2024, underscoring the need for humanitarian responses to include immunization.

Immunization coverage in the 57 low-income countries supported by Gavi, the Vaccine Alliance have improved in the past year, reducing the number of un- and under-vaccinated children by roughly 650 000. At the same time, signs of slippage are emerging in upper-middle- and high-income countries that have previously maintained at least 90% coverage. Even small declines in immunization coverage can dramatically raise the risk of disease outbreaks and place additional strain on already overstretched health systems.

"The good news is that we have managed to reach more children with life-saving vaccines. But millions of children remain without protection against preventable diseases, and that should worry us all," said UNICEF Executive Director Catherine Russell. "We must act now with determination to overcome barriers like shrinking health budgets, fragile health systems along with misinformation and access constraints because of conflicts. No child should die from a disease we know how to prevent."

Broadening protection against vaccine-preventable diseases

Despite these challenges, countries – especially those supported by Gavi – continue to introduce and scale up vaccines, including against human papillomavirus (HPV), meningitis, pneumococcal disease, polio, and rotavirus.

For example, large national scale-ups of the HPV vaccine and revitalization efforts in countries that have previously introduced the vaccine, have boosted global coverage by 4% in the past year. In 2024, 31% of eligible adolescent girls globally received at least 1 dose of the HPV vaccine – most doses were administered in countries using a single-dose schedule. While far from the 90% coverage target by 2030, it represents a substantial increase from the 17% coverage in 2019.

"In 2024, lower-income countries protected more children than ever before, with coverage rates increasing across all Gavi-supported vaccines," said Dr Sania Nishtar, CEO of Gavi, the Vaccine Alliance. "Yet population growth, fragility and conflict present major hurdles to achieving equity, leaving the most vulnerable children and communities at risk. Continued commitment from governments and partners will be critical to saving lives and protecting the world from infectious disease threats."

Coverage against measles also improved, with 84% of children receiving the first dose and 76% receiving the second dose, which shows slight increase from the previous year. An estimated 2 million more children were reached in 2024, but the overall coverage rate is far below the 95% needed in every community to prevent outbreaks.

This results in more than 30 million children remaining under-protected against measles, leading to more large or disruptive outbreaks. In 2024, the number of countries experiencing large or disruptive measles outbreaks rose sharply to 60, nearly doubling from 33 in 2022. **The promise of protecting every child is at risk.**

Although the community demand for childhood vaccination remains high and protection against more diseases is expanding, the latest estimates highlight a concerning trajectory. National and global funding shortfalls, growing instability worldwide, and rising vaccine misinformation threaten to further stall or even reverse progress which would risk increases in severe disease and deaths from vaccine-preventable diseases.

WHO and UNICEF call on governments and relevant partners to:

- close the funding gap for Gavi's next strategic cycle (2026–2030) to protect millions of children in lower-income countries and global health security;
- strengthen immunization in conflict and fragile settings to reach more zero-dose children and prevent deadly disease outbreaks;
- prioritize local-led strategies and domestic investment, embedding immunization firmly within primary health care systems to close equity gaps;
- counter misinformation and further increase vaccine uptake through evidence-based approaches; and
- invest in stronger data and disease surveillance systems to guide high-impact immunization programmes.

FDA Encourages Industry Leaders to Streamline, Enhance Product Recall Communications to Safeguard Foods for Infants and Children

NEWS PROVIDED BY

Food and Drug Administration

By FDA News Team

Study: **FDA Encourages Industry Leaders to Streamline, Enhance Product Recall Communications to Safeguard Foods for Infants and Children**

Current as of July 9, 2025

The U.S. Food and Drug Administration today called for increased attention to product recall communications from industry leaders involved in the manufacturing and distribution of infant formula, baby foods, and foods intended for children.

As food production and distribution systems continue to advance alongside new communication technologies, the FDA is encouraging industry to examine how they communicate with the public, and continue to work with the Agency, whenever a product is recalled.

"Today I am asking food industry leaders to join me in my commitment to radical transparency, with a focus on ensuring the safety and wellbeing of infants and children," said FDA Commissioner Marty Makary, M.D., M.P.H. "Protecting our most vulnerable is not just a moral duty—it is our responsibility. For many children, infant formula is their only source of nutrition. That's why it's vital that we use every tool at our disposal to enhance recall communication about these products and other foods for children."

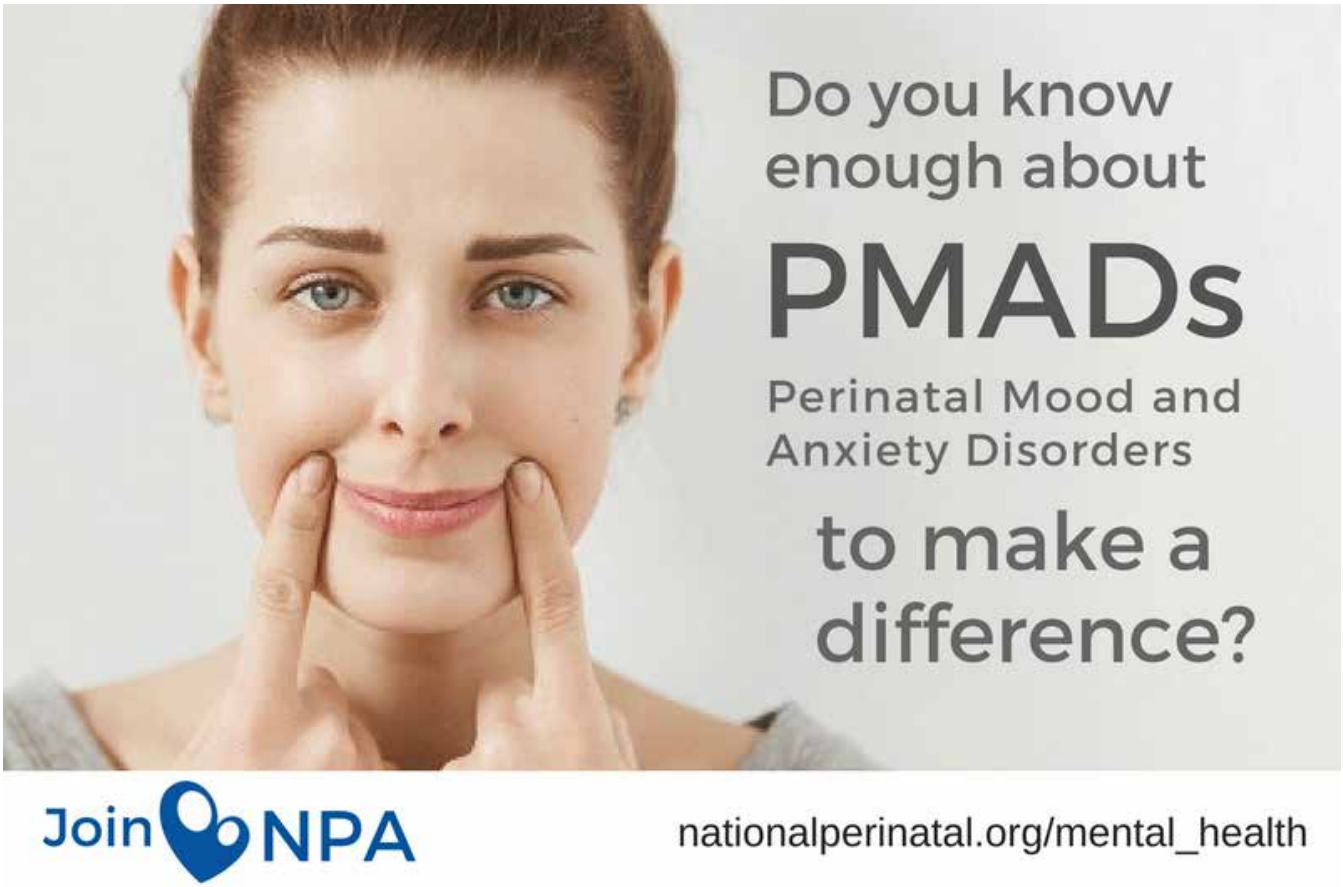
This outreach to industry leaders amplifies and supports the FDA's priorities and recent efforts, including Operation Stork Speed, an FDA Expert Panel on Infant Formula, and increased stakeholder engagement.

"By issuing this letter, we are taking concrete steps to help protect our nation's children. We look forward to working with industry to increase public awareness of recalls involving infant formula, baby foods, and other foods intended for children," said FDA Deputy Commissioner for Human Foods Kyle Diamantas. "We will also be creating a centralized, consumer-oriented webpage on FDA.gov focused on these products, ensuring that parents and caregivers can easily access the information necessary to protect the health and wellbeing of their kids."

These enhancements, which require increased public-private partnerships, and sufficient resources and time, will provide increased information to parents and caregivers about the foods they rely on to nourish their children.

The initiative reflects a commitment to increased collaboration with industry leaders, focused on placing the public's needs first, empowering parents, protecting our children, and fostering a healthier future for generations to come.

NT



Keeping Your Baby Safe
from respiratory infections

RSV
COVID-19
colds
flu

How to protect your little ones from germs and viruses

Cold and flu season can be dangerous - especially for vulnerable infants and children. Fortunately, there are proven protective measures that we can take to stay healthy.

Here's what you can do...

Wash Your Hands

- This is the single, most important thing you can do to stop the spread of viruses.
- Use soap.
- Wash for more than 20 seconds.
- Use alcohol-based hand sanitizers.



Limit Contact with Others



- Stay home when you can.
- Avoid sick people.
- Wear a face mask when out.
- Change your clothes when you get home.
- Tell others what you're doing to stay safe.

Provide Protective Immunity

- Hold your baby skin-to-skin.
- Give them your breast milk.
- Stay current with your family's immunizations.



Take Care of Yourself

- Stay connected with your family and friends.
- Drink more water and eat healthy foods.
- Seek mental health support.
- Sleep when you can.



Get Immunized

Vaccinations save lives. Protecting your baby from RSV, COVID-19, flu, and pertussis lowers their risks for complications from respiratory infections.



WARNING

Never Put a Mask on Your Baby

- Because babies have smaller airways, a mask can make it harder for them to breathe.
- Face masks and their straps pose a risk of suffocation and strangulation.
- Remember, a baby can't remove their mask if they're having trouble breathing.



If you feel sick or are positive for COVID-19

- Wash with soap and water and put on fresh clothes before holding or feeding your baby.
- Wear a mask to help stop viruses from spreading.
- Watch out for symptoms like fever, confusion, or trouble breathing.
- Ask for help caring for your baby and yourself while you recover.



We can help protect each other.
www.nationalperinatal.org/rsv

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Leadership

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

Advocacy

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

Consultation

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

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How to Care for a Baby with Signs of Withdrawal

Use the Right Words

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

Treat Us as a Dyad

Parents and babies need each other. Help us bond. Whenever possible, provide my care alongside my parents and teach them how to meet my needs.

Support Rooming-In

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

Promote Kangaroo Care

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

Try Non-Pharmacological Care

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

Provide Lactation Support

Human milk is important to my gastrointestinal health and breastfeeding is recommended when my parent is HIV-negative and receiving medically-supervised care. Help my family reach our pumping and feeding goals.

Treat My Symptoms

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

Academy of Perinatal Harm Reduction
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Medical Legal Issues in Cases of Persistent Pulmonary Hypertension of the Newborn (PPHN)

Jay P. Goldsmith, MD, Jonathan K. Muraskas, MD

Case:

The mother was a 34-year-old gravida 1, para 0 at the time of birth. She presented to a Level 3 hospital at 21:06 hours on 07/16/2021 at 40 $^{3}/_{7}$ weeks gestation (EDD estimated at 7/12/21), reporting no fetal movement since the day before. The obstetrician on call declined to order a biophysical profile (BPP) at that time despite the history of no fetal movement. Mother was admitted and placed on electronic fetal monitoring, which was interpreted as a Category II strip shortly after arrival and remained that way throughout the night and early morning hours. At 08:02 AM, a cesarean section was called by the new obstetrician on call. A BPP result was pending at that time and was later reported as 2 out of 8, with the only points awarded for amniotic fluid. The baby was delivered at 9:07 AM with a birth weight of 6 pounds 2 ounces and a head circumference of 33 centimeters. Thick meconium-stained fluid was noted after artificial rupture of membranes during the cesarean section. Apgar scores of 2 and 7 were assigned at one and five minutes of age. The baby had bulb suction, PPV, and CPAP for resuscitation. The cord blood gas (noted as "mixed") revealed a pH of 6.99.

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At 11:01 AM, a chest x-ray showed opacification of both lungs, consistent with meconium aspiration syndrome. The baby was intubated and given surfactant. His respiratory status worsened as a result of the meconium aspiration, and he was placed on a high-frequency ventilator. Later that evening, inhaled nitric oxide (iNO) was started, and the baby was heavily sedated. Despite a FiO_2 of 100%, the baby had very borderline PaO_2 levels but remained without significant acidosis. Oxygen index (OI) calculations ranged between 25 and 38.

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The following day, the baby was transferred to a Level 4 NICU for possible extracorporeal membrane oxygenation (ECMO). During transport, the baby deteriorated and required hand ventilation and chest compression in the ambulance. On admission to the Level 4 NICU, he was crashed onto ECMO with a V-A approach. Over the next several days, cranial ultrasounds were done daily, and on the 3rd ECMO day, an intracranial bleed was noted. The baby was decannulated and managed with conventional ventilation and eventually discharged. The follow-up evaluation has revealed significant motor and cognitive impairments. A malpractice suit was filed against the obstetricians and the neonatologists, claiming delays in doing the cesarean section and delays in referring the

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Transition of the pulmonary circulation at birth:

Persistent pulmonary hypertension of the newborn (PPHN) is a relatively common neonatal morbidity resulting from the failure of the fetus to make normal cardiopulmonary transition at birth. In utero, elevated pulmonary vascular resistance (PVR) in the fetal lung impedes pulmonary blood flow, causing blood to be shunted through the foramen ovale and ductus arteriosus directly from the right atrium to the systemic circulation, thereby bypassing the lungs. Pulmonary blood flow accounts for only 15–20% of the combined ventricular output in the term fetus in utero. Failure of the PVR to decrease at birth results in hypoxic respiratory failure since the newborn is no longer being oxygenated via the placenta. This clinical syndrome occurs in about 2 per 1000 term live births. Although the entity was initially called persistent fetal circulation (PFC) due to the circulation abnormalities observed by cardiac catheterization in cyanotic newborns who were erroneously thought to have cyanotic congenital heart disease, the disease was renamed because fetal circulation is dependent on the placenta for gas exchange. Once the baby is born, the placenta is detached from the uterus. Over the past 3 decades, research into the pathophysiology of delayed decrease in PVR and new treatment strategies for PPHN (especially high frequency ventilation, inhaled nitric oxide, and ECMO) has greatly improved the outcomes for this disease. (1, 2)

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With the inflation of the neonatal lungs at birth, a rapid reduction in PVR usually occurs secondary to increased oxygen tension and pulmonary vasodilation, increasing pulmonary blood flow. Systemic vascular resistance increases with the removal of low-resistance placental circulation and the functional closure of the foramen ovale and ductus arteriosus. Disruptions in these processes (e.g., failure to initiate spontaneous respirations or intrauterine acidemia) may result in sustained elevation of PVR after birth. A fluid-filled lung and the presence of vasoactive mediators, such as thromboxane A2 and serotonin, in utero keep the PVR elevated. (1, 2) Maternal use of selective serotonin uptake inhibitors in pregnancy has been reported to be associated with postnatal elevation of PVR, although the risk may be modest. (3) Many biological and biochemical pathways function to promote or impair the natural reduction of PVR at the time of birth. These biological considerations are beyond the scope of this discussion but can be reviewed in numerous references.

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Etiology of PPHN:

PPHN is generally divided into primary and secondary categories. Primary PPHN (often called "black lung PPHN") is generally seen without any pulmonary parenchymal pathology with relatively normal chest x-rays. This syndrome accounts for a minority of the newborns who develop this disease. Secondary PPHN is usually a complication of some pulmonary parenchymal pathology, such as meconium aspiration syndrome, GBS pneumonia, congenital diaphragmatic hernia, and many others. Numerous genetic

mutations predispose neonates to PPHN. (1, 2, 4) Review of these mutations is beyond the scope of this manuscript. A significant proportion of PPHN is not predictable and probably non-preventable.

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Pathophysiology and Clinical Classification of PPHN:

Multi-factorial changes in the pulmonary vascular structure evolve over the first hours and days of neonatal life—a failure of the PVR to decrease after birth results in hypoxemia, acidemia, and clinical cyanosis. Clinically, there may be a difference between oxygen saturations in the upper and lower extremities (upper extremity 5–10% higher than lower extremity) due to right-to-left shunting across the ductus arteriosus. (2) Often, the neonate has very labile hypoxemia caused by external stimuli (handling, noise, venipunctures, etc.) due to changes in the balance between systemic vascular resistance and PVR. The right ventricle (RV) may become hypertrophic and dilated as it tries to pump against the high PVR. This may ultimately result in RV dysfunction that further worsens the hypoxic vicious cycle. Based on this pathophysiology, PPHN has been classified into four categories: (1, 2, 5, 6)

Underdevelopment: Neonates with pulmonary hypoplasia will have underdevelopment of the pulmonary arterial bed and increased PVR, leading to PPHN. This may be due to a space-occupying lesion of the chest, most commonly congenital diaphragmatic hernia (CDH). Other causes of pulmonary hypoplasia include a variety of diagnoses leading to maternal oligohydramnios, including prolonged rupture of membranes in the second trimester, renal agenesis, or other renal causes of decreased fetal urine production. The severity of the PPHN and the outcomes in these cases depend on the degree of resultant pulmonary hypoplasia.

Intravascular sludging: Decreased pulmonary blood flow may be due to increased blood viscosity, which can cause increased PVR and result in decreased tissue oxygen delivery, leading to PPHN. The most common cause of this phenomenon is polycythemia, causing hyperviscosity, but hyperviscosity is also seen during therapeutic hypothermia (TH), which may worsen PPHN in babies who have TH treatment for intrapartum hypoxic ischemic encephalopathy (HIE). (4)

Maladaptation: Intrapartum asphyxia resulting in a delayed decrease in PVR may cause pulmonary vasoconstriction and hypoxic respiratory failure. Concurrent phenomena, such as meconium aspiration syndrome (MAS) and other pulmonary diseases (e.g., RDS, pneumonia), contribute to this problem. In utero aspiration of meconium may cause inflammation, chemical pneumonitis, and inactivation of surfactant. PPHN will be exacerbated by acidemia and hypoxemia associated with neonatal pulmonary diseases, including such usually mild diseases as transient tachypnea of the newborn (TTN).

Maldevelopment: Chronic intrauterine hypoxia, for various reasons, may result in hypertrophy of the medial musculature of the pulmonary arterial bed, leading to PPHN. This process is often referred to as vascular remodeling and follows the principles of Poiseuille's Law, which states that the flow of blood across a constant length of tube (a blood vessel) is inversely proportional to the radius of that tube (blood vessel). Thus, narrowing of the lumen of the pulmonary blood vessels by chronic in utero hypoxia or maternal medications may result in increased PVR, decreased pulmonary blood flow, and "idiopathic" PPHN. This process takes several days to occur and will not result acutely from intrapartum asphyxia.

"Based on this pathophysiology, PPHN has been classified into four categories:
1. Underdevelopment...
2. Intravascular sludging...
3. Maladaptation...
4. Maldevelopment..."

Treatment:

The treatment of PPHN depends on the etiology and severity of the process. Oxygen, supportive care, and time are often the only therapies needed for a mild and partially delayed decrease in PVR seen with TTN. Standard care practices include minimal handling, optimizing cardiac output, maintaining a relatively normal pH, and the use of sedation and/or paralysis as necessary. The most severe forms of pulmonary hypoplasia and congenital diaphragmatic hernia (CDH) often require ECMO and may, unfortunately, result in death or significant morbidities. The Extracorporeal Life Support Registry, which tracks neonatal ECMO cases in the United States, reports that as of 2019, over 27,000 cases of neonatal respiratory failure had been treated with ECMO. Of these, 74% survived to discharge. The highest survival rate was with MAS (92%) and the lowest with CDH (51%), sepsis (51%), and pneumonia (45%). Among the complications, intracranial hemorrhage was seen in 7%, CNS infarction was noted in 7%, and seizures occurred in 9% of patients undergoing ECMO. The number of neonatal respiratory cases requiring ECMO has decreased from a high of over 1,500 per year in the early 1990s to less than 800 cases per year in 2021, primarily due to advances in respiratory management (the use of

HFOV), medical therapies (particularly iNO and surfactant), and supportive care. Most cases of maladaptation can be managed with medical and ventilation therapies alone. The number of cases of MAS requiring ECMO has continued to decline, while the cases of CDH have shown little change over the past decade. (7) On the other hand, maldevelopment and pulmonary hypoplasia are more likely to require more significant therapies, including HFOV, iNO, and ECMO.

"The treatment of PPHN depends on the etiology and severity of the process. Oxygen, supportive care, and time are often the only therapies needed for a mild and partially delayed decrease in PVR seen with TTN. Standard care practices include minimal handling, optimizing cardiac output, maintaining a relatively normal pH, and the use of sedation and/or paralysis as necessary. The most severe forms of pulmonary hypoplasia and congenital diaphragmatic hernia (CDH) often require ECMO and may, unfortunately, result in death or significant morbidities."

Major subjects of litigation:

Litigations in PPHN cases generally are due to complications which occur from the treatment or failure of treatment in term or often post-term babies, often with impaired transition to neonatal life and/or meconium aspiration syndrome. The plaintiff will claim that the obstetrician's failure to do an earlier cesarean section or operative vaginal delivery led to intrapartum asphyxia resulting in PPHN and/or meconium aspiration syndrome. This resulted in HIE or a complication, such as an intracranial hemorrhage, if ECMO is necessary. Underdevelopment and intravascular sludging etiologies for the PPHN are generally not subject to litigation. The question in most cases for the lay jury is whether maladaptation or maldevelopment was the cause of the PPHN. On the neonatal side, the plaintiff will claim that the resuscitation of a depressed newborn led to sustained acidosis that resulted in PPHN. Other claims are that inadequate respiratory care or correction of low blood pressure was delayed, resulting in increased morbidity or mortality. A baby who was initially only on oxygen with a nasal cannula deteriorates and eventually requires significant resuscitation and/or transport and ECMO with subsequent morbidity or mortality. The plaintiff argues that earlier recognition of the PPHN, which complicates the respiratory condition, could have been achieved by performing cardiac echocardiography or transferring to an ECMO center before the OI reached 40, thereby avoiding these unfortunate outcomes.

Outcome of the case:

"The number of neonatal respiratory cases requiring ECMO has decreased from a high of over 1,500 per year in the early 1990s to less than 800 cases per year in 2021, primarily due to advances in respiratory management (the use of HFOV), medical therapies (particularly iNO and surfactant), and supportive care. Most cases of maladaptation can be managed with medical and ventilation therapies alone."

The plaintiffs refused the offers of settlement, and the case proceeded to trial. Defense argued that the baby had vascular remodeling (maldevelopment), and earlier delivery would not have avoided the need for ECMO. They further argued that the neonatal providers met the standard of care prior to transport and transferred the baby when he met OI criteria. A large verdict for the plaintiff was rendered by the jury, which was divided among the delivery hospital, the obstetrician, and the Level 3 neonatologists.

"Underdevelopment and intravascular sludging etiologies for the PPHN are generally not subject to litigation. The question in most cases for the lay jury is whether maladaptation or maldevelopment was the cause of the PPHN."

Recommendations:

1. After resuscitation of a depressed term neonate, providers should attempt to normalize blood pressure and acid-base balance as quickly as possible to avoid PPHN.
2. Babies who require 100% FiO_2 for resuscitation should be carefully assessed for the development of PPHN, since the use of high oxygen concentrations may depress enzymatic pathways that lower PVR. (8)
3. Attempts should be made to optimize cardiac output, but inotropic agents to increase systemic blood pressure will also raise PVR and should be used judiciously. Providers should be comfortable with normal blood pressures for gestational age, postnatal age, and weight, provided adequate urine output and no metabolic acidosis are present. They should not attempt to boost blood pressures above normal levels to increase pulmonary blood flow.
4. Providers should search for evidence of chronic intra-uterine hypoxia, which may lead to PPHN or make it more challenging

to treat. Such findings as chronic maternal illness and medication use in pregnancy, decreased fetal movement, fetal growth restriction, abnormal Ponderal index (weight in grams/length in cm^3 plotted according to gestational age), increased nRBCs, abnormal placental pathology, etc. will often be clues to neonatal pulmonary vascular remodeling and signal a more difficult form of PPHN to treat.

5. The use of therapeutic hypothermia (TH) for babies with PPHN who marginally meet the TH criteria should be carefully considered since TH will increase PVR and may push the baby onto ECMO. Many neonatologists are cooling babies who are Sarnat stage 1, a treatment which is outside of standard accepted criteria (i.e., to use TH for only Sarnat stage 2 and 3) and should be employed cautiously if the baby has significant PPHN. The outcomes of babies who require both TH and ECMO are not encouraging. (9)

6. Providers should measure oxygen index or other indicators of respiratory failure and consider transporting patients to an ECMO center at an OI of 25 rather than waiting for the indicator to be 40. (10) If the baby with significant PPHN is being cared for in a non-ECMO center, it is better to transfer early before he becomes clinically unstable.

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Acknowledgement:

Satyan Lakshminrushimha, MD, an internationally known expert on PPHN, reviewed and contributed to this article.

Disclosures: The authors report no disclosures.

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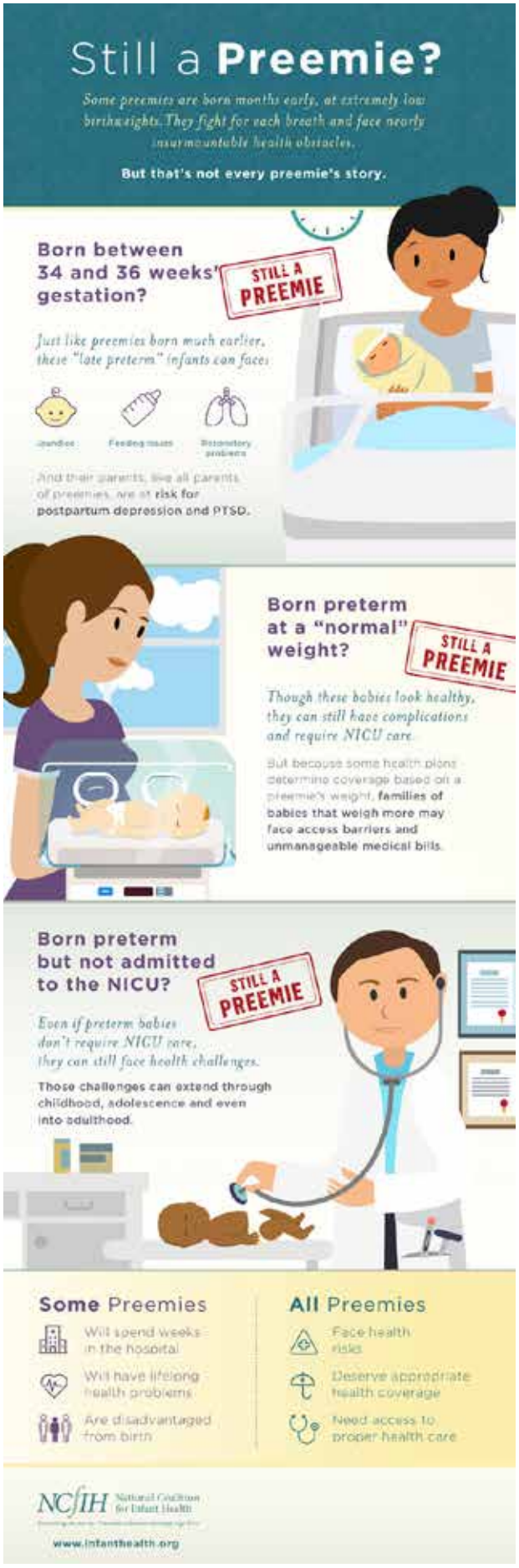


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2024

Protecting your baby and family from

Respiratory Viruses:

What parents need to know this RSV and flu season

Like COVID-19, RSV (Respiratory Syncytial Virus) and flu affect the lungs and can cause serious breathing problems for children and babies. Talk to your family about the risks.

Certain diagnoses can make children and babies more vulnerable for serious complications from respiratory viruses - including prematurity, chronic lung disease, and heart conditions.

You can limit the spread of viruses by wearing a mask, washing your hands with soap & water, using an alcohol-based hand sanitizer, and getting vaccinated.

The fewer germs your baby is exposed to, the less likely they are to get sick. Let people know you need their help to stay well. Limit visitors. Avoid crowds. Stay away from sick people.

Immunizations save lives. Stay up-to-date with your family's flu vaccinations and COVID-19 boosters. This helps our community stay safe by stopping the spread of deadly viruses.

Babies older than 6 months can get a flu shot and COVID-19 vaccinations. Now there are new vaccines for RSV for adults and antibody shots for babies that can help protect them.

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Implementing a Rapid Whole Exome Sequencing Order Set in EpicCare® to Accelerate Neonatal Diagnosis and Care

Valerie Tran, MD, Francis Chan, MD, Jennifer Shin, MSc, CGC, Durga Cherukuri, PhD, Kimberly Hillyer, DNP, RN, Robin Clark, MD, Hua Wang MD, PhD

Abstract

Rapid whole-exome sequencing (rWES) has emerged as a transformative diagnostic tool in neonatal intensive care units (NICUs), offering high diagnostic yields and the timely identification of genetic conditions that can alter acute care management. Despite its clinical value, rWES is often underutilized or delayed due to fragmented workflows, reliance on manual communication, and varying levels of provider familiarity. At our tertiary care institution, we utilize EpicCare® as our electronic health record (EHR). We implemented a dedicated SmartSet® (order set) to streamline the rWES ordering process, enhance documentation, and support interdisciplinary coordination. This article outlines the rationale, design, deployment, and potential impact of this SmartSet, offering a scalable and replicable framework for institutions seeking to implement precision diagnostics more efficiently in NICU settings.

EpicCare®, SmartSet®, SmartPhrase®, Secure Chat®, and Aura® are trademarks of Epic Systems Corporation.

"The clinical utility of rapid whole exome sequencing (rWES) in neonatal and pediatric critical care is well established, with diagnostic yields ranging from 30% to 60%, depending on patient selection and phenotype."

Background

The clinical utility of rapid whole exome sequencing (rWES) in neonatal and pediatric critical care is well established, with diagnostic yields ranging from 30% to 60%, depending on patient selection and phenotype (1–9). Early molecular diagnosis through rWES can significantly impact clinical decision-making, enable targeted prognostic counseling, and help avoid unnecessary or invasive procedures (2, 5, 7–9). Despite its benefits, broader implementation of rWES is often limited by several logistical challenges. These include inconsistent communication between clinical teams, reliance on the availability of genetic counselors for consent and coordination, manual processes for securing pathology approvals, and the lack of standardized documentation protocols (10, 11).

Commercial laboratories, such as Baylor Genetics and GeneDx®, have developed EpicCare Aura integrations to streamline laboratory-EHR interoperability. However, these tools primarily address data exchange and do not resolve the practical workflow barriers faced by neonatal intensive care unit (NICU) and clinical genetics teams. Notably, there is a lack of published reports detailing institution-specific EHR customizations—such as SmartSet —that support rWES ordering in neonatal settings (10).

"Early molecular diagnosis through rWES can significantly impact clinical decision-making, enable targeted prognostic counseling, and help avoid unnecessary or invasive procedures. Despite its benefits, broader implementation of rWES is often limited by several logistical challenges."

Recognizing this gap, our institution partnered with stakeholders across neonatology, pathology, genetic counseling, and clinical informatics to design a SmartSet within EpicCare. This tool integrates key elements—including rWES clinical indications, ordering guidance, approval workflows, and specimen collection instructions—directly into the EHR system to support the delivery of timely and standardized care (10, 11).

SmartSet Design and Functional Implementation

I. Pre-Implementation Workflow Challenges

Prior to SmartSet deployment, workflows for rapid whole-exome sequencing (rWES) in the NICU were characterized by fragmented communication, manual coordination, and inconsistent documentation. These inefficiencies delayed test initiation and hindered the timely integration of results into patient care. Key challenges included variable provider familiarity with genomic testing, limited availability of genetics professionals for consent and counseling, and the lack of standardized protocols for test ordering, sample handling, and documentation of results.

Before the SmartSet, the rWES process relied on:

- A genetics consultation initiated by the NICU team
- Email-based approval requests to the pathology molecular laboratory director
- Genetic counseling- (GC-) led coordination of parental consent, sample collection, and test send-out
- Manual order entry and communication are conducted outside the EHR

Additional barriers included:

- Limited GC availability on nights, weekends, or holidays
- Monthly trainee turnover with inconsistent onboarding
- Fragmented interdisciplinary communication
- Lack of centralized resources within EpicCare to support ordering and documentation

These challenges are well-documented in the literature, with studies highlighting how the absence of streamlined processes and unclear role delineation among neonatologists, geneticists, genetic counselors, and laboratory personnel can obstruct timely diagnosis of monogenic conditions in critically ill neonates (4, 10, 12, 13).

"These challenges are well-documented in the literature, with studies highlighting how the absence of streamlined processes and unclear role delineation among neonatologists, geneticists, genetic counselors, and laboratory personnel can obstruct timely diagnosis of monogenic conditions in critically ill neonates."

II. SmartSet Development Process

To overcome these obstacles, a multidisciplinary team—including neonatology, clinical genetics, genetic counseling, pathology, and informatics—collaboratively mapped the existing workflow, identified pain points, and defined a streamlined process for patient selection, consent, ordering, and logistics, drawing on successful models in the literature (4, 12–14).

The SmartSet was embedded in EpicCare and designed to:

- Include rWES clinical indications and eligibility criteria
- Route approvals via EpicCare Staff Messaging or Secure Chat rather than email
- Automate ordering using pre-checked panels (Trio, Duo, Proband-only)
- Provide embedded instructional content for ordering, approvals, and specimen handling workflows

This design aligns with evidence supporting the use of EHR-integrated clinical decision support (CDS) tools to enhance the appropriateness and timeliness of genetic test utilization—particularly for non-genetics providers (15, 16).

Additionally, the SmartSet featured:

- Structured fields for phenotype documentation
- Consent attestation—with links to required consent forms that need to be printed, signed, and sent with the specimen.
- Sample tracking integration for internal coordination and research use

III. SmartSet Functional Components

- The SmartSet includes an instruction section that lists the name of a SmartPhrase. Users can use this SmartPhrase to access the criteria and published guidelines for justifying rWES ordering.
- Workflow instructions also include EpicCare Messaging routing, which enables secure and traceable approval communication with pathology.
- Pre-Checked Orders: Trio WES, Duo WES, or Proband-only based on clinical scenario
- Instructional Content: Guides order entry, consent, specimen preparation, and lab contact within the SmartSet

This EHR-integrated decision support tool aimed to automate documentation, improve communication, and reduce variation in test coordination. Its design aligns with evidence showing that embedding clinical decision support within the EHR improves the appropriateness, timeliness, and equity of genetic testing—particularly among non-genetics providers (4, 15, 16).

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Workflow Transformation and Anticipated Impact

I. Pre-Implementation (Manual Workflow)

Before the SmartSet was introduced, the typical workflow included the following steps:

1. Genetics Consult Initiated

   A neonatologist or NICU provider identified a patient with suspected genetic disease and requested a formal genetics consultation.

2. Geneticist Evaluation and rWES Recommendation

   The on-call clinical geneticist evaluated the patient and determined whether whole-exome sequencing (rWES) was indicated. This rationale was documented in the genetics consultation note.

3. Pathology Approval via Email

   The GC emailed the clinical molecular pathology director to request test approval, including justification.

4. Approval Received via Email

5. Once approval was granted, no formal documentation was captured within EpicCare, making tracking and transparency difficult.

6. Consent and Specimen Collection Coordinated by GC

7. The GC obtained informed consent, reviewed the testing details with the family, and arranged for sample collection (blood or buccal swab) from the proband and parents.

8. Manual Test Ordering

   Orders were manually entered into EpicCare. The GC downloaded the lab requisition from an external website, filled it out by hand, attached a clinical summary, and physically submitted the materials to the lab.

9. Inconsistent Documentation

   Without embedded guidance in EpicCare, steps varied among providers, often resulting in errors or omissions—particularly among rotating resident physicians and other trainees.

II. Post-Implementation (SmartSet-Enabled Workflow)

The implementation of the SmartSet introduced a standardized, integrated workflow within EpicCare, resulting in improved timeliness, coordination, and reliability:

1. Consult with SmartPhrase for rWES Indications

   The geneticist recommends rWES following evaluation. A predefined SmartPhrase helps non-geneticist providers (e.g., NICU residents, pediatric hospitalists) recognize clinical scenarios appropriate for rWES. The SmartPhrase also promotes consistency in documentation and improves handoffs across shifts.

2. Pathology Approval via EpicCare Staff Message

   The GC, or if unavailable, the NICU resident physician, sends a Staff Message or Secure Chat within EpicCare to the molecular pathology director, including a clinical justification. NICU attending physicians and relevant team members are included in the communication for visibility. This approach ensures centralized documentation and real-time communication.

3. SmartSet® Used to Place Orders

   After approval is received (in-thread), the SmartSet® is launched to initiate:

   - Trio, Duo, or Proband-only rWES
   - Consent documentation
   - Pre-filled lab-specific orders with test codes
   - Linked requisition forms and instructions

4. Consent and Order Coordination

   Consent discussions and order entries are documented in EpicCare. The SmartSet includes contact information for requesting buccal swab kits, improving logistics for parental sample collection.

5. Specimen Collection and Requisition Management

   The SmartSet provides step-by-step specimen collection protocols (e.g., EDTA blood for probands; buccal swabs for parents), along with printable requisitions and internal guides. Lab contact information is embedded for real-time coordination.

6. Test Dispatch Within 24–48 Hours

   With all components embedded and completed within EpicCare—including approvals, consent, and order submission—samples are typically dispatched to the testing lab within 1–2 days. All steps are traceable within the EHR for auditability and follow-up.

This streamlined SmartSet workflow minimizes delays, reduces human error, and ensures standardized care delivery, especially during weekends or when GCs are unavailable. It also enhances provider confidence and integrates best practices into routine NICU operations.

III. Anticipated Impact

The SmartSet implementation is expected to improve efficiency, documentation quality, and interdisciplinary coordination significantly. The performance metrics were identified during pilot testing in the Table above.

Initial qualitative feedback from NICU resident physicians and GCs indicates that the SmartSet reduces cognitive load, minimizes missed steps, and is particularly valuable during overnight shifts and care transitions.

"The implementation of the SmartSet introduced a standardized, integrated workflow within EpicCare, resulting in improved timeliness, coordination, and reliability"

Discussion:

Our initiative aligns with an expanding body of literature that emphasizes the critical role of electronic health record-(EHR-) integrated tools in optimizing genetic testing workflows in hospital settings. Structured clinical decision support (CDS) and workflow standardization have been demonstrated to enhance the timeliness, appropriateness, and equity of genetic test utilization, as well as the documentation and follow-up of results (4, 10, 11, 14, 17). For example, Campbell et al. (18) demonstrated that an in-EHR patient tracking system improved documentation, accelerated result follow-up, and helped identify disparities in access to care. Recent studies further support that EHR-integrated interventions can reduce time to diagnosis, increase rates of appropriate genetic testing, and decrease healthcare resource utilization while mitigating inequities in genomic services (10, 14, 17).

The SmartSet was explicitly designed to address operational

Table. Results of pilot testing

Metric	Pre-Implementation	With SmartSet	Improvement
Time from rWES decision to pathology approval	2–4 days (email-based)	≤ 2 days (EpicCare messaging)	~50–70% reduction
Time from order placement to sample send-out	3–5 days	≤ 3 days	~40–60% reduction
Documentation quality	Outside the EMR	Fully embedded in EpicCare	Improved structure and traceability
Communication workload	High (manual, fragmented)	Streamlined and visible	Enhanced team coordination

inefficiencies identified in the literature, including delays in communication, a lack of standardized ordering protocols, and reliance on individual memory or experience (4, 10, 14, 17, 19). These issues have been cited as barriers to implementing rapid genomic sequencing in NICUs, despite the strong evidence for its diagnostic and clinical value (1, 3, 5, 10).

"The SmartSet complements such integrations by embedding test indications, interdisciplinary messaging, specimen logistics, and lab coordination directly into EpicCare. This promotes real-time collaboration between genetics, neonatology, pathology, and nursing."

While commercial platforms, such as Epic Aura, support test ordering and result return between EHRs and external labs, they do not address the internal coordination challenges that are critical to successful implementation. The SmartSet complements such integrations by embedding test indications, interdisciplinary messaging, specimen logistics, and lab coordination directly into EpicCare. This promotes real-time collaboration between genetics, neonatology, pathology, and nursing. Notably, the SmartSet also includes standardized educational tools—such as SmartPhrases and embedded guidance—to support NICU resident physicians and non-genetics providers. This not only enhances decision-making and minimizes variation during off-hours or staff transitions but also improves provider confidence and onboarding consistency.

Multidisciplinary collaboration was foundational to the success of this initiative. Active engagement from genetics providers, EpicCare analysts, NICU staff, and pathology ensured that the SmartSet was clinically relevant, technically feasible, and sustainable. Iterative improvements based on real-time feedback helped drive adoption and enhanced utility in varied clinical scenarios. This collaborative model is consistent with prior reports, which show that participatory implementation improves genomic workflows and supports scalability (1, 4, 10, 14, 17, 19).

Ultimately, the SmartSet reinforces team-based care, improves efficiency and accuracy, and provides a replicable framework for integrating rapid genomic testing into critical care settings. It demonstrates how customized EHR solutions can elevate diagnostic consistency and accelerate the delivery of precision medicine to critically ill neonates (3, 11, 14, 17).

"This initiative represents the first reported effort to implement a SmartSet for rWES in the NICU. It offers a scalable model for institutions seeking to modernize genomic diagnostics and reduce variability in care. This initiative underscores the importance of multidisciplinary collaboration, iterative feedback, and thoughtful integration of workflows."

Conclusion:

Embedding a SmartSet for rapid whole-exome sequencing (rWES) into the EpicCare EHR in the NICU has the potential to significantly improve diagnostic timeliness, documentation quality, and interdisciplinary communication. It streamlines the diagnostic process, enabling earlier identification of monogenic conditions and a faster return of actionable results—critical for acutely ill neonates. As precision medicine continues to advance, institutions should consider adopting customized EHR tools as low-cost, high-impact solutions to streamline genetic workflows.

This initiative represents the first reported effort to implement a SmartSet for rWES in the NICU. It offers a scalable model for institutions seeking to modernize genomic diagnostics and reduce variability in care. This initiative underscores the importance of multidisciplinary collaboration, iterative feedback, and thoughtful integration of workflows. While delayed adoption by clinical teams may pose a challenge, continuous feedback and long-term outcome tracking will be key to refining the tool and sustaining its impact.

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PubMed PMID: 38386321; PubMed Central PMCID: PMC10884880 next-generation sequencing wet work from the Israeli Ministry of Health and receiving next-generation sequencing reagents, bioinformatics solution, editing assistance, and open access publication fee from Illumina during the conduct of the study, and receiving speaking fees from Illumina Shine the Light Event and XPeer outside the submitted work. Dr. Amir reported receiving compensation for next-generation sequencing wet work from the Israeli Ministry of Health, as well as next-generation sequencing reagents, bioinformatics solutions, editing assistance, and open-access publication fees from Illumina during the conduct of the study. Dr Baris Feldman reported compensation for next-generation sequencing wet work from the Israeli Ministry of Health and next-generation sequencing reagents, bioinformatics solution, editing assistance, and open access publication fee from Illumina during the conduct of the study and receiving honorarium and travel expenses from Illumina and speaker's fee from XPeer channel educational video. No other disclosures were reported.

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***Disclosures**: The authors reported no disclosures.*

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Acknowledgments: We acknowledge Subhadra Ramanathan, CGC; Laura Wilson, MD; and Vellore Kasturi, MD, from our Division of Genetics, for their active involvement and valuable feedback throughout the development of the SmartSet.



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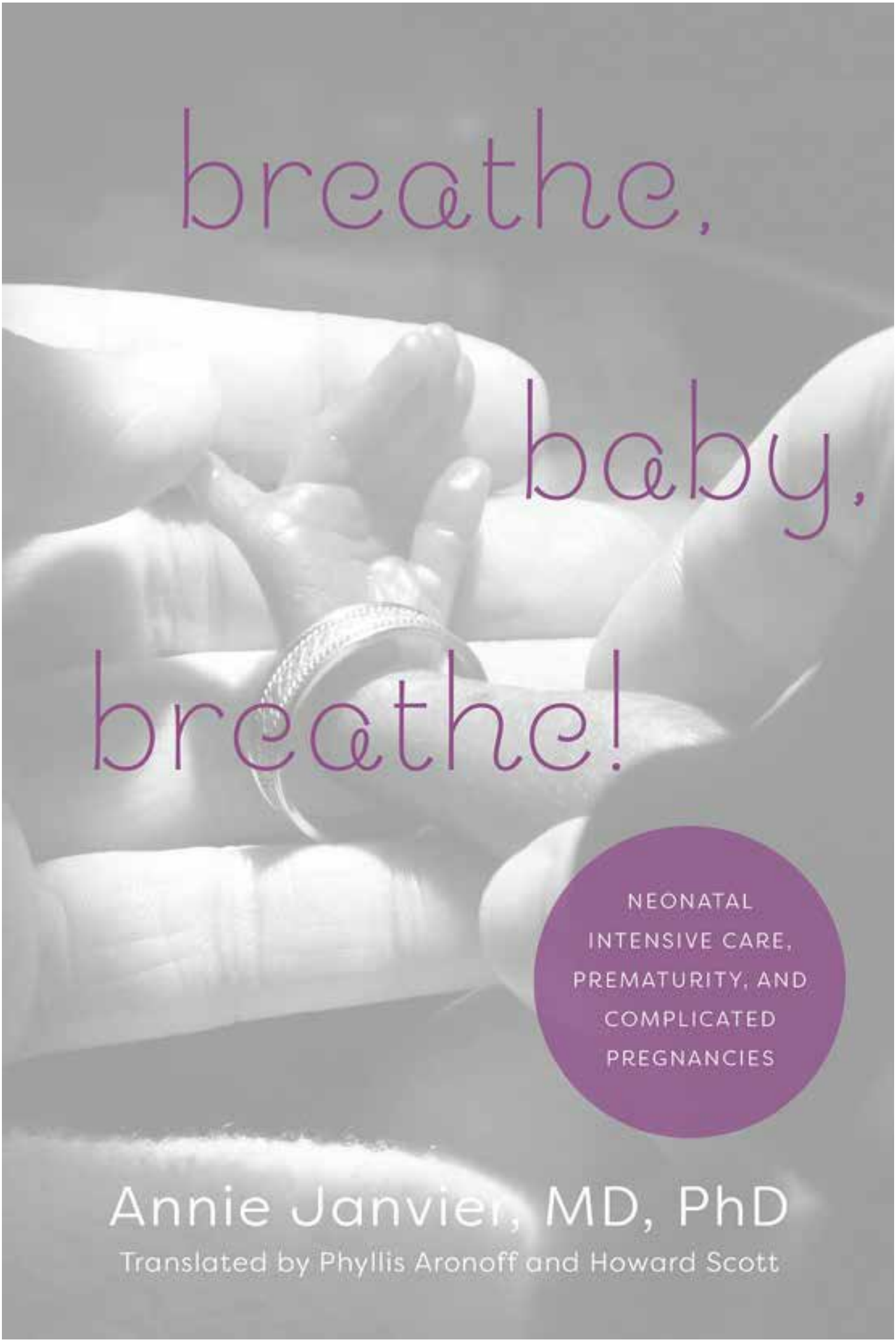
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Annie Janvier, MD, PhD
Translated by Phyllis Aronoff and Howard Scott



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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 guidlines limit their access to RSV preventative treatment, increasing these babies' risk.

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Family Centered Care: Summer 2025 Newsletter

Morgan Kowalski

"To address the challenges that exist in implementing FCC practices, we offer free educational webinars with engaging, live Q&A sessions and free monthly office hours sessions."

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Disclosures: *The author has no relevant disclosures.*

NT

Organizational Partners

Vol. 12 07/2025

FCC TASKFORCE NEWSLETTER

The **first** international, multicenter collaborative initiative solely dedicated to **quality improvement in NICU Family-Centered Care**.

In This Issue

- Supporting Families Beyond Discharge
- May '25 Webinar Summary
- Trauma-Informed Care Corner
- Executive Council Update
- FCC Taskforce Information

FAMILY-CENTERED CARE TASKFORCE

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Part Five: 'Aria's Journey: Connecting Through Our Shared Humanity'

by Jessi Barnes, MSN, RN, RNC-NIC, NPD-BC, C-ELBW, NICU Parent

Content Warning: The following is an artistic interpretation of what being a premature baby could be like. If you've experienced a preterm birth, please take care when reading.

Since the last time we talked, I have mastered chestfeeding! It took us a while to get things sorted out, but my team of helpers really supported us through all the learning curves. Now I'm trying to figure out how to eat from a bottle. Who knew there were so many ways to eat? It feels different every time, and that makes it hard for me to learn what to do. It would be helpful if things could be more consistent. Mom can't be here all the time, and they said I have to figure this out if I want to go home. (I really want to go home.) They have special helpers who focus on teaching me how to eat from the bottle. They have special helpers for everything in here! Mom and Dad have been taking turns learning how to help me eat. This is the longest part, I think. Learning how to breathe was one thing, but eating is a whole other challenge! I know Mom and Dad are tired, but they are here supporting me through this last lesson. We'll get through it together!

Practical tips for supporting learning how to eat from a bottle:

- **Follow the baby's cues.** They will let you know if they are interested or capable of learning how to eat. They get to call all the shots!
- **Normalize the ups and downs of eating in discussions with families.** It can be one of the most frustrating times for parents. Their baby has made it through other challenges, but eating is a huge milestone that each baby conquers at a different time.
- **Be intentional about focusing on the baby's experience of eating rather than the volume eaten.** We want positive neuropathways around eating for these tiny people!

For Part One/Aria's birth, catch up here.
For Part Two/Aria's admission, catch up here.
For Part Three/Aria's first time skin-to-skin, catch up here.
For Part Four/Aria's first time breastfeeding, catch up here.

07/2025

SUPPORTING FAMILIES BEYOND DISCHARGE

REIMAGINING NICU DISCHARGE THROUGH A FAMILY-CENTERED LENS

WITH JESS DAIGLE, MD, FAAP, NICU PARENT

In the NICU, discharge is not just a clinical milestone—it's an *emotional transition into the unknown*.

For families who've lived in a state of constant vigilance, where monitors replaced lullabies and updates came before sleep, discharge marks both freedom and fear. ***True family-centered discharge planning begins long before the paperwork.*** It's a gradual process of preparing, empowering, and honoring the family's voice.

I'll never forget one mom who stood quietly at her baby's bedside on the day of discharge. We had reviewed the feeding plan and the follow-up appointments, but before she left, she looked at me and said, "What if I don't wake up to feed him in time? The nurses won't be there anymore." She didn't need more instructions, ***she needed reassurance, presence, and a reminder that we believed in her***, too.

My reply to this parent sounded like, "You will. That instinct is already in you. **You've *been* showing up for your baby, and you'll keep showing up, just in a new rhythm.** Remember, it's not about being perfect, it's about being present."

Discharge planning means asking not only "Is this baby stable enough to go home?" but also "Have we equipped this family to feel confident and connected once they walk out the doors?" It's noticing who's missing from rounds, who's nodding without understanding, and who needs an extra day—not for the baby, but for themselves.

NICU professionals can support family-centered discharge in three major ways:

1. Start discharge conversations early.
Introduce the idea of going home at least 1-2 weeks in advance so families can emotionally and logistically prepare. Don't let it come as a surprise.

2. Teach in layers, not just once.
Spread out education on equipment use, feeding plans, and warning signs over time to improve retention and reduce overwhelm.

3. Ask, "What worries you most about going home?"
This simple question often reveals the unspoken fears that need your attention most.

Discharge from the NICU should never feel for families like they're being released—***it should feel like they're being carried forward with support, clarity, and compassion.*** That is what family-centered care looks like in practice—not just at the bedside, but at the threshold of home.

07/2025

MAY '25 WEBINAR SUMMARY

WITH BOB CICCO, MD

Our May Webinar provided strategies for **safely and successfully increasing the utilization of skin-to-skin care** in all infants while overcoming barriers that exist in promoting this important practice. Watch a recording of this free educational webinar **here!**

"**Removing Barriers to Safer Skin-to-Skin Care" with Ashley Weber, PhD, RN, RNC-NIC and Yamile Jackson, PhD, PE, PMP**

The results of a survey taken prior to this talk showed that when parents show signs of drowsiness during skin-to-skin care, 64% of respondents wake the parent and reposition the baby and 41% stop the session and provide education and support. Furthermore, 54% of respondents reported not having a unit protocol to support safe skin-to-skin care. WHO recommends 8-24 hours of skin-to-skin care each day, which can be comprised of multiple sessions. As a point of reference, 3hr of Kangaroo Care is considered a longer session, however parents tend to become distracted and drowsy after roughly 45 minutes. Ashley and Yamile provide **insights to maintain safety while continuing to promote skin-to-skin care:**

- Our inability to develop strategies to address safety during skin-to-skin sessions is a roadblock in achieving longer sessions.
- If you're worried about safety during skin-to-skin care, the answer isn't to shorten sessions, but to strategize about how to safely support longer ones.
- Allowing longer sessions of skin-to-skin care requires more planning, but the benefits of this care make that planning worthwhile.
- Parental distractions and drowsiness will occur. **We should plan for how to manage these rather than forbid skin-to-skin care.**
- The risks of adverse events related to parents being distracted or falling asleep are real but can be reduced by instituting appropriate controls.
- It's essential to find ways to support the baby without the parents having to use their hands. This can include having the parents reclined and using kangaroo wraps.
- Safety control protocols must be monitored, evaluated, and modified if necessary to assure ongoing safety.
- It is better to control risk through education, stabilization, and monitoring than to avoid risk by not allowing skin-to-skin care.

"Engagement of Families in a State-Wide QI Initiative on Skin-to-Skin Care" with Susan Bowles, DNP, APRN-CNS, RNC and Lelis Vernon, SQIL

Sue and Lelis shared the results of a statewide quality improvement project focused on improving skin-to-skin care across Florida. This project was done through their state's Perinatal Quality Collaborative and emphasizes the **importance of family engagement and participation in achieving true quality improvement in care**. Some key results and takeaways from this project are:

- ANY QI project will benefit greatly from having parent consultants in order to assure that the project will promote change that is consistent with FCC principles.
- The primary drivers for this QI project were the pillars of FCC: Family Participation, Dignity and Respect, Collaboration and Information Sharing.
- Not only was prompt initiation of skin-to-skin care increased during the project, but there was also an increase in the use of mother's own milk at the time of discharge for all populations.
- Time to initiation of skin-to-skin care was most improved in Black and Hispanic populations.
- Skin-to-skin care was increased without any increase in unplanned extubations. All institutions developed a policy to have two staff members assist with transferring the baby to the parent's chest.
- Educating families on the value of skin-to-skin care reduces their fear of initiating it.
- With any QI project, it is important to track the changes that have be made to assure they are sustainable.

07/2025

TRAUMA-INFORMED CARE CORNER

THE COURAGE TO BE GOOD: A CALL TO CARE WITH INTEGRITY

WITH MARY COUGHLIN, MS, NNP, NCC-E, TRAUMA INFORMED PROFESSIONAL

How hard is it to be good? It's a question that has echoed through my recent work — not as a moral dilemma, but as a trauma-informed inquiry. In a world that often rewards efficiency over empathy, and perfection over presence, being "good" — truly good — can feel like an act of quiet defiance.

In the NICU, goodness isn't abstract. It lives in the pause before a painful procedure. It's embedded in the choice to speak with respect to a family overwhelmed by fear. It shows up in our commitment to relational safety — even on the hardest days.

Trauma-informed care reminds us that every human behavior tells a story — including our own. And yet, we've been conditioned to separate the personal from the professional, to keep our griefs quiet and our hearts hidden. But goodness isn't sterile. It's relational.

To be good in this context is not just about clinical competence; it is about caring with integrity. It's about showing up consistently, compassionately, and consciously — even when we're tired, even when the system makes it hard. Goodness lives in our willingness to connect, to be seen, and to see others fully.

This is where the **B.U.F.F.E.R.™** framework meets real-life care:

- **Belonging** — because no one should feel like a visitor in their child's story.
- **Understanding** — because behavior is a reflection of experience, not worth.
- **Forgiveness** — because healing means we get to try again.
- **Frameworks** — because structure and soul are not mutually exclusive.
- **Equanimity** — because our calm becomes someone else's lifeline.
- **Respect** — because dignity is a birthright, not something earned.

So, how hard is it to be good?

Hard enough to require intention.
But beautiful enough to keep choosing it — again and again.

A Thread of Gold
by Mary Coughlin



Click here to enlarge

This Summer, **let's reclaim goodness not as a nicety, but as a clinical, ethical, and human imperative.** Let it be the throughline of every interaction, every decision, every moment of care.

Because in a world that feels increasingly fractured, goodness is a radical act of repair. And we are the ones who carry the thread.

With heart, Mary

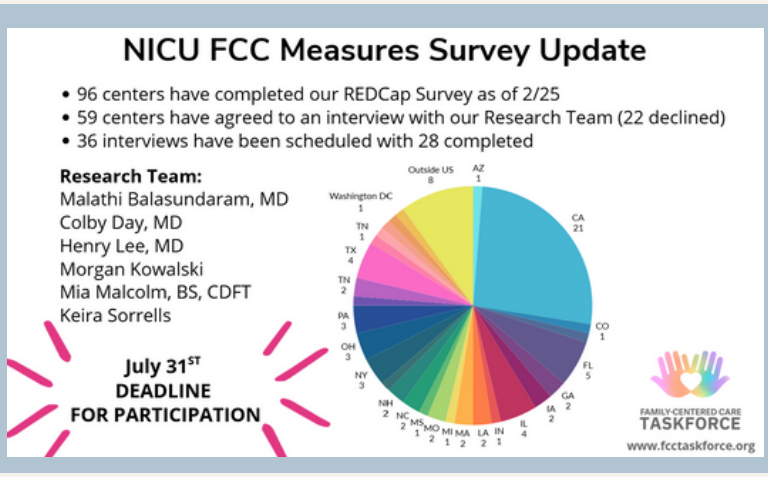
07/2025

EXECUTIVE COUNCIL UPDATE

WITH MALATHI BALASUNDARAM, MD & MORGAN KOWALSKI

The FCC Taskforce's Executive Council held its second quarterly meeting of 2025 on June 24th with 21 members joining virtually via Zoom!





Asses your unit's performance in delivering Family-Centered Care. **Click here** to register for the survey!

We are grateful to the **16 family-led** and **22 healthcare-based** organizations supporting our work by sharing our free educational webinars and office hours sessions!





We're thrilled to welcome six new members to our Executive Council, and our first Healthcare Partner representing the social work community! Learn more about our Executive Council here.

07/2025

THANK YOU FOR READING

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Colby Day, MD
Keira Sorrells, NICU Parent

Program Manager
Morgan Kowalski , NICU Parent

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Co-Chairs
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Mary Coughlin, MS, NNP, NCC-E
Laura Hedli, MS

Mission Statement

We exist to equip and support NICUs as they seek to begin or strengthen Family-Centered Care in their units.

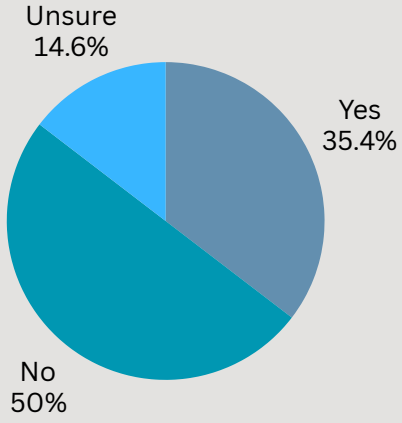
Why We Exist

To address the challenges that exist in implementing FCC practices, we offer free educational webinars with engaging, live Q&A sessions and free monthly office hours sessions.

Our key strength is equal partnership between clinicians and family partners in everything we do.

In a survey of 48 NICUs across the U.S., 65% said they don't have an FCC Committee in their unit.

Does your NICU currently have an FCC Committee?



Membership



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70 Countries
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FCC Taskforce Webinar

September 11, 2025
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Screening Now: Standardizing Mental Health Assessments for NICU Parents



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Long-Term Outcomes: Preparing Families for Future Health



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FCC Taskforce Program Overview

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FAMILY-CENTERED CARE TASKFORCE

FCC TASKFORCE OFFICE HOURS

Who? Facilitated by one Healthcare Partner and one Family Partner from our Executive Council and attended by members like you!

What? An informal meeting where members can bring their unit's specific challenges and barriers around implementing family-centered care practices and brainstorm solutions for overcoming them with their peers.

Where? Zoom! These sessions are not recorded so folks can feel safe sharing.

When? 11am Pacific Time / 2pm Eastern Standard Time

Why? Don't reinvent the wheel! Modify what's worked for other units to suit your own.

Register Here

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Pictured: Baby Kole with his Dad

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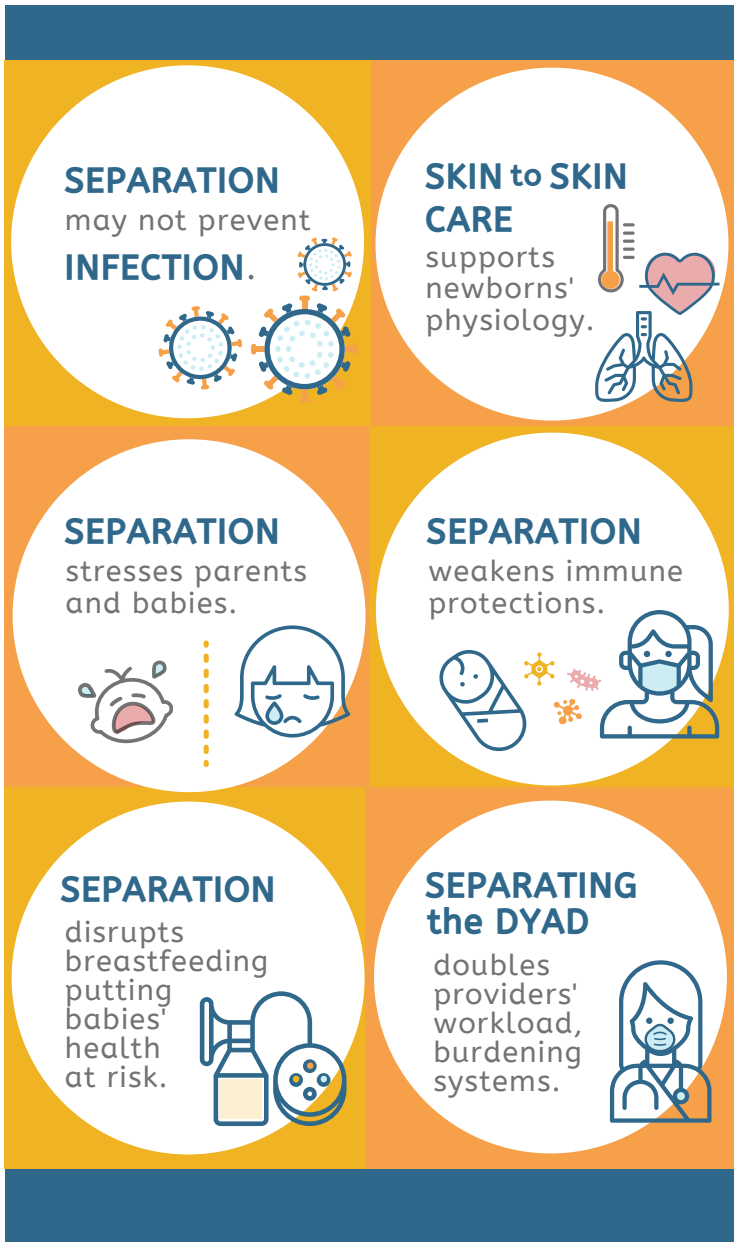
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Should Infants Be Separated from Mothers with COVID-19? First, Do No Harm

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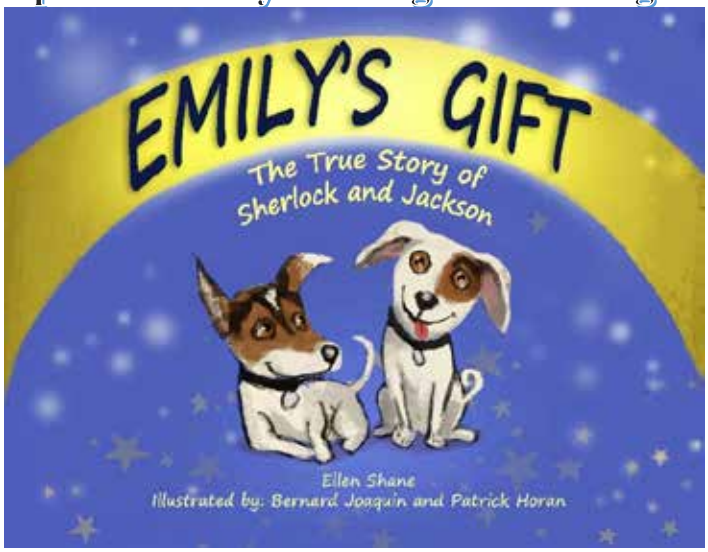
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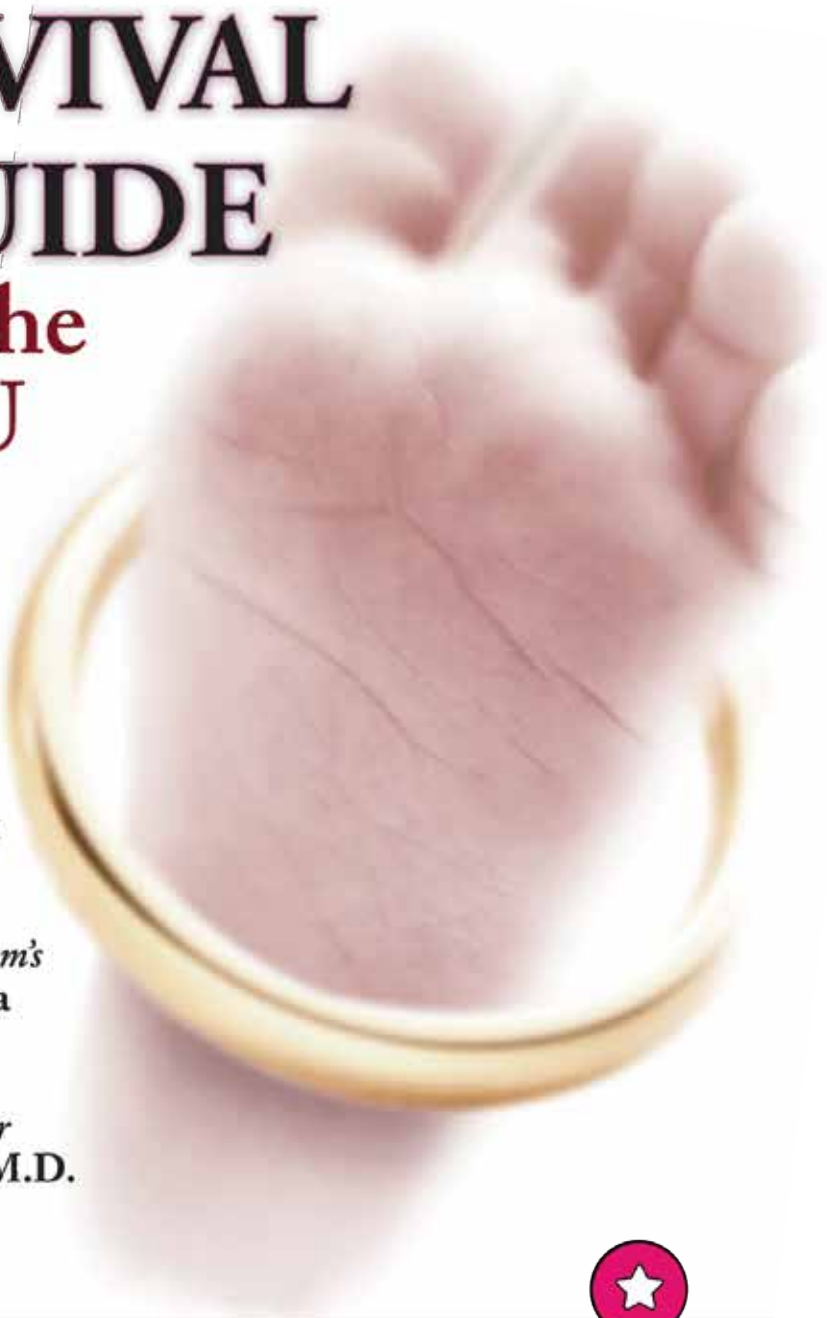




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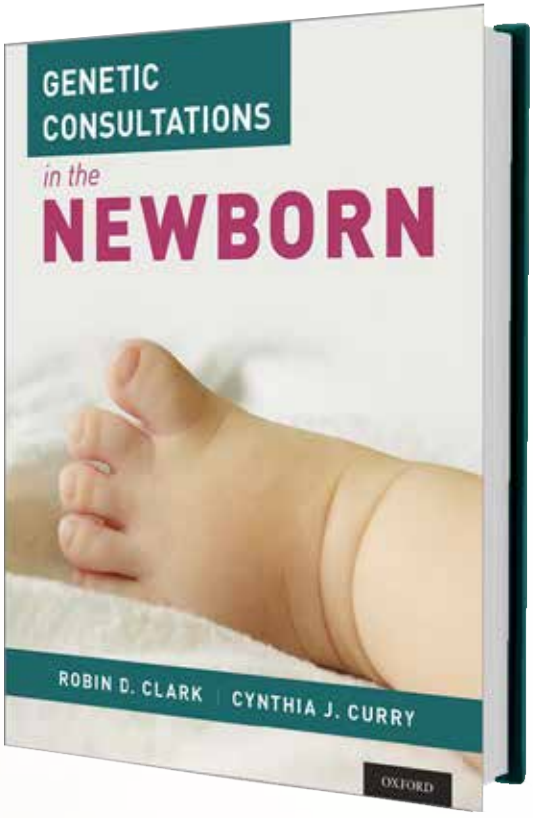
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Clinical Pearl: The Clinical Utility of Artificial Intelligence (AI) in Neonatal Neuromonitoring

Gustave H. Falciglia, MD, MSCI, MSHQPS, Joseph R. Hageman, MD, Mitchell Goldstein, MD, MBA, John Sullivan, MD, PhD

Joseph R. Hageman, MD:

The European research project AI4NICU (1), a group of clinicians and biomedical engineers, recently presented a commentary on the clinical utility of artificial intelligence (AI) applications in neonatal neuromonitoring (2). *Kulakowski et al*. commented that state-of-the-art clinical brain monitoring is essential for providing "optimal neurocritical care" to at-risk newborn infants (2). There are an increasing number of modalities to monitor brain function, including physical exams, electroencephalograms (EEG), near-infrared spectroscopy (NIRS), and several imaging modalities; however, analyzing these data is challenging (2). Each modality is imperfect, susceptible to artifacts, and may be challenging to interpret. They argue that AI has the potential to enhance the analysis of these complex data and aid in the diagnosis of neurological conditions in newborns.

"Kulakowski et al. commented that state-of-the-art clinical brain monitoring is essential for providing "optimal neurocritical care" to at-risk newborn infants. There are an increasing number of modalities to monitor brain function, including physical exams, electroencephalograms (EEG), near-infrared spectroscopy (NIRS), and several imaging modalities; however, analyzing these data is challenging. "

Gustave H. Falciglia, MD:

Kulakowski et al. define AI as a "general, nonspecific term that covers a range of statistical learning methods, many with little associations to the broader field of machine intelligence" (2). This is a broad definition and may mean different things to different people. The term "AI" is used casually, with Google Trends revealing an exponential rise in its search volume since 2023 (3). It is helpful to further define AI as generative vs. non-generative (i.e., discriminative) (4). Generative AI has analyzed patterns in old data to generate new information (4). ChatGPT is an example of this type and is a large language model (LLM) (2). LLMs have analyzed large bodies of text, making connections between related words and concepts, and will predict the text in response to a question (5). Discriminative AI, however, aims to classify or categorize a collection of data, thereby making a prediction (4). For example, which pattern does this constellation of EEG tracings, physical exam findings, and laboratory values correspond to: an infant with hypoxic ischemic encephalopathy (HIE) or one without HIE? The commentary is devoted to the latter, which may improve the "clinical decision-making process by uncovering new insights in the data" (2).

"It is helpful to further define AI as generative vs. non-generative (i.e., discriminative). Generative AI has analyzed patterns in old data to generate new information...Discriminative AI, however, aims to classify or categorize a collection of data, thereby making a prediction."

The authors conclude that developing AI tools to support decision-making for neonatal neurocritical care requires:

1. "Sufficiently large and diverse data sets to represent the expected population heterogeneity;
2. An awareness of bias and its potential negative impact;
3. Transparency in model development, and, in particular, explainability of models where possible, to build trust and confidence;
4. Adherence to AI medical device regulation (MDR) throughout the life cycle of the product; and
5. Clinical evaluation through rigorous validation and postmarket surveillance. (2)"

Generating accurate and useful predictive AI models will require large datasets. Outcomes such as seizure or HIE are relatively rare; therefore, the number of patients needed to observe to detect

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an outcome of interest will be high (2). Variation is ubiquitous and may occur at the patient level (e.g., each baby has a different resting heart rate) or at the institutional level (e.g., different NICUs have a different mix of acuity and patients) (2). This will require collecting data from multiple institutions, necessitating institutional review board oversight, attention to patient privacy and protected health information (PHI), and data use agreements across different institutions (2). Furthermore, the data will need to be acquired or structured in a similar manner to facilitate consolidation.

Once datasets are acquired, the development of predictive models should be compared to a gold standard. In the case of EEG reads, this may be comparing the model's output to the "inter-rater performance of the human reviewer" (2). Attention should be made to avoid overfitting data. Overfitting occurs when a model becomes overly accurate in describing the data. It accounts for all the subtleties and nuances of the data. By accounting for the individual and institutional level variation, it becomes excellent at explaining the data from which it was developed but does worse at explaining data from different patients or institutions (6). Therefore, it is essential to develop models using a "training" dataset and then validate their accuracy on "test" datasets that are distinct from the training dataset (2). Developing AI models from large datasets and testing the model's performance on diverse data also helps mitigate the risk of bias in model development by ensuring that conclusions are drawn from a representative sample (2).

"Therefore, it is essential to develop models using a 'training' dataset and then validate their accuracy on 'test' datasets that are distinct from the training dataset. Developing AI models from large datasets and testing the model's performance on diverse data also helps mitigate the risk of bias in model development by ensuring that conclusions are drawn from a representative sample."

Clinicians may be reluctant to adopt AI recommendations if it is not clear how AI models work (2). In a traditional statistical model, the clinician may be able to reproduce the result using model variables such as beta coefficients in a linear regression. Kulakowski et al. note that AI models may behave as a "black box," where clinicians input data into the model, an outcome is predicted, but the process remains unclear (2). This nature may stem from the proprietary nature of AI—companies producing AI have an incentive to avoid competitors copying technology; however, the obscure nature may also be a result of model complexity that moves well beyond simple logistic or linear regression. The authors advocate for "explainable AI (XAI) techniques," where the model predicts an outcome and also provides the rationale for the clinician (2). For example, XAI might highlight the aspects of clinician data or MRI results that were most salient in generating the AI prediction (2).

Finally, the authors recommend "adherence to AI medical device regulation (MDR)". Good MDR would 1) evaluate AI for and stratify AI by risk, 2) ensure that AI are developed using training and testing datasets that are large enough to represent the target population, 3) assure transparency in the "use or purpose" of the AI, and 4) perform "postmarket surveillance" to identify safety issues emanating from AI's use (2).

"Good MDR would 1) evaluate AI for and stratify AI by risk, 2) ensure that AI are developed using training and testing datasets that are large enough to represent the target population, 3) assure transparency in the 'use or purpose' of the AI, and 4) perform 'postmarket surveillance' to identify safety issues emanating from AI's use."

I thought our readers would be very interested in AI expert and neurologist, Dr. John Sullivan's thoughts about this commentary:

This was a fascinating paper. I wanted to share with you some of my thoughts about the article.

In my opinion, the article gives a comprehensive roadmap addressing ethical, technical, regulatory, and clinical aspects of AI integration in neonatal neuromonitoring. The authors focus on augmenting clinician decision-making, not replacing it. The emphasis on explainable AI (XAI) to promote transparency and understandability as well as bias mitigation to build clinical trust are key insights. Moreover, I agree that a realistic awareness of regulatory frameworks (FDA, EU, AI Act), will accelerate development, enhance trust and adoption and hopefully mitigate legal and ethical risks. Lastly, a focus on EEG-based applications (e.g., seizure detection) may serve as a good initial platform due to data availability and standardization, continuous monitoring, and the fact that there are existing regulatory-approved devices.

"Lastly, a focus on EEG-based applications (e.g., seizure detection) may serve as a good initial platform due to data availability and standardization, continuous monitoring, and the fact that there are existing regulatory-approved devices."

As a counterpoint, the article has a weighted focus on EEG, while

valuable other modalities (NIRS, MRI) are less developed within the context of the article. Additionally, data scarcity and variability limit model development and generalizability, which is [a] limiting but not insurmountable problem currently. There may also be very real and practical workflow integration and IT challenges that were not explored in depth within the article. This can be a significant barrier to implementation. Implementation, however, may begin with pilot projects targeting automated EEG interpretation (seizure detection, EEG grading). Also, engaging clinical stakeholders early could help define practical workflow integration needs. In addition, steps to develop small, institution-specific data 'biobanks' to support initial AI model training might be a way in which small steps lead to proof of concept. Moreover, pursuit of federated learning partnerships where feasible could also help to broaden dataset diversity and limit small dataset bias. Finally, there is a need to build clinician trust, which in part could be developed through explainable AI outputs, which would serve to make the AI 'decision-making process transparent, understandable, and interpretable to human users. In all, I believe attempting AI integration holds potential to enhance diagnostic consistency, reduce clinician burden, and improve real-time decision support, particularly in resource-limited settings. Though we are still in the 'infancy' (appropriate word choice?) of its integration. This may help avoid perpetuating current inconsistencies in interpretation, clinician fatigue, and missed opportunities for earlier intervention. While regulatory and operational challenges are significant, the potential to improve neonatal neurological outcomes justifies exploration and investment.

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***Disclosures**: The authors have no relevant disclosures.*

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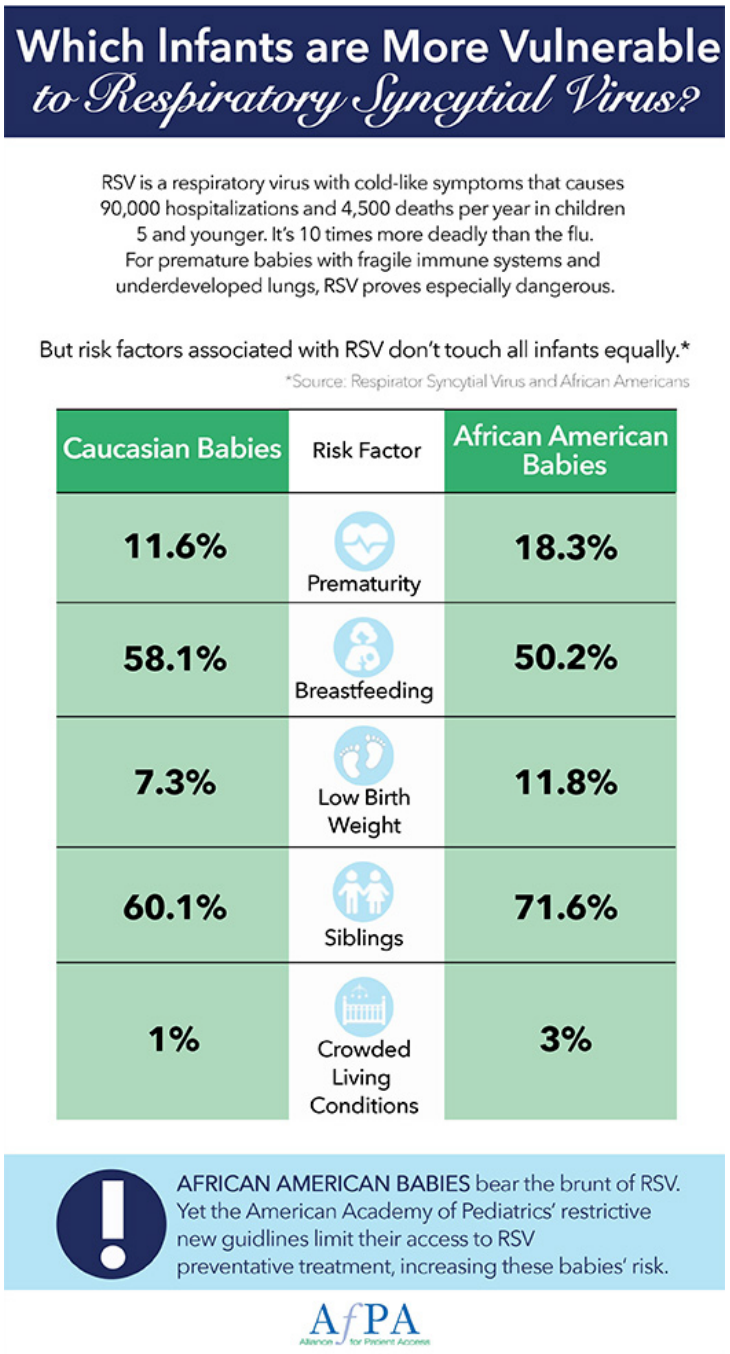
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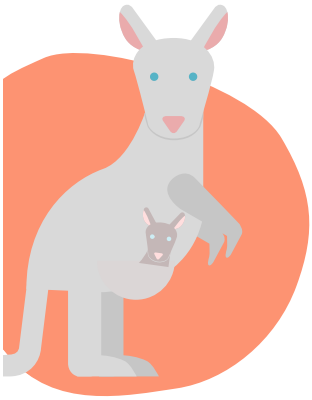
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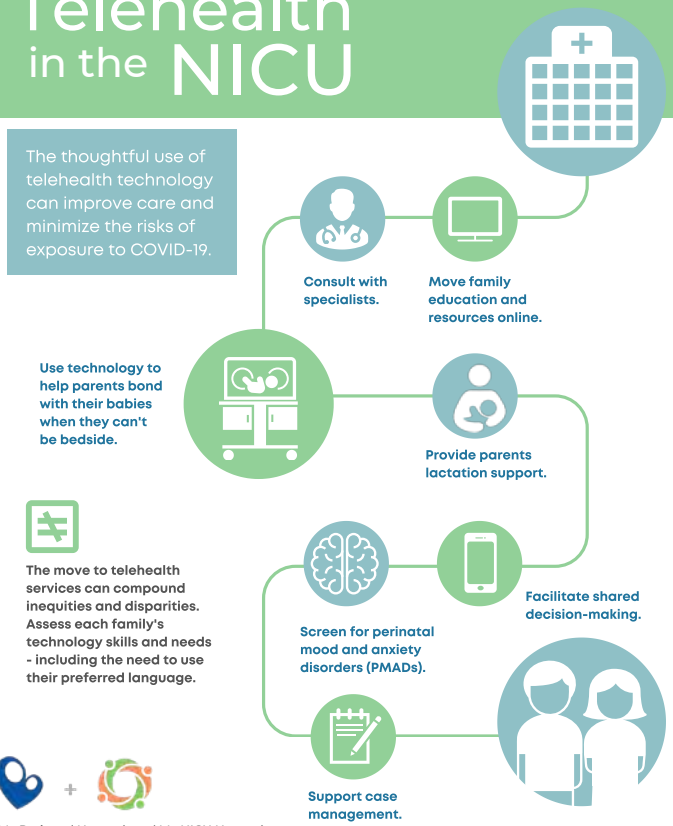
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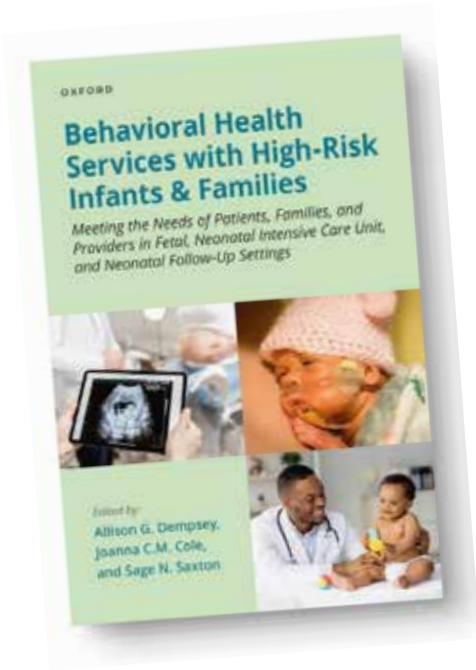
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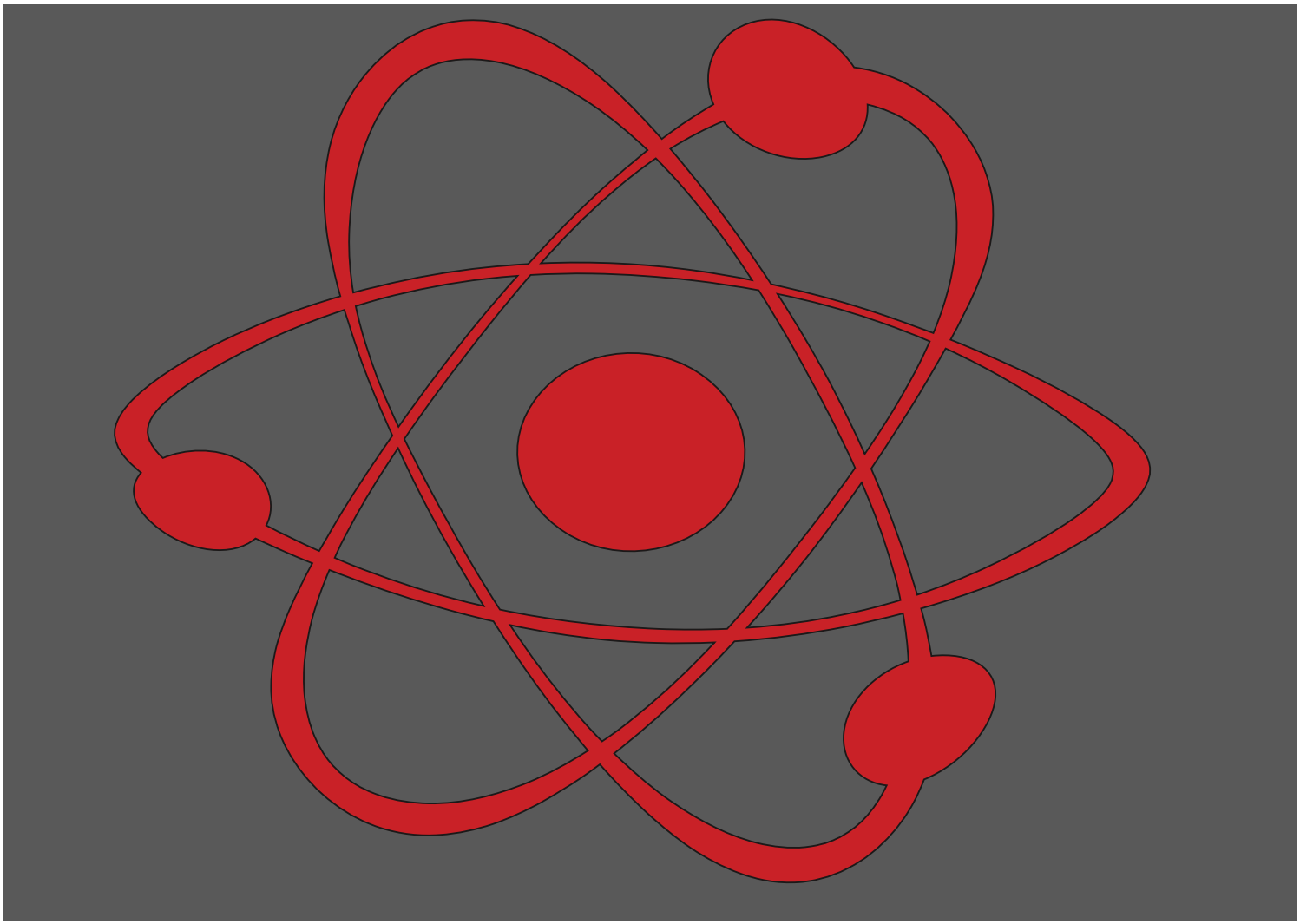
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Publication
Mitchell Goldstein, MD
Loma Linda Publishing Company
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We are looking for experienced or new graduate Neonatal Nurse Practitioners (NNPs) who are excited to join a cohesive team that practices in a collaborative, fast-paced, high-acuity setting.

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For more information, please contact:

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WE ARE HIRING

NICU DIETICIAN SPECIALIST 2

Full job summary and link to apply below

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Qualifications:

- Bachlor's Degree or Master's degree in Nutrition and Dietetics or Nutrition-related field required
- Two years of clinical nutrition experience required
- One year in Pediatrics preferred
- RD/RDN required
- CCS paneling required within one year of hire date

Annette Gonzales | Recruiter | LLUH HRM| ACGonzales@llu.edu

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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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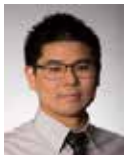
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Neonatology and the Arts

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

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

Logos and trademarks will usually not qualify for publication.

This month we continue to landscapes, feature artistic works created by our readers on the next to last page as well as photographs of birds on rear cover. Dr. Zahera Etter provides "Another Angle on Mount Fuji" a For this edition, our art was graciously provided by Colleen Kraft, MD. It is a work called "The Maze" done by her son Tim. Our bird is from Dr. Shah, "Steller's Jay" from Sedonia.



Lily Martorell, MD

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Manuscript Submission: Instructions to Authors

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

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

3. There is no charge for submission, publication (regardless of number of graphics and charts), use of color, or length. Published content will be freely available after publication. There is no charge for your manuscript to be published. NT does maintain a copyright of your published manuscript.

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 "NLM" format (APA 7th is no longer acceptable). Bibliography Software should be used to facilitate formatting and to ensure that the correct formatting and abbreviations are used for references. EndNote X9 is suggested.

X9 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.

10. Only manuscripts that have not been published previously will be considered for publication except under special circumstances. Prior publication must be disclosed on submission. Published articles become the property of the Neonatology Today and may not be published, copied or reproduced elsewhere without permission from Neonatology Today.

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Invitation to Apply:

Seeking content development experts for an AAP Project Advisory Committee (PAC)

The White Zone – Developing A Perinatal Loss Toolkit for LMICs

The Need: Over 2.4 million neonatal deaths and 2.6 million stillbirths occur each year; 98% occur in Low- and Middle-Income Countries (LMICs). While programs such as Helping Babies Breathe (HBB) and Essential Newborn Care (ENC 1 and 2) have revolutionized how providers in LMICs train in and provide neonatal resuscitation and post-delivery care for small and sick newborns, gaps remain in how to best offer end-of-life care and post-loss psychosocial care in these settings.

The Babies: HBB and ENC 1 begin with assessing if a baby is crying and conclude with the "Red Zone" where a baby who is unable to sustain an appropriate heart rate and/or respirations is provided with PPV support as someone attempts to get help. Within the HBB/ENC framework, we could imagine several babies for whom an extension of this framework to include palliative/perinatal loss guidelines could be helpful:

1. A stillbirth for whom no resuscitation is attempted. (Stillbirth)
2. A baby who proceeds through the red zone but never has a heartbeat or breathing despite the best resuscitative efforts of the team. (Stillbirth)
3. A baby who proceeds through the red zone who, after 20 or so minutes still has a very low heartbeat and/or gasping breathing. (Anticipated neonatal death)
4. A preterm baby who is too small for ongoing support, based on local resource constraints or resuscitation guidelines, despite a sustained heart rate and breathing. (Anticipated neonatal death)

The Approach: Create a suite of resources that could accompany ENC 1 and 2, focused on end-of-life care and perinatal loss. These resources would be less algorithmic than ENC, as local practices around death vary significantly – meaning there is not one "right" way to approach this care. Rather, the "White Zone Toolkit" would combine structured guidance about symptom management as well as reflective tools for implementing contextually and culturally appropriate post-loss care. This could consist of, but is not limited to, the following:

1. Structured guidance on what physiologic changes may happen at the end of life (ex: gasping) as well as pharmacologic and non-pharmacologic options for symptom management.
2. Reflective questions about if/when to offer seeing or holding of the baby.
    - Data shows that many women want to see and/or hold their infant following stillbirth or neonatal death but are often not offered that opportunity based on historic cultural norms.
3. Reflective questions about cultural traditions around loss and if/how these practices can be supported by those attending the delivery.
4. Anticipatory guidance guides on how mothers may still produce milk and how to manage those symptoms.
5. Anticipatory guidance on potential maternal mental health needs. Reflective questions on how to approach mental health and psychosocial support after loss.
6. Access to a set of adaptable practice scenarios that could help providers gain experience in handling perinatal loss and communicating with families surrounding perinatal loss.

NICU BABY'S *Bill of Rights*

1 The Right to *Advocacy*

My parents are **my voice** and **my family** are **my best advocates**.

My parents know me well. They are my voice and my best advocates. They need to be knowledgeable about my progress, medical needs, and prognosis, so they celebrate my achievements and support me when things get challenging.

2 The Right to *My Parents' Care*

Welcome my family and **include them** in everything we do.

My parents are my essential caregivers. In order to care for me, they need lots of opportunities to learn. Ensure that hospital policies and protocols, including hours & rounding, are as inclusive and expansive as possible. Then be patient with them.

3 The Right to *Bond With My Family*

Create opportunities for my family and me **to be together and bond**.

Bonding is crucial for my healthy growth and development. Support my parents so that we can practice skin-to-skin care as soon and as often as possible. Encourage them to read, sing, and talk to me.

4 The Right to *Neuroprotective Care*

Protect my **developing mind** and **senses**.

Protect me from things that startle, stress, or overwhelm me. Support things that calm me. Ensure I get as much sleep as possible. My brain is developing for the first time - and faster than it ever will again. The way I'm cared for today will affect me as I continue to grow & develop.

5 The Right to *Be Nourished*

Support our feeding decisions and **help us develop our skills**.

Encourage my parents to feed me at the breast or by bottle, whichever way works for us both. Support our feeding goals and make sure my parents know all the nutrition options available to meet my needs.

6 The Right to *Personhood*

Respect me as the **amazing, unique individual** that I am.

Use my name. Talk to me before touching me. If one of my siblings passes away, ask my family how we want to talk about and acknowledge them.

7 The Right to *Confident and Competent Care Giving*

Support my parents and caregivers.

The NICU may be a traumatic place for my parents. Ensure that they receive tender loving care, information, education, and as many resources as possible to help inform them about my unique needs, development, diagnoses, and more.

8 The Right to *Family-Centered Care*

Teach my family **how to care for me**.

Help me feel that I am a part of my own family. Teach my parents, grandparents, and siblings how to read my cues, how to care for me, and how to meet my needs. Encourage them to participate in or perform my daily care activities, such as bathing and diaper changes.

9 The Right to *Healthy and Supported Parents*

Care for our **mental health** and **wellbeing**.

My parents may be experiencing a range of new and challenging emotions. Be patient, listen to them, and lend your support. Share information with my family about resources such as counseling, support groups, & peer-to-peer programs, which can help reduce the impact of perinatal mood and anxiety disorders (PMADs).

10 The Right to *Inclusion and Belonging*

Celebrate what makes us special and unique.

Celebrate our diversity. Honor what makes us unique. Ensure that my parents, grandparents, siblings, and friends feel accepted and welcomed in the NICU, and respected and valued in all forms of engagement and communication.

NPN
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