Vol. 39 No. 3
Summer 2026

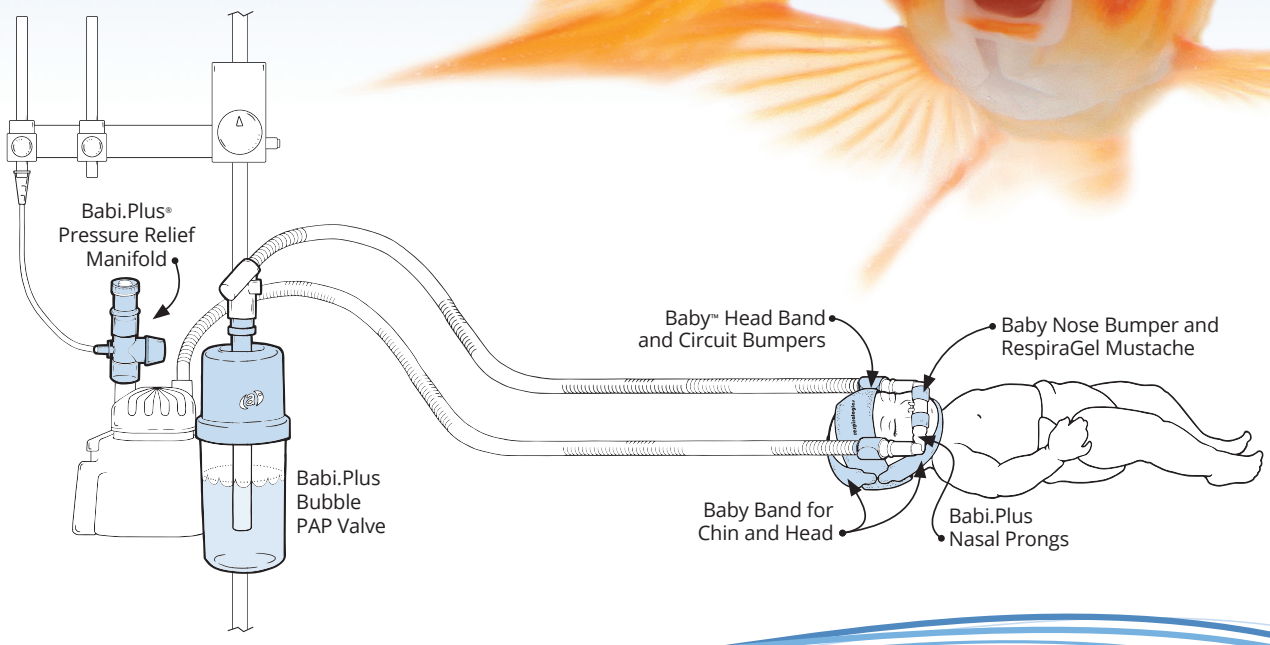
neonatal INTENSIVE CARE

The Journal of Perinatology-Neonatology

Are you bubbling?

Babi.Plus is the standard of care for non-invasive ventilation, providing a gentle approach to improve ventilation and optimize neonatal outcomes.

To start optimizing ventilation in your NICU contact us at 4info@respiralogics.com



respiralogics™

3545 Airway Drive, Suite 104 • Reno, NV 89511
775 954 0160 • www.respiralogics.com

Servo-n

Versatility in neonatal ventilation

From the very first breath, the Servo-n ventilator delivers everything you need for neonatal respiratory support—precision, protection, and peace of mind in one powerful solution.

Servo ventilators, over 50 years of innovation

Scan the QR-code to learn more about Servo-n

www.getinge.com

GETINGE

neonatal INTENSIVE CARE

Vol. 39 No. 3
Summer 2026

Table of Contents

5 News

8 Alternative Birth: Homebirth, Waterbirth, and Maternal Positions in Labor

10 The Most Powerful Therapy in the NICU Isn't Technology Related

13 From Milk Bank to Bedside: Why Donor Milk Labeling Needs a Safer Standard

16 Passy Muir Valve Use and Early Mobility for the Pediatric Patient Requiring Extracorporeal Membrane Oxygenation (ECMO)

24 A Baby's Bill of Rights in the NICU: Ensuring Accurate Medication Administration and the Use of Neonatal-Specific Enteral Feeding Systems

27 Addressing the Catastrophic Clinical and Economic Costs of Neonatal IV Failure

29 Neonatal Intensive Care Unit Admission Among Infants Born Full-Term to CDC's COVID-19 Vaccine Pregnancy Registry Participants: A Matched Cohort Study

Editorial Advisory Board

News

☐ Summer 2026

JASMINE Trial Demonstrates Prolacta's Human Milk-Based Fortifiers Deliver Superior Growth

A landmark clinical trial published in the *Journal of Perinatology* has resolved a long-standing dilemma facing Japan's neonatal clinicians: how to provide the critical early nutrition that extremely premature infants need for growth and neurodevelopment while maintaining the country's exceptionally low rate (<2%) of necrotizing enterocolitis (NEC), an often fatal intestinal disease. The answer, the study found, lies in feeding these fragile infants Prolacta Bioscience's 100% human milk-based fortifiers, versus Japan's standard practice of avoiding or markedly delaying cow milk-based fortifiers (CMBF) due to the known risk of NEC and other complications. Across 11 Japanese neonatal intensive care units (NICUs), the JASMINE randomized trial found that early fortification with Prolacta's fortifiers delivered significantly faster growth (weight gain 14.30 ± 2.86 vs. 11.96 ± 3.08 g/kg/day, $p < 0.0001$, PPS) and earlier achievement of full feeds (20.0 vs. 25.9 days; $p = 0.03$), with fewer days on antibiotics (adjusted $p = 0.002$), while demonstrating a safety profile consistent with Japan's standard of care. Japan is a world leader in preterm infant survival, with 80–90% of infants born at 22–24 weeks' gestation surviving to discharge. But those outcomes came with an unintended cost. Inadequate nutritional intake potentially left vulnerable infants without the nutritional support essential for growth and brain development. "There is great hesitancy to feed and fortify infants with cow milk-based products early. In Japan, a practice has become widespread of not feeding infants until the mother's own milk becomes available, and this delay can subsequently impair infant growth and neurodevelopment," said lead author Katsumi Mizuno, MD, PhD, Department of Pediatrics, Showa University School of Medicine, Tokyo, Japan. "In addition, there is a tendency to avoid the use of cow milk-derived human milk fortifiers in very low birth weight infants with a history of gastrointestinal surgery, which may likewise compromise growth and development. With the results of this trial and the release of the human milk-based fortifier drugs in Japan, Japanese doctors will no longer have to compromise nutrition for safety." "Japan's clinicians recognized that better growth today has direct implications for neurodevelopment, cognitive outcomes, and quality of life for their most fragile infants," said Melinda Elliott, MD, FAAP, neonatologist and chief medical officer at Prolacta. "Dr Mizuno began by requesting Prolacta's products for compassionate use and has created a pathway that ensures Japanese infants don't just survive but thrive." Human milk contains intact milk fat globules (MFGs) that are essential for delivering brain-critical fats and nutrients that support neurodevelopment in premature infants.4 Prolacta's human milk-derived fat modular, Prolact CR, played a central role in the JASMINE protocol. More than 95% of the infants in the human milk arm of the JASMINE study received Prolact CR, which is composed of 25% human milk fat and maintains the intact human MFG. Prolact CR was shown in a separate study to significantly increase weight and length velocity in very low birth weight infants. In addition to intact MFGs, all of Prolacta's nutritional products contain a wide spectrum of human milk oligosaccharides (HMOs), the third-most-abundant component in human milk after lactose and lipids.6 Compared to cow milk-based products, Prolacta's fortifiers contain significantly higher concentrations of beneficial bioactive components like immunoglobulin A and epidermal growth factor. The Japanese-led JASMINE trial was a randomized, controlled, open-label, multicenter study that evaluated the use of Prolacta's human milk-based feeding protocol in comparison to the Japanese Standard Diet, with a common practice to withhold or delay CMBF to avoid complications.

Promising Findings

Masimo announced the findings of a study evaluating the accuracy of Masimo SET pulse oximetry among critically ill neonates and demonstrating less than 1% overall statistical bias. Importantly,

neonatal INTENSIVE CARE

ISSN 1062-2454
Published five times each year by

Goldstein and Associates, Inc.

10940 Wilshire Blvd., Suite 600
Los Angeles CA 90024
Phone: 310-443-4109
Fax: 310-443-4110
E-mail: s.gold4@verizon.net
Web: www.nicmag.ca

Publisher/Editor in Chief
Steve Goldstein

Managing Editor
Christopher Hiscox

Senior Editor
Vincent Terrier

News Editor
Chris Campbell

Associate Editor
Jordana Hammeke, Susan Goldstein

Circulation, Coverage, Advertising Rates: Complete details regarding circulation, coverage, advertising rates, space sizes, and similar information are available to prospective advertisers. Closing date is 45 days preceding date of issue.

Change of Address: Notices should be sent promptly to Circulation Department. Provide old mailing label as well as new address; include zip code or postal code. Allow two months for change.

Editorial Contributions may be sent by e-mail and will be handled with reasonable care: however, publishers assume no responsibility for safety of art work, photographs, or manuscripts. Every precaution is taken to ensure accuracy, but the publishers cannot accept responsibility for the correctness or accuracy of information supplied herein or for any opinion expressed. Editorial closing date is the first day of the month preceding month of issue.

Cover: Abstract. Red and Green Gradation [with some cinnibar in vertical format] (1921). Paul Klee (German, 1879 - 1940).

there were no clinically meaningful skin pigmentation-related discrepancies and no occult hypoxemic events among Black or Hispanic patients, and in only one Caucasian patient overall.

The Neonatal Pulse Oximetry Accuracy and Disparities by Skin Pigmentation (NeoPODS) study findings were presented from the podium at the Pediatric Academic Society in Boston, MA on April 27 by lead author Dr Heather Siefkes on behalf of colleagues at the University of California, Davis and the University of Mississippi, Jackson, alongside online publication in the *Journal of Pediatrics*. As the authors noted, "[W]e found no evidence of clinically meaningful skin tone-related discrepancies, suggesting equitable monitoring performance for this device in this clinical setting." These promising results—from an NIH-funded study that exclusively evaluated Masimo SET in a vulnerable, clinically fragile patient population—add to previously published evidence of its strong performance under the most challenging real-world conditions across all skin tones. The INSPIRE feasibility study, published late last year, showed that SET pulse oximetry performed accurately on critically ill adult medical ICU patients of all skin tones, without any occult hypoxemic events—results similar to the newly published NICU findings, as well as prior evaluations of Masimo SET's accuracy by skin tone. The results of the full INSPIRE study—involving approximately 500 adult patients—are expected to be published later this year. As Dr Siefkes' team points out, even when conducted prospectively, with real-world patients, past studies of pulse oximetry accuracy by skin tone in newborns have not used quantitative, objective measurements to classify pigmentation, or have other methodological shortcomings and limitations. Some prior studies have found that oxygen saturation measured by noninvasive pulse oximetry (SpO_2) can overestimate arterial blood oxygen saturation (SaO_2), which can lead to occult hypoxemia. Noting that accurate detection of hypoxemia is especially important in NICU patients, since it drives many care pathway decisions, the NeoPODS researchers thus set out to conduct a prospective accuracy study in this patient population, hospitalized NICU patients, with rigorous technical methodology: tightly paired, time-synchronized SpO_2-SaO_2 measurements and objectively classified skin pigmentation across a range of gestational ages using the same sensors and monitors for all patients. Their primary outcome was the mean bias between paired, simultaneously measured SpO_2 and SaO_2 values, and their secondary outcome, understanding how that bias differed by skin tone. The researchers enrolled patients between July 2022 and July 2025 at two tertiary NICUs at UC Davis and UM Jackson. The patients were hospitalized newborns up to ten days old, of at least 26 weeks gestational age, with an indwelling arterial catheter and at least one clinically indicated arterial blood draw. Masimo RD SET Neo sensors connected to Radical-7 Pulse CO-Oximeters and Root monitoring platforms were used to continuously record SpO_2 data before, during, and after arterial blood gas (ABG) sampling. SaO_2 values were directly measured with on-site laboratory analyzers and then paired with the corresponding average SpO_2 for the 30 seconds preceding each blood draw. In addition to recording parent-reported race, each patient's skin tone classification was objectively assessed with a variety of methods, including melanin index and individual typology angle (ITA)—the latter a continuous, quantitative measure of skin pigmentation recommended by the FDA in their 2025 draft guidance for pulse oximeter manufacturers. Data was captured by a SkinColorCatch device, and visual scoring was performed by clinicians blinded to each other's observations using the Massey-Martin and the Fitzpatrick scales. From among 100 newborns enrolled over the three years, 136 paired SpO_2-SaO_2 readings collected from 70 patients met the technical criteria for inclusion in the final analysis. The patients' median gestational age was 28.4 weeks and median gestational weight was 1085 grams (very low birth weight). As identified by their parents, 40% of the patients were Black and 23% were Hispanic. As objectively assessed, their skin pigmentations spanned the full range of ITA classifications and most, but not the darkest, points of the Massey-Martin and Fitzpatrick scales. The researchers found that overall mean bias between noninvasive SpO_2 and invasive SaO_2 was -0.98% ± 2.80% (95% confidence interval, -1.45% to -0.52%), which is not a clinically significant amount, and means that, on average, SpO_2 slightly *under*estimated, not overestimated, SaO_2. In fact, there was only one data pair meeting the definition of occult hypoxemia (SaO_2<88% when SpO_2≥92%), collected from a patient with the lightest ITA skin tone classification; there were zero cases of occult hypoxemia among Black or Hispanic patients. The authors concluded that their study is "a novel prospective study of newborns using objective skin pigmentation and closely paired SpO_2 and SaO_2 measurements assessing pulse oximeter accuracy across skin tones. Our study did not find clinically meaningful pigmentation-related bias. We believe this study provides some reassurance on equitable and accurate care in the NICU for this specific device and population. Our study supports the need for additional age-specific and device-specific pulse oximeter performance assessments."

Blood Gas Measurement Analysis in NICU Setting

Etiometry announced that a retrospective analysis was presented at the Pediatric Academic Societies (PAS) 2026 Meeting, evaluating changes in blood gas measurement frequency following clinical adoption of its IVCO2 Index in a Level IV Neonatal Intensive Care Unit (NICU). Investigators compared outcomes before and after implementation and reported 10% fewer blood gas measurements

per day in the post-implementation period, while the rate of clinically significant hypercapnia detection, as measured by blood gas analysis, remained unchanged. Respiratory failure is a common reason for NICU admission. While oxygen levels can be continuously monitored using pulse oximetry, carbon dioxide (pCO2) monitoring remains challenging. Non-invasive monitoring methods can be inconsistent and, in some cases, pose risks of patient injury (e.g., skin burns from transcutaneous monitoring), leaving clinicians reliant on invasive blood sampling to detect hypercapnia, a process that is painful and carries its own procedural risks.

The study evaluated the impact of Etiometry's IVCO2 Index, an FDA-cleared adjunctive index derived from routinely collected bedside physiologic data and laboratory measurements. The IVCO2 Index continuously tracks the likelihood that, if a blood gas were to be performed, the resulting PaCO2 would be above a defined threshold. An increasing IVCO2 Index can prompt clinical attention to the patient. The IVCO2 index provides partial quantitative information and should be interpreted alongside other clinical data. Researchers examined whether implementation of the algorithm was associated with changes in blood gas measurement testing while preserving the detection of clinically significant hypercapnia. Investigators analyzed a retrospective cohort of 614 neonates, comparing outcomes before and after IVCO2 implementation. Despite the post-implementation group being more premature and requiring longer durations of mechanical ventilation, clinicians obtained 10% fewer blood gas measurements per day after adoption of the algorithm. Importantly, the rate of detected hypercapnia remained unchanged. "These results suggest decision support may help clinicians be more targeted in their use of invasive testing," said lead author Luke Viehl, MD, a neonatologist and assistant professor of pediatrics in the Division of Newborn Medicine at Washington University School of Medicine in St. Louis. "Reducing unnecessary blood gas draws may help lessen procedural burden in critically ill newborns." In addition to reduced testing frequency, the study found that respiratory severity scores and ventilator days were higher in the post-implementation cohort, underscoring that improvements occurred despite increased illness severity. Visual analyses showed a shift toward more targeted use of blood gases to evaluate elevated pCO2 levels following implementation, further supporting the algorithm's clinical utility. The authors note that the findings support further evaluation of decision-support approaches that may reduce procedural burden in NICU workflows. These findings are based on a retrospective analysis from a single center.

Fetal Growth Restriction Guidelines Converge on Surveillance but Differ on Key Definitions

Six major international and national guidelines on fetal growth restriction (FGR) converge on Doppler-based surveillance and standard preterm interventions but diverge substantially on how FGR is defined and how fetal deterioration is monitored. Major discrepancies include the use of biometric thresholds vs Delphi consensus criteria, the role of ductus venosus and computerized cardiotocography, and the application of angiogenic biomarkers. Researchers conducted a systematic search of MEDLINE from database inception to March 2026 using MeSH terms and keywords related to FGR and guidelines, supplemented by manual screening of reference lists. A total of six guidelines were included: three national (Canada, UK, France), one US society guideline (Society for Maternal-Fetal Medicine [SMFM]), and two international societies (International Society of Ultrasound in Obstetrics and Gynecology [ISUOG], International Federation of Gynecology and Obstetrics [FIGO]), published predominantly

Continued on page 21…

Alternative Birth: Homebirth, Waterbirth, and Maternal Positions in Labor

BM Petrikovsky, MD, PhD and D Alyeshmerni

Introduction

Childbirth practices have evolved dramatically over the last century, shaped by medical advancements, shifting social norms, and growing access to hospital-based care. While modern obstetrics has greatly improved maternal and neonatal outcomes through skilled providers, pain management, and emergency interventions, alternative birthing such as homebirth, waterbirth, etc. have gained renewed popularity. Many families seek these options for greater comfort, autonomy, and a more natural birth experience. However, these practices raise important questions regarding safety, access to emergency care when needed, and outcomes for both mother and newborn. This editorial explores the benefits and risks associated with homebirth, water immersion during labor, and alternative maternal positions.

Homebirth

Until relatively recently, homebirth was the only way women delivered. Once advancements were made, like professionalization of obstetrics, policy/insurance, advancements in pain management, and availability of experienced doctors in cases of emergency, it only took 35 years for urban births in hospitals to jump from 5% to over 75%. Some still choose to give birth at home mainly for control, privacy, avoiding what they see as unnecessary interventions, negative past hospital experiences, or wanting family involved in a home setting.

Because of the unexpected complications that can arise during labor and delivery, a low-risk pregnancy in the hospital can quickly become a high-risk one at home. In the United States, about one-third of births are performed by cesarean section. Limited access to emergency obstetric care increases maternal and newborn morbidity. The biggest risk occurs when homebirth is attempted in high-risk situations (breech, twins, VBAC) or when transfer is delayed. Some patients have complained that their midwives discouraged them from going to the hospital, either because they overestimated their ability to treat complications at home or feared that hospital staff would stigmatize the patient or take invasive measures. The resulting delays can put women at risk during their most vulnerable moments in childbirth, in some cases turning a complicated delivery into a life-threatening one. Hospitals can be hesitant to accept homebirth patients for several reasons. Some doctors worry that they could be held legally responsible for a problem that arose at home. It can also be challenging to properly treat patients without having observed the full course of their labor.

BM Petrikovsky is a Professor of Obstetrics and Gynecology, an Editorial Board Member, and ACOG Life Member.

National summaries report neonatal mortality rates of approximately 0.5 per 1,000 for hospital births versus 1-2 per 1,000 for homebirths involving low-risk patients. Similarly, analyses of nearly 14 million US births from 2007-2010 found intrapartum and early neonatal mortality of 1 per 1,000 for home births compared with 0.32 per 1,000 for hospital births, attended by certified nurse-midwives (a threefold higher risk). Risk differences tend to be greater for nulliparous women and have shown low Apgar scores and neurologic complications in home births compared with hospital births.

Waterbirth

Water immersion during labor and birth has become increasingly popular in the last several decades. The idea is that immersion in water during the first stage of labor will help the mother achieve pain relief, relaxation, a shortened labor, and decreased use of analgesia. A 2022 review found water immersion in the first stage to significantly reduce the use of epidurals, opioids, and episiotomies, as well as increase in maternal satisfaction. There is much debate around the risks and safety of water immersion during the second stage of labor and delivery. Possible neonatal risks of delivery under water include infection, respiratory distress, hyponatremia, seizures, and cord avulsion, among others. (Figure 1.)

Alternate Maternal Positions

While the supine position provides healthcare providers with easy access to monitor the fetus, alternative maternal positions (side-

Figure 1. Underwater birth. Used with permission. Female Patient. 1997,22;7-14.

lying, hands-and-knees, or standing) may help improve comfort for the mother. Upright positions (standing, squatting, or kneeling) shorten the second stage by 6 minutes on average in women without epidural anesthesia. MRI pelvimetry studies show that these postures in labor can increase the pelvic outlet and midpelvic diameters. Some positions may be tiring for individual patients and clinicians may adjust for fetal monitoring needs. Major guidelines encourage free movement and upright/non-supine pushing unless there is a medical reason not to do so.

Conclusions

While alternative birthing practices may offer increased comfort, autonomy, and satisfaction for women, they carry important safety considerations. Evidence suggests that homebirths are associated with higher neonatal and maternal risks.

An author has a clear recollection of several hysterectomies in patients with postdelivery hemorrhages at home which would have been likely avoided if delivery had taken place in the hospital. In all those cases of maternal transfers, multiple blood transfusions and hysterectomies were life-saving procedures.

As an obstetrician with 50 years of experience, I cannot support the practice of homebirthing, even for low-risk women. The problem is that risk factors for rare but life-threatening complications of pregnancy are poorly calculated. Often, a 45-year-old obese diabetic woman with a history of severe hemorrhages will undergo an uneventful delivery, while a young and healthy woman will develop fetal distress (when the baby does not tolerate labor) and will end up with a handicapped child because of delayed cesarean section due to transport delay.

Homebirth attendants usually monitor fetal heart rate by intermittent auscultation. However, this practice is mostly useless because in cases of severe fetal compromise, help (cesarean section) is not readily available. Conservative measures (oxygen, changing maternal positions, etc.) are not helpful in cases of real emergency. Therefore, homebirth today is like Russian roulette with one bullet in a revolver. For those who are passionate about homebirth I would suggest a birthing center attached or in very close proximity to the maternity hospital—a recommendation I am hesitant to give! One can argue that pregnancy, labor, and delivery are natural events, and I would agree. So is a tsunami. It's not for nothing that textbooks on possible obstetrical complications of pregnancy and birth are thicker than the Talmud, and it takes many years of training to become a competent obstetrician—over 15, to be exact.

The only exception to the rule occurred in Vienna, Austria with Dr Semmelweis. He noticed that maternal mortality in the doctors' service was three times that of the mortality in the midwives' service. In 1847, he proposed handwashing with a chlorinated solution between cases. As a result, maternal mortality dropped drastically and he reported his findings in his 1861 book entitled *Etiology, Concept and Prophylaxis of Childbed Fever*. This was the only time when homebirth was safer for both mother and child.

References

1 Cluett ER, Burns E, Cuthbert A. Immersion in water during labour and birth. Cochrane Database Syst Rev, 2021;5:CD000111.
2 Grünebaum A, McCullough LB, Sapra KJ, et al. Early and total neonatal mortality in relation to birth setting in the United States, 2006–2009. Am J Obstet Gynecol, 2014;211(4):390.e1–390.e7.
3 Malloy MH. Infant outcomes of certified nurse midwife attended homebirths: United States 2000 to 2004. J Perinatol, 2010;30(9):622–627.
4 Michel SC, Rake A, Treiber K, et al. MR obstetric pelvimetry: Effect of birthing position on pelvic bony dimensions. Am J Roentgenol, 2002;179(4):1063–1067.
5 Petrikovsky BM. Personal Communications.
6 Petrikovsky BM. Waterbirth: A more natural approach to delivery. Female Patient, 1997;22:6-12.
7 Semmelweis I. The etiology, concept, and prophylaxis of childbed fever. Translated by K. Codell Carter. University of Wisconsin Press. 1983.
8 Thomasson M, Treber J. From home to hospital: The evolution of childbirth in the United States, 1927-1940. Explor Econ Hist. 2008;45:76-99.

The Most Powerful Therapy in the NICU Isn't Technology Related

Family-Centered Care as a Clinical Intervention

Anduin Anderle, RN, ANCL-N

Abstract
Neonatal intensive care has long been defined by technological advancement and clinical precision. However, accumulating evidence demonstrates that relational interventions, particularly family-centered care (FCC) produce measurable physiologic, developmental, and psychosocial benefits. Practices such as skin-to-skin care (kangaroo care), parental voice exposure, and structured family integration improve neonatal stability, growth, and neurodevelopment, all of which are critical to long-term outcomes. This article traces the evolution of family engagement in the neonatal intensive care unit, from early parent-exclusion models to contemporary large-scale FCC initiatives and highlights emerging evidence supporting parental holding during therapeutic hypothermia. Recent advocacy and implementation efforts led by impactful organizations such as Hope for HIE, Newborn Brain Society and the Family-Centered Care Taskforce illustrate how even the most technology-driven therapies can coexist with parental presence. Family-centered care is reframed not as a philosophy, but as a biologically active, neuroprotective clinical intervention.

Introduction

For much of its history, the neonatal intensive care unit was designed around control of the environment, clinical expertise, sterility, and the latest technologies, while families remained adjacent to care rather than integrated within it. Survival tended to be the singular priority, and anything perceived as destabilizing, including parental presence, was often restricted.

Over time, both lived experiences and evidence began to challenge this model. One of our biggest revelations?

The most powerful therapy in the NICU does not require years of medical education, electricity, calibration, or software updates. It is the presence of a parent.

For many clinicians and nurses, the movement toward family-centered care has been deeply personal. Witnessing families navigate vulnerability, separation, and altered attachment revealed that survival alone was not enough. Family feedback and bedside observation reinforced what research would later confirm: parental presence is therapeutic. For the babies we care for and their families.

Anduin Anderle, is a a neonatal advocate and Sr. Strategic Clinical Specialist at Ceribell supporting rapid brain monitoring through point-of-care EEG.

Family-centered care is no longer aspirational. It is measurable, evidence-based, and increasingly recognized as a clinical intervention.

The Evolution of Family Engagement in the NICU

Early family-centered care initiatives focused on intentional inclusion: participation in bedside rounds, engagement in caregiving, and shared decision-making. These changes reframed the parent role from passive observer to active collaborator, improving communication, consistency, and trust.

As these efforts expanded, multicenter collaboratives began formalizing FCC through structured frameworks such as family-centered care committees, family partnership councils, and quality-improvement initiatives designed to sustain engagement beyond individual champions.[1] Systematic reviews now consistently demonstrate that FCC interventions are associated with improved infant outcomes which include feeding tolerance, growth, and reduced length of stay as well as meaningful improvements in parental mental health and satisfaction.[2]

Despite much progress, implementation remains inconsistent. Unit culture, historical practice patterns, and perceived safety concerns continue to influence how fully families are integrated into care.[3]

Connection is Biology, Not just Comfort

As FCC initiatives have expanded, research has helped us to understand why family presence matters on a physiological level.

Skin-to-skin care, long associated with improved thermoregulation and cardiorespiratory stability, is now linked to measurable differences in brain development and white matter organization.[4-5] Even modest increases in daily skin-to-skin exposure during hospitalization are associated with improved neurodevelopmental outcomes at one year of age.[4] These benefits also have been found to extend beyond the infant, correlating with reductions in parental stress hormones and symptoms of postpartum depression.

Any baby admitted to the NICU will experience disrupted sensory experiences that would otherwise be constant during standard delivery and discharge to home and late gestation maternal voice, rhythmic movement, and continuous touch. Family-centered interventions help bridge the gap to these biologically necessary inputs during critical periods of brain development.

The Power of a Parent's Voice

Among the simplest and most accessible NICU interventions is the parent's voice.

Maternal voice exposure has been shown to improve physiologic stability, feeding tolerance, growth, and early language-related neural pathways.[6-7] Preterm infants demonstrate preferential neurologic responses to their mother's voice compared with other auditory stimuli, indicating biologically meaningful recognition.

When parents cannot remain at the bedside, recorded voice interventions offer a developmentally appropriate bridge, with evidence demonstrating improved growth parameters and neurobehavioral organization.[8] Supporting communication at the bedside also provides parents an opportunity to provide their baby with "medicine" only they can provide.

Bonding Reconsidered as a Clinical Variable

Bonding has long been framed as an emotional outcome. It is now understood as a physiologic process.

Skin-to-skin contact stimulates oxytocin release in both infants and male and female parents, supporting autonomic regulation, stress reduction, and attachment formation. These neurohormonal responses translate into measurable improvements in infant stability and parental well-being.[9]

Relational care, therefore, is not supplemental it is quantifiable and clinically relevant.

Expanding FCC: Parental Holding During Therapeutic Hypothermia

Therapeutic hypothermia (TH) for hypoxic-ischemic encephalopathy has historically been defined by separation. Concerns regarding temperature instability and equipment dislodgement often limited parental holding.

Emerging evidence has challenged this assumption and many NICUS are all in. This is an exceptionally important initiative as in the past parents have not been able to hold their babies during therapeutic cooling and rewarming which is typically 80hrs in total.

Observational and cohort studies demonstrate that carefully selected, clinically stable infants can be safely held during TH without significant changes in core temperature, vital signs, or equipment integrity.[10-11] Parents report reduced stress, higher satisfaction, and stronger emotional connection during an otherwise isolating therapy.

In 2026, Hope for HIE formally endorsed family-centered practices during therapeutic hypothermia, including safe holding and supportive touch, in response to the updated American Academy of Pediatrics clinical report.[12] That same year, the HIE Hold-A-Thon, co-led by Hope for HIE and the Newborn Brain Society, launched as *a global clinician-led initiative encouraging NICUs to develop evidence-based, locally determined holding guidelines during cooling.*

These efforts mark a critical evolution: even during the most technology-intensive therapies, family connection is now recognized as compatible with and supportive of neuroprotective care.

Trauma-Informed Care and Restoring the Parent Role

NICU hospitalization is inherently traumatic. Parents of infants with HIE experience particularly high rates of anxiety, depression, and post-traumatic stress, driven by separation and loss of caregiving role.[13]

Family-centered care mitigates these effects by restoring identity, agency, and connection. Supporting physical presence, voice, and touch even when babies are very small, intubated and during therapeutic hypothermia aligns directly with trauma-informed care principles.

Becoming a Family-Centered Care Ambassador

Family-centered care transformation begins at the bedside. Unit caregivers can lead change by:

- Prioritizing skin-to-skin care as a clinical intervention
- Incorporating parental voice into daily routines
- Explicitly inviting families into rounds and shared decision-making
- Advocating for safe holding practices during high-acuity therapies, including therapeutic hypothermia
- Identifying and addressing systemic barriers to participation

Technology, Design, and Integration

Technology has transformed neonatal survival but has also introduced unintended barriers. Equipment and NICU care area design and workflow can restrict access, limit holding, and deprioritize relational care.

Future innovations must focus on integration rather than replacement designing systems that support family presence rather than competing with it. NICU design requires similar balance: while single-family rooms improve privacy and arguably- infection control, they may also increase parental isolation. A more holistic approach to technology and spatial design should promote milestone development, intimacy and community to support whole-family care.

Conclusion

The NICU has evolved from an environment where families were peripheral to one where they are essential.

Family-centered care should be a core clinical tenet with measurable impact on outcomes.

"The most powerful therapy in the NICU has never been something we built. It has always been something we nurture."

References

1 Balasundaram M, Lee HC, Hedli LC, et al. Improving commitment to family-centered care in the NICU: A multicenter quality improvement project. *J Perinatol.* 2025;45:1627–1635.

2 Hodgson CR, Mehra R, Franck LS. Infant and family outcomes related to family-centered care interventions in the NICU: A systematic review. *Children.* 2025;12(3):290.

3 Lee J. Neonatal family-centered care: Evidence and practice models. *Clin Exp Pediatr.* 2024;67(4):171–177.

4 Lazarus MF, Marchman VA, Brignoni Pérez E, et al. Inpatient skin-to-skin care predicts 12-month neurodevelopmental outcomes in very preterm infants. *J Pediatr.* 2024;274:114190.

5 Travis KE, Scala M, Feldman HM. Skin-to-skin contact

associated with brain changes in preterm infants. *Neurology.* 2025.
6 Filippa M, Kuhn P. Early parental vocal contact in neonatal units: Rationale and clinical guidelines. *Front Neurol.* 2024;15.
7 Travis KE, Scala M, Feldman HM. Skin-to-skin contact associated with brain changes in preterm infants. *Neurology.* 2025.
8 Qi M, Gong J, Xie Z, et al. Effects of recorded maternal voice on growth and heart rate in premature infants. *J Pediatr Nurs.* 2023;72:e122–e129.
9 Franck LS, O'Brien K. The evolution of family-centered care. *Birth Defects Res.* 2019;111(12):1048–1056.
10 Craig A, Deerwester K, Fox L, Jacobs J, Evans S. Maternal holding during therapeutic hypothermia for infants with neonatal encephalopathy is feasible. *Acta Paediatr.* 2019;108(9):1597–1602.
11 Gancarski M, et al. Parental holding during therapeutic hypothermia: Safety and experience. *Pediatr Res.* 2025.
12 Hope for HIE. Position statement on the AAP clinical report: Therapeutic hypothermia for neonatal HIE. 2026. https://hopeforhie.org
13 Sagaser A, Pilon B, Goeller A, Lemmon M, Craig AK. Parent experience of HIE and hypothermia: A call for trauma-informed care. *Am J Perinatol.* 2022;41(5):586–593.

From Milk Bank to Bedside: Why Donor Milk Labeling Needs a Safer Standard

A new collaboration between AngelEye Health and the University of California Health Milk Bank aims to improve donor milk tracking in hospitals

Alison Wolf CPNP, IBCLC and Katherine "Kat" Kays, RN, RNC-NIC, CSPO

For fragile neonates and infants, donor human milk can be central to survival, growth, and recovery. In hospital units caring for medically fragile infants, feeding isn't a routine task. It's part of the clinical care plan for patients whose health can change quickly and whose safety depends on accuracy at every step.

The American Academy of Pediatrics' 2026 clinical report emphasizes the clinical value of human milk for hospitalized, very low birth weight infants. It notes that fortified mother's own milk is the preferred source of nutrition in the neonatal intensive care unit (NICU), and that pasteurized donor human milk is recommended when mother's own milk is unavailable, insufficient, or contraindicated.

That clinical reality should shape how donor milk is received, documented, and used once it enters the hospital. The issue isn't that donor milk is unregulated. Milk banks operate under important oversight, including FDA requirements and state-level requirements that may include tissue bank licensing. The remaining gap is more specific. Donor milk information isn't always transferred in a standardized, system-readable format that every hospital can use consistently without a workaround.

For a substance collected from one human body and given to some of the smallest and most vulnerable patients in healthcare, the information attached to each bottle should remain clear and traceable from the milk bank to the bedside.

The Traceability Gap Begins at the Label

The current donor milk workflow relies on many handoffs. Milk banks process and distribute frozen donor milk bottles to hospital partners. Hospitals then receive, verify, document, store, and eventually administer that milk to infants. Each step depends on accurate information about what the milk is, where it came from, how it was processed, and which lot or batch it belongs to.

The volume moving through this system is continuing to grow. The Human Milk Banking Association of North America (HMBANA) announced that its network of nonprofit milk banks dispensed a record 13 million ounces of pasteurized donor human milk in 2025, a 12% increase from the previous year.

Alison Wolf CPNP, IBCLC, is the Executive Director at the University of California Health Milk Bank.

Katherine "Kat" Kays, RN, RNC-NIC, CSPO, is the Vice President of Product at AngelEye Health.

As donor milk use grows, hospitals need labels that can move cleanly into the systems used to receive human milk into hospital units. Proprietary or inconsistent labels can prevent staff from scanning barcode data into existing workflows, leaving them to reenter information by hand or create duplicate labels before the milk reaches patients. Every workaround increases the chance that critical product information will be delayed or entered incorrectly, which can slow a hospital's response if a recall or safety concern arises.

Hospitalized infants, especially in the NICU, have little margin for that kind of uncertainty. Donor milk supports infants whose health can change quickly, and safety systems should reflect that reality. This is why labels must be more than human-readable. They must be parsable, meaning software systems can interpret the information consistently and move it into the right workflow without manual translation.

Donor Milk Deserves Stronger Transparency

A lack of standardized product information would be difficult to imagine in other human-origin workflows. For blood, tissue, and other medical products, hospitals expect a clear chain of custody because patient safety depends on knowing what is being used, where it came from, and how to act quickly if a concern arises.

Donor milk should be approached with the same rigor. Just as important, donor milk banks deserve systems and tools that help

them provide this transparency in a cost-effective and efficient way for the hospitals they serve.

A similar foundation already exists for donor milk. ICCBBA, the organization used worldwide for blood and tissue, which manages the universal ISBT 128 standard, has emphasized the need for clear product information from donation through use. ISBT 128 supports that goal by assigning a globally unique identifier and a shared structure to donor milk products, enabling hospitals and milk banks to use them for safety monitoring.

That shared structure matters because a barcode shouldn't become unreadable or unusable simply because a hospital uses a different internal system than the milk bank that supplied the bottle. Donor milk banks shouldn't need technical degrees or software engineers on staff to create labels that any hospital system can read. They need better support for the critical work they do and the products they provide.

This is not a call to add unnecessary burden to milk banks or hospitals. It's a call to make existing product information easier to transfer, interpret, and use. Donor milk safety depends on clear information, but donor milk banks also need practical tools that make transparency achievable at scale.

Standardization Requires More Than Good Intentions

Milk banks and hospitals aren't ignoring this problem. They've been working within systems that were never designed for the current scale and complexity of donor milk use.

Many US nonprofit milk banks don't have large technology teams or software engineers to build custom labeling tools. ISBT 128 provides the standardized code and language, but milk banks still need a practical way to generate compliant, universally readable labels without building technology from scratch.

A standard only works at scale when organizations can actually adopt it. For donor milk banks, that means a solution must fit into existing workflows, support the information hospitals need, and avoid a disruptive software overhaul. For hospital partners, it means receiving donor milk with barcode information that can be scanned and used in the systems already supporting clinical inventory and feeding workflows.

That's the gap AngelEye Health and the University of California Health Milk Bank are working to close through a powerful tool appropriately dubbed SafeScan. The collaboration brings together AngelEye's hospital workflow and technology experience with UC Health Milk Bank's operational knowledge of donor milk distribution, labeling needs, and hospital partner requirements.

What SafeScan Brings to Milk Banks and Hospitals

SafeScan enables ISBT 128-compliant, transparent barcodes and labels on donor milk, giving donor milk banks a usable system for labeling the milk bottles they prepare and provide to hospitals. For the hospitals they serve, those barcodes support electronic tracking and tracing of donor milk as a product of human origin, helping strengthen patient safety from receipt through bedside use.

The software is designed to be straightforward for milk banks and useful for hospitals. Milk bank data points can be uploaded to the labeling program, printed onto labels, and affixed to donor milk bottles before distribution. Once the bottles arrive at the hospital, the barcode information can support receiving, documentation, inventory management, feeding workflows, and recalls.

Rather than requiring milk banks to build a homegrown system or hospitals to rely on manual entry, the goal is for donor milk from any participating nonprofit milk bank to be scannable and usable by any hospital. Hosted and supported through AngelEye's MilkTracker feeding management platform, SafeScan is designed to make donor milk data more accessible across hospital systems while complementing existing milk bank workflows.

The collaboration also reflects the shared responsibility behind donor milk safety. Milk banks understand processing and distribution realities. Hospitals understand the pressures of receiving and administering donor milk in busy clinical settings. Technology partners can connect those needs through tools that make data accessible at the right moment. When those perspectives come together, transparency becomes easier to put into practice.

The Standard Hospitalized Infants Deserve

For hospitalized infants, safer donor milk tracking depends on making the right information available at the right moment, without adding avoidable complexity for the milk banks and hospitals responsible for each handoff.

The implementation of SafeScan is designed to be straightforward. In practice, a milk bank may create a batch of donor milk that includes 20 to 100 bottles, with each bottle requiring a label that identifies the batch it belongs to. The batch information can be uploaded or entered into SafeScan, which automatically generates a unique QR code and ISBT 128-compliant label for every bottle in that batch. Once those bottles reach hospital partners, care teams can scan and use the barcode data for receiving, documentation, feeding workflows, and recalls.

Donor milk moves through a chain of trust before it reaches the bedside. Protecting the most vulnerable infants takes coordination across milk banks, hospitals, clinical care teams, and technology partners. Each group plays a role, but they need systems that make the right information clear at every checkpoint.

By helping milk banks create universally readable labels before donor milk is distributed, AngelEye Health and the University of California Health Milk Bank are addressing a gap that should no longer be treated as inevitable. For hospitalized infants, safety depends on knowing what each bottle contains, where it came from, and how to act quickly if a concern arises.

The infants receiving donor milk are among the most vulnerable patients in healthcare. The systems protecting that milk should be built with the same level of care. Donor human milk serves as a critical bridge to health for medically fragile infants, supported by a chain of trust that extends from the initial donation to the final recipient. Tools like SafeScan ensure that this connection is reinforced by data as reliable as the milk itself. By replacing fragmented workarounds with a unified language of safety, we honor both the donor's gift and the dedication of the clinical teams who manage it. Protecting the most vulnerable patients requires a system built on total transparency from the first scan at the milk bank to the final check at the bedside.

If you'd like to learn more about the universal barcode project, contact Alison Wolf at akwolf@health.ucsd.edu.

For more information about SafeScan, contact Lauren James, MSN, RN, RNC-NIC, CBC at ljames@angeleyehealth.com.

Passy Muir Valve Use and Early Mobility for the Pediatric Patient Requiring Extracorporeal Membrane Oxygenation (ECMO)

Laura Brooks MEd, CCC-SLP, BCS-S, Tara Hall OTR/L, CBIS, NTMTC, Kelsey Titgen PT/DPT, Jessica Rindone PT/DPT, and Micheal Heard, RN, FELSO

What is ECMO?

Extracorporeal Membrane Oxygenation (ECMO) is a treatment for patients with severe respiratory failure or circulatory failure, who have failed maximal medical management. Many unique aspects to using ECMO in children exist, including indications, circuit configuration, and cannulation sites.[1] Common indications for ECMO in infants and children include patients with respiratory diagnoses (respiratory distress syndrome, pneumonia, congenital diaphragmatic hernia, meconium aspiration); cardiac diagnoses (congenital heart disease, myocarditis); or transplantation candidacy (heart, lung). ECMO utilizes a circuit that consists of a blood pump, either a centrifugal or roller head, and an artificial lung (oxygenator) to support the heart and lung function. Circuit configuration varies between ECMO programs (see Figure 1).

Figure 1. 1. Venous drain (Deoxygenated blood) 2. Membrane Oxygenator 3. Arterial Filter 4. Arterial return (Oxygenated blood) 5. Continuous Kidney Replacement Therapy (CKRT) 6. Blood pump. Used with permission by © Kazandjian and Dikeman (2022) *Communication and Swallowing Management of Tracheostomized and Ventilator Dependent Individuals*, 3rd Edition, Eat Speak Breathe Publishing, NY. Chapter 9, Brooks, pediatrics.

ECMO provides support to the patient with the oxygenator and blood pump. The oxygenator is where gas exchange occurs, removing carbon dioxide (CO_2) and diffusing oxygen (O_2). Gas exchange occurs via sweep rate (liters per minute) delivered via a blender, with a percentage of oxygen. Sweep rate is determined by the level of CO_2 the practitioner desires to maintain in the patient's arterial blood gas. The higher the sweep rate, the more CO_2 is removed. Additionally, the level of oxygen delivered to the oxygenator via sweep allows a PaO_2 to be achieved as desired. The blood pump flow rate (liters per minute) allows this oxygenated blood to be returned to the patient via the venous or arterial system, therefore augmenting the heart and lung function. The higher the blood flow rate, the more oxygenated blood is delivered to the patient.

Author details can be found at the end of this article.

What are the differences between VV ECMO and VA ECMO?

The two main configurations of ECMO are based on cannulation sites: Veno-venous (VV) and Veno-arterial (VA). Simply stated, VV ECMO drains blood from the venous system and returns oxygenated blood from the ECMO circuit to the venous system. Veno-venous ECMO is primarily employed for respiratory failure, where hypoxia and/or hypercarbia are causing significant morbidity and may contribute to the patient's death. Veno-venous ECMO allows the oxygenated blood to be circulated through the heart to the lungs, allowing for normal physiological circulation (see Figure 2).

Veno-arterial ECMO drains blood from the venous system but returns the ECMO circuit blood to the arterial system and is often used to support primary or secondary cardiac failure in patients who are unable to maintain adequate circulation. Returning the oxygenated blood to the arterial system essentially bypasses the heart, with the blood delivered to the left side of the heart. In this way, the heart function is augmented with the ECMO blood flow. Finally, in pediatrics, patients can be too small for cannulation techniques to use VV ECMO and may require VA cannulation due to vessel size or lack of an appropriately sized dual-lumen catheter.

What are the different cannulation sites?

Cannulation sites for ECMO in pediatric patients vary based on the configuration of ECMO used and the size of the patient. Veno-venous ECMO may employ a single site by using a double-lumen cannula placed in the right internal jugular. Infants and toddlers use the Crescent RA Jugular Dual Lumen Catheter (Medtronic, Minneapolis, MN) or the Avalon Elite Dual Lumen Catheter (Getinge, Gothenburg, Sweden), which are placed into the right atrium, and larger patients may use the Crescent Jugular Dual Lumen Catheter or the Avalon Elite Catheter, which terminate in the inferior vena cava. These single-site cannulas are usually placed percutaneously and allow simultaneous drainage of deoxygenated blood and return of oxygenated blood. The dual-lumen catheters

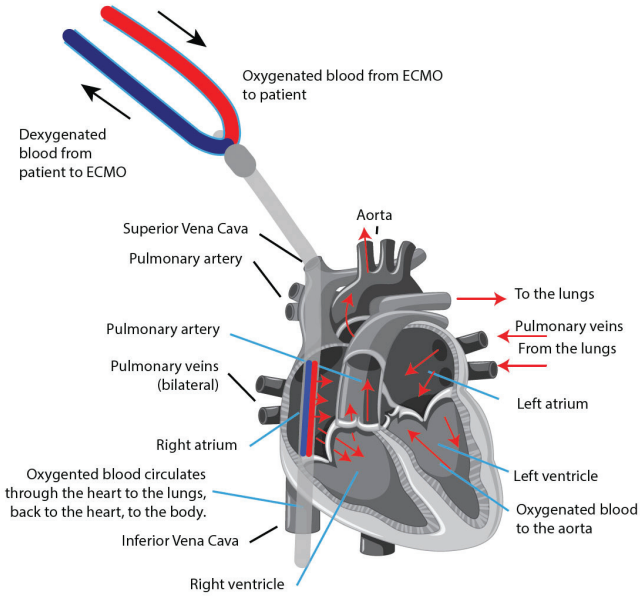


Figure 2. Used with permission by © Kazandjian and Dikeman (2022) *Communication and Swallowing Management of Tracheostomized and Ventilator Dependent Individuals*, 3rd Edition, Eat Speak Breathe Publishing, NY. Chapter 9, Brooks, pediatrics.

are excellent for facilitating early mobility. Veno-venous access may also include the femoral veins, the saphenous veins, or the internal jugular vein with a single lumen catheter, or any combination of these sites to allow drainage of blood and return of oxygenated blood from the ECMO circuit (see Table 1).

Table 1.

Vein/Artery	Location	Purpose
Vein		
Femoral	Thigh	Moves blood from tissues of the lower leg to the heart
Saphenous	Superficial in leg	Sends blood from legs and feet to the heart
Internal jugular	Each side of the neck	Collects blood from the brain and superficial regions of the face and neck to the right atrium of the heart
Artery		
Carotid	Each side of the neck	Provides the brain's blood supply
Femoral	Top of thigh	Provides blood to lower extremities and anterior abdominal wall
Subclavian	Below clavicles	Supplies bilateral upper extremities and some contribution to head and neck

Veno-arterial ECMO uses single catheters placed in veins as described above and then catheter(s) are placed in an artery such as the right common carotid artery, femoral artery, or subclavian artery (see Table 1).

Additionally, central or transthoracic cannulation may be used in cardiac failure patients. Central cannulation is more invasive, requiring opening of the chest for access to the right atrium and aorta, and often used in pediatric patients who have previously undergone cardiopulmonary bypass for repair of congenital cardiac defects.

Passy Muir® Valve Benefits

The Passy Muir Tracheostomy & Ventilator Swallowing and Speaking Valve (PMV) is the only bias-closed, no-leak speaking valve due to the design of the membrane diaphragm. Exhaled air moves exclusively through the patient's upper airway. This maximizes the opportunity for voicing, sensation, managing secretions (by coughing or swallowing), improvement in swallowing function (particularly hyolaryngeal excursion), and weight shifting.[2-12] Patients who are on ECMO and awake often experience anxiety that comes with feeling "air hunger" and reporting the sensation of "not (being) able to breathe". The PMV restores verbal communication for patients with a tracheostomy on mechanical ventilation, which is beneficial when navigating the complexities of ECMO and mobilization, particularly air hunger.

The PMV also assists with motor tasks during and outside of early mobility sessions. When a tracheostomy tube is placed in the trachea, the respiratory system and intrathoracic (ITP) and intra-abdominal (ITA) pressures are diminished by having an open system. [10-11] Airflow is redirected through the tracheostomy tube, and the patient is no longer using the upper respiratory airway – airflow does not go through the upper airway and vocal cords. With an open tracheostomy tube and therefore, an open system, thoracic pressures cannot be increased, compromising sitting, pushing, and standing. For individuals without a tracheostomy, the glottis is engaged (vocal cords close) to restrict the expiratory lung volume to stabilize the chest and upper body. [10-11] Placing a Passy Muir Valve on the tracheostomy hub or in-line with the ventilator circuit closes the system and restores a patient's ability to use the glottis to control expiratory flow and improve ITP and IAP.

Additionally, patients on ECMO, who are candidates for lung transplant, often need to demonstrate the ability to walk a certain goal distance before they undergo a lung transplant. This underscores the importance of early mobility for the patients on ECMO, particularly those on mechanical ventilation.

Early Mobility for the Pediatric Patient on ECMO

Research in pediatric ECMO mobility is limited, but data in adult-focused studies show that early mobility with patients cannulated for VA or VV ECMO is safe and feasible with the appropriate members of an experienced, multidisciplinary team.[13] Recommended personnel during ECMO mobility sessions include, but are not limited to, the ECMO physician (at a minimum, they are available on the unit), bedside nurse, ECMO Specialist, ECMO Primer (perfusionist), physical therapist, occupational therapist, and respiratory therapist (if an invasive airway is present). For patients with a tracheostomy, the speech-language pathologist can assist with PMV placement prior to mobilization and nonverbal communication for patients who are intubated. The child life specialist also has an important role in providing coping strategies to ease anxiety for patients who are moving while attached to many large, complex machines.

Progression of positions outside of supine may include ring sitting, short sitting, sitting edge of bed, standing, walking, and more.[13] Upright positioning has many benefits including increased postural strength, improved pulmonary toileting, improved respiratory coordination, and increased engagement with the environment. As mentioned above, control of airflow by glottal structures is a primary determinant of thoracic pressure and may have a role in the control of postural stability. [10-11] For patients with a tracheostomy, the use of a Passy Muir Valve during those tasks

restores the ability to engage the glottis to control airflow and assist with early mobility.

There are important considerations for rehabilitation clinicians to consider when working with patients on VV and VA ECMO. A patient on VV ECMO should have arterial pressures that trend toward the normal range for the patient's age. However, they will also have arterial oxygen saturations of 80-95% because of mixing deoxygenated blood secondary to the disease state and status on ECMO. A patient on VA ECMO may have lower arterial blood pressures and normal saturations. Clinicians treating ECMO patients should be aware of arterial saturation and pressure goals as set by the medical team.

Prior to initiating an ECMO mobility session, safety and screening tools should be utilized. First, a physician's order should be placed, outlining goals for the patient. These goals should be discussed with the team and a documented plan made. Second, an assessment of the cannulation sites should be undertaken to ensure the integrity of sutures, connections of circuitry tubing, and the ability to move the limb or neck. The session should begin with a baseline assessment of the vital signs, circuit readings, patient cognition, and patient willingness to participate. Monitoring these values while mobilizing will help to assess patient tolerance. The ECMO Specialist will provide immediate interventions on the ECMO system to increase support as needed. Collection of data from daily sessions, including mobility level achieved, how well it was tolerated, and any required interventions, will assist the team in future endeavors.

Passy Muir Valve Candidacy

Despite the evidence supporting the benefits of speaking valve application, many patients are underserved due to a lack of clinician and physician consensus as to candidacy. Members of the medical team may consider the following questions: Is the patient too young? Is the patient too small? Is the patient too sick? Can the patient tolerate the speaking valve with any degree of airway obstruction or narrowing? Is the patient a candidate for PMV while on ECMO?[2,12] While further research is required to help answer many of these questions, the current literature does support speaking valve trials with medically complex pediatric patients under certain conditions.[12] However, it is critical to have a multidisciplinary team involved in determining candidacy by ensuring that no contraindications for speaking valve application exist and that the patient meets the criteria established by the facility. The multidisciplinary team for the patient requiring ECMO may include an otolaryngologist, pulmonologist, cardiologist, hospitalist, speech-language pathologist, and respiratory care practitioner.

With non-ECMO patients who require a tracheostomy due to lung compromise, physicians may be concerned that the application of a speaking valve will decrease the support provided by the ventilator due to the leak that occurs with cuff deflation. The concern is that the "leak" between the tracheostomy tube and the trachea will release too much pressure or volume support through the upper airway and not allow enough of the ventilator support into the lungs. When a patient is on ECMO and mechanical ventilation via a tracheostomy, the lungs are not responsible for oxygenation and ventilation. Therefore, the leak created with cuff deflation for PMV use is not a concern for the medical team. If the patient is not on ECMO but a Valve is to be used in-line with mechanical ventilation, the multidisciplinary team determines what ventilator adjustments may be needed to compensate for the leak and maintain good ventilation.

Case study

We present a 17-year-old female with a recent history of orthotopic heart transplant (OHT) who was admitted to the Cardiac Intensive Care Unit (CICU) with viral symptoms in the setting of a recent COVID-19 diagnosis. She was well-known by the CICU staff due to her OHT, and it was felt that she would be best served in the CICU even with her primary diagnosis of respiratory failure. Despite maximal medical management, including progression from high flow nasal cannula (HFNC) during the day and continuous positive airway pressure (CPAP) via mask interface during sleep to BiPAP (bilevel positive airway pressure support), she ultimately required intubation and mechanical ventilation. She was febrile with chest pain, and the CT scan of her lungs was consistent with COVID-19 pneumonia. Her level of hypoxia and hypercarbia warranted ECMO cannulation with a 32fr (32 French) Avalon Dual Lumen Catheter placed in the right internal jugular.

Reason for tracheostomy. After a short period of stabilization on ECMO, she was re-awakened and extubated. She began early mobility with an HFNC, but she reported anxiety about her respiratory status on ECMO with the sensation and perception that she is not "breathing." Her anxiety and feeling of air hunger resulted in oxygen desaturations and increased work of breathing impacting her ECMO flow, and she was re-intubated. After endotracheal intubation, it was felt that she would benefit from a tracheotomy. A 6.0 cuffed adult Shiley tracheostomy tube was placed (Medtronic, Minneapolis, MN), and she remained on mechanical ventilation. Her first trach change was five days later, and she was ready to resume early mobility with physical therapy and occupational therapy.

Use of the Passy Muir Valve. She also could have her first Passy Muir Valve trial in-line with mechanical ventilation with the speech-language pathologist (SLP) and respiratory therapist (RT). She remained on pressure control ventilation with the following settings: peak inspiratory pressure (PIP) 20 cmH_2O and positive end-expiratory pressure (PEEP) 10 cmH_2O. For her initial PMV trial, the RT deflated her cuff, and the SLP placed the PMV in-line in her ventilator circuit using various adapters. An analog manometer was placed between the patient's trach and the PMV to measure trans-tracheal pressure (TTP) to determine airway patency. TTP was 10 cmH_2O, which was consistent with the delivered PEEP of 10 cmH_2O indicating a patent airway. Of note, when TTP is measured with a patient on mechanical ventilation, the manometer will not go to zero at end-expiration; instead, it will reflect the PEEP being delivered by the ventilator.

The patient was dysphonic (breathy vocal quality) but could verbally communicate. She presented with multiple cough events throughout the session after the PMV was placed , which was expected as she was exhaling out her upper airway and sensing secretions that had been pooling. As she coughed up her secretions, she required less suctioning of her tracheostomy. She asked for small tastes of water and a popsicle and was cleared by the medical team, consuming without signs of dysphagia. She wore the PMV for 30 minutes with stable vital signs throughout the session. Physical therapy and occupational therapy arrived after the session, and the patient kept the PMV on during early mobility treatment, given the strict 1:1 supervision. She started to take small PO trials of thin liquids via controlled single sips outside of her therapy sessions. Her vocal quality continued to improve over time, with only mild

breathiness and roughness. The SLP demonstrated to Mom and the nurse (RN) how to remove and re-insert the PMV in-line in the ventilator circuit. The mother independently demonstrated the placement and removal of the PMV. The patient transitioned to wearing the PMV during all awake hours as tolerated.

Conclusion

Patients with severe respiratory or circulatory failure who are tracheostomy and ventilator-supported and require ECMO may be candidates for Passy Muir Valve use. PMV use in this population restores the use of the glottis (vocal cords) to assist communication, swallowing, and early mobility.[14] The optimal success of early mobility in pediatric patients requires a collaborative approach with a multidisciplinary team to ensure safety, provide effective patient care, and accomplish both patient and family goals.

Author Details

Laura Brooks M.Ed., CCC-SLP, BCS-S received her undergraduate degree from the University of Florida and her master's degree from the University of Virginia. She has been a speech lan-guage pathologist since 1999 and has been board-certified in swallowing disorders since 2012. She is a Clinical Specialist at Children's Healthcare of Atlanta, working with pediatric patients in the intensive care units and acute care units. She specializes in the management of pediatric dysphagia and tracheostomy/ventilator-dependent patients. She has published research, journal articles, case studies, and textbook chapters related to pediatric dysphagia and tracheostomy/ventilator-dependence. She serves on the Bioethics Committee, Global Tracheostomy Committee, and ICU Liberation/Early Mobility Committee at Children's Healthcare of Atlanta.

Tara Hall OTR/L has been an occupational therapist for six years. She earned her undergraduate degree from the University of Georgia and her master's degree in occupational therapy from Augusta University in 2017. She works at Children's Healthcare of Atlanta. Tara works in pediatric acute care with a primary focus on treating in the Pediatric Intensive Care Unit (PICU) and serving as the OT representative on the ICU Liberation Team. She is a Certified Brain Injury Specialist and has her Neonatal Touch and Massage Certification.

Kelsey Titgen, PT, DPT, received her undergraduate degree from the University of South Carolina and her physical therapy doctorate from Emory University. She has been a physical therapist at Children's Healthcare of Atlanta since 2018, specializing primarily in the cardiac ICU. She is one of the rehab team leaders who has continued to progress ECMO mobility in both the PICU and CICU.

Jessica Rindone PT/DPT has been a physical therapist for seven years. She earned her undergraduate degree at the University of Georgia and her doctorate in Physical Therapy from Mercer University in 2016. She works at Children's Healthcare of Atlanta. She works primarily in the intensive care units and serves as the cardiac physical therapy lead.

Micheal Heard, RN, FELSO has been a practicing 'ECMOlogist' for over 30 years, having started the ECMO programs at Miami Children's Hospital and the University of Virginia, and has been instrumental in program growth and development for the Children's Healthcare of Atlanta's ECMO Center. She is a charter member of the Extracorporeal Life Support Organization. She has been involved in many research projects, including the use of inhaled nitric oxide, tidal flow ECMO, and the use of Venovenous ECMO in pediatric patients. She has presented at multiple conferences on a variety of subjects related to ECMO, as well as presenting numerous times on ECMO therapies, technology, and education. She has written chapters and co-edited (4th Edition) the ELSO ECMO Specialist Training Manuals. She has written a chapter on Nursing Care of the Pediatric Patient on ECMO for the 5th Edition of the ELSO Red Book and is a co-author on Management of Children with Respiratory Failure for the 6th Edition of the ELSO Red Book. Finally, Micheal is a co-founder of the Award for Excellence in Life Support Committee and continues to serve as co-chair.

References

1 Erdil, T., Lemme, F., Konetzka, A., Cavigelli-Brunner, A., Niesse, O., Dave, H., Hasenclever, P., Hübler, M., & Schweiger, M. (2019). Extracorporeal membrane oxygenation support in pediatrics. *Annals of Cardiothoracic Surgery, 8*(1), 109–115. https://doi.org/10.21037/acs.2018.09.08

2 Brooks, L. (2022). CH.9 Management of the tracheostomized and ventilator dependent pediatric patient. In M. Kazandjian & K. Dikeman *Communication and Swallowing Management of Tracheostomized and Ventilator Dependent Individuals*, (3rd Edition, pp.237-277).

3 Hess, D. R., & Altobelli, N. P. (2014). Tracheostomy tubes. *Respiratory Care*, *59*(6), 956–973. https://doi.org/10.4187/respcare.02920

4 Hoffmann, L., Bolton, J., & Ferry, S. (2008). Passy Muir speaking valve use in a children's hospital: An interdisciplinary approach. *Perspectives on Voice and Disorders, 1(8)*, 76–77.

5 Suiter, D. M., McCullough, G. H., & Powell, P. W. (2003). Effects of cuff deflation and one-way tracheostomy speaking valve placement on swallow physiology. *Dysphagia*, *18*(4), 284–292. https://doi.org/10.1007/s00455-003-0022-x

6 Sutt, A., Cornwell, P. L., Mullany, D., Kinneally, T., & Fraser, J. F. (2015). The use of tracheostomy speaking valves in mechanically ventilated patients results in improved communication and does not prolong ventilation time in cardiothoracic intensive care unit patients. *Journal of Critical Care, 30*(3), 491-494. https://doi.org/10.1016/j.jcrc.2014.12.017

7 Torres, L. Y., & Sirbegovic, D. J. (2004). Clinical benefits of the Passy-Muir tracheostomy and ventilator speaking valves in the NICU. *Neonatal Intensive Care,17*, 20–23.

8 Watters K. F. (2017). Tracheostomy in Infants and Children. *Respiratory care*, *62*(6), 799–825. https://doi.org/10.4187/respcare.05366

9 Hull, E. M., Dumas, H. M., Crowley, R. A., & Kharasch, V. S. (2005). Tracheostomy speaking valves for children: tolerance and clinical benefits. *Pediatric Rehabilitation, 8*, 214–219. https://doi.org/10.1080/13638490400021503

10 Massery, M. (2014). Expert interview: The role of the Passy-Muir valve in physical therapy. *Talk Muir*, 2-4.

11 Massery, M., Hagins, M., Stafford, R., Moerchen, V., & Hodges, P. W. (2013). Effect of airway control by glottal structures on postural stability. *Journal of Applied Physiology (Bethesda, Md. : 1985)*, *115*(4), 483–490. https://doi.org/10.1152/japplphysiol.01226.2012

12 Brooks, L., Figueroa, J., Edwards, T., Reeder, W., McBrayer, S., & Landry, A. (2020). Passy Muir Valve tolerance in medically complex infants and children: Are there predictors for success? *The Laryngoscope*, *130*(11), E632–E639. https://doi.org/10.1002/lary.28440

13 Ongkasuwan, J., Turk, C. L., Rappazzo, C. A., Lavergne, K. A., Smith, E. O., & Friedman, E. M. (2014). The effect of a speaking

valve on laryngeal aspiration and penetration in children with tracheotomies. *The Laryngoscope*, *124*(6), 1469–1474. https://doi.org/10.1002/lary.24457

14 Shkurka, E., Child, H., Balls, J., Melkhuln, E., Carter, L., Compton, V., Marscheider, R., McConnell, R., Meenaghan, S., Milburn, N., Nugent, G., Peasbody, G., & Rimmer, L. (2022). Early rehabilitation and mobilisation of neonatal and paediatric extracorporeal membrane oxygenation patients: A UK and Ireland consensus document. *Perfusion, 39*(1), 174 – 181. https://doi.org/10.1177/02676591221132676

News…continued from page 7
between 2015 and 2024. Inclusion criteria required national or international clinical practice guidelines published from 2010 onward and available in English, with unanimous agreement from all authors for final inclusion. Data extraction focused on predefined domains including definition, differentiation between small for gestational age and FGR, prediction and prevention strategies, surveillance tools and frequency, delivery timing and mode, and labor induction methods. Dual data checking with consensus resolution was performed, and extracted data were cross-checked against original guideline documents by all coauthors to ensure accuracy. Four of six guidelines adopt the Delphi consensus criteria for FGR definition, while SMFM uses only estimated fetal weight or abdominal circumference below the 10th centile, and the French guideline uses a nuanced distinction based on longitudinal growth trends and Doppler findings.

Maternal Prepregnancy BMI and Birth Length Associated With Risk for Atopic Dermatitis

Among Scandinavian mother-child pairs, a higher maternal prepregnancy BMI and greater birth length were associated with increased odds of atopic dermatitis in offspring by 3 years of age, whereas shorter birth length was associated with lower odds. Researchers conducted an exploratory analysis of the PreventADALL study to determine the associations of maternal prepregnancy BMI, newborn anthropometric measurements, and fetal growth with the risk for atopic dermatitis by 3 years of age. A total of 2107 mother-child pairs were included for the prepregnancy BMI analysis, 2035 pairs for newborn anthropometric measurements, and 1590 pairs for fetal growth assessments; all infants were born after 35 weeks of gestation without serious illnesses. Fetal thoracic and abdominal circumferences were measured using ultrasonography at mid-pregnancy and again at birth, along with birth weight and length. A higher maternal prepregnancy BMI was associated with increased odds of atopic dermatitis in offspring by the age of 3 years (adjusted odds ratio [aOR], 1.03; $P = .043$). Greater birth length was associated with higher odds of atopic dermatitis in offspring by 3 years of age (aOR, 1.06; 95% CI, 1.01-1.12), whereas shorter birth length was associated with lower odds (aOR, 0.71; 95% CI, 0.51-1.00). No associations were observed between birth weight; thoracic, abdominal, or upper arm circumference at birth; and fetal growth and the risk for atopic dermatitis in offspring. "Our results highlight the importance of early-life growth patterns for the development of atopic dermatitis," the authors of the study wrote.

Preterm Birth and Low Birth Weight Tied to Learning Challenges

Preterm birth and low birth weight were associated with lower intelligence quotient (IQ), poorer academic performance, and a greater need for special educational support. Stronger associations were noted for earlier gestational ages and lower birth weights. Researchers conducted an umbrella review and meta-analysis to investigate the associations between preterm birth or low birth weight and cognitive or educational outcomes. They synthesized evidence from 40 systematic reviews (22 with meta-analyses and 18 with narrative syntheses) that included studies involving children, adolescents, or adults. Cognitive outcomes were measured as general cognitive ability using age-appropriate standardized instruments, which included developmental assessments and IQ tests. Educational outcomes were classified into four areas: academic attainment, type and length of schooling, need for additional educational support, and educational costs. The dataset comprised 788 effect estimates from primary studies. Subgroup analyses explored associations based on gestational age, birth weight, and age at assessment. Individuals born preterm or with low birth weight had reduced general, nonverbal, and verbal IQs. Academic performance was poorer among individuals born preterm or with low birth weight in measures of reading, word identification, and spelling. The magnitude of the associations decreased with increasing gestational age or birth weight and attenuated with increasing age. Individuals born preterm or with low birth weight had a higher likelihood of having special educational needs. The academic performance of children born preterm or with low birth weight was rated lower by teachers; self-assessments and evaluations by mothers also indicated poorer performance. "Preterm birth and low birth weight were associated with persistent cognitive and educational disadvantages across the life course, underscoring the importance of early identification and long-term monitoring to inform health and educational planning," the authors of the study wrote.

How Babies Process Pain—and Sugar's Role in Relieving It

A sugar solution placed in the mouth before a needle insertion likely curbs newborns' pain, according to a new Cochrane review. The finding—combined with a 2023 Cochrane review and others—suggests that the longstanding practice now has enough evidence to be standardized across hospitals and used as a "gold standard" in clinical trials, the researchers said. It also adds to growing research on the effects of nonpharmacologic pain interventions for infants—and hints at lingering gaps in our understanding of how babies process pain. "The brain of a neonate is not just a small adult brain—it's substantially different," said Lorenzo Fabrizi, PhD, chair of developmental systems neuroscience at University College London, London, England, who was not involved in the analysis. Researchers developed a 10-point pain intensity scale based on a composite of several validated infant pain assessment tools measuring behaviors (crying and limb movement) and physiologic signs (increased heart rate and reduced oxygen saturation). The sugar solution—a mixture of sucrose (table sugar) and water—reduced pain scores by 2.1 points compared with no intervention and by 3.5 points when combined with a pacifier compared with a pacifier alone. (The minimal clinically important difference in pain scores was 1.3 points.) Sucrose probably reduced pain compared with breastfeeding but made little to no difference compared with skin-to-skin contact, according to the analysis, which included 29 randomized controlled trials involving 2767 newborns. Because infants can't self-report—the clinical "gold standard" for assessing pain—there will always be limits to what we can infer about their internal experience. Fabrizi encourages caution in assuming that a lower behavioral pain score translates to lower pain. "Sucrose reduces behavioral reactivity and physiologic reactivity to tissue damage, but we cannot say with certainty that pain is less," Fabrizi said.

Human Milk Tied to Fewer Respiratory Admissions in Preemies

Infants born very preterm (< 32 weeks of gestational age) who were discharged from the hospital on any human milk feeding had significantly lower odds of respiratory hospital admissions during their first 18 months than those who were discharged from the hospital on exclusive formula feeding. Researchers conducted a prospective observational study to evaluate the association between human milk feeding and long-term respiratory morbidity during the first 18 months of life in infants born very preterm. They included 338 infants born very preterm (< 32 weeks of

Continued on page 40…

ONSITE GAS SOLUTIONS:
Your On-Site Gas Provider for Supply and Service

Optimize Your Medical Gas Operations

Medical gas logistics is resource-intensive and critically important in the provision of patient care. That's why ONSITE GAS SOLUTIONS from Linde Healthcare is designed to provide the support you need to manage your medical gas supply requirements while reducing overall costs.

Contact your Linde Healthcare representative today!
Call 1-800-772-4059.

Scan to explore this solution and other offerings from Linde Healthcare.

Why Choose ONSITE GAS SOLUTIONS?

With ONSITE GAS SOLUTIONS, an experienced ONSITE GAS Specialist becomes an integral part of your daily operations, acting as an extension of your team.

From cylinder management and inventory optimization to compliance, safety, training, and joint planning, ONSITE GAS SOLUTIONS delivers tailored services to enhance your facility's gas distribution.

Our program is designed to boost operating efficiency, minimize waste, and empower your staff to focus on their core responsibilities. Unlock greater operational value with ONSITE GAS SOLUTIONS.

Features

Cylinder & inventory management
- → Right size inventory
- → Enhance space utilization
- → Improve storage compliance
- → Reduce after hour emergency deliveries

Training & assistance
- → Linde employee(s) on-site
- → Deliveries and pickups at point of use/care
- → Safe gas handling training and technical advice
- → Manage paperwork and orders related to medical gases

Linde Gas & Equipment Inc.
10 Riverview Dr, Danbury, CT 06810, USA
Phone 800.225.8247, www.lindedirect.com

As Easy as It Should Be.

GRAB ‘N GO® Vision Gas Delivery System – Mobile Gas Therapy for the Future.

GRAB ‘N GO® Vision Gas Delivery System

- → Integrated single knob regulator
- → Angled gauge for optimum readability
- → Luminescent gauge face
- → Ergonomic handle

Contact your Linde Healthcare representative today!
Call 1-800-772-4059.

Linde Gas & Equipment Inc.
10 Riverview Dr, Danbury, CT 06810, USA
Phone 800.225.8247, www.lindedirect.com

Living Healthcare

A Baby's Bill of Rights in the NICU: Ensuring Accurate Medication Administration and the Use of Neonatal-Specific Enteral Feeding Systems

Constance Girgenti, MSN, RN, VA-BC and Teon Smith, BSN, RN, VA-BC

Abstract
Neonates admitted to the Neonatal Intensive Care Unit (NICU) are uniquely vulnerable to medication and device-related errors due to their size, physiology, and dependence on highly precise care. This manuscript proposes a "Baby's Bill of Rights" framework emphasizing two fundamental rights: (1) the right to accurate medication administration and (2) the right to neonatal-specific enteral feeding systems. Emerging evidence, including work by Dr Keliana O'Mara and colleagues, highlights the risk of dosing variability associated with non–neonatal-specific connector systems, particularly in low-volume medication delivery. These findings, combined with human factors, engineering principles and infection prevention concerns, support the need for device designs tailored specifically to neonates. Adoption of neonatal-specific systems represents both an evidence-based and ethical imperative to improve patient safety outcomes in the NICU.

Introduction

Patient safety remains a cornerstone of neonatal care, yet neonates continue to face disproportionate risks related to medication administration and device design. Unlike adult populations, neonatal patients require extremely small, weight-based dosing volumes, where even minimal deviations can result in clinically significant harm.

Standardization efforts, such as the adoption of universal enteral connector systems, have improved safety in preventing misconnections across healthcare settings. However, applying these systems universally across all patient populations may overlook critical differences in neonatal physiology and care requirements.

Constance Girgenti, MSN, RN, VA-BC, National Clinical Nurse Educator, is an influential nurse leader recognized for her expertise in neonatal intensive care, with a special focus on human milk advocacy, vascular access, and point-of-care ultrasound. She is a national and international speaker who is passionate about advancing neonatal and vascular access practices through education, innovation, and evidence-based care. Connie received the 2016 Association for Vascular Access Impact Award and the 2021 Lasallian Nursing Graduate Award. She is also a distinguished member of Sigma Theta Tau International Honour Society of Nursing, recognizing her commitment to nursing excellence and leadership.
Teon Smith, BSN, RN, VA-BC, is a NICU/PICU nurse with a passion for medication safety and excellence in vascular access care. An award-winning and influential nurse leader, Teon is dedicated to advancing safe, evidence-based practices across neonatal and pediatric patient populations through education, advocacy, and clinical expertise.

This paper proposes a "Baby's Bill of Rights" framework, advocating for neonatal-specific considerations in both medication administration and enteral feeding system design.

The Right to Accurate Medication Administration-Dosing Precision in Neonates

Medication administration in the NICU demands exceptional precision. Neonatal doses are often less than 1 ml, requiring delivery systems that minimize variability and residual volume. The Institute for Safe Medication Practices (ISMP) has identified neonates as a high-risk population for medication errors due to dose calculation complexity and device limitations (ISMP, 2020).

Evidence of Dosing Variability

Emerging evidence has demonstrated that enteral connector design can significantly impact dosing accuracy. Work by Dr Keliana O'Mara and colleagues has highlighted variability in delivered medication volumes when using non–neonatal-specific systems, particularly due to increased dead space and the need for additional flushing.

These studies suggest that even small, retained volumes within connectors can result in underdosing or delayed delivery, which is clinically significant in neonatal patients receiving critical medications.

Regulatory guidance further reinforces the importance of precision in low-volume medication delivery. The US Food and Drug Administration (FDA) has highlighted the risks associated with small-volume dosing, emphasizing the need for systems that support accurate measurement and delivery, particularly when administering doses less than 1 ml. In neonatal care, where such volumes are routine, even minimal discrepancies in delivery can have clinically significant consequences.

Clinical Implications

From both a pharmacologic and ethical perspective, neonates have the right to systems that ensure accurate, consistent medication delivery.

In neonatal populations, the clinical implications of dosing variability may extend beyond subtherapeutic or delayed treatment effects. Variability in medication delivery has the potential to contribute to changes in clinical status that may be difficult to distinguish from early signs of sepsis. As described in the work of Dr. Keliana O'Mara and colleagues, inconsistencies in low-volume medication delivery may introduce uncertainty in clinical

assessment, which in some cases could prompt further diagnostic evaluation.

In the NICU, this may include initiation of sepsis workups, transition to NPO status, initiation of empiric antibiotic therapy, placement of intravenous access, and additional laboratory testing. While these interventions are appropriate when infection is suspected, unnecessary escalation of care carries its own risks, including disruption of enteral feeding, increased procedural exposure, and potential impact on antimicrobial stewardship.

These concerns are not isolated. Broader literature in neonatal pharmacology and medication safety has consistently highlighted the challenges of low-volume dosing, the impact of device-related dead space, and the increased risk of variability in medication delivery in this population.

The Right to Neonatal-Specific Enteral Feeding Systems- Human Factors and Device Design

Human factors engineering emphasizes that medical devices should be designed for their intended users and environments. Neonates represent a distinct population with unique requirements, and device design must reflect this (FDA, 2018; AAMI, 2018).

A "one-size-fits-all" approach is inconsistent with these principles and may inadvertently introduce risk. This concept is widely accepted in neonatal care, where equipment and therapies are routinely tailored to the unique needs of this population. Neonates are not managed using scaled-down adult equipment; rather, they require devices specifically designed for their size and physiology, including incubators, ventilators, and monitoring systems.

Extending this principle to enteral feeding systems is both logical and necessary. The expectation that a universal connector design can safely meet the needs of all patient populations, including those requiring extremely low-volume precision, warrants careful reconsideration.

Limitations of Universal Connector Systems in the NICU

While ENFit™ connectors have improved safety in preventing enteral misconnections, concerns have been raised regarding their use in neonatal populations, including:

- Increased dead space leading to dosing inaccuracies
- Additional manipulation required for medication delivery
- Complex cleaning protocols that may increase infection risk

O'Mara's work further underscores that these design characteristics can impact medication delivery accuracy in low-volume neonatal dosing scenarios.

Advantages of Neonatal-Specific Systems

Neonatal-specific enteral feeding systems are designed to:

- Minimize dead space and residual volume
- Support accurate, low-volume dosing
- Reduce system manipulation
- Align with infection prevention practices

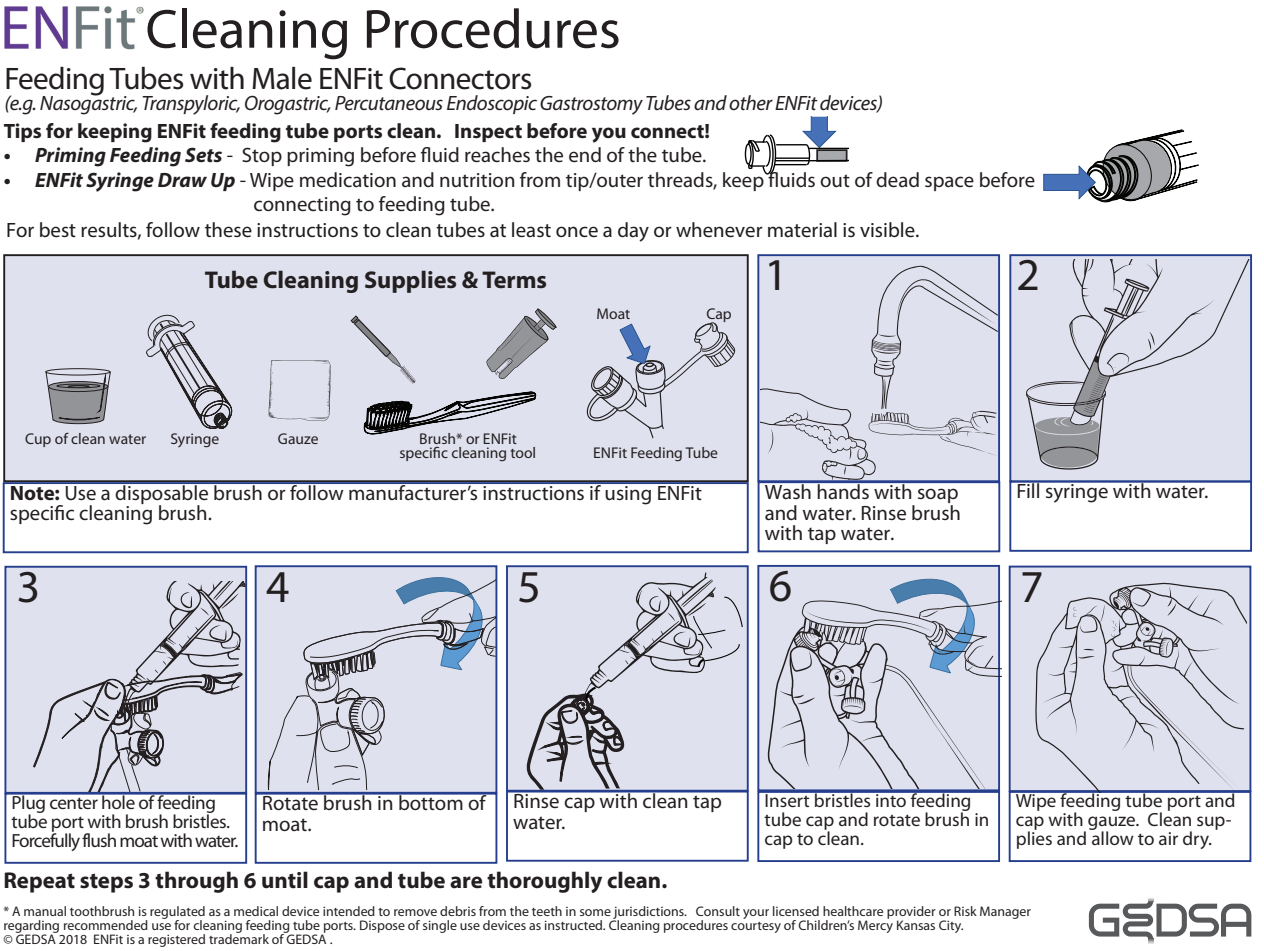


Figure 1

These features directly address the risks identified in neonatal care and support safer, more efficient workflows.

A Baby's Bill of Rights in the NICU

Based on current evidence and clinical best practices, the following rights are proposed:

1. **The Right to Accurate Medication Administration**
   Neonates have the right to delivery systems that ensure precise, reproducible dosing with minimal variability.
2. **The Right to Population-Specific Medical Devices**
   Medical devices used in neonatal care should be specifically designed for neonatal physiology and clinical needs.
3. **The Right to Minimized Infection Risk**
   Care processes and devices should reduce manipulation and support effective infection prevention strategies.
4. **The Right to Evidence-Based Care**
   Clinical practices and device selection should be guided by neonatal-specific evidence and outcomes data.

These rights reinforce a fundamental principle of neonatal care: clinical decisions, technologies, and systems must be designed specifically for this population, rather than adapted from adult models.

Discussion

The tension between standardization and specialization in healthcare is particularly evident in neonatal care. While universal systems offer benefits in reducing certain types of errors, they may introduce new risks when applied to populations with unique needs.

The work of O'Mara and others highlights the importance of evaluating device performance specifically within neonatal contexts. These findings reinforce the need for targeted solutions that prioritize dosing accuracy, safety, and workflow efficiency.

Adopting neonatal-specific enteral feeding systems aligns with broader patient safety initiatives and supports improved clinical outcomes. Furthermore, it reflects a commitment to ethical care by recognizing and addressing the unique vulnerabilities of neonatal patients.

Safe enteral medication administration in the NICU requires not only accurate dosing but also consistent adherence to aseptic technique. Device design plays a critical role in shaping workflow, particularly with respect to the number of steps required for preparation, administration, and post-use cleaning.

Enteral connector systems that require multi-step cleaning processes may inadvertently introduce variability in practice. The Global Enteral Device Supplier Association (GEDSA) has published recommended cleaning procedures for ENFit™ connectors that include multiple sequential steps such as flushing, mechanical wiping, and repeated cleaning cycles depending on use conditions. While these steps are intended to reduce contamination, they also increase the number of manipulation points within the system (See Figure 1).

Each additional step introduces an opportunity for inconsistency in technique, time delays in medication administration, and potential contamination, particularly in high-acuity NICU environments where clinicians are managing multiple critically ill patients. This is especially relevant given the immature immune systems of neonates and their increased susceptibility to infection.

Furthermore, increased handling of connectors may contribute to biofilm formation if cleaning is incomplete or inconsistent, compounding infection risk over time. From a human factors perspective, systems that require fewer steps and minimize manipulation are more likely to support reliable, reproducible practice and improved patient safety outcomes (FDA, 2018; AAMI, 2018).

Conclusion

Neonates in the NICU depend entirely on healthcare providers and systems to safeguard their well-being. Accurate medication administration and the use of neonatal-specific enteral feeding systems are essential components of safe, high-quality care.

A "Baby's Bill of Rights" provides a framework for advocating for these standards and ensuring that neonatal care practices are aligned with both evidence and ethics.

Ultimately, doing what is right for neonates means designing and implementing systems specifically for them—not adapting solutions intended for other populations. In neonatal care, precision is not optional, and neither is the responsibility to ensure that every device reflects the unique needs of the patient it serves.

References

- Association for the Advancement of Medical Instrumentation (AAMI). (2018). *Human factors engineering—Design of medical devices*. AAMI.
- Food and Drug Administration (FDA). (2018). *Applying human factors and usability engineering to medical devices: Guidance for industry and FDA staff*. US Department of Health and Human Services.
- Food and Drug Administration (FDA). (2016). *Use of oral dosing devices with calibrated markings to improve dosing accuracy for orally administered liquid drug products.* US Department of Health and Human Services.
- Institute for Safe Medication Practices (ISMP). (2020). *Medication safety guidelines for neonatal patients*. ISMP.
- O'Mara, K., et al. (2020). Medication dosing accuracy and enteral connector dead space in neonatal populations. *Journal of Pediatric Pharmacology and Therapeutics, 25*(4), 300–307.
- O'Mara, K., et al. (2022). Impact of enteral connector design on low-volume medication delivery in neonates. *Neonatal Pharmacology Review, 14*(2), 85–92.
- Sutherland, A., Phipps, D. L., Tomlin, S., & Ashcroft, D. M. (2019). Mapping the prevalence and nature of drug-related errors among hospitalized children in the United Kingdom: A systematic review. *Drug Safety, 42*(5), 601–613.
- Taylor, J. A., Delaney, B., & Brownstein, D. (2021). Infection prevention considerations in neonatal enteral feeding systems. *Journal of Neonatal Nursing, 27*(3), 145–151.

Addressing the Catastrophic Clinical and Economic Costs of Neonatal IV Failure

John Rudoy, Healthcare Industry Practice Leader at Aon; Erin Wendell, President of ivWatch

Nearly every patient admitted to a hospital, including many of those in outpatient settings, receives a peripheral intravenous (IV) line. However, those lines fail nearly 50% of the time, with a quarter progressing towards severe extravasation. When this occurs, medication intended for the patient's vein leaks into the tissue surrounding the IV site, which can be extremely problematic both clinically and financially.

In these cases, complications often ensue, requiring additional care and hospital days. As a result, nearly 1 in 20 patients will be faced with longer recovery and hospital stays, but some may experience life-altering injuries.

While the consequences of extravasation are exceedingly risky for patients, hospitals must also consider the financial cost that these injuries expose. They often require transfer to the ICU and additional care that can include wound debridement, fasciotomies, grafts, and, in extreme cases, amputation. Often, this care goes unreimbursed, and hospital satisfaction scores decline, leading to revenue loss.

Perhaps the highest financial risk severe extravasations pose is costly malpractice lawsuits. While the average cost of such a lawsuit is in the mid-six figures, some single judgments have reached significantly higher. One extravasation injury is one too many.

John Rudoy leads consulting and analytics projects within Aon's Managed Care Reinsurance team. He focuses on helping healthcare organizations navigate shifting reimbursement structures and business models by developing new analytical and financial management capabilities, and building new intra- and interindustry partnerships. John has broad expertise in the healthcare industry, and through two decades of work, he has focused on conceiving and implementing strategies for organizations seeking to navigate the volatility and uncertainty inherent in the US healthcare system.

Erin Wendell serves as President of ivWatch, where she leads the strategic vision and direction for the company across sales, clinical, marketing, R&D, and operations. Since joining ivWatch in 2020, she has significantly raised the company's profile and expanded awareness of IV safety as a critical patient care issue. Under her leadership, ivWatch has been recognized as one of Fast Company's Most Innovative Companies, named to the Inc. Best in Business list in the Health Products category, and selected as a finalist in the Fierce Life Sciences Innovation Awards. Erin has also been recognized personally for her work in driving narrative change around IV injuries, earning honors from PR Daily's Top Women in Marketing and PM360's ELITE 100 in the Disruptor category.

Why NICU Patients are at the Greatest Risk of IV Injury

Some studies report that peripheral IV failure rates among the high-risk neonate population are nearly 80% versus up to 50% for the general population. This is because neonatal patients have uniquely fragile and small-caliber veins, and even the smallest available catheters—such as a 26-gauge—may occupy a disproportionately large percentage of the vessel diameter. This high catheter-to-vein ratio significantly increases the risk of infiltration, extravasation, and other vascular access-related complications. The risk is even greater in extremely preterm infants, whose vessels are not only smaller but also more fragile and reactive. The smallest amount of fluid leaking outside the vein can have detrimental outcomes.

In neonates, early signs of infiltration or extravasation can be subtle or hard to detect. Swelling may be minimal or difficult to visualize, especially under phototherapy or in fragile skin. Infants cannot verbalize pain or discomfort, so clinicians rely heavily on visual and tactile cues. Unfortunately, these signals can be misinterpreted, identified too late–after serious injury has already progressed–or missed entirely, particularly when care is intentionally provided in a way that minimizes disturbance to the infants' sleep, which is imperative to their development. In the NICU, every peripheral IV should be monitored continuously, regardless of the patient's gestational age, clinical condition, or the type of fluid being infused. The risk of infiltration or extravasation is always present. In neonates, the margin for error is extremely small.

Because of their immature immune system, neonates are more vulnerable to infection when the skin barrier is compromised. Even a small infiltration or extravasation can become a portal for bacteria, and in some cases, lead to sepsis.

We know from multiple studies that neonatal sepsis increases the risk of poorer neurodevelopmental outcomes—things like delayed cognitive or motor development—especially in very preterm or low birth weight infants. The exact impact can vary, but the risk is real and clinically significant.

The impact on parents and caregivers is also substantial. When they see a new IV placed in another hand or foot, it can be alarming. It raises questions about what happened and adds stress to an already difficult time. Sensor technology can help reduce that stress when they know their baby is being continuously monitored for complications.

Quantifying the costs of detecting extravasations as they occur

Medical technology company ivWatch has created a device that detects extravasations before they cause severe harm, reducing complications by more than 90%. To gauge how this translates to financial risk for hospitals, Aon used proprietary access to medical malpractice claims data and hospital cost data to validate a model that calculates the potential costs facing healthcare organizations that do not employ this technology.

Aon found that the typical 150-bed pediatric hospital implementing ivWatch's proprietary sensor technology can expect a return of approximately $8.9M to $13.4M. The cost reduction is driven by lower liability costs, less uncompensated remedial care, and increased satisfaction scores.

This model estimated that the average hospital will likely see approximately 1,500 severe extravasations annually. This relies on literature that demonstrates approximately 46% of admitted patients will receive a peripheral IV with a high-risk drug, 56% of those IVs will fail, and 53% of those extravasations will be severe. After ivWatch implementation, the proportion of severe extravasations drops to 4%. It's important to note that pediatric hospitals are at higher risk, as the proportion of severe extravasations is 15% lower in general hospital settings.

A study published in July 2025 by The BMJ (British Medical Journal) analyzed the use of ivWatch's sensor technology in the early detection of infiltration and extravasation events in neonates. It found that although the overall number of events remained consistent throughout the study across two groups, injuries were far less severe when ivWatch was used versus the control group where it was not utilized. The number of events with more than 30% estimated tissue involvement decreased from 243 to 54. Events affecting more than 15% of the surrounding tissue fell from 2,613 cases to 180, a decrease of 78% and 93%, respectively.

Conclusion

The costs to the vulnerable patient population receiving care in NICUs, solely in terms of patient outcomes, are reason enough to implement early detection technology. In fact, a review published in *Frontiers in Pediatrics* concludes that neonate pain has significant long-term effects on neurosensory function, cognition, behavior, pain processing, and health outcomes that persist into childhood and even adulthood.

This research has also shown that preterm babies experiencing pain via a NICU experience and treatment remember the trauma and consequently contend with more stress hormones, higher heart rate, and lower oxygen saturation when later exposed to similar pain. Pain experiences in preterm and extremely preterm children and young adults have also been shown to negatively influence neurodevelopmental outcomes, including altered pain response in later life.

While early IV injury detection in the NICU represents a positive step forward in overall care for one of the most vulnerable patient populations, it also reduces the financial impact on the healthcare organizations providing this care by millions. This represents a considerable benefit to both patients and providers.

Neonatal Intensive Care Unit Admission Among Infants Born Full-Term to CDC's COVID-19 Vaccine Pregnancy Registry Participants: A Matched Cohort Study

Lauren Head Zauche[a], Sabrina A Madni[a], David K Shay[a], Christine K Olson[a,b], Aliza Machefsky[a,c], Shana E Godfred Cato[a,d], and Andrea J Sharma[a,b]

Abstract

To estimate incidence of neonatal intensive care unit (NICU) admission among infants born to women receiving COVID-19 vaccines during pregnancy versus among infants born to unvaccinated women. We matched full-term infants from the United States Centers for Disease Control and Prevention's (CDC) COVID-19 Vaccine Pregnancy Registry (C19VPR) to full-term infants from CDC's Pregnancy Risk Assessment Monitoring System (PRAMS) with participant report of NICU admission available. We used 1:1 convenience sampling to match by maternal age, race, and ethnicity (n = 5,487 pairs). Adjusted incidence ratios (aIR) for NICU admission were calculated using Poisson regression; sensitivity analyses included a state-based match. NICU admission incidence was lower among C19VPR infants than PRAMS infants (7.7% vs 11.3%, aIR: 0.81, 95% CI: 0.65, 0.99). The highest aIR estimate generated through sensitivity analyses was 0.86 (95% CI: 0.67, 1.11). No evidence for an increased risk of NICU admission was found among infants born to vaccinated versus unvaccinated women.

Introduction

Early in the COVID-19 pandemic (2020–2021), SARS-CoV-2 infection during pregnancy increased risks for neonatal morbidity and mortality, including admission to the neonatal intensive care unit (NICU) and neonatal SARS-CoV-2 infection.[1,2] Data from the Surveillance for Emerging Threats to Mothers and Babies Network found that among neonates tested for SARS-CoV-2 born to women diagnosed with SARS-CoV-2 within 2 d of delivery, 4.6% were positive.[3] Vaccination during pregnancy may confer protection to infants for the first months of life.[4,5] No associations between COVID-19 vaccination and increased risk of spontaneous abortion[6] or stillbirth[7] have been documented. However, concerns about fetal health after COVID-19 vaccination may increase vaccine hesitancy.[8]

Data from the National Vital Statistics System show that 8.7–9.8% of all infants born in the United States during 2016–2023 were admitted to a NICU.[9] NICU admission rates are lower for infants born term or post-term: early term (37–38 weeks' gestation; 6.2–7.1%), full term (39–40 weeks' gestation; 3.5–3.8%), and post-term (≥41 weeks' gestation; 4.6–4.8%).[9] Newborns are admitted to NICUs for many reasons.[10] NICU admission has public health implications: it is associated with increased risk of infections, invasive medical interventions, increased family stress, and high costs to families.[10] Several studies and meta-analyses found no increased risk of NICU admission among neonates born to COVID-19 vaccinated women compared to neonates of unvaccinated women.[11–17] However, few studies have been conducted in the United States or have examined risk of NICU admission among full-term infants. Prematurity accounts for nearly half of NICU admissions in the United States.[10,18] A substantial proportion (23.5–38%) of preterm deliveries are medically indicated due to maternal complications such as pre-eclampsia.[19,20] An increased risk of preterm birth has not been observed among COVID-19 vaccinated pregnant populations.[11,13] By assessing risk of NICU admission among full-term infants, the potentially confounding effect of preterm birth is eliminated. The Centers for Disease Control and Prevention's (CDC) COVID-19 Vaccine Pregnancy Registry (C19VPR) monitored pregnancy and infant outcomes following vaccination during or just prior to pregnancy to identify potential safety concerns.[21] Our objective was to report incidence of NICU admission among infants in C19VPR. We estimated incidence of NICU admission among C19VPR participants' infants born ≥37 weeks' gestation and compared to a matched cohort of infants of unvaccinated women enrolled in CDC's Pregnancy Risk Assessment Monitoring System (PRAMS).[22]

Methods

Study design and data sources

We conducted a matched cohort study using data from C19VPR and PRAMS. We identified potential participants for C19VPR among women ≥18 y who enrolled in CDC's V-safe from December 2020 through June 2021.[21] Participants resided in all 50 states, Washington D.C., and Puerto Rico. V-safe participants

[a]Immunization Safety Office, National Center for Emerging and Zoonotic Infectious Diseases, CDC, Atlanta, GA, USA; [b]US Public Health Service Commissioned Corps, Rockville, MD, USA; [c]Department of Gynecology and Obstetrics, Emory University School of Medicine, Atlanta, GA, USA; [d]Division of Pediatric Emergency Medicine, University of Utah, Salt Lake City, UT, USA. Lauren Head Zauche, PhD, MSN qnz7@cdc.gov Immunization Safety Office, National Center for Emerging and Zoonotic Infectious Diseases, CDC, 1600 Clifton Road, Mailstop H16-3, Atlanta, GA 30329, USA.

reporting receipt of ≥1 original monovalent COVID-19 vaccine (i.e., Pfizer-BioNTech, Moderna, or Johnson & Johnson/Janssen) in the 30 d before the pregnancy-associated last menstrual period or during pregnancy were invited to participate in C19VPR. Participant-reported data were collected about demo-graphics, medical history, gestational health, pregnancy outcomes, delivery and postpartum complications, and infant health from January 2021 through August 2022. Complete C19VPR methodology is available.[21] PRAMS is a cross-sectional state-based surveillance system used to monitor maternal and child health.[23] Complete PRAMS methodology is available.[22] Briefly, state birth certificate files were the sampling frame for identifying women who had a live birth during the surveillance year. Only one infant from multiple gestation pregnancies was eligible in each sample frame. Monthly, participating states drew a stratified random sample of 100–250 women 2–6 months after delivery. PRAMS sites oversampled subpopulations of interest based on research and programmatic needs. Because this was a matched cohort study, weighting of PRAMS data was unnecessary. The PRAMS questionnaire was mailed to women 2–6 months after a live birth to monitor pregnancy-related behaviors and experiences, with telephone follow-up for non-respondents. The PRAMS questionnaire varied by jurisdiction, consisting of core questions common to all jurisdictions, standard questions available for inclusion, and jurisdiction-developed questions.

To identify a cohort of PRAMS participants ≥18 y with no COVID-19 vaccination during pregnancy, we used data from 2019, 2020, and 2021. Participant report of NICU admission ("After your baby was delivered, was he or she put in an intensive care unit (NICU)?") was available for inclusion in PRAMS questionnaires. To maximize comparability with C19VPR, participants from states implementing the NICU question formed the potentially eligible PRAMS comparison group; six states (Delaware, Kentucky, Mississippi, New Jersey, New Mexico, and Utah) included this question in 2019, 2020, and 2021 ques-tionnaires. PRAMS participants from 2019 and 2020 were assumed to be unvaccinated and were eligible for matching as nearly all had given birth prior to large-scale administration of COVID-19 vaccines, which began December 14, 2020.[24] Beginning in 2021, Delaware, New Jersey, and Utah included a question about COVID-19 vaccination in pregnancy. Women who reported not receiving a COVID-19 vaccine were eligible for matching. In total, 12,111 PRAMS infants were eligible for matching. C19VPR was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy, 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq. The PRAMS protocol was approved by the CDC Institutional Review Board (IRB #2233).

Study cohort and analyses

The full C19VPR cohort included 23,249 participants reporting on 23,628 fetuses or infants. We excluded non-live births (n = 2,251), preterm infants (n = 1,664), and infants missing a response to "Was your baby admitted to the neonatal intensive care unit?" (n = 160), resulting in 19,544 term live births.

Because the participant-report NICU admission question was implemented in only six states, we restricted the C19VPR cohort to participants from states with NICU admission rates in range of these six states (10.0% to 14.2%) based on 2016–2023 National Center for Health Statistics (NCHS) data,[9] for the primary analysis (n = 7,547).[a] Although NCHS data (birth certificate-based) are not directly comparable with participant-reported data, we assumed nondifferential misclassification of NICU admission across states.

We matched infants of C19VPR and PRAMS participants by maternal age categories (<30, 30–39, and ≥40 y) and maternal race and ethnicity (Non-Hispanic [NH] Black, NH-White, Hispanic, NH-Asian, and NH-Other). To maximize sample size, C19VPR infants from multiple gestation pregnancies (e.g., twins) were eligible to be matched individually; however, we were unable to match on plurality given limited sample size of multiple gestation pregnancies. We matched without replacement, as matching with replacement can reduce statistical independence, potentially biasing results.[25] Several systematic imbalances between infants born prior to COVID-19 vaccine availability and those born while it was in use could exist; therefore, we preferentially matched C19VPR infants to PRAMS infants born in 2021. The primary analysis included 5,487 matched pairs.

For a more direct comparison, we conducted a state-based sensitivity analysis that restricted the C19VPR cohort to infants in the six states that asked about NICU admission in PRAMS (n = 1,142 matched pairs; Figure 1). Because maternal COVID-19 illness during pregnancy was unknown for a large proportion of PRAMS participants, we conducted a sensitivity analysis for both the primary and state-based sensitivity analyses wherein we assumed all unknown COVID-19 illness statuses to be positive.

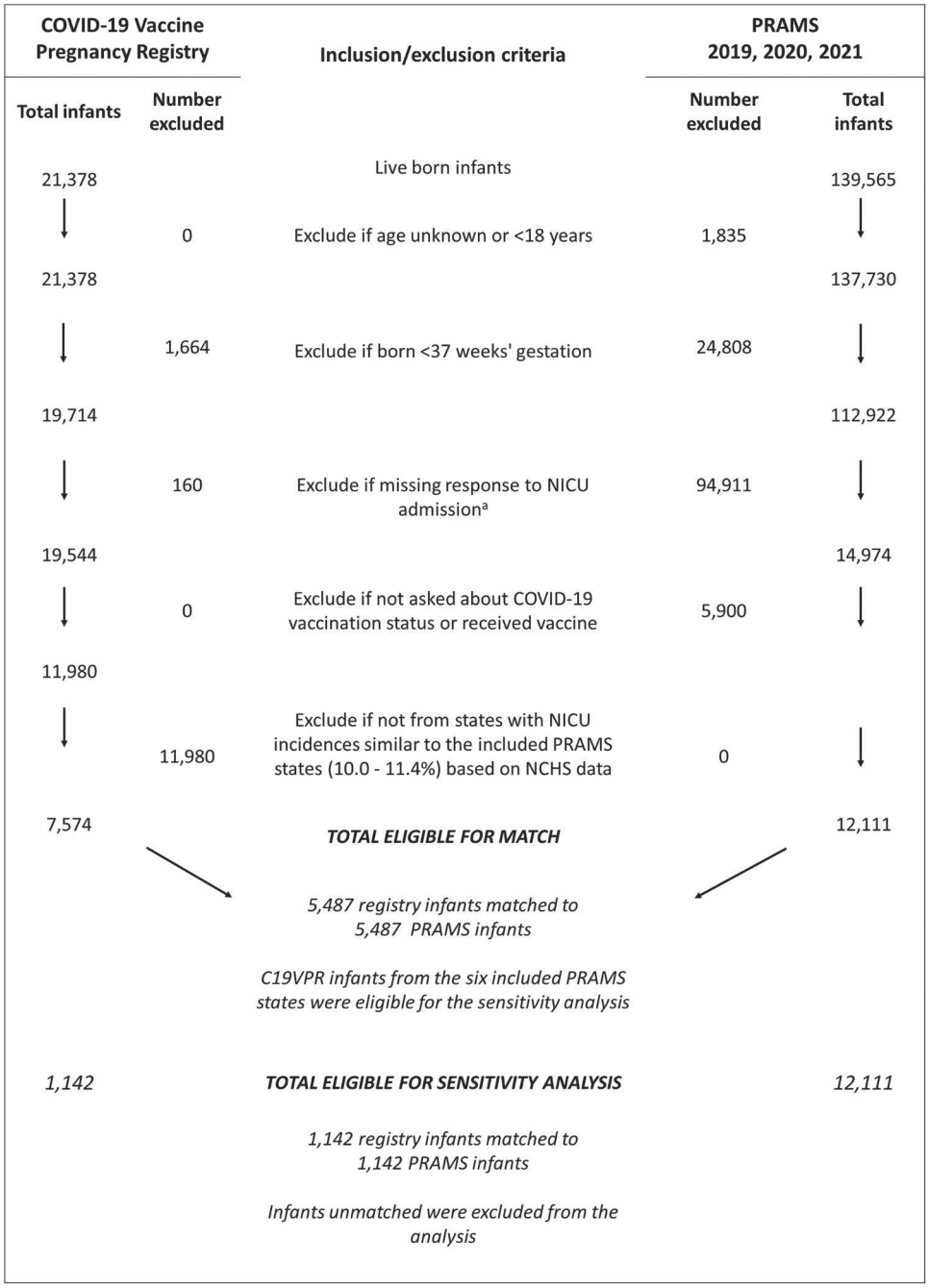
Descriptive statistics were calculated for matched participants and their infants for both C19VPR and PRAMS, and for unmatched participants and their infants from C19VPR. We assessed covariates associated with NICU admission in the C19VPR cohort including manufacturer of first COVID-19 vaccine dose received, timing relative to pregnancy of receipt of the COVID-19 vaccine dose conferring C19VPR eligibility ("registry-eligible vaccine"), maternal age group at delivery (<30, 30 to 39, or ≥40 y), race and ethnicity, healthcare personnel status, urbanicity of residence, parity, obesity (pre-pregnancy body mass index (BMI) ≥30 kg/m^2), hypertension (preexisting or diagnosis of hypertensive disorder of pregnancy), diabetes (preexisting or gestational), plurality, delivery method, gestational age at delivery (early term, 37 to 38 weeks' gestation; term, 39 to 40 weeks' gestation; and late or post-term, ≥41 weeks' gestation), infant birthweight category (<2,500, 2,500 to 3,999, and ≥4,000 grams), COVID-19 illness during pregnancy, and infant sex. We examined differences in delivery method (vaginal vs. cesarean) using a chi-square test to serve as a negative control as delivery method was not expected to be different based on vaccination status. Poisson regression models with robust variance (accounting for matched pairs as clusters) were used to estimate crude and adjusted incidence ratios (aIR) and 95% confidence intervals (CIs) of NICU admission among C19VPR infants compared to PRAMS infants for both primary and sensitivity analyses.[26,27] We used chi-squared tests to identify covariates associated with both COVID-19 vaccination and NICU admission. Covariates meeting this criterion and other covariates with theoretical importance were included in the multivariable model using a stepwise approach and retained if their inclusion resulted in a ≥ 10% change in the estimated association between exposure and outcome.[28,29] Urbanicity, parity, hypertensive disorders of pregnancy, obesity, preexisting or gestational diabetes, COVID-19 illness during pregnancy, gestational age at delivery group, birthweight group, state, and birth year were identified as confounders. We found weak correlations (all Spearman r values < 0.20) among maternal confounders with known associations (i.e., obesity, hypertension, diabetes); therefore, these variables

were included in the model. We found moderate correlation (Spearman r value = 0.22) between infant birthweight group and gestational age at delivery, so we excluded gestational age at delivery from models. Data about COVID-19 illness in pregnancy were collected for C19VPR participants but not for all PRAMS jurisdictions, so illness could not be included in comparative analyses.

SAS (version 9.4; SAS Institute, Cary, North Carolina, USA) was used for analyses.

Results

Among infants born at term to women in the C19VPR cohort with information available about potential NICU admission (n = 19,544), most were born to participants who received either Pfizer-BioNTech (n = 11,563, 59.1%) or Moderna (n = 7,460, 38.2%) COVID-19 vaccines (Table 1). The registry-eligible vaccine was the first COVID-19 vaccine received for most (97.1%) participants. Mothers of about one-third of infants received a registry-eligible vaccine either within 30 d before their last menstrual period (n = 1,658, 8.5%) or during the first trimester (n = 5,502, 25.8%).



Abbreviations: PRAMS, Pregnancy Risk Assessment Monitoring Survey ; NCHS, National Center for Health Statistics
[a]Question about NICU admission asked during interview to COVID-19 Vaccine Pregnancy Registry participants. Only seven jurisdictions in PRAMS included a question on NICU admissions (Delaware, Kentucky, Mississippi, New Jersey, New Mexico, and Utah).

Figure 1. CDC COVID-19 vaccine pregnancy registry and pregnancy risk assessment monitoring systems consort diagram.

Table 1. Bivariate associations between neonatal intensive care unit admission and covariates among full-term CDC COVID-19 Vaccine Pregnancy Registry infants (n = 19,544).[a]

			Neonatal intensive care unit (NICU) admission reported by participant				
	Total Infants		No		Yes		
	N = 19,544	Column%	n = 18,194	93.0%	n = 1,360	7.0%	*p*-value[b]
Manufacturer of first COVID-19 vaccine dose							.53
Pfizer-BioNTech	11,563	59.1	10,747	92.9	816	7.1	
Moderna	7,460	38.2	6,947	93.1	513	6.9	
Janssen	531	2.7	500	94.2	31	5.8	
Timing of COVID-19 vaccine dose conferring C19VPR eligibility							.76
Pre-pregnancy (up to 30 d before LMP)	1,658	8.5	1,533	92.5	125	7.5	
First trimester	5,052	25.8	4,709	93.2	343	6.8	
Second trimester	7,894	40.4	7,350	93.1	544	6.9	
Third trimester	4,950	25.3	4,602	93.0	348	7.0	
Maternal age at delivery (years)							.02
<30	3,436	17.6	3,180	92.6	256	7.5	
30–39	15,282	78.2	14,253	93.3	1,029	6.7	
40+	836	4.3	761	91.0	75	9.0	
Maternal race/ethnicity							.67
Non-Hispanic Black	416	2.1	385	92.6	31	7.5	
Non-Hispanic White	15,635	80.0	14,541	93.0	1,094	7.0	
Hispanic	1,788	9.1	1,662	93.0	126	7.0	
Non-Hispanic Asian	1,175	6.0	1,095	93.2	80	6.8	
Other	540	2.8	511	94.6	29	5.4	
Healthcare personnel							.05
No	11,001	56.3	10,206	92.8	795	7.2	
Yes	8,310	42.5	7,768	93.5	542	6.5	
Not reported	243	1.2	220	90.5	23	9.5	
Urbanicity of residence							
Urban	18,295	93.6	16,996	92.9	1,299	7.1	<.01
Rural	1,228	6.3	1,170	95.3	58	4.7	
Not reported	31	0.2	28	90.3	3	9.7	
Nulliparous							<.01
No	11,433	58.5	10,779	94.3	654	5.7	
Yes	8,121	41.5	7,415	91.3	706	8.7	
Obesity							<.01
No	15,752	80.6	14,743	93.6	1,009	6.4	
Yes	3,802	19.4	3,451	90.8	351	9.2	
Hypertension (preexisting or HDP)							<.01
No	16,696	85.4	15,645	93.7	1,051	6.3	
Yes	2,858	14.6	2,549	89.2	309	10.8	
Diabetes Mellitus (preexisting or GDM)							<.01
No	17,527	89.6	16,351	93.3	1,176	6.7	
Yes	2,027	10.4	1,843	90.9	184	9.1	
SARS-CoV-2 infection in pregnancy							.62
No	18,839	96.3	17,534	93.1	1,307	6.9	
Yes	715	3.7	662	92.6	53	7.4	
Plurality							<.01
Singleton	19,235	98.4	17,911	93.1	1,324	6.9	
Multiple	319	1.6	283	88.7	36	11.3	
Delivery method							<.01
Cesarean	5,679	29.0	5,045	88.8	634	11.2	
Vaginal	13,841	70.8	13,118	94.8	723	5.2	
Not reported	34	0.2	31	91.2	3	8.8	
Birth year							.31
2020	39	0.2	35	0.2	4	0.3	
2021	19,312	98.8	17,964	98.7	1,348	99.1	
2022	202	1.0	194	1.1	8	0.6	
Unknown	1	0.0	1	0.0	0	0.0	
Gestational age at delivery							<.01
Early term (37–38 weeks)	5,726	29.3	5,147	89.9	579	10.1	
Term (39–40 weeks)	12,530	64.1	11,849	94.6	681	5.4	
Late or post-term (≥41 weeks)	1,298	6.6	1,198	92.3	100	7.7	
Birthweight (grams)							<.01
<2500	338	1.7	271	86.5	67	19.8	
2500 to 3999	17,180	87.9	16,090	93.7	1,090	6.3	
≥4000	17,180	9.0	1,596	90.6	166	9.4	
Not reported	274	1.4	237	86.5	37	13.5	
Infant sex							<.01
Female	9,546	48.8	8,996	94.2	550	5.8	
Male	9,958	50.9	9,152	91.9	806	8.9	
Not reported	50	0.3	46	92.0	4	8.0	

Abbreviations: HPD, hypertensive disorder of pregnancy, GDM, gestational Diabetes Mellitus; LMP, last menstrual period.
[a]C19VPR enrolled women who were vaccinated just prior to or during pregnancy from December 15, 2020 through June 20, 2021. Infant birth dates ranged from December 19, 2020, to February 10, 2022.
[b]Chi Squared tests were used to assess the difference in distributions between groups.

Mothers of most infants were 30–39 y old (n = 1,282, 78.2%), NH White (n = 15,635, 80.0%), lived in urban areas (n = 18,295, 93.6%), and had a previous pregnancy (n = 11,433, 58.5%). A high percentage of infants had mothers who identified as healthcare personnel (n = 8,310, 42.5%). Most pregnancies were singletons (n = 19,235, 98.4%). Most infants were born vaginally (n = 13,841, 70.8%) and between 39–40 weeks' gestation (n = 12,530, 64.1%).

NICU admission was reported for 1,360 (7.0%) full-term C19VPR infants. Manufacturer of COVID-19 vaccine, timing of COVID-19 vaccination relative to pregnancy (i.e., pre-pregnancy period or by trimester), and racial and ethnic group were not associated with NICU admission (Table 1). NICU admission was significantly associated with maternal age at delivery; participants aged 30–39 y reported NICU admission less often (6.7%) than younger (7.5%) and older participants (9.0%) (Table 1). Participants reporting NICU admission had a higher prevalence of obesity (9.2% vs 6.4%), hypertension (10.8% vs 6.3%), and diabetes (9.1% vs 6.7%) than those not reporting admission. First pregnancies (8.7% vs 5.7%), multiple gestation pregnancies (11.3% vs 6.9%), and cesarean deliveries (11.2% vs 5.2%) were associated with NICU admission. NICU incidence was higher among those born early-term (10.1%) and late or post-term (7.7%) compared to term (5.4%). A higher proportion of males were admitted to the NICU compared to females (8.9% vs 5.8%).

Incidence of NICU admission was higher among matched C19VPR infants versus unmatched (7.7% vs 6.7%, Table 2). Mothers of matched C19VPR infants were more likely to have received the Moderna vaccine (40.5% vs 37.2%). Mothers of all unmatched infants were over 30 y old, and 80.0% were NH-White. Timing of receipt of the registry-eligible vaccine was similar between matched and unmatched C19VPR participants.

Table 3 displays characteristics of PRAMS and C19VPR infants in the primary analysis. Compared to C19VPR participants, more PRAMS participants had obesity, hypertension, and diabetes, and fewer PRAMS participants lived in urban areas and were nulliparous. More C19VPR participants reported known SARS-CoV-2 infection during pregnancy compared to PRAMS participants. More infants were born early-term and late or post-term among C19VPR. More infants were born <2,500 grams or ≥4,000 grams in PRAMS. There were no significant differences for plurality or infant sex. We found no differences between C19VPR and PRAMS participants for delivery method ($p = .96$ [Table 3]). After adjusting for confounding, participant-reported NICU admission was lower among C19VPR infants compared to PRAMS infants (7.7 vs 11.3%, aIR: 0.81, 95% CI: 0.65, 0.99). Results were consistent in the state-based sensitivity analysis and in analyses assuming all women with unknown COVID-19 illness status during pregnancy did have COVID-19 illness (Figure 2). The highest point estimate was observed in the adjusted sensitivity analysis (aIR: 0.86, 95% CI: 0.67, 1.11).

We obtained medical records for a convenience sample of infants with reported NICU admission (n = 148). Among these 148 infants, NICU admission was confirmed after record review for 85.1% (95% CI: 79.4%, 90.9%), suggesting that participant reports had a relatively high positive predictive value for medical record documentation.

Discussion

This matched cohort study evaluated NICU admission as a potential concern among infants born to women receiving COVID-19 vaccines during pregnancy. The incidence of NICU admission was similar among infants born to participants who received a COVID-19 vaccine during pregnancy (C19VPR) and infants born to unvaccinated PRAMS participants. In a sensitivity analysis that matched infant pairs by state of birth, we examined confounding variables using a stepwise approach and used the most parsimonious model. While this model adjusted for different variables than the primary analysis, the results of the primary and sensitivity analyses are similar. Results are also similar in models assuming women with unknown COVID-19 illness status during pregnancy did have COVID-19 illness. No evidence of association between COVID-19 vaccination during pregnancy and NICU admission was found in any analysis.

Our results are consistent with those from previous studies, which found no increased risk of NICU admission among infants of women who received at least one dose of a COVID-19 vaccine during pregnancy compared with infants of unvaccinated women.[13–15,30–32] Two previous studies have demonstrated a protective effect, with a lower risk of NICU admission among infants of vaccinated pregnant women.[13,15] Lower risk of NICU admission may be attributable to lower incidence of SARS-CoV-2 infection among vaccinated mothers; in our study, fewer PRAMS participants reported known SARS CoV-2 infection during pregnancy, but status of SARS-CoV-2 infection during pregnancy was unknown for almost one-third of PRAMS participants.

Our findings add to existing evidence in two ways. First, we found no evidence of an increase in incidence of NICU admission in term-born infants whose mothers received a COVID-19 vaccine. Previous studies have included preterm infants, but few have adjusted for infant birthweight or gestational age at delivery, which are associated with NICU admission.[13–15,30–32] An analysis assessing risk of NICU admission among full-term infants in a large registry-based study of births in Sweden and Norway demonstrated no increased risk of NICU admission among infants of women vaccinated against SARS-CoV-2 during pregnancy.[31]

Second, our study provides US-based data on NICU admissions after maternal vaccination. Previous studies have been conducted in other countries, including Canada, Israel, United Kingdom, Sweden, and Norway.[13–15,30–32] Significant regional variation in NICU admission exists, as clinical guidelines and protocols for intensive care and availability of intensive care (e.g., bed space, number of neonatal specialists, presence of transition nurseries) differ geographically, especially for infants born ≥37 weeks' gestation.[33–35] Previous data demonstrate overreporting of NICU admission in PRAMS, compared to medical records, with a positive predictive value of 74.6%,[36] lower than that observed in the C19VPR cohort (85%). While we assessed positive predictive value among 148 C19VPR participants, we did not have medical records for the PRAMS participants in this study. Nearly 43% of C19VPR participants self-identified as healthcare personnel, higher than the general population; employment history was not available for PRAMS enrollees. Participant report of NICU admission likely differs by knowledge and experience with healthcare. Receipt of care from NICU staff, transfer to the NICU for a short observation period, or admission to a special care nursery may be perceived inaccurately as a NICU admission. Differences in participant employment may contribute to differences in positive predictive values, which may bias our results away from the null.

This report has several strengths, including enrollment of infants born to women vaccinated in the pre-pregnancy period (within

Table 2. Characteristics of infants born to the CDC COVID-19 Vaccine Pregnancy Registry participants: matched vs. unmatched pregnant women (n = 19 554).[a]

	Unmatched		Matched		
	n = 14,067	Col %	n = 5,487	Col %	*p*-value[b]
Neonatal intensive care unit admission					<.01
No	13,131	93.4	5,063	92.3	
Yes	936	6.7	424	7.7	
Manufacturer of first COVID-19 vaccine dose					<.01
Pfizer-BioNTech	8,433	60.0	3,310	57.0	
Moderna	5,238	37.2	2,222	40.5	
Janssen	396	2.8	135	2.5	
Timing of COVID-19 vaccine dose conferring C19VPR eligibility					.97
Pre-pregnancy (up to 30 d before LMP)	1,190	8.5	468	8.5	
First trimester	3,631	25.8	1,421	25.9	
Second trimester	5,671	40.3	2,223	40.5	
Third trimester	3,575	25.4	1,375	25.1	
Maternal age at delivery (years)					<.01
<30	2,109	15.0	1,317	24.2	
30–39	11,364	80.8	3,918	71.4	
40+	594	4.2	242	4.4	
Maternal race/ethnicity					.04
Non-Hispanic Black	283	2.0	133	2.4	
Non-Hispanic White	11,255	80.0	4,380	79.8	
Hispanic	1,313	9.3	475	8.7	
Non-Hispanic Asian	850	6.0	325	5.9	
Other	366	2.6	174	3.2	
Healthcare personnel					<.01
No	8,053	57.3	2,948	53.7	
Yes	5,851	41.6	2,459	44.8	
Not reported	163	1.2	80	1.5	
Urbanicity of residence					<.01
Urban	13,215	93.9	5,080	92.6	
Rural	821	5.8	407	7.4	
Not reported	31	0.2	0	0.0	
Nulliparous					.04
No	8,289	58.9	3,144	57.3	
Yes	5,778	41.1	2,343	42.7	
Obesity					.94
No	11,330	80.5	4,422	80.6	
Yes	2,737	19.5	1,065	19.4	
Hypertension (preexisting or HDP)					.75
No	12,004	85.3	4,692	85.5	
Yes	2,063	14.7	795	14.5	
Diabetes Mellitus (preexisting or GDM)					.11
No	12,578	89.4	4,949	90.2	
Yes	1,489	10.6	538	9.8	
SARS-CoV-2 infection in pregnancy					.48
No	13,561	96.4	5,278	96.2	
Yes	506	3.6	209	3.8	
Unknown	1	0.0	0	0.0	
Plurality					.41
Singleton	13,831	98.3	5,404	98.5	
Multiple	236	1.7	83	1.5	
Delivery method					.96
Cesarean	4,092	29.1	1,587	28.9	
Vaginal	9,951	70.7	3,890	70.9	
Not reported	24	0.2	10	0.2	
Birth year					<.01
2020	27	0.2	12	0.2	
2021	13,872	98.6	5,440	99.1	
2022	167	1.2	35	0.6	
Not reported	1	0.0	0.0	0.0	
Gestational age at delivery					<.01
Early term (37–38 weeks)	4,104	29.2	1,622	29.6	
Term (39–40 weeks)	8,981	63.8	3,549	64.7	
Late or post-term (≥41 weeks)	982	7.0	316	5.8	
Birthweight (grams)					.22
<2500	233	1.7	105	1.9	
2500 to 3999	12,339	87.7	4,841	88.2	
≥4000	1,299	9.2	463	8.4	
Not reported	196	1.4	78	1.4	
Infant sex					.08
Female	7,153	50.9	2,805	51.1	
Male	6,871	48.8	2,675	48.8	
Not reported	43	0.3	7	0.1	

Abbreviations: HPD, hypertensive disorder of pregnancy, GDM, gestational Diabetes Mellitus; LMP, last menstrual period.

[a]C19VPR enrolled women who were vaccinated just prior to or during pregnancy from December 15, 2020 through June 20, 2021. C19VPR infant birth dates ranged from December 19, 2020 to February 10, 2022. PRAMS participants were enrolled from 2019–2021; infants in PRAMS were born during 2019–2022.

[b]Chi Squared tests were used to assess the difference in distributions between matched and unmatched groups. Missing values were excluded from chi-squared tests assessing distribution for delivery method and infant sex.

Table 3. Demographic characteristics of CDC COVID-19 Vaccine Pregnancy Registry (C19VPR) infants and infants born to Pregnancy Risk and Monitoring System (PRAMS) participants from 2019–2022 matched on maternal race and ethnicity and age.

	PRAMS 2019–2022[a] (unvaccinated)		C19VPR 2020–2022[b] (vaccinated)		
	n = 5,487	Col %	n = 5,487	Col %	*p*-value[c]
Participant report of neonatal intensive care unit admission					<.01
No	4,865	88.7	5,063	92.3	
Yes	622	11.3	424	7.7	
Manufacturer of first COVID-19 vaccine dose					N/A
Pfizer-BioNTech	–	–	3,310	57.0	
Moderna	–	–	2,222	40.5	
Janssen	–	–	135	2.5	
Timing of COVID-19 vaccine dose conferring C19VPR eligibility					N/A
Pre-pregnancy (≤30 d before LMP)	–	–	468	8.5	
First trimester	–	–	1,421	25.9	
Second trimester	–	–	2,223	40.5	
Third trimester	–	–	1,375	25.1	
Maternal age at delivery (years)					1.0
<30	1,317	24.2	1,317	24.2	
30–39	3,918	71.4	3,918	71.4	
40+	242	4.4	242	4.4	
Maternal race/ethnicity					1.0
Non-Hispanic Black	133	2.4	133	2.4	
Non-Hispanic White	4,380	79.8	4,380	79.8	
Hispanic	475	8.7	475	8.7	
Non-Hispanic Asian	325	5.9	325	5.9	
Other	174	3.2	174	3.2	
Healthcare personnel					N/A
No	–	–	2,948	53.7	
Yes	–	–	2,459	44.8	
Not reported	–	–	80	1.5	
Urbanicity of residence					<.01
Urban	4,657	84.9	5,080	92.6	
Rural	830	15.1	407	7.4	
Nulliparous					<.01
No	4,125	75.2	3,144	57.3	
Yes	1,362	24.8	2,343	42.7	
Obesity					<.01
No	4,032	73.5	4,422	80.6	
Yes	1,455	26.5	1,065	19.4	
Hypertension (preexisting or HDP)					<.01
No	4,584	83.4	4,692	85.5	
Yes	903	16.5	795	14.5	
Diabetes Mellitus (preexisting or GDM)					<.01
No	4,773	87.0	4,949	90.2	
Yes	714	13.0	538	9.8	
SARS-CoV-2 infection in pregnancy					<.01
No	3,646	66.5	5,278	96.2	
Yes	93	1.7	209	3.8	
Unknown	1,748	31.9	0	0.0	
Plurality					.25
Singleton	5,418	98.7	5,404	98.5	
Multiple	69	1.3	83	1.5	
Delivery method					.96
Vaginal	3,894	71.0	1,587	28.9	
Cesarean	1,592	29.0	3,890	70.9	
Not reported	1	0.0	10	0.2	
Delivery year					<.01
2019	2,605	47.5	0	0.0	
2020	2,401	37.2	12	0.2	
2021	641	11.7	5,440	99.1	
2022	200	3.6	35	0.6	
Gestational age at delivery					<.01
Early term (37 – 38 weeks)	840	15.3	1,622	29.6	
Term (39 – 40 weeks)	4,364	79.5	3,549	64.7	
Late or post-term (≥41 weeks)	283	5.2	316	5.8	
Birthweight (grams)					<.01
<2500	398	7.3	105	1.9	
2500 to 3999	4,609	84.0	4,841	88.2	
≥4000	480	8.8	463	8.4	

(*Continued*)

Table 3. (Continued).

	PRAMS 2019–2022[a] (unvaccinated)		C19VPR 2020–2022[b] (vaccinated)		
	n = 5,487	Col %	n = 5,487	Col %	*p*-value[c]
Not reported	0	0.0	78	1.4	
Infant sex					.14
Female	2,727	49.7	2,805	51.1	
Male	2,760	50.3	2,675	48.8	
Not reported	0	0.0	7	0.1	

Abbreviations: HDP, hypertensive disorder of pregnancy; GDM, gestational Diabetes Mellitus; LMP, last menstrual period; NA, not applicable.
[a]PRAMS participants include those from six states with participant report of NICU admission (Delaware, Kentucky, Mississippi, New Jersey, New Mexico, and Utah). Participants from 2021 and 2022 were excluded if they reported receiving a COVID-19 vaccine or if they did not provide a response to question asking whether they received a COVID-19 vaccine.
[b]C19VPR enrolled women who were vaccinated just prior to or during pregnancy from December 15, 2020 through June 20, 2021. Infant birth dates ranged from December 19, 2020 to February 10, 2022. C19VPR infants were restricted to those born in states with similar NICU admission rates to the included PRAMS states based on National Center for Health Statistics data (10.0 to 14.2%; Alaska, Alabama, Arkansas, Colorado, District of Columbia, Delaware, Iowa, Idaho, Illinois, Indiana, Kentucky, Louisiana, Missouri, Mississippi, Montana, North Dakota, Nebraska, New Jersey, New Mexico, Nevada, New York, Ohio, Pennsylvania, South Carolina, South Dakota, and Utah).
[c]Chi Squared tests were used to assess the difference in distributions between cohorts. Missing values were excluded from chi-squared tests assessing distribution for delivery method and infant sex. Maternal age group and race/ethnicity were matching variables; thus, distributions are completely concordant.

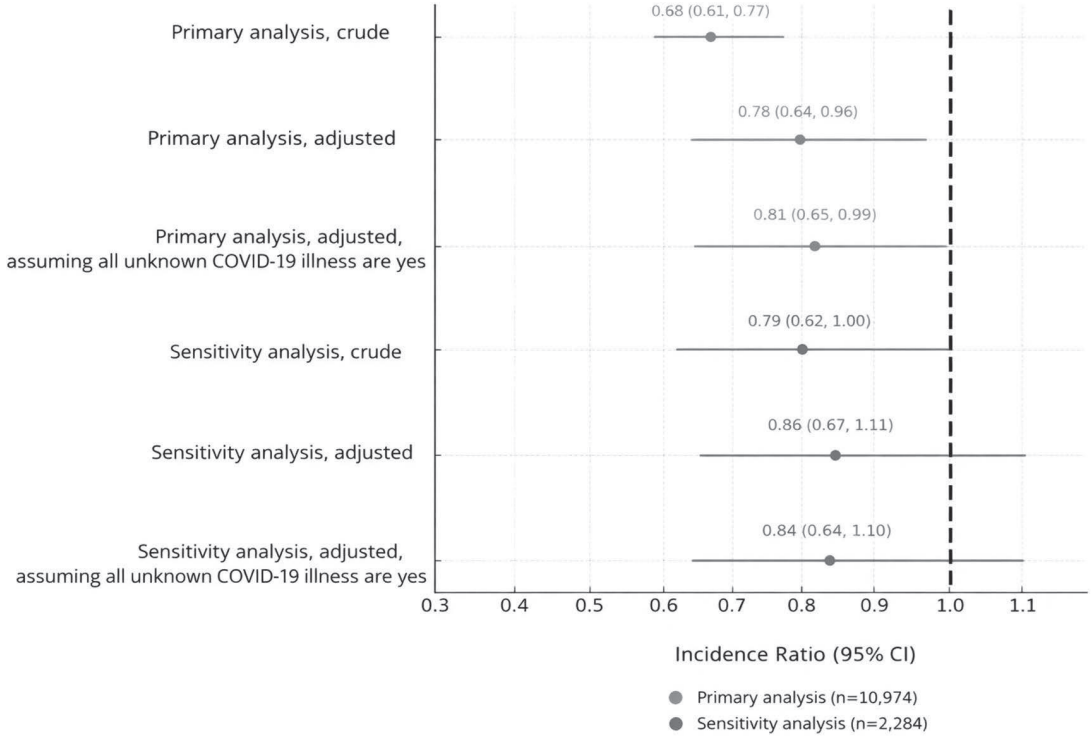


Figure 2. Adjusted[a] incidence ratio of neonatal intensive care unit (NICU) admission among full-term infants in CDC's COVID-19 Vaccine Pregnancy Registry (C19VPR)[b] compared with the pregnancy risk Assessment Monitoring System (PRAMS) based on participant report.[c] Primary analysis: Infants born to women participating in C19VPR from states with similar NICU admission rates to included PRAMS states based on NCHS data (10.0–11.2%; Alaska, Alabama, Arkansas, Colorado, District of Columbia, Delaware, Iowa, Idaho, Illinois, Indiana, Kentucky, Louisiana, Missouri, Mississippi, Montana, North Dakota, Nebraska, New Jersey, New Mexico, Nevada, New York, Ohio, Pennsylvania, South Carolina, South Dakota, and Utah). Sensitivity analysis: Infants born to women in C19VPR from included PRAMS states (Delaware, Kentucky, Mississippi, New Jersey, New Mexico, and Utah). [a]Adjusted for urbanicity, parity, hypertensive disorders of pregnancy, high body mass index (≥30 kg/m^2), preexisting or gestational diabetes, COVID-19 illness during pregnancy, gestational age at delivery group (37–38 weeks' gestation, 39–40 weeks' gestation, and ≥41 weeks' gestation), birthweight group (<2,500 grams, 2500–3999 grams, and ≥4,000 grams), state, and birth year. [b]C19VPR enrolled women who were vaccinated just prior to or during pregnancy from December 15, 2020 through June 20, 2021. Infant birth dates ranged from December 19, 2020 to February 10, 2022. [c]PRAMS participants include those from six states with participant report of NICU admission. Participants from 2021 and 2022 were excluded if they reported receiving a COVID-19 vaccine or if they did not provide a response to question asking whether they received a COVID-19 vaccine.

30 d before the last menstrual period) and first trimester, whereas many other studies did not include, or had a small percentage of, infants of women vaccinated in the first trimester.[13,30,32] We were able to assess associations between NICU admission and timing of vaccination relative to pregnancy. We matched participants by two important potential confounders, race/ethnicity and age, improving comparability between the C19VPR and PRAMS cohorts. We documented good positive predictive value between participant-report and medical record data for NICU admission.

This report has several limitations. C19VPR does not have an unvaccinated group; therefore, we used an unvaccinated cohort from PRAMS. C19VPR and PRAMS participants may not be directly comparable for several reasons. First, C19VPR is a convenience sample of early COVID-19 vaccine adopters and subject to selection bias. Second, although PRAMS employs a random sampling strategy, states may oversample for certain characteristics (e.g., preterm births) that may result in higher NICU admissions compared to a nationally representative sample.[38] Third, the PRAMS cohort only included participants from six states, while C19VPR participants lived primarily in the Southeastern United States. Regional and state variation in COVID-19 vaccine uptake has been documented in state immunization information systems data.[37] Although models adjusting by region or state were unstable due to sparse data for some states, we could adjust for urban versus rural residence. Fourth, PRAMS infants were born in 2019–2022, whereas all C19VPR infants were born after December 2020. Although some studies suggest incidence of NICU admission did not change during the COVID-19 pandemic, others identified decreases in NICU admissions, especially among full-term infants, likely due to changes in thresholds for NICU admission and earlier hospital discharge to reduce virus transmission.[38–41] Though we adjusted for birth year, changes in neonatal care practices during the COVID-19 pandemic may influence differences in NICU admission observed in this study. Data collection also differed for C19VPR and PRAMS participants. Data from PRAMS participants were collected 2–6 months after delivery whereas data from some C19VPR participants were collected as early as 4 weeks after delivery to over 6 months after delivery, depending on the timing of enrollment relative to pregnancy outcome. Because the C19VPR cohort is relatively homogenous, we were only able to match 45% of C19VPR participants with PRAMS participants. However, NICU admission incidence was not significantly different between matched and unmatched C19VPR infants. We were unable to assess timing of NICU admission after birth, length of

NICU stay, and reason for admission as these variables were not collected in PRAMS. Therefore, we were unable to discern if there were any differential patterns in NICU admission and could not differentiate between NICU admissions for serious conditions and those for minor conditions that needed a brief monitoring period Lastly, we could not adjust for some potential confounders, such as some maternal chronic diseases, socio-economic status (e.g., insurance, adequacy of prenatal care), and intrauterine substance exposure.[33,42]

Conclusion

Our report found no evidence for an increased risk of NICU admission among full-term infants whose mothers received a COVID-19 vaccine just prior to or during pregnancy (C19VPR) compared to unvacci-nated mothers (PRAMS). Our findings are consistent with those from other studies evaluating NICU admission among infants of COVID-19 vaccinated mothers and contribute to the evidence suggesting that COVID-19 vaccination during pregnancy does not increase NICU admission.

Note

[a]. Additional states included in the analytic sample for C19VPR with NCHS NICU incidence rates greater than 10.0% and less than 14.2% included Alaska, Alabama, Arkansas, Colorado, District of Columbia, Delaware, Iowa, Idaho, Illinois, Indiana, Kentucky, Louisiana, Missouri, Mississippi, Montana, North Dakota, Nebraska, New Jersey, New Mexico, Nevada, New York, Ohio, Pennsylvania, South Carolina, South Dakota, and Utah.

Acknowledgments

We would like to acknowledge members of the CDC COVID-19 Vaccine Registry Team, including Kieauna Strickland, Samantha Wotiz, John F. Nahabedian III, and Tara Johnson for their contributions to this work. We would also like to acknowledge Abt Associates for their work with interview data collection. We thank the PRAMS Working Group, which includes the PRAMS Team, Division of Reproductive Health, CDC and the following PRAMS sites for their role in conducting PRAMS surveillance and allowing the use of their data: (PRAMS Delaware, PRAMS Kentucky, PRAMS Mississippi, PRAMS New Jersey, PRAMS New Mexico, and PRAMS Utah).

Ms Madni and Dr Andrea Sharma had full access to all data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Author contributions

CRediT: **Lauren Head Zauche:** Conceptualization, Data curation, Writing – original draft, Writing – review & editing, Project administration; **Sabrina A. Madni:** Conceptualization, Data curation, Formal analysis, Writing – original draft, Writing – review & editing, Project administration; **David K. Shay:** Conceptualization, Writing – review & editing, Supervision; **Christine K. Olson:** Data curation, Writing – review & editing, Supervision; **Aliza Machefsky:** Data curation, Writing – review & editing; **Shana E. Godfred Cato:** Data curation, Writing – review & editing; **Andrea J. Sharma:** Conceptualization, Data curation, Formal analysis, Project administration, Supervision.

Funding

No external funding; CDC funds supported this work. This activity did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Notes on contributor

Lauren Head Zauche is a Nurse Consultant in the Immunization Safety Office in the Division of Healthcare Quality and Promotion at the Centers for Disease Control and Prevention.

Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

References

1 Norman M, Navér L, Söderling J, Ahlberg M, Hervius Askling H, Aronsson B, Byström E, Jonsson J, Sengpiel V, Ludvigsson JF, et al. Association of maternal SARS-CoV-2 infection in pregnancy with neonatal outcomes. JAMA. 2021;325(20):2076–2086. doi: 10.1001/jama.2021.5775.

2 Neelam V, Reeves EL, Woodworth KR, O'Malley Olsen E,

Reynolds MR, Rende J, Wingate H, Manning SE, Romitti P, Ojo KD, et al. Pregnancy and infant outcomes by trimester of SARS-CoV-2 infection in pregnancy-SET-NET, 22 jurisdictions, January 25, 2020–December 31, 2020. Birth Defects Res. 2023;115 (2):145–159. doi: 10.1002/bdr2.2081.
3 Olsen EO, Roth NM, Aveni K, Santos P, Sizemore L, Halai U-A, Nestoridi E, Barton JE, Mobley E, Siebman S, et al. SARS-CoV-2 infections among neonates born to pregnant people with SARS-CoV-2 infection: maternal, pregnancy and birth characteristics. Paediatr Perinat Epidemiol. 2022;36(4):476–484. doi: 10.1111/ ppe.12883.
4 Carlsen E, Magnus MC, Oakley L, Fell DB, Greve-Isdahl M, Kinge JM, Håberg SE. Association of COVID-19 vaccination during pregnancy with incidence of SARS-CoV-2 infection in infants. JAMA Intern Med. 2022;182 (8):825–831. doi: 10.1001/ jamainternmed.2022.2442.
5 Halasa NB, Olson SM, Staat MA, Newhams MM, Price AM, Pannaraj PS, Boom JA, Sahni LC, Chiotos K, Cameron MA, et al. Maternal vaccination and risk of hospitalization for COVID-19 among infants. N Engl J Med. 2022;387(2):109–119. doi: 10.1056/NEJMoa2204399.
6 Kharbanda EO, Haapala J, DeSilva M, Vazquez-Benitez G, Vesco KK, Naleway AL, Lipkind HS. Spontaneous abortion following COVID-19 vaccination during pregnancy. JAMA. 2021;326(16):1629–1631. doi: 10.1001/ jama.2021.15494.
7 Denoble AE, Vazquez-Benitez G, Sheth SS, Ackerman-Banks CM, DeSilva MB, Zhu J, Daley MF, Getahun D, Klein NP, Vesco KK, et al. Coronavirus disease 2019 (COVID-19) vaccination and stillbirth in the Vaccine Safety Datalink. Obstet Gynecol. 2024;144(2):215–222. doi: 10.1097/aog.0000000000005632.
8 Razzaghi H, Kahn KE, Calhoun K, Garacci E, Skoff TH, Ellington SR, Jatlaoui TC, Black CL. Influenza, Tdap, and COVID-19 vaccination coverage and hesitancy among pregnant women - United States, April 2023. MMWR Morb Mortal Wkly Rep. 2023;72(39):1065–1071. doi: 10.15585/mmwr.mm7239a4.
9 Martin JA, Osterman MJK. Increases in neonatal intensive care admissions in the United States, 2016-2023. NCHS Data Brief. 2025;(525). doi: 10.15620/cdc/174581.
10 Hughes CS, Schmitt S, Passarella M, Lorch SA, Phibbs CS. Who's in the NICU? A population-level analysis. J Perinatol. 2024;44(10):1416–1423. doi: 10.1038/s41372-024-02039-6.
11 Prasad S, Kalafat E, Blakeway H, Townsend R, O'Brien P, Morris E, Draycott T, Thangaratinam S, Le Doare K, Ladhani S, et al. Systematic review and meta-analysis of the effectiveness and perinatal outcomes of COVID-19 vaccination in pregnancy. Nat Commun. 2022;13(1):2414. doi: 10.1038/s41467-022-30052-w.
12 Ding C, Liu Y, Pang W, Zhang D, Wang K, Chen Y. Associations of COVID-19 vaccination during pregnancy with adverse neonatal and maternal outcomes: a systematic review and meta-analysis. Front Public Health. 2023;11:1044031. doi: 10.3389/fpubh.2023.1044031.
13 Fell DB, Dhinsa T, Alton GD, Török E, Dimanlig-Cruz S, Regan AK, Sprague AE, Buchan SA, Kwong JC, Wilson SE, et al. Association of COVID-19 vaccination in pregnancy with adverse peripartum outcomes. JAMA. 2022;327(15):1478–1487. doi: 10.1001/jama.2022.4255.
14 Fell DB, Dimanlig-Cruz S, Török E, Håberg SE, Regan AK, Kaufman JS, Platt RW, Gravel CA, Bruce L, Shah PS, et al. Pregnancy, fetal, and neonatal outcomes after a first booster dose of COVID-19 vaccine during pregnancy in Ontario, Canada: population based, retrospective cohort study. BMJ Med. 2023;2(1):e000632. doi: 10.1136/ bmjmed-2023-000632.
15 Jorgensen SCJ, Drover SSM, Fell DB, Austin PC, D'Souza R, Guttmann A, Buchan SA, Wilson SE, Nasreen S, Schwartz KL, et al. Newborn and early infant outcomes following maternal COVID-19 vaccination during pregnancy. JAMA Pediatr. 2023;177(12):1314–1323. doi: 10.1001/jamapediatrics.2023.4499.
16 Rahmati M, Yon DK, Lee SW, Butler L, Koyanagi A, Jacob L, Shin JI, Smith L. Effects of COVID-19 vaccination during pregnancy on SARS-CoV-2 infection and maternal and neonatal outcomes: a systematic review and meta-analysis. Rev Med Virol. 2023;33(3):e2434. doi: 10.1002/rmv.2434.
17 Zhang D, Huang T, Chen Z, Zhang L, Gao Q, Liu G, Zheng J, Ding F. Systematic review and meta-analysis of neonatal outcomes of COVID-19 vaccination in pregnancy. Pediatr Res. 2023;94(1):34–42. doi: 10.1038/s41390-022-02421-0.
18 Harrison W, Goodman D. Epidemiologic trends in neonatal intensive care, 2007-2012. JAMA Pediatr. 2015;169 (9):855–862. doi: 10.1001/jamapediatrics.2015.1305.
19 Ananth CV, Vintzileos AM. Maternal-fetal conditions necessitating a medical intervention resulting in preterm birth. Am J Obstet Gynecol. 2006;195(6):1557–1563. doi: 10.1016/j. ajog.2006.05.021.
20 Goldenberg RL, Culhane JF, Iams JD, Romero R. Epidemiology and causes of preterm birth. Lancet. 2008;371 (9606):75–84. doi: 10.1016/s0140-6736(08)60074-4.
21 Madni SA, Sharma AJ, Zauche LH, Waters AV, Nahabedian JF, Johnson T, Olson CK. CDC COVID-19 vaccine pregnancy registry: design, data collection, response rates, and cohort description. Vaccine. 2024;42 (7):1469–1477. doi: 10.1016/j. vaccine.2023.11.061.
22 Shulman HB, D'Angelo DV, Harrison L, Smith RA, Warner L. The Pregnancy Risk Assessment Monitoring System (PRAMS): overview of design and methodology. Am J Public Health. 2018;108(10):1305–1313. doi: 10. 2105/ajph.2018.304563.
23 Centers for Disease Control and Prevention. Pregnancy Risk Assessment Monitoring System. Updated 2024 May 15 [accessed 2024 Nov 29]. https://www.cdc.gov/prams/php/ methodology/index.html.
24 US Department of Health and Human Services. COVID-19 vaccines. [accessed 2024 Apr 22].
25 Iwagami M, Shinozaki T. Introduction to matching in case-control and cohort studies. Ann Clin Epidemiol. 2022;4(2):33–40. doi: 10.37737/ace.22005.
26 Chen W, Qian L, Shi J, Franklin M. Comparing performance between log-binomial and robust Poisson regression models for estimating risk ratios under model misspecification. BMC Med Res Methodol. 2018;18 (1):63. doi: 10.1186/s12874-018-0519-5.
27 Yelland LN, Salter AB, Ryan P. Performance of the modified Poisson regression approach for estimating relative risks from clustered prospective data. Am J Epidemiol. 2011;174(8):984–992. doi: 10.1093/aje/kwr183.
28 Lee PH. Should we adjust for a confounder if empirical and theoretical criteria yield contradictory results? A simulation study. Sci Rep. 2014;4(1):6085. doi: 10.1038/srep06085.
29 VanderWeele TJ, Ding P. Sensitivity analysis in observational research: introducing the E-value. Ann Intern Med. 2017;167(4):268–274. doi: 10.7326/M16-2607.
30 Blakeway H, Prasad S, Kalafat E, Heath PT, Ladhani SN, Le Doare K, Magee LA, O'Brien P, Rezvani A, von Dadelszen P, et al. COVID-19 vaccination during pregnancy: coverage and safety. Am J Obstet Gynecol. 2022;226(2):.e236.1–.e236.14. doi: 10.1016/j.ajog.2021.08.007.
31 Magnus MC, Örtqvist AK, Dahlqwist E, Ljung R, Skår F, Oakley L, Macsali F, Pasternak B, Gjessing HK, Håberg SE, et al. Association of SARS-CoV-2 vaccination during pregnancy with pregnancy outcomes. JAMA. 2022;327(15):1469–1477. doi:

10.1001/jama.2022.3271.
32 Theiler RN, Wick M, Mehta R, Weaver AL, Virk A, Swift M. Pregnancy and birth outcomes after SARS-CoV-2 vaccination in pregnancy. Am J Obstet Gynecol MFM. 2021;3(6):100467. doi: 10.1016/j.ajogmf.2021.100467.
33 Haidari ES, Lee HC, Illuzzi JL, Lin H, Xu X. Utility of birth certificate data for evaluating hospital variation in admissions to NICUs. Hosp Pediatr. 2020;10(2):190–194. doi: 10.1542/hpeds.2019-0116.
34 Pineda R, Kati K, Breault CC, Rogers EE, Mack WJ, Fernandez-Fernandez A. Nicus in the US: levels of acuity, number of beds, and relationships to population factors. J Perinatol. 2023;43(6):796–805. doi: 10.1038/s41372-023-01693-6.
35 Saelee R, Zell E, Murthy BP, Castro-Roman P, Fast H, Meng L, Shaw L, Gibbs-Scharf L, Chorba T, Harris LQ, et al. Disparities in COVID-19 vaccination coverage between urban and rural counties - United States, December 14, 2020-January 31, 2022. MMWR Morb Mortal Wkly Rep. 2022;71(9):335–340. doi: 10.15585/ mmwr.mm7109a2.
36 Dietz P, Bombard J, Mulready-Ward C, Gauthier J, Sackoff J, Brozicevic P, Gambatese M, Nyland-Funke M, England L, Harrison L, et al. Validation of self-reported maternal and infant health indicators in the Pregnancy Risk Assessment Monitoring System. Matern Child Health J. 2014;18(10):2489–2498. doi: 10.1007/s10995-014-1487-y.
37 Greene NH, Kilpatrick SJ, Wong MS, Ozimek JA, Naqvi M. Impact of labor and delivery unit policy modifica-tions on maternal and neonatal outcomes during the coronavirus disease 2019 pandemic. Am J Obstet Gynecol MFM. 2020;2(4):100234. doi: 10.1016/j.ajogmf.2020.100234.
38 Harrison WN, Wasserman JR, Goodman DC. Regional variation in neonatal intensive care admissions and the relationship to bed supply. J Pediatr. 2018;192:73–79.e4. doi: 10.1016/j.jpeds.2017.08.028.
39 Hawco S, Rolnik DL, Woolner A, Cameron NJ, Wyness V, Mol BW, Black M. The impact of mitigation measures on perinatal outcomes during the first nine months of the COVID-19 pandemic: a systematic review with meta-analysis. Eur J Obstet, Gynecol, Reprod Biol. 2022;274:117–127. doi: 10.1016/j.ejogrb.2022.05.007.
40 Kocherlakota P, Lin L, Gill H, Joseph J, Trydal L. Effect of the COVID-19 pandemic on well-baby nursery. Am J Perinatol. 2021;39(6):683–690. doi: 10.1055/a-1673-0708.
41 Riley T, Nethery E, Chung EK, Souter V. Impact of the COVID-19 pandemic on perinatal care and outcomes in the United States: an interrupted time series analysis. Birth. 2022;49(2):298–309. doi: 10.1111/birt.12606.
42 Sriram K, Umer A, Hamilton C, John CC, Lilly C. Abstract p387: risk factors for neonatal intensive care unit admission; project watch, 2012-2017. Circulation. 2020;141(Suppl_1):AP387–AP387. doi: 10.1161/circ.141. suppl1.P387.w

News…continued from page 21
gestational age; median gestational age, 29.6 weeks; median birth weight, 1170 g) admitted to the neonatal unit at a tertiary referral hospital in Spain between 2020 and 2024. All infants received exclusively human milk during hospitalisation, which consisted of the mother's own milk and/or pasteurised donor human milk matched to recipients' gestational age and lactation stage; formula was introduced only shortly before discharge when needed. Infants were categorised on the basis of the type of feeding at discharge (exclusive or mixed human milk vs exclusive formula), the predominant type of human milk received during hospitalisation (> 50% donor human milk vs > 50% mother's own milk), and the severity of bronchopulmonary dysplasia (BPD; no BPD/grade 1 vs grade 2-3). All infants were followed up from birth until 18 months to assess long-term respiratory outcomes. Infants discharged on human milk feeding had fewer respiratory hospital admissions than those discharged on exclusive formula feeding (15% vs 25%), with 45% lower odds after adjusting for BPD (adjusted odds ratio, 0.55; $P < .05$ for both). Respiratory hospital admissions during the first 18 months of life, emergency department (ED) visits, or the incidence of BPD did not differ significantly between infants who received predominantly pasteurised donor human milk and those who received the mother's own milk during hospitalisation. Infants with grade 2-3 BPD experienced significantly higher respiratory hospital admissions (33% vs 15%) and had more frequent ED visits for bronchiolitis or bronchospasm (60% vs 36%) than those without BPD or with grade 1 BPD ($P < .01$ for both). The incidence of grade 2-3 BPD did not differ significantly according to the predominant type of human milk received during hospitalisation or the type of feeding at discharge. "Our findings highlight the potential value of supporting human milk feeding at discharge in very preterm infants, both as a marker of intended post-discharge feeding practices and as a modifiable and feasible intervention to reduce respiratory morbidity," the authors wrote.

Danaher Buys Masimo in Huge Deal

Masimo Corporation, a leading global medical innovator, announced that it has entered into a definitive agreement pursuant to which Danaher Corporation will acquire Masimo for $180 per share in cash, representing a total consideration of $9.9 billion. The Transaction has been unanimously approved by both Masimo's Board of Directors and Danaher's Board of Directors. Masimo will become a standalone business unit and brand within Danaher's Diagnostics segment and will operate autonomously while strengthening Danaher's offering in acute care settings.

Katie Szyman, Chief Executive Officer of Masimo, stated: "We look forward to joining Danaher and continuing our growth and momentum as the global leader in patient monitoring. Danaher shares our commitment to investing in talent and innovation and will be an ideal fit to help power the next chapter of Masimo. Importantly, becoming part of Danaher's Diagnostics segment will strengthen our ability to scale our monitoring technologies globally and accelerate our mission of delivering Masimo innovations that empower clinicians to transform patient care."

Michelle Brennan, Chairman of Masimo's Board of Directors, stated: "This transaction represents a unique opportunity to deliver certain and premium value for Masimo's shareholders, enhance outcomes for customers and patients, and provide compelling career growth paths for our employees across the world. The Board evaluated a broad range of opportunities over the past several months—which included pursuing our standalone strategy—and engaged with multiple other potential partners. Ultimately, it became evident that this transaction with Danaher was the most value-enhancing path for Masimo and all its stakeholders." The Transaction is subject to the satisfaction or waiver of certain closing conditions, including the receipt of required regulatory approvals. It is expected to close in the second half of 2026. Masimo will report its fourth quarter and full-year 2025 results on February 26. Due to the Transaction, Masimo will not be hosting an earnings conference call. Centerview Partners LLC acted as financial advisor to Masimo, and Morgan Stanley & Co. LLC also provided financial advice to Masimo. Sullivan & Cromwell LLP and White & Case LLP served as legal advisors to Masimo in connection with the Transaction. Longacre Square Partners acted as strategy and communications advisor to Masimo. Masimo (NASDAQ: MASI) is a global medical technology company that develops and produces a wide array of industry-leading monitoring technologies, including innovative measurements, sensors, patient monitors, and automation and connectivity solutions. Our mission is to improve life, improve patient outcomes, reduce the cost of care, and take noninvasive monitoring to new sites and applications. Masimo SET Measure-through Motion and Low Perfusion pulse oximetry, introduced in 1995, has been shown to outperform other pulse oximetry technologies in over 100 independent and objective studies, which can be found at www.masimo.com/evidence/featured-studies/feature.

Early Neonatal Infection Linked to Cognitive Risk Later

Among infants born near term to term, early-onset neonatal infection (EONI), particularly sepsis and meningitis, was associated with a higher risk for intellectual disability and special educational needs; early-onset meningitis was linked to a markedly higher risk for cognitive impairment than early-onset sepsis. Researchers conducted a nationwide cohort study to evaluate whether EONI among infants born near term to term is linked to long-term cognitive impairment, particularly intellectual disability and the need for special educational support. EONI was defined as sepsis or meningitis occurring within the first week after birth and included both probable cases (a physician-assigned diagnosis of infection using standardised disease codes) and culture-positive cases (a pathogen cultured from the blood or cerebrospinal fluid). Data from linked national registries, including a medical birth register in Denmark, were used. The analysis included 993,362 liveborn infants born near term to term between 1997 and 2013, with follow-up until 2021. Outcomes were intellectual disability and special educational needs. Intellectual ability was defined using standardised codes. Special educational needs were defined as provision received in either a regular or special education class with at least 9 hours per week on average. Overall, 8267 infants had early-onset sepsis and 149 had early-onset meningitis; of these, 260 had culture-positive sepsis and 31 had culture-positive meningitis. Early-onset sepsis was associated with a higher risk for intellectual disability (adjusted hazard ratio [aHR], 2.24; 95% CI, 1.93-2.60) and an increased risk for special educational needs (aHR, 1.49; 95% CI, 1.40-1.59). Infants with early-onset meningitis had an approximately eightfold higher risk for intellectual disability and a nearly threefold higher risk for special educational needs. Higher risks for intellectual disability and special educational needs were observed in the full cohort (probable plus culture-positive EONI), and similar outcomes were observed in culture-positive EONI alone. "EONI in near-term to term children, defined by both probable and culture-positive infections, was associated with an increased risk of intellectual disability and special educational needs. Early-onset meningitis was less frequent than sepsis but associated with higher risks," the authors of the study wrote. This study was led by Mads Andersen and Gunvor Bak Rohde, Pediatrics

and Adolescent Medicine, Aarhus University Hospital, Aarhus, Denmark. It was published online on February 24, 2026, in *Archives of Disease in Childhood—Fetal and Neonatal Edition*.

More Parents Declining Vitamin K Shot for Newborns

A small but growing number of parents in the US are declining the routine vitamin K injection for their newborns. Preliminary findings from a new review suggest that although the US refusal rate is still less than 1%, investigators report that it is trending upward in the US and globally. "Vitamin K refusal, though uncommon, is rising and poses disproportionate neurologic risk, including intracranial hemorrhage [ICH], death, and long-term disability," study investigator Beatriz De Faria Sousa, a medical student and researcher at Florida International University Herbert Wertheim College of Medicine in Miami, said. The increasing rate of refusing the vitamin K shot appears to reflect broader healthcare hesitancy among parents, she added. Vitamin K is a vital nutrient needed for normal blood clotting. Newborns are born with very low levels of the vitamin and receive only limited amounts through breast milk. When a newborn has insufficient vitamin K, they may develop vitamin K deficiency bleeding (VKDB). Infants with VKDB can present with ICH, which carries a significant risk for mortality and long-term neurologic disability, said De Faria Sousa. Research shows that a single intramuscular (IM) injection of vitamin K at birth effectively protects against VKDB. The shot has been routinely administered since the American Academy of Pediatrics first recommended it in 1961, with other organizations—including the Canadian Paediatric Society—subsequently adopting similar guidance. However, despite proven safety, the investigators noted that refusal of IM vitamin K is rising worldwide, paralleling vaccine hesitancy. The goal of the study was to review recent trends in vitamin K refusal and assess resulting neurologic consequences. The analysis included 25 peer-reviewed studies identified through a systematic literature review covering 2005-2025. These comprised retrospective cohort studies, surveys, qualitative studies, case series, national surveillance reports, and reviews and were conducted in several countries, including the US, Canada, New Zealand, Australia, and Scotland. The results showed that refusal rates in the US remain low—below 1% in most hospitals—but pointed to upward trends in some states. In Minnesota, for example, the rate rose from 0.9% in 2015 to 1.6% in 2019. In California, Connecticut, and Iowa, refusal rates ranged from 0.2% to 1.3% in 2018-2019.

Midtrimester Cervix Predicts Recurrent Preterm Birth

Women with a history of spontaneous preterm birth (sPTB) and a cervical length > 25-30 mm during the midtrimester had approximately threefold higher odds of recurrent sPTB before 37 weeks of gestation than those with a cervical length > 30 mm; however, a change in cervical length from 14 + 0 to 23 + 6 weeks was not associated with recurrent sPTB. Researchers conducted a retrospective cohort study to evaluate whether cervical length shortening is associated with a recurrent sPTB in women with a history of sPTB and a cervical length > 25 mm before 24 weeks of gestation. They included 469 singleton pregnancies in women with a prior sPTB before 34 weeks of gestation who had a subsequent singleton pregnancy with multiple cervical length measurements before 24 weeks of gestation, all > 25 mm, from two academic hospitals in Netherlands between February 2005 and September 2021. The cervical length was measured transvaginally by experienced sonographers following the Fetal Medicine Foundation guidelines at three timepoints —14 + 0 to 18 + 6, 19 + 0 to 20 + 6, and 21 + 0 to 23 + 6 weeks. Shortening was defined as at least a 1 mm decrease from the prior measurement and was reported using a clinical cutoff of 5 and 10 mm or more. The primary outcome was sPTB, defined as birth before 37 weeks of gestation that began with spontaneous contractions or spontaneous rupture of membranes. Researchers assessed the association between cervical length shortening during the second trimester and sPTB before 37, 34, and 28 weeks of gestation. Overall recurrence rates of sPTB were 21.1% before 37 weeks, 9.0% before 34 weeks, and 1.9% before 28 weeks of gestation. At 21 + 0 to 23 + 6 weeks, women with a cervical length > 25-30 mm had higher odds of recurrent sPTB before 37 weeks of gestation than those with a cervical length > 30 mm (odds ratio, 3.6; 95% CI, 1.91-6.66). The change in cervical length from 14 + 0 to 23 + 6 weeks was not associated with the risk for sPTB before 37, 34, and 28 weeks of gestation; however, the absolute cervical length was strongly linked to recurrent sPTB. "The absolute cervical length is more associated with a sPTB than a decrease in cervical length. This study supports the current guidelines which advise to continue serial cervical length measurements at least up to 23 + 6 weeks of gestation," the authors wrote. This study was led by Emilie V.J. van Limburg Stirum and Sofie H. Breuking, Amsterdam UMC, University of Amsterdam, Amsterdam, Netherlands. It was published online on February 23, 2026, in Archives of Gynecology and Obstetrics.

Activity Before and During Pregnancy Linked to Enhanced Infant Motor Development

Maternal physical activity before and during pregnancy is associated with improved neurodevelopmental outcomes in children, particularly motor function between age 6 months and 1 year. Among 38,219 mother-child pairs, higher prepregnancy activity showed more than 30% higher odds for enhanced gross motor skills at 6 months, while midpregnancy activity demonstrated 60% higher odds for fine motor development. Researchers analyzed data from the Japan Environment and Children's Study, a nationwide birth cohort that recruited approximately 100,000 mother-child pairs between January 2011 and March 2014, with 38,219 pairs included in the final analysis after exclusions. Maternal physical activity levels were assessed using the International Physical Activity Questionnaire (IPAQ) at two timepoints: before pregnancy and during midpregnancy (16-27 weeks' gestation), with physical activity classified into three categories based on metabolic equivalent minutes per week. Child neurodevelopment was evaluated using the Ages and Stages Questionnaires, Third Edition (ASQ-3) at 6-month intervals from 6 months to 3 years of age, assessing five developmental domains: communication, gross motor skills, fine motor skills, problem solving, and personal-social skills. Multivariable logistic regression models were used to examine associations between maternal physical activity and child neurodevelopment, adjusting for gestational age, birth weight, maternal age, prepregnancy BMI, predelivery BMI, group childcare attendance, siblings, family income, and parental education. Analysis was conducted between June 2024 and June 2025, with participants excluded if they had missing ASQ-3 data at any timepoint, maternal BMI outliers of ±5 standard deviations, or maternal physical activity outliers according to IPAQ guidelines. Higher prepregnancy physical activity was associated with higher odds across all ASQ-3 domains at 6 months, with particularly strong associations in communication (odds ratio [OR] vs no activity, 1.61; 95% CI, 1.04-2.45), gross motor skills (OR vs no activity, 1.37; 95% CI, 1.22-1.54), and fine motor skills (OR vs no activity, 1.32; 95% CI, 1.13-1.54) domains. Midpregnancy physical activity showed associations with higher odds in gross motor skills (moderate to high activity vs no activity OR, 1.18; 95% CI, 1.06-1.33), fine motor skills (moderate to high activity vs no activity OR, 1.60; 95% CI, 1.37-1.86), and problem solving (moderate to high activity vs no activity OR, 1.23; 95% CI, 1.10-1.38)

domains at 6 months. At 3 years of age, maternal physical activity showed limited associations, with only prepregnancy activity linked to higher odds in the problem-solving domain (OR, 1.16; 95% CI, 1.01-1.34), while midpregnancy activity showed no association with any ASQ-3 domain. More midpregnancy physical activity was associated with reduced rates of preterm birth (4.1% overall, with 5.5% in no activity group vs 3.3% in high activity group; $P < .001$) and low birth weight of < 5.5 lb (8.8% in no activity group vs 7.3% in high activity group; $P < .001$). "In this cohort study of mother-child pairs, maternal physical activity before and during pregnancy was associated with child neurodevelopment, particularly for motor function between 6 months and 1 year of age. Further investigations are required to find the physiological mechanisms explaining how maternal physical activity affects child neurodevelopment," wrote the authors of the study. The study was led by Io Kumasaka, MD, Department of Development and Environmental Medicine, Tohoku University Graduate School of Medicine, Sendai, Japan, and Chiharu Ota, MD, PhD, Department of Pediatrics, Tohoku University Hospital, Sendai, Japan. It was published online March 3 in JAMA Network Open.

Every second counts in the NICU – so you need to start iNO therapy fast

The ULSPIRA Solution™ has you covered

Scan to visit **ulspira.com** to view ULSPIRA TS Safety Statement

Take your iNO therapy to a new level

ULSPIRA TS™

Our iNO delivery device features a short Pre-Use Check to start treatment fast – in about 5 minutes, vs. up to twice as long for some devices. Plus:

- **Fully disposable patient consumables/ kits** for decreased contamination risk
- **High ppm delivery,** even with high flows
- **Automatic cylinder switch and purge** to prevent therapy interruptions
- **24/7/365 access** to Clinical Application Specialists (RRTs) via our dedicated hotline

ULSPIRA Care+™

Our Total Gas Management (TGM) program provides you with a TGM tech as your single point of contact to handle daily, routine tasks. Plus:

- **Cylinder management and transport** by hightly trained technicians
- **Multiple pricing options** to manage your spend and eliminate counting cylinders and tracking iNO usage
- **Inventory control and supply management,** letting staff focus more on patient care

ULSPIRA Solution™

The ULSPIRA Solution™ includes an easy-to-use nitric oxide (NO) delivery device and our customizable program for service and support. Now you can spend less time on routine tasks so that you can focus on what's most important – your patients.

Don't delay – ask for your in-person demo today at ulspira.com

Always *There*

Airgas Therapeutics
an Air Liquide company

NEOTECH®
People • Passion • Products

Leads that Lasts!

NeoLead®
ECG ELECTRODES

Featuring a unique combination of hydrogel and NeoBond Hydrocolloid for longer lasting, more effective adhesion.

Standard (not shown)
The first with hydrocolloid

Mini
Same sensor, smaller footprint

Radiolucent
Nearly invisible on x-rays

Micro
Ideal limb leads

5-up Pediatric (not shown)
Multi-channel, continuous monitoring

Made in the USA

Clinician Invented

FOR A FREE SAMPLE
VISIT
neotech-neonatalic.com

For more information visit neotech-neonatalic.com