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The ULSPIRA TS™ Nitric Oxide Therapy System is intended for use by healthcare professionals for the delivery of nitric oxide (NO) and the monitoring of inspired NO, NO_2 and O_2 concentrations for a patient undergoing inhaled Nitric Oxide (iNO) therapy.

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DEVICE WARNINGS

- Persons using ULSPIRA TS must be trained and experienced in its use to ensure effective administration of nitric oxide and to avoid injury to the patient or to others resulting from inhalation of excess NO, NO2 or other reaction products.
- Always perform a Pre-Use Check before connecting ULSPIRA TS to the patient. Only use the system if the Pre-Use Check is successfully passed.
- If an unintended treatment interruption occurs, use the backup system.
- ULSPIRA TS must not be used in an MRI environment.

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Publisher's Note

This Winter issue of *Neonatal Intensive Care* marks an important milestone for our publication as we introduce a new digital edition designed to expand access, deepen engagement, and better serve the evolving needs of the NICU community.

For decades, *Neonatal Intensive Care* has been trusted as a clinical and professional resource for neonatologists, nurses, respiratory therapists, and NICU leaders. The new digital edition builds on that foundation while opening the door to a more flexible and accessible reading experience. Readers will notice a more dynamic cover presentation, expanded editorial content, and a broader range of articles per issue—allowing us to address more clinical topics, emerging research, and practical challenges facing neonatal care teams.

Perhaps most importantly, the digital format enhances how content can be used and shared. Articles are now easier to access across devices, simpler to share with colleagues, and more practical for education, discussion, and reference within the NICU. Whether reviewing a clinical feature during rounds, forwarding a relevant article to a team member, or revisiting a past issue for guidance, the digital edition supports real-world use in ways print alone cannot.

This expanded access also allows us to bring more voices and perspectives into each issue—highlighting new research, evolving best practices, and innovations that directly impact patient care. Our goal is not only to inform, but to create a platform that supports collaboration, learning, and continuous improvement across neonatal care settings.

We are proud to introduce this new chapter for *Neonatal Intensive Care* and look forward to continuing our mission of delivering timely, relevant, and clinically meaningful content—now with greater reach and flexibility than ever before.

— **Steve Goldstein**
Publisher
Goldstein & Associates, Inc.

News

☐ Winter 2026

Two Rare Neurologic Disorders Added to US Newborn Screening Panel

The US Department of Health and Human Services (HHS) has added two rare congenital neurologic disorders — Duchenne muscular dystrophy (DMD) and metachromatic leukodystrophy (MLD) — to the newborn screening panel, stating that early detection will give children access to FDA-approved therapies that can slow disease progression.

"Early data changes the entire trajectory for affected children and their families," said Health Resources and Services Administration (HRSA) Administrator Tom Engels in a statement. "A confirmed result in infancy replaces years of guesswork and helps families make informed decisions about treatment and support," he added.

HHS noted that most children with DMD or MLD are diagnosed at ages 4-5, by which time substantial muscle loss or functional decline has often already occurred. In the US, DMD affects an estimated 1 in 3600 male births, primarily boys, whereas MLD occurs in roughly 1 in 40,000 births. The agency said the decision to add both conditions to the Recommended Uniform Screening Panel (RUSP) followed "scientific review and public comment." The additions were initially proposed in two separate publications in the Federal Register in August. HHS had by then fired — without explanation — all the members of the Advisory Committee on Heritable Disorders in Newborns and Children, the two-decade-old panel that developed the RUSP. The committee was disbanded in April, which "came just weeks before a scheduled vote on whether to recommend metachromatic leukodystrophy and Duchenne muscular dystrophy for inclusion on the RUSP," attorneys Spreeha Choudhury and Richard Hughes IV wrote in an article in *Health Affairs* that warned of the potential implications of its dissolution. The HRSA-administered advisory committee has never been reconstituted; however, the evidence it reviewed and prepared in support of adding DMD and MLD remains available on the committee's homepage.

Antenatal Steroids Tied to Lower BPD Risk in Preemies

Antenatal corticosteroid (ACS) courses administered before delivery in pregnancies at high risk for preterm birth were associated with a reduced risk for moderate-to-severe bronchopulmonary dysplasia (BPD) in very preterm infants, with complete courses offering greater protection. Researchers conducted a prospective, multicenter cohort study to evaluate the association between ACS exposure and BPD in very preterm infants and to assess the potential mediating effects of respiratory distress syndrome and invasive mechanical ventilation. They enrolled 1097 preterm infants (median gestational age, 28.71 weeks; 44% girls among those with known sex) who were admitted to an NICU within 24 hours of birth and hospitalized for more than 2 weeks. ACS exposure was classified as a complete course (two doses of betamethasone or four doses of dexamethasone administered ≥ 24 hours before delivery), an incomplete course (1-2 doses of betamethasone or 1-4 doses of dexamethasone given < 24 hours before delivery), or no ACS. The primary outcome was moderate-to-severe BPD at 36 weeks' corrected gestational age, as per standard BPD severity criteria; BPD was defined as oxygen dependence for ≥ 28 days. Secondary outcomes were severe respiratory distress syndrome and the duration ofinvasive mechanical ventilation. Complete ACS courses were associated with a lower risk for moderate-to-severe BPD than no ACS (adjusted risk ratio [aRR], 0.68; $P = .02$); incomplete ACS courses showed a smaller protective association (aRR, 0.78; $P = .04$). Compared with no ACS, complete ACS courses were linked with a lower risk for severe respiratory distress syndrome (aRR, 0.67; $P = .002$) and with a reduction in the duration of invasive mechanical ventilation

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(beta-coefficient = -2.003; $P < .001$). The protective association of complete ACS courses was strongest among singleton infants ($P = .004$), those born at 28+0 to 28+6 weeks' gestation ($P = .01$), and those delivered vaginally ($P = .01$). Mediation analysis indicated that ACS reduced the risk for BPD through both a direct pathway (62%) and indirect pathways (38%) — by lowering the risk for severe respiratory distress syndrome or reducing the duration of invasive mechanical ventilation and through a combined pathway linking both. "Emphasizing the importance of timely ACS completion and postnatal airway management may help optimize neonatal pulmonary outcomes," the authors wrote. "[The study] provides, however, a significant contribution in clarifying the mechanisms of action of ACS at a population level (the why)," experts wrote in a commentary accompanying the journal article. This study was led by Liang Gao, MM, Women and Children's Hospital, School of Medicine, Xiamen University, Xiamen, China. It was published online on November 26, 2025, in *JAMA Network Open*.

Early Cervical Length Measurement Shows Promise in Predicting Preterm Birth Risk in Twin Pregnancies

In twin pregnancies, cervical length (CL) assessment during the first trimester might be useful in predicting the risk for spontaneous preterm birth before 34 weeks of gestation; CL measurements below 35 and 30 mm warranted closer follow-up. However, a history of preterm birth remained the strongest independent predictor. Researchers conducted a retrospective multicentre cohort study with a case-control analysis in Poland from 2015 to 2023 to determine whether the CL measurement during the first trimester independently contributes to the prediction of spontaneous preterm birth before 34 weeks of gestation in twin pregnancies. They evaluated 2004 women with twin pregnancies (1590 dichorionic and 414 monochorionic) who had two live foetuses at the time of scan at 11-13 weeks of gestation without any major abnormalities. Participants were divided into two groups on the basis of timings of delivery: those who delivered at 24 + 0 to 33 + 6 weeks of gestation and those who delivered after 34 weeks of gestation. CL measurements were performed using transvaginal ultrasonography according to International Society of Ultrasound in Obstetrics and Gynecology guidelines; CL cutoffs of 30 and 35 mm were evaluated. Spontaneous preterm birth before 34 weeks of gestation was reported in 226 twin pregnancies (11.3%). Women who delivered at 24 + 0 to 33 + 6 weeks of gestation had a higher prevalence of CL measurement below 35 mm (49.6% vs 22.3%) and below 30 mm (16.4% vs 3.9%; $P < .001$ for both) during the first trimester than those who delivered after 34 weeks of gestation. Before 34 weeks of gestation, CL measurements below 35 and 30 mm during the first trimester were associated with approximately 3.4-fold and 4.9-fold higher odds of spontaneous preterm birth, respectively ($P < .05$ for both). Maternal risk factors such as a history of preterm birth and type 1 or 2 diabetes were associated with approximately 19-fold and 3.5-fold higher odds of spontaneous preterm birth, respectively ($P < .05$ for both). After multivariable adjustment, a history of preterm birth was the only independent predictor of spontaneous preterm birth before 34 weeks of gestation. "The assessment of CL in the first trimester helps to distinguish the group of twins which need a close follow up," the authors wrote. This study was led by Magdalena Litwińska, 1st Department of Obstetrics and Gynaecology, Medical University of Warsaw, Warsaw, Poland. It was published online on December 12, 2025, in *BMC Pregnancy and Childbirth*.

Neonatal Hypoglycaemia Admissions Drop After British Framework Implementation, Without Added Risk

The implementation of the British Association of Perinatal Medicine (BAPM) hypoglycaemia management framework reduced term neonatal unit admissions for hypoglycaemia by one third without increasing short-term adverse events. Notably, more than half of the admitted infants for hypoglycaemia had no BAPM framework-defined risk factors. Researchers conducted a retrospective observational cohort study using data from the UK National Neonatal Research Database to evaluate changes in term neonatal unit admissions for hypoglycaemia and short-term adverse events before and after the publication of BAPM hypoglycaemia management framework. They included 284,646 term infants admitted to neonatal units in England and Wales between January 2012 and December 2020. The analysis compared admission rates and outcomes across two 36-month epochs: pre-framework (April 2014 to March 2017) and post-framework (May 2017 to April 2020). The primary outcome was the admission rate of term infants to the neonatal unit for hypoglycaemia per 1000 term live births. Secondary outcomes included the admission time from birth, length of stay, short-term adverse events (seizures, severe brain injury, and mortality), and avoidable admissions (requiring only enteral feeds). Risk factors were defined as per the BAPM management framework (maternal diabetes, foetal growth restriction, and maternal beta-blocker use). The mean annual admission rate of term infants with hypoglycaemia decreased from 4.9 (95% CI, 4.8-5.1) to 3.3 (95% CI, 3.1-3.4) per 1000 term live births post-framework. No increase in seizures, severe brain injury, or mortality was observed; the proportion of potentially avoidable admissions declined from 12.8% to 8.9%. Over half of all term infants (53.5%) admitted for hypoglycaemia had no BAPM framework-defined risk factors; among these, 29% were small for gestational age (birth weight, 2nd-9.9th centile), and 15% were large for gestational age (birth weight > 90th centile). "Our finding that 29% of all infants admitted for primary hypoglycaemia without BAPM risk factors are born with a birth weight on the 2nd centile to the 9.9th centile and 15% are born LGA [large for gestational age] (birth weight >90th centile) supports the need for future research to evaluate the potential impact of these additional risk factors on term NNU [neonatal unit] hypoglycaemia admissions and maternity workload. Targeted screening of these groups may facilitate earlier intervention and contribute to a reduction in neonatal admissions," the authors wrote. This study was led by Behrouz Nezafat Maldonado, Imperial College London, and Frances Conti- Ramsden, King's College London, both in London, England. It was published online on December 03, 2025, in *Archives of Disease in Childhood - Fetal and Neonatal Edition*.

Declines in Newborn Vitamin K Uptake Raise Safety Concerns

New research shows that an increasing number of newborns are not receiving a vitamin K injection designed to prevent excessive bleeding. The percentage of babies that did not receive a vitamin K shot rose from 2.92% in 2017 to 5.18% in 2024, according to a retrospective cohort study published in *JAMA*. Clinicians warned that rising vaccine hesitancy may contribute to distrust in routine preventive medications and necessitate conversations with expectant parents before birth. "Medical misinformation has certainly changed the landscape of conversations surrounding preventative health, including things like vitamin K," said Kristan Scott, MD, attending physician in the Division of Neonatology at Children's Hospital of Philadelphia, Philadelphia, who led the study. "Topics that used to be more straightforward, like vaccines, routine medications like vitamin K, and other uniformed practices, have not been as straightforward anymore, and they require more time, more reassurance, and more dialogue." Usually administered by a nurse within 6 hours after delivery, the shot was first recommended in the 1960s by the American Academy of Pediatrics (AAP). The AAP in 2019 included "public education about intramuscular vitamin K administration at birth" as one of the organization's top 10 priorities due to reports of parents refusing the shot. Receiving the injection at birth has been associated with a reduced risk of developing vitamin K deficiency bleeding, which occurs when an infant cannot stop bleeding internally or externally because they lack enough of the vitamin to form a clot. Newborns who do not receive the vitamin K shot are 81 times more likely to develop severe bleeding than infants who get the shot. They are also at risk for this bleeding for up to 6 months following birth. The study did not investigate the causes of the increase, but Scott said caregiver refusal is the most probable explanation, although some infants may also have had allergies or conditions that made vitamin K inadvisable. Scott said parents often refuse the shot due to concerns about side effects, doubts about its necessity, or the mistaken belief that vitamin K is a vaccine.

Bacterial Meningitis Screening Tool Performs Well in Infants

Most international guidelines recommend lumbar punctures for all infants who have a fever at 28 days or younger to rule out bacterial meningitis. Clinical prediction tools may allow for more selective testing, but little is known about how well they perform

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ChatGPT Warns: "Don't Trust ChatGPT"

BM Petrikovsky MD PhD, BI Dynkin Esq, T Klune, D Alyeshmerni

Introduction

Wikipedia defines three main domains of artificial intelligence (AI): data, computer vision, and natural language processing. The data domain involves collecting and analyzing various types of data such as audio, video, text, etc. AI is created by writing computer programs that use machine learning techniques to identify patterns and make decisions based on large amounts of data. This data (texts, images, audio, or video) is fed to the AI, allowing it to learn and improve over time. Specialized algorithms, sometimes involving neural networks, help the AI to perform tasks such as recognizing patterns, making predictions, or generating new content. Wikipedia further states that AI systems can make mistakes due to limitations in their training data, the complexity of the tasks they're asked to perform, and the inherent nature of their design. These mistakes can manifest as incorrect information, misinterpretations of user intent, or even "hallucinations" where the AI fabricates information. There is a danger in the tendency of patients and doctors to trust AI-generated responses even when they may be inaccurate. Thus, Shekar et al[1] found that both medical professionals and ordinary people alike rated ChatGPT's answers to clinical questions as "more valid and trustworthy than they actually were," despite many answers being incorrect. By accepting AI responses, physicians may delay appropriate intervention or treatment, resulting in adverse outcomes.

Missing pathology during colonoscopy by doctors relying on AI has been documented. Budzyn et al[2] reported that endoscopists who regularly used AI missed significant pathology. Based on other reports of potentially endangering patients' wellbeing, Abdulnour et al[3] suggested a need for clinical supervision of AI use in medicine.

Methods

ChatGPT is a consumer-facing tool designed to be as widely used for as many diverse tasks as possible. In enterprise versions of large language models (LLMs), it is possible to use a variety of methods, including finetuning and retrieval augmented generation (RAG) to provide a tailored response that is far less prone to hallucinations. This is particularly useful in the medical field, where healthcare provides can leverage electronic medical records to create expert AI systems that won't just have general intelligence, but can have highly specialized and tailored knowledge. In view of the above, we decided to ask ChatGPT itself to address the issue of its own incompetence and potential danger for high-risk obstetrical patients. Please find ChatGPT's response below:

Results

"In recent years, AI tools such as ChatGPT have entered the public sphere at an unprecedented pace. While these technologies offer exciting opportunities for education, communication, and accessibility, their unregulated use in medicine, particularly in obstetrics and gynecology, raises serious concerns. Many patients now turn to ChatGPT for guidance on sensitive issues such as pregnancy, fertility, labor, or high-risk obstetric complications. This trend, though understandable in a world where instant answers are valued, is potentially dangerous. When patients substitute professional medical counseling with AI-driven responses, they risk confusion, anxiety, and even harmful outcomes.

The first concern is accuracy. ChatGPT, while sophisticated, is not designed to deliver individualized medical advice. Its outputs are generated from patterns in data rather than from clinical judgement or real-time assessment. Obstetrics and gynecology often deal with urgent, complex, and high-risk conditions where small nuances, lab results, gestational age, or a patient's past medical history, make the difference between reassurance and a life-threatening emergency. For example, a patient with symptoms of preeclampsia may ask ChatGPT about headaches during pregnancy. The system could provide a generalized explanation, such as dehydration or normal hormonal changes, and fail to emphasize the urgent need for blood pressure monitoring. Such omissions could delay critical medical attention and jeopardize maternal and fetal health.

A second issue is the emotional impact. Many patients approach AI tools out of anxiety or curiosity, but the information provided can worsen rather than ease their worries. ChatGPT often presents responses in a confident and polished manner, which may give the impression of authority even when the content is incomplete or incorrect. Patients, particularly those already vulnerable during pregnancy, may find themselves overwhelmed by conflicting information. They may receive overly broad answers that do not apply to their case or frightening possibilities that were never relevant to them in the first place. Instead of reassurance, they are left with heightened uncertainty and mistrust of their physicians, eroding the patient-doctor relationship essential in obstetrics and gynecology.

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

A third risk lies in patients' tendency to substitute AI guidance for direct communication with their doctors. In high-risk obstetrics especially, the stakes are simply too high for such shortcuts. Management decisions regarding preterm labor, gestational diabetes, or abnormal ultrasounds require not only medical expertise but also nuanced judgement, ethical considerations, and shared decision-making between patient and provider. These are processes that cannot be replicated by a chatbot. If patients begin to prioritize ChatGPT's recommendations over their physician's, it can lead to misinformed choices, noncompliance with critical treatments, and delays in lifesaving interventions.

Equally troubling is the growing trend among younger physicians and trainees to rely on ChatGPT themselves. Instead of turning to senior colleagues who have accumulated years of practical expertise, they look to AI for quick answers. While the temptation is understandable, ChatGPT is fast, accessible, and confident, this habit undermines the traditional apprenticeship model of medicine.

Furthermore, the legal and ethical frameworks for AI in medicine are still underdeveloped. Physicians are accountable for their guidance and actions, bound by licensing, evidence-based practice, and ethical standards. AI systems, however, carry no such responsibility. When misinformation leads to harm, there is no clear line of accountability. This creates a dangerous gray area in which patients may rely on tools that are fundamentally unregulated in clinical contexts."

Busch et al[4] studied attitude towards AI in medicine and surveyed around 14,000 patients in 74 clinics in 43 countries. 57.6% of patients viewed the use of AI in medicine positively. However, some differences emerged within the cohort: men were slightly more favorable at 59.1% than women at 55.6%. The more severe a person's own illness, the more negative their attitude toward AI. More than half of patients in very poor health rated medical AI "extremely negative" or "rather negative" (26.6% and 29.2%, respectively).

ChatGPT continues: "The responsible use of AI in medicine must be gradual, carefully validated, and integrated under physician oversight. ChatGPT and similar platforms may have future roles in patient education, providing general background information or assisting with health literacy. However, these roles must be clearly distinguished from diagnostic or treatment guidance. For now, their unsupervised use in obstetrics and gynecology, whether by patients or inexperienced doctors, is premature. Physicians must remain the primary source of counseling, while patients must be encouraged to view AI tools only as supplementary resources, never substitutes.

While ChatGPT represents a remarkable advance in technology, its application in patient counseling and medical decision-making in obstetrics and gynecology is fraught with risks. The tool is prone to inaccuracies, fosters confusion and anxiety, undermines physician-patient trust, and lacks accountability. Even among doctors, the overreliance on ChatGPT can displace mentorship and the careful transmission of clinical judgement from senior to junior physicians. For patients, particularly those navigating high-risk pregnancies, the consequences of misinformation can be profound and irreversible."

Conclusion

Artificial intelligence has great potential as an assistive tool in medicine, particularly in supporting providers by improving efficiency and occasionally identifying findings that might otherwise be overlooked. However, as highlighted in this article, sole reliance on AI has documented errors in judgement and diagnostics accuracy. At present, AI should complement—not replace clinical expertise and physician oversight.

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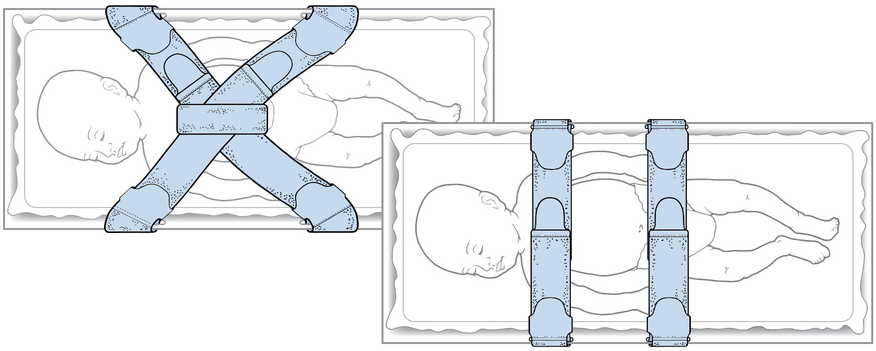

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Minimizing False Positives in Newborn Screening is a Critical Priority

Mike Pattrick, BSc

Newborn screening represents one of public health's greatest success stories, allowing for early detection and intervention of rare but serious conditions that could otherwise lead to severe disability or death. However, the effectiveness of these programs hinges not only on identifying affected infants but also on minimizing false positive results. Recent research in the field, including studies published in the International Journal of Neonatal Screening,[1,2] demonstrates that advances in screening technology are making significant strides in reducing false positive rates.

The true impact of false positives

When a newborn screening test incorrectly flags a healthy baby as potentially having a serious condition (a "false positive" result), it often triggers a cascade of consequences that extend far beyond the initial screening result. These false positives can create substantial burdens for healthcare systems, laboratories, and most importantly, families.

For clinical laboratories, each false positive necessitates confirmatory testing, additional staff time, and resources that could otherwise be directed toward truly affected infants. This represents a significant operational challenge in systems already managing high testing volumes with finite resources.

For families, the hidden costs are primarily emotional but no less significant. Parents receiving notification of an abnormal screening result often experience intense psychological distress, including anxiety, depression, and disrupted bonding with their newborn. Even after confirmatory testing reveals their child is healthy, studies show that some parents continue to perceive their child as vulnerable or fragile for months or even years afterward.[3,4] Research has found that mothers who received false positive results showed higher stress levels than those who received normal results, with effects persisting even after the false positive was resolved.[5,6]

Understanding the causes of false positives

False positive results in newborn screening stem from multiple factors, most of which are inherent to the screening process rather than reflecting any deficiency in laboratory practices:

- **Biological variability:** Newborns naturally exhibit wide variations in metabolite levels during the first days of life, particularly as they transition from fetal to independent metabolism.[7]
- **Timing of sample collection:** Samples collected too early (before 24 hours of age) may show transitional metabolic patterns that mimic pathological states.[8]
- **Prematurity and low birth weight:** Premature infants often display different metabolic profiles that can trigger flags in screening algorithms designed primarily for full-term newborns.[9]
- **Maternal conditions:** Certain maternal health conditions or medications can affect newborn metabolite levels without indicating disease in the infant.[10]
- **Technical limitations:** All screening methodologies have inherent technical limitations and established cutoff values that balance sensitivity against specificity.

Understanding these factors helps contextualize false positives as an inherent challenge in screening rather than a reflection of laboratory performance.

The economic burden

The financial impact of false positives can be substantial. Each false positive result often triggers a series of follow-up procedures:

- Immediate recall of the infant for confirmatory testing
- Consultations with specialists
- Additional specialized laboratory analyses
- Potential hospital admissions for observation
- Parental lost work time and travel expenses

A single false positive can cost the healthcare system in unnecessary follow-up care, while simultaneously reducing parents' productivity and increasing their out-of-pocket expenses during an already challenging time. An economic analysis stated that a reduction of false positive results had the largest impact on costs, and that "besides the financial impact and psychosocial impact, a reduction in false positives also prevents an unnecessary burden on the pediatric and laboratory healthcare system."[11]

Mike Pattrick is the Global Strategic Marketing Manager of Reproductive Health and Infection Diagnostics at Revvity, focused on maternal, fetal, and newborn health. He has worked within the healthcare industry for over 20 years in various rolls from administration to sales to marketing. His experience has been gained through a variety of companies from small venture set ups to large global corporations.

Technological advancements reducing false positives

Recent research, including a study published in the International Journal of Neonatal Screening,[1] highlights significant progress in reducing false positive rates through advanced screening technologies. The research examined various approaches and platforms noting that some had improvements in false positive rates while still maintaining necessary clinical sensitivity. For example, the study showed that screening for Tyrosinemia type 1 by measuring succinylacetone (as opposed to tyrosine) lowers both false positive and false negative rates, and that using the NeoBase 2 Non-derivatized MSMS kits provided the lowest false positive rates compared to any other analytical assay tested.

By employing sophisticated algorithms and improved analytical methods, modern screening approaches maintain excellent clinical sensitivity while reducing the number of healthy infants flagged for unnecessary follow-up. This represents a crucial advancement in newborn screening technology that benefits laboratories, healthcare systems, and families alike.

Balancing sensitivity and specificity

The challenge in newborn screening has always been maintaining the delicate balance between identifying affected infants (sensitivity) while minimizing false alarms (specificity). Missing a diagnosis can have devastating consequences, but having an excessive number of false positives, can also prove challenging. Contemporary screening approaches use advanced statistical methods and machine learning to optimize cutoff values, improving the precision of abnormal result identification.[12] This represents a significant evolution from earlier screening methodologies that often erred heavily on the side of sensitivity at the expense of specificity.

The path forward

As newborn screening programs continue to expand to include more conditions, providing low false positive rates becomes increasingly critical. Technological advancements point toward a future where newborn screening can achieve both comprehensive condition coverage and high accuracy.

For program administrators and laboratory directors, selecting solutions with demonstrated lower false positive rates should be a key consideration in program planning. The benefits extend beyond laboratory efficiency to include improved patient care, reduced healthcare costs, and protection of the parent-infant relationship during a critical developmental period.

As a trusted partner to laboratories worldwide, Revvity is committed to supporting accurate and efficient testing processes. We work diligently to help laboratories minimize false positives[1] and deliver reliable results, enabling healthcare providers to share important information with families about their newborns' health.

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New Study Highlights Significant Reduction in Severe NICU IV Infiltration Injuries with Early Detection Technology

Jaclyn Lautz, PhD

Peripheral IV therapy is a routine part of care in NICUs, but it comes with a multitude of risks. Among the most concerning is Peripheral IV Infiltration/Extravasation (PIVIE), which, while common, can be especially harmful to premature or medically fragile infants.

New research published in *BMJ Open* shows that continuous monitoring using early detection technology can offer a safer approach to IV therapy management. The study found that although the frequency of infiltration events remained constant, the severity of injuries decreased significantly when continuous monitoring technology was used in conjunction with standard observational methods.

Study Overview

Conducted at the Women's Wellness and Research Centre in Doha, Qatar, the four-year retrospective cohort study analyzed 32,292 peripheral IV insertions in neonates between 2019 and 2022. In the first half of the study, clinicians relied solely on traditional observation methods—namely Touch, Look, Compare (TLC)—to detect IV complications. In the second half, TLC was combined with ivWatch, a continuous monitoring system that uses near-infrared light to detect early changes in tissue at the IV site, which could indicate fluid leaking outside of the vein and into the subcutaneous tissue.

The ivWatch system continuously scans the area around the catheter for subtle tissue changes that might precede visible signs of infiltration. This is especially important in neonates, who often cannot express discomfort or pain, and whose skin and veins are especially delicate.

Dr Lautz has a broad range of experience in the healthcare field, specifically in medical device research, product development, global regulatory strategy, quality compliance and operations. Before joining ivWatch in 2018, where she currently serves as chief operating officer, she was an Advisory Manager at PricewaterhouseCoopers (PwC) in the Pharmaceutical and Life Sciences Operations practice. Prior to joining PwC, Dr Lautz was the Director of Regulatory Affairs and Quality Assurance at ivWatch from July 2014 to April 2017. Dr Lautz has a PhD in Mechanical Engineering from Duke University and a BS in Biomedical Engineering from Boston University. Dr Lautz was awarded the NSF Graduate Research Fellowship and the NSF Engineering Innovation Fellowship for her graduate studies at Duke University.

Key Findings: Lower Severity, Same Frequency

One of the most notable findings was that while the rate of infiltration and extravasation remained essentially unchanged—29.9% in the TLC-only group versus 30.1% in the group monitored with ivWatch—the severity of those events was markedly different. In the TLC-only group, 52.9% of cases were classified as severe or serious harm based on swelling percentage (using a grading scale of 15 or above). In contrast, the ivWatch group saw a 93.3% reduction in the severity of infiltration events, with all detections occurring before clinical identification by staff.

That drop matters. Severe IV injuries in neonates can result in lasting complications, including tissue damage, nerve injury, and scarring. Early identification of these events is crucial to minimizing harm.

Because ivWatch detects changes in tissue before symptoms become visible or painful, it enables faster intervention. This early action appears to be the key to reducing the progression to more severe injury.

Device Use Linked to Timely Removal of Catheter

The study also examined how long catheters remained in place before needing to be removed. In the TLC-only group, catheters remained in place for an average of 35.6 hours, while those in the ivWatch group averaged 32.4 hours. The reduced dwell time with ivWatch shows that complications were identified and addressed earlier, allowing for timely removal and helping to prevent emergency interventions or the need for reinsertion.

Kaplan-Meier survival curve analysis reinforced these results, indicating improved catheter performance and a lower rate of serious events when optical monitoring was used.

Clinical Implications: Early Alerts Lead to Quicker Action

The ivWatch system uses continuous light-based monitoring around the IV site and alerts clinicians at the first signs of a potential infiltration, enabling them to respond before complications arise. Even though some alerts may not result in physical signs of infiltration like swelling or redness, these notifications often correspond to early or subclinical changes that still need to be addressed. In other words, they provide a window of opportunity for clinicians to act before an issue escalates.

The study also found that babies born at earlier gestational ages and those with longer catheter dwell times faced higher risks of PIVIE, making proactive monitoring even more critical in these populations. ivWatch's sensitivity helps direct attention where it is most needed.

Considerations and Limitations

As the study was conducted at a single site, the results may not fully reflect what could occur in other NICU environments. Also, the hospital switched from PTFE to polyurethane catheters partway through the research, which could have influenced PIVIE rates. That said, the data showed no statistically significant differences linked to the change in catheter material.

Bringing a technology like ivWatch into routine use also comes with real-world challenges. Beyond purchasing the equipment, hospitals must invest time in staff training and update established protocols. Still, when weighed against the substantial economic and clinical costs of managing serious infiltration injuries, the findings strongly support integrating the device into standard care.

Looking Ahead

This study builds on existing research highlighting how continuous monitoring can improve NICU safety. While peripheral IV complications remain common, combining TLC checks with real-time optical monitoring provides a practical way to help mitigate their impact.

In the high-pressure environment of NICUs where nurses juggle the care of multiple infants, a predictive system that detects subtle changes in the optical properties of tissue around an IV site isn't just helpful, it's critical. As this study demonstrates, the system can intervene before infiltration injuries rapidly escalate, preventing harm before it occurs in this vulnerable patient population.

This proactive protection shields neonates from injuries that can have lifelong implications, such as long-term physical damage and psychological trauma, as well as extended hospitalizations and multiple costly interventions. Because every second counts for clinicians and patients alike, it provides an invaluable layer of defense.

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in identifying infants at low risk for a life-threatening bacterial infection. Researchers, led by Brett Burstein, MDCM, PhD, MPH, with the Montreal Children's Hospital, McGill University Health Centre in Montreal, Quebec, Canada, assessed the diagnostic accuracy of the updated Pediatric Emergency Care Applied Research Network (PECARN) prediction rule and found that it had high sensitivity but lower specificity for identifying febrile infants 28 days or younger with invasive bacterial infections. There were no missed cases of bacterial meningitis, according to the paper. Findings were published online in *JAMA*. The researchers performed a study analyzing pooled data from four published prospective international cohort studies of well-appearing, full-term infants (at least 37 weeks' gestation) 28 days or younger who presented with fever (temperature ≥ 38.0 °C (100.4 °F) over the past 16 years. Among 1537 infants 28 days or younger, 69 (4.5%) had invasive bacterial infections, including 11 (0.7%) with bacterial meningitis. Overall, 632 (41.1%) met low-risk criteria. The prediction tool had a sensitivity of 94.2% (95% CI, 85.6%-97.8%), specificity of 41.6% (95% CI, 36.7%-46.7%), positive predictive value of 6.9% (95% CI, 4.8%-9.9%), and negative predictive value of 99.4% (95% CI, 98.1%-99.8%) for invasive bacterial infections. "In a secondary analysis of 2531 infants from the two US-based cohorts from which the rule was originally derived and the four validation cohorts, 96 (3.8%) had invasive bacterial infections, 22 (0.9%) had bacterial meningitis, and 1079 (42.6%) were classified as low risk; rule performance was similar," the researchers report. "No infants with bacterial meningitis were misclassified in the primary or secondary analyses." They wrote that their data should inform guidelines and decisions shared between families and providers for low-risk infants aged 28 days or younger who present with fever.

Pregnancies in Systemic Sclerosis: High Live Birth Rates Despite Adverse Pregnancy Outcomes

Pregnancies in women with systemic sclerosis (SSc) showed a 91.4% live birth rate, but women with SSc had higher rates of adverse pregnancy outcomes, such as preeclampsia, preterm birth, and severe postpartum hemorrhage, than those in the general population. Nearly 40% of pregnancies had worsening of disease during pregnancies or within 12 months postpartum. Researchers prospectively analyzed data from an observational study on pregnancy in women with rare autoimmune diseases, conducted at 76 hospitals in France; they included pregnant women with SSc or very early diagnosis of SSc, with data collected up to 1 year postpartum using electronic case reports. A total of 58 pregnancies in 52 women (median age at pregnancy, 34 years; median disease duration, 3 years) enrolled between May 2014 and December 2020 were included, comprising those with diffuse cutaneous SSc (n = 16), limited cutaneous SSc (including those with SSc sine scleroderma; n = 30), or a very early diagnosis of SSc (n = 6). The primary objectives included assessing the proportion of pregnancies with composite adverse pregnancy outcomes, which included the occurrence of any complication related to placental insufficiency, preterm birth at or before 34 weeks, small-for-gestational-age infants, or fetal death after 22 weeks of gestation, with or without neonatal death within a month. They also assessed any worsening of maternal disease. Single pregnancies were matched for maternal age and gestational status with pregnancies in the French general population using data from the 2016 French perinatal survey (n = 530) to assess differences in outcomes. The study also assessed other pregnancy-related complications, such as

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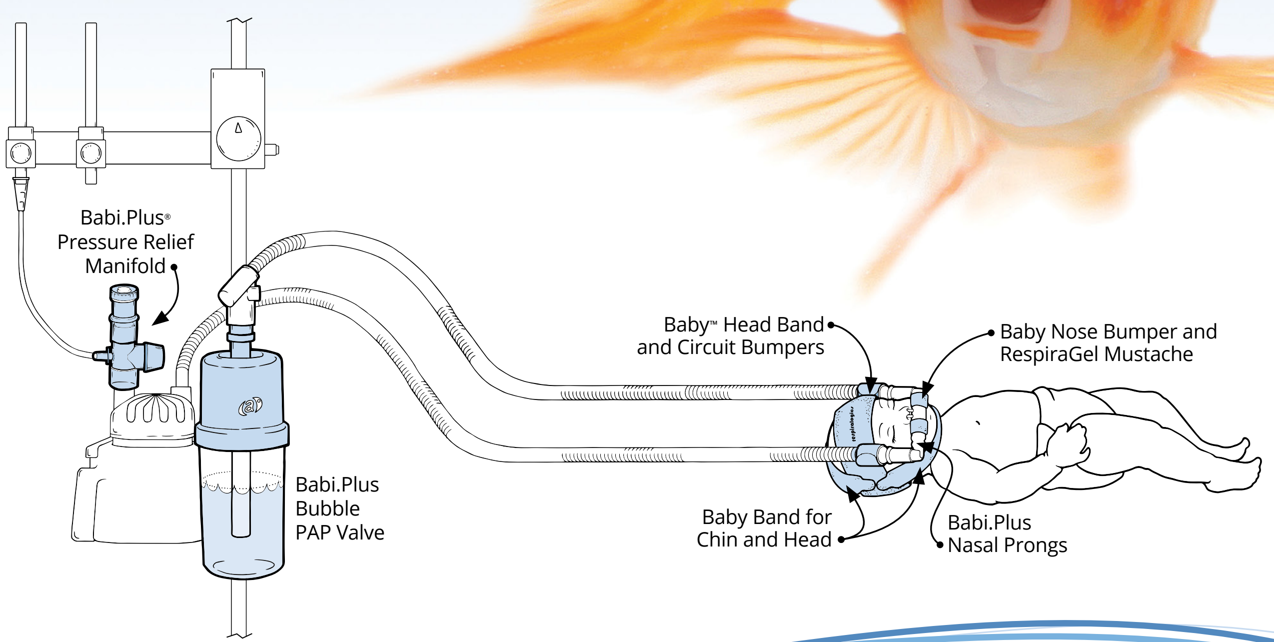

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Forecasting the Future: How Predictive Analytics is Transforming Neonatal Jaundice Management

Lia Butler, BSHA and Anduin Anderle, RN

Abstract
Neonatal jaundice is one of the most common conditions seen in newborns, and, in most cases, it's entirely manageable. Yet it remains the leading cause of readmission during the first month of life.[1] This article explores how jaundice is currently detected and treated, where existing guidelines fall short, and how predictive analytics is emerging as a game-changing tool for forecasting bilirubin trends, enabling earlier intervention, and improving outcomes for babies and families alike.

Introduction
Jaundice is the most frequently encountered medical condition among newborns during their first two weeks of life.[2] Approximately 60% of full term and 80% of preterm babies develop clinical jaundice in the first week after birth.[3]

For parents, discharge day is supposed to be a celebration. The moment they finally get to take their baby home. But for some, joy turns to disappointment when bilirubin levels rise unexpectedly, forcing their newborn into the NICU for phototherapy and a subsequent prolonged hospital stay. Others notice the tell-tale yellowing of their baby's skin days later, at home.

That discovery often triggers a wave of fear and frustration packing up the newborn, rushing to the pediatrician or emergency department, and bracing for more tests or an overnight admission. In both scenarios, what should be quiet bonding time is replaced by anxiety, logistical hurdles, and disrupted breastfeeding routines.

> "Psychological tension of mothers due to concerns for newborn's health, their husband and other children who were alone at home, was even more intolerable than physical exhaustion."[4]

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Anduin Anderle, RN, Neonatal Care Solutions Marketing Manager USA, is a neonatal care advocate representing Dräger, an international leader in medical and safety technology.

BiliPredics: Forecasting Bilirubin Trends
The Dräger BiliPredics solution uses a proprietary algorithm to forecast an infant's risk of jaundice up to 60 hours in advance, helping clinicians identify at-risk newborns before bilirubin levels peak. Delivered as an easy-to-use web application, it supports more informed clinical decision-making, reduces unplanned readmissions, and improves family satisfaction by enabling proactive, preventative care.[5,6,7]

Key Benefits
- Forecast bilirubin progression with fewer tests
- Replace unplanned readmissions with scheduled follow-ups
- Supports 2022 AAP Guideline with visual risk tracking
- Generates formatted reports for families and pediatricians
- Helps reduce clinician burnout and enhances patient safety

While the emotional toll on families is undeniable, the burden extends well beyond the home. Clinicians face the challenge of identifying and managing jaundice risk before bilirubin levels peak, often within a short postpartum window. When cases are missed or follow-up is delayed, readmissions become inevitable, disrupting care teams, straining hospital capacity, and driving up costs.

Jaundice isn't just emotionally taxing, it's expensive. It is the single most common reason for newborn hospital readmissions in the first month of life, adding an estimated $700 million annually to U.S. healthcare spending, stretching already-thin clinical resources, and contributing to staff burnout.[5,6,7]

With healthcare systems facing mounting financial and staffing pressures, there is a growing need for evidence-based tools that improve communication with parents, allow for proactive treatment, and help keep babies safely out of the hospital whenever possible.

Harnessing the power of predictive analytics offers a way forward. By turning vast amounts of clinical data into actionable forecasts, predictive tools give clinicians the ability to anticipate bilirubin trends before they become critical, changing the trajectory of care for newborns and their families.

This article covers conventional approaches to jaundice detection and management, American Academy of Pediatrics

(AAP) guidelines, challenges faced by clinicians in forecasting bilirubin trends, and how predictive analytics can support informed clinical decision making.

Neonatal Jaundice: Common but Not Always Harmless

Neonatal jaundice primarily results from the normal metabolic transition from the womb following birth.[8] But in 10% of all newborns, bilirubin levels increase to levels that require treatment, making phototherapy treatment necessary.[9]

A key challenge for clinicians is assessing jaundice risk during the first hours of life, often before bilirubin levels peak and while newborns are still in the hospital.[10,11] While the average length of stay postpartum for a vaginal birth in the US is 48 hours,[12] bilirubin levels usually peak between the third and seventh day after birth.[13]

Early discharge protocols mean that many babies leave the hospital before significant bilirubin rises occur, and some may not receive adequate risk assessment or follow-up.[14] This gap creates the potential for underdiagnosis, delayed phototherapy, and, in rare but serious cases, bilirubin-induced neurologic dysfunction (BIND), including kernicterus.[15]

Guidelines and Gaps

In August 2022, the American Academy of Pediatrics (AAP) published its Clinical Practice Guideline Revision: Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation, which updated and replaced its 2004 Guideline.[16]

Key updates from the Guideline include:[17]

- Increased thresholds for initiating phototherapy or exchange transfusion.
- Guidance on when follow-up or repeated measurement of bilirubin should occur.
- Determination of when escalation of care is warranted.
- Risk assignment revision for developing significant hyperbilirubinemia (eliminating race and ethnicity as independent variables).

The 2022 Guideline provides clear and comprehensive recommendations for discharging a neonate after birth and recommending follow-up checks.[18] When effectively implemented, they can substantially reduce adverse outcomes, as evidenced by one study showing a decline in jaundice-related readmissions from 3.9% to 2.1%.[19]

However, Guideline implementation presents several barriers:[20]

- **Complexity and training requirements:** Effective adherence depends on thorough staff training. Peer-reviewed research published in June 2025 reported "a significant increase in lack of adherence" to the 2022 Guideline compared with the 2004 Guideline. The researchers described adherence as "suboptimal" and stressed how "improved efforts are needed to enhance compliance with the Guideline, which may in turn help minimize unnecessary interventions."[21]
- **Limited predictive capabilities:** Current bilirubin risk assessments are based on a limited number of clinical parameters, such as gestational age, day of life, and presence or absence of risk factors.[22]
- **Risk zone volatility:** Up to 80% of neonates change risk zones after discharge (e.g., move from a low-risk zone to a higher risk zone or vice versa).[23] While current computer-based bilirubin tools display measured bilirubin values, they do not predict anticipated bilirubin levels and potential risk zone changes.[24,25]

The Power of Predictive Analytics
Predictive analytics in jaundice management allows clinicians to:

- **Identify at-risk infants before discharge**, enabling timely intervention.
- **Replace unplanned readmissions** with scheduled follow-ups, reducing family travel burden.
- **Support evidence-based decisions** aligned with updated AAP Guideline.
- **Improve communication transparency** with families and primary care providers through visual reports and EHR integration.

Parents as Partners in Prevention

The AAP emphasizes that parent education is critical to preventing severe jaundice. Families should leave the hospital with:

- Written information about jaundice
- Their baby's bilirubin level and other relevant labs
- Clear instructions for follow-up appointments and warning signs to watch for

As Harvard Health advises: "Before going home, you should receive written information about jaundice, your baby's bilirubin level, and exactly when your baby should be seen again."[26]

But even with education, the lack of forward-looking tools means that some cases slip through the cracks.[27]

The Promise of Predictive Analytics

Predictive analytics uses historical and real-time data to identify patterns and forecast future outcomes. In jaundice management, that means predicting bilirubin levels before they peak, so intervention can happen earlier, and often without a readmission.[28]

Cloud-based clinical decision support tools now allow clinicians to forecast jaundice risk up to 60 hours in advance. These systems:[29]

- Align with the 2022 AAP Guideline.
- Display intuitive visual graphs for risk tracking.
- Generate reports that can be shared with families and pediatricians.

A recent multi-site clinical trial demonstrated that predictive analytics significantly improved post-discharge risk identification and communication aross care teams.[30]

Real-World Impact: Benefits for Parents, Clinicians and Hospitals

The use of predictive analytics in jaundice management can offer benefits throughout the continuum of care.[31]

For parents: The technology facilitates early and transparent communication about jaundice risk, allowing families to better understand and prepare for potential care needs.

By enabling proactive management, predictive analytics can reduce the likelihood of distressing and disruptive unplanned readmissions, supporting family bonding and peace of mind. Reports generated can be shared with pediatricians, helping ensure continuity of care after discharge.

For babies: It promotes timely interventions that align with family-centered care initiatives, as indicated in the proposed NICU Baby's Bill of Rights.[32] The technology also helps minimize exposure to preventable complications and hospital-related stressors.

For clinicians: It helps streamline workflows and reduce documentation, and provides risk-adjusted forecasts that support informed, individualized care planning. By aligning with the AAP Guideline, predictive technology can enhance both clinical decision-making and regulatory compliance.

For hospitals and health systems: Predictive analytics can help enhance discharge planning accuracy by providing predictive insights into neonatal jaundice risk, enabling more informed and timely care decisions. By helping to avoid unnecessary phototherapy, extended hospital stays, and costly readmissions, the tool can contribute to more efficient use of resources and reduced overall care costs.

Additionally, the technology can help support safer transitions from hospital to home, promoting continuity of care while optimizing staff time and operational efficiency.

Conclusion

Despite being one of the most common conditions in newborns, neonatal jaundice continues to result in unnecessary readmissions, preventable complications, and emotional turmoil for families. While the AAP's clinical Guideline offers a valuable framework the lack of predictive capability and inability to incorporate personalized medicine limit its impact in real-world practice.

Predictive analytics offers a transformative advancement, empowering clinicians to forecast bilirubin trends, initiate earlier interventions, and communicate risk more effectively. By embracing these technologies, NICUs can help reduce the burden on overstretched staff, enhance family-centered care, and set a new standard for neonatal health outcomes.

As neonatal care continues to evolve, predictive analytics stands out not just as an innovation, but as a necessity for delivering safer, smarter and more compassionate care for our smallest, most vulnerable patients.

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Beyond the Binder: The Digital Transformation of Patient Safety for the Joint Commission Readiness in 2026

Suzanne Smith, MS, RD, LDN, IBCLC and Caroline Steele, MS, RD, IBCLC, FAND

Executive Summary

The Joint Commission (TJC) has undertaken its most radical transformation since 1965. The new Transformation 360 initiative is shifting healthcare compliance from episodic, binder-based audits to a continuous, data-driven model of "always-on excellence." This overhaul has streamlined requirements to focus on "what matters most," reducing the Hospital Accreditation Program (HAP) standards from 1,551 to just 774.

Effective January 1, 2026, a new framework of 14 National Performance Goals will guide this new era. Surveyors will demand that healthcare organizations not just *tell* them about safety protocols but *show* demonstrable proof of their effectiveness through real-time observation and data verification.

This shift presents a significant challenge for organizations reliant on manual processes, which are prone to error and lack the data transparency required for the new standards. The demand for continuous readiness, validated staff competency, and digital proof of compliance requires a modern infrastructure. Timeless Medical Systems® (TMS) provides the essential software solutions to bridge this gap, transforming complex TJC demands into streamlined clinical workflows. Our platform delivers digital proof, real-time dashboards, and staff competency tools necessary to thrive in this new era of healthcare quality.

Section 1. The Seismic Shift: Deconstructing The Joint Commission's 2026 Vision

The healthcare industry has been forced to "change the engine while flying the plane" in the wake of the COVID-19 pandemic. Recognizing that this turbulence created a unique opportunity for transformational change, the Joint Commission convened its inaugural "Unify 2025" conference to facilitate learning and rapid transformation across the industry. This event marked the official launch of Transformation 360, an initiative described as the most radical transformation in healthcare quality assurance since the inception of Medicare in 1965. The stated goal of this initiative is to move the entire industry from complexity to clarity, focusing on what matters most to elevate safety and quality for everyone.

This new vision is driven by a simple, powerful philosophy articulated at the conference: "If everything matters, then nothing matters—thus we are shifting to focusing on what matters most." This is not just a theoretical shift; it has led to concrete action. TJC undertook a comprehensive review of its standards to determine if they were relevant, redundant, or had a worthwhile rate of return for safety. The result was a dramatic streamlining of requirements, exemplified by the reduction of the Hospital Accreditation Program (HAP) standards from 1,551 to just 774.

Underpinning this entire initiative is a new philosophical framework called "Safety 3.0." This marks a significant evolution from the traditional Safety 1.0 "find-and-fix" model, which focused solely on examining adverse events. The new approach incorporates the principles of Safety 2.0, which examines why things "go right" to gain adaptable insights for excellence. The resulting Safety 3.0 model is a combination of both approaches that underpins the entire Transformation 360 initiative.

Operationally, this new vision is designed to move organizations from "episodic survey readiness to always-on excellence." This is being implemented through a new Continuous Support Model, which introduces virtual or on-site "touchpoints" between the standard three-year survey events. This collaborative approach, combined with a shift to more "boots on the ground" assessments, demands that hospitals maintain a constant state of compliance and have systems in place to prove it at any time. This new reality requires a fundamental change in how hospitals operate—moving from static policies and reactive audits to dynamic, proactive, and data-centric systems of safety. TMS platform directly facilitates the "always-on excellence" aspect of Safety 3.0, bridging the technical detail back to the business solution.

Section 2. The New Survey Reality: From 'Telling' to 'Showing'

The days of preparing for a survey by auditing policy binders are over. The new TJC survey process is built on a "boots on the ground" approach of direct observation and data verification.

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Standard & Domain	The Old Way: "Telling"	The New Way: "Showing"
NPG.01.01.01: Patient Identification	Auditing policy binders to confirm a written two-person identifier rule.	Observing a live feeding and asking, "Show me the digital audit trail for this specific bottle, proving correct patient identification from receiving to preparation through administration."
HR.11.03.01/HR.11.04.01: Staff Competency	Reviewing staff files for paper sign-off sheets or supervisor attestations for annual training.	"Show me your data on staff adherence to safe feeding protocols and how you document competency with return demonstration, not just attestation."
IC.04.01.01 / EM.12.02.09: Infection Control & Recalls	Checking for written policies on managing recalls and following FDA alerts.	During a simulated recall, asking, "Show me how your system can instantly identify every patient and nutrition product affected."
NPG.02.03.01: Culture of Safety	Discussing the hospital's process for manually reporting adverse events.	"Show me your dashboard of 'near miss' data for feeding errors and how you use it for performance improvement activities to prevent future incidents."
PC.12.01.09: Provision of Care	Verifying that the therapeutic diet manual is current and approved.	"Show me how your system ensures and documents that the correct nutrition product and additives are used for each patient, in accordance with clinical guidelines."

Figure 1. The "Then vs. Now" of TJC Compliance for Enteral Nutrition Safety.

The defining question from surveyors will now be, "Show me how you are assessing and measuring these outcomes." This creates a clear distinction between past and future compliance activities.

Section 3. The Technology Imperative: Building Your Digital Proof

Manual processes and disconnected data sources are fundamentally incompatible with the demands of this new era. Answering the "show me" questions posed by the 2026 standards requires a cohesive digital ecosystem. A system that integrates barcode scanning, automated data capture, and real-time analytics is no longer just a best practice—it is an essential tool for demonstrating compliance.

TMS provides this critical infrastructure. Our platform directly supports the new TJC framework by providing immutable, time-stamped proof for key standards:

- **Patient Safety via Correct Identification (NPG.01.01.01):** The Timeless Medical Systems® barcode scanning system ensures the right patient receives the right care by validating patient and product information at every step. This robust process moves an organization from manual checks to a data-driven system that fulfills the "show me" requirement for correct feeding administration.
- **Culture of Safety (NPG.02.03.01):** The system automatically tracks "near misses" and errors, providing the data needed for leaders to manage and improve their safety program, moving beyond reactive reporting.
- **Staff Competency (HR.11.03.01 & HR.11.04.01):** By reinforcing proper technique with every scan, the TMS system serves as an integral tool for ongoing education and provides a measurable way to document staff competence in safe nutrition administration, a key requirement under the new standards.
- **Infection Control (IC.04.01.01):** Requires implementing hospital-wide infection surveillance and prevention policies, alongside communication with the Quality Assessment and Performance Improvement (QAPI) program to address identified issues. TMS supports this by enforcing standardized policies for safe handling and storage of nutrition products. It also digitally captures and monitors critical data points—such as expiration dates, storage temperature excursions, and preparation near-misses—providing the data needed to proactively track and reduce infection risks related to nutrition preparation.
- **Emergency Management (EM.12.02.09)** TJC explicitly mandates that hospitals be able to document, track, monitor, and locate all resources and assets, including nutritional products, during an emergency or recall event. To meet this level of accountability, hospitals must apply the same digital inventory and validation controls traditionally used for medication management to enteral nutrition.
- **Medication Management (MM.02.01.01 & MM.05.01.17)** The ability to track inventory and patient usage through scanning is a powerful mechanism for managing product shortages (MM.02.01.01) and ensuring compliance with written protocols for approved product substitutions. Furthermore, the digital audit trail is the core technology required for organizations to retrieve and handle all recalled products according to a formal written policy (MM.05.01.17). Enteral nutrition (including human milk, donor milk, fortifiers, and formulas) is prescribed within the hospital setting just like medications. Consequently, processes for dealing with shortages and recalls should mirror that of medications.
- **Provision of Care (PC.12.01.09) & Environmental Control (PE.04.01.01):** Scanning enteral feedings and validating products supports the mandate that nutritional needs are met in accordance with **clinical practice guidelines and recognized dietary practices**. The system indirectly supports environmental control by ensuring and tracking the proper handling and use of temperature-sensitive products.

Section 4. The TMS Blueprint for Success: A Case Study

Challenge: A Level IV neonatal intensive care unit (NICU) was struggling with a high-risk, manual, two-person check system for preparing and administering human milk and enteral feedings. This process was creating workflow bottlenecks, was prone to error, and generated no actionable data for their performance improvement activities, leaving them vulnerable under the new TJC standards.

Solution: The hospital implemented the Timeless Medical Systems (TMS) platform for end-to-end barcode verification of all enteral nutrition components. The system was integrated with their existing workflows to ensure every product was scanned and validated against the correct patient from preparation to administration.

Result: Within six months, the NICU achieved a 99.9% scanning compliance rate. They completely eliminated manual logs and could now produce an on-demand digital audit trail for any feeding, thereby satisfying the TJC's "show me" requirement under NPG.01.01.01. Their dashboard of "near miss" data became the primary tool in performance improvement meetings, enabling them to proactively identify system vulnerabilities as required by NPG.02.03.01. Furthermore, the validated human milk tracking system provided immediate, accurate data to support their Perinatal Care (PC-05 & PC-06) initiatives for improving human milk usage. Finally, adherence to standardized protocols enforced by the scanning system contributed to a measurable decrease in infection control events and hospital-acquired infections (HAIs) related to milk and formula handling. This NICU is now fully prepared to demonstrate "always-on excellence" for their next TJC survey.

Section 5. Your Action Plan for 2026 Readiness

Transitioning to a state of continuous readiness requires a strategic and systematic approach. Authoritative sources like the American Society for Parenteral and Enteral Nutrition (ASPEN) and Institute for Safe Medication Practices (ISMP) recommend barcode scanning for all enteral nutrition to enhance patient safety, aligning with the TJC's mandate to follow clinical practice guidelines under PC.12.01.09.

Use this checklist to begin your journey toward 2026 compliance:

- **Audit Your Data:** Identify where your "proof of compliance" for patient identification, staff competency, and recall management lives today. Is it accessible in real-time?
- **Analyze Your Workflows:** Where do manual gaps, like two-person checks, introduce risk and prevent data capture, creating a systemic lapse in safety management?
- **Empower Your Frontline:** Evaluate if your current tools hinder your staff or empower them to easily demonstrate safe practices. An intuitive scanning system is a powerful tool for reinforcing proper technique and documenting competency as required by the HR chapter.
- **Schedule a Readiness Assessment:** Let the experts at Timeless Medical Systems® help you evaluate your readiness for the new TJC standards. We provide the tools to not only meet the 2026 requirements but to lead in this new era of patient safety and quality.

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delivery outcomes and postpartum complications, along with predictive factors for adverse pregnancy outcomes and disease worsening. Overall, 91.4% of pregnancies resulted in live births, of which 26.4% had composite adverse pregnancy outcomes, with placental insufficiency in 22.6% (including preeclampsia in 13.2% and fetal growth restriction in 9.4%), preterm birth at or before 34 weeks in 3.8%, and small-for-gestational-age infants in 11.3%. Of the eight pregnancies in women with very early diagnosis of SSc, fetal losses occurred in two before 22 weeks of gestation, and 33.3% of the remaining had a composite adverse pregnancy outcome. Worsening gastroesophageal reflux disease occurred in 34.5% of all pregnancies, and disease worsening during pregnancies or within 12 months postpartum occurred in 39.7% of pregnancies. Women with SSc vs general population had higher rates of preeclampsia (13.2% vs 3.0%), preterm birth before 37 weeks (13.2% vs 5.8%), and severe postpartum hemorrhage (11.3% vs 1.3%; $P < .05$ for all). Diffuse cutaneous SSc (odds ratio [OR], 3.7; 95% CI, 1.1-12.4) and prior cutaneous vascular involvement (OR, 3.7; 95% CI, 1.2-11.5) were linked to disease worsening, whereas the presence of anticentromere antibodies showed an inverse association with disease worsening (OR, 0.2; 95% CI, 0.1-0.8). "These findings underscore the importance of obstetric-specific monitoring for pregnant women with systemic sclerosis or VEDOSS [very early diagnosis of SSc], particularly for early detection and management of preeclampsia," the authors wrote.

Extremely Early-Onset Foetal Growth Restriction Linked to High Perinatal and Maternal Risk

Pregnancies complicated by extremely early-onset foetal growth restriction (FGR), defined as a diagnosis ≤ 26 weeks of gestation, had a high risk for adverse outcomes, including perinatal death, genetic and structural anomalies, and preeclampsia. Nearly half of these affected pregnancies had preterm births ≤ 32 weeks of gestation. Researchers conducted a systematic review and meta-analysis to evaluate perinatal and maternal outcomes in singleton pregnancies complicated by extremely early-onset FGR. Among 14 studies (2818 pregnancies) included in the systematic review, 13 (2573 pregnancies) were included in the meta-analysis. The primary outcome was perinatal death, including both intrauterine and neonatal death. Overall, perinatal death occurred in 16.0% of pregnancies with extremely early-onset FGR, with intrauterine and neonatal death occurring in 8.8% and 6.2%, respectively. Genetic and structural anomalies were identified in 9.6% and 23.2% of foetuses, respectively. Preeclampsia affected 21.6% of pregnancies. Preterm birth before 32 and 28 weeks of gestation occurred in 54.6% and 23.3% of pregnancies, respectively; 45.6% of women underwent caesarean section. Overall, 30.5% of infants had composite adverse perinatal outcomes, including perinatal death, any perinatal morbidity, and/or NICU admission; 38.3% showed neurologic morbidity; 21.7% showed respiratory distress syndrome; and 61.8% had intact survival during the follow-up. "Women with a fetus affected by extremely early-onset FGR should be counseled on the high risk of short- and long-term maternal morbidity associated with Cesarean section, which should be balanced against the high risk of PND [perinatal death] and significant perinatal morbidity due to prematurity," the authors wrote. This study was led by M. Piergianni, Center for Fetal Care and High-Risk Pregnancy, University of Chieti, Chieti, Italy. It was published online on November 14, 2025, in Ultrasound in Obstetrics & Gynecology.

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Breaking Barriers: Overcoming Hesitation in Introducing the Passy Muir Valve in the NICU

Gabriela Ortiz, BSRT, RCP

For infants in the Neonatal Intensive Care Unit (NICU) who require tracheostomy or prolonged mechanical ventilation, everyday functions like breathing, swallowing, and communicating may be profoundly altered. These disruptions can have cascading effects on developmental milestones, feeding progression, and even the infant-parent bond. The Passy Muir Valve Tracheostomy & Ventilator Swallowing and Speaking Valve (PMV) is a one-way speaking valve that is designed to restore more normal airflow patterns and has long been used safely across pediatric and adult populations. However, its adoption in NICU settings remains inconsistent.

Many NICUs continue to view the PMV as too risky, too advanced, or simply unnecessary for infants, particularly those who are pre-verbal. But clinical evidence, neonatal case reports, and growing interdisciplinary experience tell a different story. With thoughtful protocols and team training, PMV use can be safe, effective, and transformative for medically fragile infants.

When considering common misconceptions, addressing barriers to use, and highlighting evidence-based practices, this support lessens the hesitation surrounding Passy Muir Valve use in the NICU.

Misconception #1: "Neonatal airways are too small for safe PMV use."

Size-related hesitation remains one of the most persistent barriers among clinicians. The idea that the neonatal airway is too small or fragile to support redirected airflow is understandable.

Several pediatric studies, including those involving infants just days old, demonstrate strong tolerance to PMV trials. Watters (2017) reports neonates as young as 13 days have safely used the Valve.[1] Retrospective reviews have found:

- Many infants and toddlers tolerate PMV well, even during initial trials[2-3]
- Many demonstrate immediate improvements in airflow, comfort, and early vocalization[2]
- Most reported challenges are resolved through gradual trialing, not outright contraindication.

What matters is not age alone, but a structured readiness evaluation: ensuring cuff deflation (or uncuffed trach), sufficient airflow around the tracheostomy tube, and careful monitoring.[1] When readiness criteria are satisfied, age and size should not be viewed as limiting factors for PMV success. Instead, a cautious, protocol-driven approach makes PMV trials feasible even in our smallest patients.

Misconception #2: "The PMV is only useful for speech, and infants don't need to speak yet."

This misconception underestimates the physiological impacts of PMV use. While the Valve is known for enabling phonation, communication is only one of many benefits. In fact, many of the most critical advantages of the PMV are physiological.

Evidence-based benefits include:

Restoration of normal respiratory pressures: the PMV redirects exhaled air through the upper airway, re-establishing positive airway pressure. This helps:

- Support swallowing safety
- Reduce aspiration
- Improve airway protection

Improved secretion management: With restored airflow and subglottic pressure, infants often demonstrate:

- More effective cough
- Reduced suctioning needs
- Improved airway clearance

Enhanced feeding outcomes: For infants transitioning to oral feeding, especially those with a tracheostomy tube:

- PMV use can improve coordination of suck-swallow-breathe pattern
- Some infants re-establish the ability to breastfeed[4]
- Swallow physiology becomes more "typical," reducing risk and discomfort

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Early social and developmental benefits: Even pre-verbal infants benefit from:
- Restoration of cry (a critical communication and bonding tool)
- Cooing and early vocal play
- Improved parent-infant interaction and responsiveness

Speech is only the tip of the iceberg. PMV restores normal physiology, strengthens development, and supports family engagement long before language emerges.

Barrier: Lack of a Clear NICU Protocol
NICU clinicians often lack standardized criteria and guidelines for PMV readiness, defined monitoring parameters, clear interdisciplinary roles (RT, SLP, ENT, neonatology), and step-by-step procedures for trial initiation.

NICU-specific protocols should be specific, and implemented with patient selection guidelines:
- Readiness checklists
- Stepwise trial schedules
- RT & SLP co-treatment models
- Clear documentation guidelines
- Troubleshooting and escalation procedures if concerns arise

Where implemented, these protocols may result in:
- Increased referrals
- Better trial success
- Improved feeding outcomes
- Greater clinician confidence
- Fewer delays in PMV introduction

Misconception #3: "PMV trials are too risky for medically fragile infants."

While concerns about desaturation, distress, or airway compromise are understandable, evidence shows these fears may be unfounded as it has shown that PMV trials are safe when performed within protocol.[1] Adverse events are rare and usually addressed promptly (desaturation, increased work of breathing, or behavioral distress). Infants who struggle initially often succeed with adjusted positioning, slower pacing, or a second trial. Only a small percentage require discontinuation due to physiological intolerance.

Some infants with chronic respiratory conditions even show reduced work of breathing with PMV use due to improved airway dynamics. With careful selection, continuous monitoring, and interdisciplinary support, most safety concerns resolve quickly.

Evidence: Success Stories from NICU and Pediatric Practice
Research studies using patients illustrate real-world outcomes and trends. For example, Da Cunha de Lima et al. (2021) reported safety during breastfeeding following infant tracheostomy and placement of a PMV. Mothers reported decreased difficulty in feeding and breathing and better management of secretions. This was observed once the child acclimated to redirected airflow by the infant demonstrating coordinated swallowing, decreased pooling of secretions, and a reduction in the number of airway aspirations.[4]

Hull et al. (2009) reported that speaking Valves enhance communication. They studied subjects achievement of phonation. The emotional impact on the family was profound, reinforcing the role of early vocal access in bonding, communication, and family-centered care.The infant's parents expressed significant distress that they had never heard their baby cry. Following initiation of a Passy Muir Valve trials, vocalization (cry) emerged immediately, parents became more actively engaged in caregiving, and the infant demonstrated emerging cooing behaviors during social interaction.[5]

These cases point out the PMV's role not only as a communication tool, but as a developmental and physiologic intervention. While pediatric-specific data remains limited, findings from adult populations support these observations. Sutt et al., (2017) demonstrated that restoring a closed respiratory system through speaking Valve use improved lung recruitment and overall respiratory mechanics, facilitating more efficient weaning from mechanical ventilation. These physiologic principles are highly relevant when considering PMV use in ventilator-dependent infants and impact quality of life.[6]

Practical Recommendations for Overcoming Barriers in the NICU

1. Build a clear protocol, including:[7]
- Readiness assessment
- Contraindications list
- Monitoring guidelines
- Stepwise trial progression
- Defined RT/SLP collaboration

2. Train the entire interdisciplinary team. Involving:
- Respiratory therapy
- Speech-language pathology
- Nursing
- ENT
- Neonatology

3. Start with controlled, brief trials:
- 1-10 minutes, gradually extend trial length as tolerated.
- Direct monitoring
- Cuff deflated (or uncuffed tube)
- Close attention to work of breathing, color, and comfort

4. Engage families, offering:
- Clear explanations of benefits
- Opportunities to witness early vocalizations
- Education on signs of tolerance

5. Track outcomes by monitoring:
- Tolerance rates
- Feeding improvements
- Parent satisfaction
- Time to decannulation
- Reduction in suctioning or respiratory events

Conclusion: A Call to Action for the Modern NICU

Hesitation around the Passy Muir Valve in the NICU is understandable, but it is increasingly being adopted for use. Evidence continues to grow, demonstrating that structured, interdisciplinary PMV use is safe, well-tolerated, and beneficial for even our smallest patients who are medical stable.

This is not simply about speech. It is about:
- Restoring normal physiology
- Supporting airway protection
- Improving swallowing and feeding
- Enhancing development
- Strengthening parent-infant bonds
- Promoting holistic care for infants with tracheostomies

It may be time for NICUs to move beyond fear and toward evidence. With the right protocol, the right collaboration, and the right mindset, the PMV becomes a powerful therapeutic ally in neonatal care.

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AI-powered Point-of-care Tech

Ceribell announced it has received US FDA 510(k) clearance for its next-generation Clarity algorithm to detect electrographic seizures in newborns pre-term and older, making Ceribell the first and only AI-powered point-of-care EEG technology available to detect electrographic seizures in all ages of patients, from pre-term neonates through adults. By combining proprietary algorithms with purpose-built hardware, the Ceribell System enables clinicians to detect non-convulsive seizures in neonatal patients in real time, supporting rapid diagnosis and treatment to help prevent serious brain injury. About 9% of NICU patients may be diagnosed with seizures, but up to 90% go undetected without EEG monitoring; delays in seizure detection and treatment can lead to lasting cognitive and language impairments, underscoring the importance of timely intervention. Recent guidelines from the American Clinical Neurophysiology Society recommend continuous EEG monitoring for neonates with a wide range of conditions that place them at high risk for seizures. This clearance was supported by EEG data from more than 700 patients — the largest known validation dataset for a neonatal seizure detection system. This follows Ceribell's FDA 510(k) clearance for its Clarity algorithm for the detection of electrographic seizures in pediatric patients ages one and older, further expanding access to rapid, AI-powered neurological monitoring.

Preterm Babies May Safely Start Full Milk Feeds on Day 1

In infants born at 30-32 weeks of gestation, feeding full milk from day 1 did not shorten hospital stay compared with gradual feeding, but it was linked to reduced use of intravenous lines and showed no higher risk for necrotizing enterocolitis. Researchers conducted an open-label superiority trial to assess whether preterm infants could be fed only full milk (60-80 mL/kg per day) through gastric tubes immediately after birth without increasing health risks. They included 2088 clinically stable infants born at 30-32 weeks of gestation (mean gestational age, 31.7 weeks; 47.6% girls) across 46 neonatal units in the UK between 2019 and 2024. Within 3 hours of birth, 1047 infants started full milk fluids, while 1041 infants received gradual milk feeding (maximum of 30 mL/kg per day on day 1) supplemented with intravenous fluids or parenteral nutrition. The primary outcome was length of hospital stay. Secondary outcomes included the incidence of necrotizing enterocolitis, rate of hypoglycemia, and survival until hospital discharge. Outcomes were reported at hospital discharge and at 6 weeks' corrected age. Longer-term follow-up to 24 months is ongoing. Infants who received full milk stayed in hospital for a mean of 32.4 days and those on gradual feeding stayed for 32.1 days, with no significant difference between the groups. Necrotizing enterocolitis occurred in 0.4% of infants in the full milk group and 0.6% in the gradual feeding group, with no significant difference; 99.6% of infants in both groups survived to discharge, and rates of hypoglycemia and serious adverse events were similar. Infants on full milk reached full enteral feeds sooner than those on gradual feeding (mean, 7.0 vs 7.9 days), had shorter durations of parenteral or intravenous nutrition, fewer intravenous lines, and fewer days in intensive care. Nonadherence to full milk feeds was reported for 37% of infants. "Despite over a third of infants not adhering to the feeding intervention as intended and length of stay not being reduced, hospitals or clinicians might still consider implementing an early milk feeding regimen for preterm infants born at 30 to 32 weeks of gestation because of the reduction in

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Moral Distress in the NICU: A Personal History and Reflection

Evan Richards

Moral Distress is an increasingly recognized contributor to burnout, emotional injury, and impaired decision-making among neonatal clinicians. This narrative describes a personal experience of Moral Distress in the NICU, framed through the mentorship and archival writings of a neonatology leader, Dr Tom Harris. The author recounts a clinical encounter involving a medically complex infant, examines the origins and consequences of Moral Distress, and applies a structured response strategy ("Four Rs") to consider alternative approaches. The narrative concludes with guidance from Dr Harris's personal writings that emphasizes compassionate communication with families amid ethically ambiguous life-and-death decisions.

Introduction

My NICU clinical mentor, Dr Tom Harris, passed away in May 2022. In one of our last conversations, he reminded me that he "wasn't going to be around forever," and asked whether he might send me several textbooks he no longer needed, saying they were regarding a topic for which we had a shared interest. I agreed without asking what topic they covered. Soon after, a box containing twelve books arrived.

During our final phone conversation, Tom mentioned that he had additional books and files he hoped I would want. He sent them to me. After he died, his daughters shipped two boxes filled with eight additional textbooks and more than eighty folders containing articles, abstracts, news clippings, photographs, and handwritten notes. Every item Tom and his daughters sent centered on a single theme: the morals and ethics of life and death in the NICU.

Tom had spent two years in seminary before redirecting his path toward medicine. This background gave him a distinctive ability to bridge spirituality and science. Yet the contents of his archives revealed that this balance was burdened by the ambiguities inherent in neonatal care. His personal writings frequently wrestled with the uncertainty surrounding decisions made for patients at the edge of viability and the Moral Distress that often accompanies such work.

As I reviewed Tom's archives, two truths became evident: the historical events that shaped life-and-death decision-making in the United States were fraught with controversy, and the ethical framework for NICU care remains filled with ambiguity—conditions that foster Moral Distress.

A Letter Rediscovered

As I sorted through the materials I pulled from a file folder a document that elicited a visceral emotional response. It was a copy of a letter I had written in 1984 titled "A Right to Die?" The letter was prompted by an encounter during my work as a respiratory therapist in the NICU where Tom served as Chief of Neonatology. He had saved the letter and placed it in a folder labeled "Moral Distress."

The case involved a medically complex intubated infant with irreversible chronic lung disease, a grade IV intraventricular hemorrhage, and on extreme ventilator settings. The baby's parents—rightly the last to let go—had finally agreed with the neonatologists that their son had no chance of survival. He was made DNR.

That evening, a nurse practitioner ordered chest physiotherapy every four hours. I questioned the order, explaining that CPT caused substantial drops in the infant's oxygen saturation and heart rate. Keeping the baby alive during treatments required aggressive manual ventilation. There were no secretion issues. The nurse practitioner insisted the order be followed, that it was precautionary, and concluded the discussion by saying, "Just do the CPT. And don't let the baby die on your watch."

I performed the CPT, struggling to keep the baby alive through what I believed to be an unnecessary and unethical intervention. Each percussion became a drumbeat toward Moral Distress.

At the time, charting was done by hand. As I wrote, my anger poured onto the page—a full sheet of exasperating and infuriating documentation describing the baby's suffering and my belief that the procedure was ill-advised and harmful. A nurse colleague saw the note and wisely suggested that I reconsider. I agreed, double-lined the entire entry, dated and

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initialed it, and wrote a concise alternative summary: *“Patient did not tolerate CPT well. Suctioning unproductive.”*

The NNP found the redacted note and took it to Risk Management and hospital leadership. I was summoned to a meeting intended to terminate my employment. Present were the RT director, NICU nurse manager, a Risk Management representative, the hospital vice president, and Dr Harris. I argued that the entry had been properly redacted and, officially, ceased to exist. They replied, “But we can still read it.” I answered, “But you aren’t supposed to.”

Just before termination, one person came to my defense. Dr Tom Harris. He acknowledged that my initial wording was not constructive, but affirmed that the content was accurate and that the CPT should not have been ordered. Tom’s advocacy saved my job.

I should have moved forward after that meeting, happy to still have a job. Instead, I wrote a one-page letter arguing that this severely compromised infant deserved the right to die—and to do so with dignity. I sent a copy to every individual present at the meeting. And now I was holding the letter Tom had placed in his archives thirty years ago.

Understanding Moral Distress

The neonatologist and bioethicist Dr Annie Janvier describes in her book “Breathe, Baby, Breathe!” (1) a file she found on her computer years after her own daughter’s NICU course. Dr Janvier had titled it “TOXIC SHIT,” and the file contained a collection of thoughts written during moments of fear, uncertainty, trauma, and fragile joy. It dawned on me after reading her book that this is where I should have placed my 1984 letter—my own Toxic Shit file—rather than distributing it to those who attended my hearing. But at the time, I failed to recognize the letter for what it was: a manifestation of Moral Distress.

Moral Distress arises when a clinician knows the ethically appropriate course of action but is constrained from taking it. Constraints may be the result of internal quandaries or external factors. The cumulative effects can be profound, influencing emotional well-being, professional identity, and the ability to provide compassionate care. In retrospect, the distress I experienced was rooted in external pressures—hierarchical decision-making, clinical orders I believed harmful, and the overwhelming moral weight of caring for a suffering infant.

Recently, when I shared this experience with a group of respiratory therapists, one asked what I could have done differently. A useful framework for answering that question is the “Four Rs” response strategy.

The Four Rs: A Framework For Responding To Moral Distress

Cynthia Shaver, MS, RN, describes four steps that may help clinicians navigate Moral Distress and reduce the risk of Moral Injury, the deeper harm that occurs when distress remains unresolved (2). Each step is followed by a self-assessment of my personal experience.

1. Recognize: Acknowledge the situation for what it is.

* I did this: I recognized that the CPT order was not indicated nor in the infant’s best interest.

2. Release: Identify what can and cannot be changed; set aside unhelpful past experiences.

*I also did this: I understood I could not change the NNP’s mind, nor alter the infant’s prognosis, but that I was required to follow written orders.

3. Reconsider: Reframe the issue or approach it from a new angle; seek mutual understanding.

*Here is where the wheels came off. Instead of becoming angry, I could have calmly asked the nurse practitioner to explain the physiological rationale for CPT in this baby’s circumstance. We might have then explored alternatives to the treatment and assured clearer communication. Looking at alternatives is a way of reconsidering.

4. Restart: With new insight, begin again—inviting collaboration and exploring constructive solutions.

*Another mistake on my part. Had I restarted, I might have recruited the primary nurse and the attending neonatologist into the discussion. I might have followed the chain of command, all the way up to Dr Harris, who I learned later felt the same way I did about the CPT order and the distress it was causing the patient.

Parents and Shared Moral Distress

Clinicians entangled in their own moral imbroglio may overlook that parents are likely navigating profound moral conflict as well. They face decisions they never imagined—decisions involving life support, suffering, and when to allow their own child to die. Tom understood this with uncommon clarity. Many of his handwritten notes and papers grappled with the ethical ambiguities of medically complex babies and how they might impact parents.

One document I found contained his personal guidance for speaking with parents of a desperately compromised infant, especially when the news is discouraging. His words remain instructive.

The Tom Harris Credo

“When referring to the child, hold the baby separate from the disease process or malformation.”

Examples:

- The baby is not ill; the baby is a beautiful child fighting an illness.
- The baby is not malformed; the baby has a malformation.
- The baby is not disabled; the baby has a disability.
- The baby is not dying; the baby is living a short life that we wish to make as beautiful and loving as possible.
- For the mother, her baby is the most beautiful child in the world.

“The crucial question the parents are waiting for you to answer is: are we prolonging life or just delaying death?”

Conclusion

In the end, the materials Tom Harris left with me—and the memories they revived—underscore the persistent ethical ambiguity at the heart of neonatal intensive care. Moral Distress is not an aberration but an inherent risk of practicing in a space where life and death coexist so intimately, and where clinicians and families must navigate choices no one is ever fully prepared to make.

Revisiting my own experience through Tom's lens, and through contemporary frameworks such as the Four Rs, offers a reminder that while we cannot eliminate Moral Distress, we can learn to recognize it, respond to it thoughtfully, and support one another through its emotional maze.

Tom's credo captures the essence of this work: to see the baby from the parents' perspective, to offer clinical clarity when the path is unclear, and to help families discern whether we are prolonging life or merely delaying death. His legacy reinforces that compassion, humility, and honest dialogue remain our most reliable guides in the morally complex world of the NICU.

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intravenous interventions without additional risks of necrotizing enterocolitis," experts wrote in an accompanying comment.

Preterm, Cesarean Births More Common in Myasthenia Gravis

Women with generalized myasthenia gravis (gMG) who become pregnant face sharply higher risks for preterm birth and cesarean delivery — and much higher healthcare costs — a new analysis of health claims data showed. Pregnant patients with gMG were 2.5 times more likely to have a preterm birth (P = .021) and 2.64 times more likely to have a cesarean delivery (P = .006) than those without the disease, said study investigator Nolan Campbell, PhD, medical director of Autoantibody Neuroimmunology at Johnson & Johnson, Horsham, Pennsylvania, and colleagues. "These are obviously outcomes we would hope to avoid, and they speak to the need to improve disease management for these patients with the goal of avoiding such outcomes," Campbell said. Pregnancy in women with gMG presents unique clinical challenges, but data on real-world outcomes remain sparse. The investigators sought to fill this gap, as evidence on how gMG affects maternal and neonatal outcomes, as well as associated healthcare costs, remains limited despite the condition's higher incidence among women of reproductive age. "In the modern treatment era for MG in the US, there is still unmet need for this population of women who are pregnant," said Campbell. The study included 97 pregnant patients with gMG and 970 pregnant individuals without the disease. Participants, aged 18-49 years, were treated between January 1, 2016, and March 30, 2023, and were identified through the Komodo Research database. The cohorts were weighted by age, race, region, insurance type, and index year to ensure comparability. Demographic characteristics were similar between groups: The mean age was 32 years, and racial distribution was 37% White, 13.4% Black or African American, 19.6% other, and 28.9% unknown. Participants were geographically distributed across the US, with 38.1% residing in the South, 28.9% in the Northeast, 18.6% in the Midwest, and 14.4% in the West. Most patients (72.2%) had commercial insurance, followed by Medicare Advantage (19.6%) and Medicaid (8.2%). Preterm birth occurred in 21.1% of those with gMG vs 9.6% of those without, and cesarean delivery rates were 21.1% and 9.9%, respectively. There were no statistically significant differences between the groups in live birth, abortion (induced or spontaneous), or ectopic pregnancy. Mean gestational age among those with live births was lower in the gMG cohort (37.0 weeks) than in the non-gMG cohort (38.2 weeks; P = .008).

US Mothers May Run Risks by Sharing Breast Milk

One in 27 first-time mothers reported noncommodified peer-to-peer milk sharing via online or personal networks outside of accredited pasteurized donor human milk (PDHM) banks, a large study in a diverse US population found. Pediatric clinicians should be aware of this practice and advise mothers about risk-reducing strategies, said Jill R. Demirci, PhD, RN, director of the Maternal/Perinatal and Reproductive Health Research Hub at the School of Nursing, University of Pittsburgh, Pittsburgh, and colleagues. The findings appeared in JAMA Network Open. "Clinicians should recognize that informal milk sharing happens across many populations of US parents and provide nonjudgmental guidance on how to mitigate risk, such as safe handling and storage," co-author Lori Uscher-

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Supporting Intubated Infants: A New, Specialized Solution for Non-Nutritive Sucking

Jessica Harnish MSN, NNP-BC and Elle Kisabeth

Non-nutritive sucking (NNS) is a reflex which infants begin to develop very early in the gestational period, around 15 weeks into pregnancy. NNS in the neonate is a primitive reflex that is predictable and rhythmical; a fundamental infant skill that is important for oral feeding and self-regulation.[1,3] It is an involuntary response elicited when a tactile input is given in or around the mouth, resulting in the infant closing the mouth around the stimulus, developing an intraoral pressure system, and engaging in rhythmical compression and suction on the stimulus.[2] The usage of a pacifier in the early days/weeks after birth is a critical way to augment this reflex. NNS plays a vital role in the growth and development of an infant. Its many physiological benefits include development of sucking behaviors, improved digestion of feeds, creating a positive oral experience, pain relief, and its use may decrease length of hospital stay.

Many preterm infants have respiratory issues, including respiratory distress syndrome (RDS) and chronic lung disease (CLD) that require oxygen supplementation ranging from a few days to several months during hospitalization in the NICU. Ororhythmic pattern development for suck may be disrupted in these infants who are routinely subjected to abnormal tactile stimulation of sensitive peri-oral and intra-oral tissues during extended periods of intubation and cannulation. Trussing the lower face and nostrils with tubes and tape also restricts the range and type of oral movements. In animal models, the combination of sensory deprivation and motor restriction has been shown to disrupt the development of sensorimotor areas of the brain, including motor cortex and cerebellum. This is consistent with the notion of a critical period during late gestation and early postnatal life, when manipulation of the trigeminal sensory field to treat RDS may significantly alter the structure and function of the developing brain, delay attainment of oromotor skills such as NNS, and may negatively impact the transition to oral feeds.[5]

An infant's sucking behaviors may widely vary throughout growth. NNS can be affected by preterm birth. Preterm infants may not have the muscle strength necessary to successfully suck.[2]

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Developing strong sucking patterns depend on NNS, and tools like pacifiers help the infant practice these sucking skills directly after birth.

NNS helps improve the way that the infant ultimately feeds and accordingly improves digestion. Effective NNS interventions not only decrease the incidence of adverse events like oxygen desaturation, apnea, and bradycardia but may also lessen long-term issues such as feeding or eating aversion.[4] Several enzymes/hormones have been implicated in the facilitation of digestion through NNS: lingual lipase, gastrin, insulin, and motilin. Experts believe that NNS stimulates the secretion of these enzymes/hormones through vagal innervation in the oral mucosa.[6] Evidence suggests that providing non-nutritive sucking opportunities to premature infants during gavage feeding may have beneficial effects on oxygen saturation, gastrointestinal function, growth, and development. NNS use has also been linked to improving the initiation and duration of the first nutritive suck, enhancing weight gain and reducing transition time between gavage and oral feeding.[6]

NNS creates a positive oral experience for the infant. NNS is one of infants' first methods of self-organization and self-soothing. Particularly with a pacifier, NNS is believed to have a calming effect on infants and is commonly used as a non-pharmacological intervention in nurseries and neonatal intensive care units.[6] The

Figure 1. The Numi pacifier fits perfectly around his breathing tube and is so easy for nurses and parents to use. It's become such a sweet, important part of his care. —NICU mom

data indicates that oral sucrose combined with NNS generates a more effective synergistic effect than either of these interventions alone.[5] When NNS and the usage of other pain reducing agents come together, infant pain and anxiety can be greatly reduced.

Study findings by Pineda et al consistently revealed that infants who had increased length of time on a mechanical ventilator or other respiratory supports had reduced NNS performance.[2] These critical infants do not have the tools to gain the skill, comfort and stability they so desperately need. Drawing on 20 years of clinical experience observing pacifiers modified for this specific patient population, WarriorNP developed Numi™, a breakthrough pacifier specifically engineered for intubated infants. Supporting NNS even during endotracheal intubation, Numi's™ innovative design fits comfortably under the endotracheal tube, keeping it midline and secure without compromising infant comfort. Crafted from BPA-free, medical-grade silicone, Numi™ is soft, flexible, and safe—offering soothing comfort and essential oral motor stimulation from the earliest moments of life. By reducing discomfort and helping prevent oral aversion, Numi™ supports the healthy development of sucking patterns and promotes positive oral experiences for even the most medically fragile newborns. With Numi™, babies can experience the benefits of NNS—no matter their medical condition. Numi™ is available in 2 sizes, for all warriors big and small. Please visit **www.warriornp.com/numi-nicu-pacifier** for your free sample.

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Pines, PhD, a senior policy researcher at RAND Corporation in Arlington, Virginia, said. The results highlight persistent gaps in breastfeeding support and access to PDHM, especially for low-income families. "Expanding equitable access to professional lactation support and donor milk could reduce interest in informal milk sharing," said Uscher-Pines. PDHM is rarely accessible for healthy infants because it is prioritized for preterm and medically fragile newborns and is also expensive. The study used data from a 2024 randomized clinical trial of telelactation support that recruited nulliparous women of 33-37 weeks' gestation across 39 states from July to December 2022. Data were available for 1909 of 2108 enrolled participants with a mean maternal age of 29.6 years. The demographically diverse cohort included 32% Black individuals, 3% American Indians or Alaska Native populations, 5.1% Asians, and 51.5% White individuals.

New Study Demonstrates Feasibility of Screening Newborns for Genetic Trait Leading to High Cholesterol

A new study published in JAMA Cardiology shows familial hypercholesterolemia (FH) can be detected in newborns using a dried blood spot, a test used for other types of genetic screening in infants. The condition carries a high risk for morbidity and premature death, especially for people who inherit genetic defects from both parents (ie, homozygous inheritance). The disorder is autosomal dominant, so inheriting the defect from even one parent (ie, heterozygous inheritance) predisposes a child to lifelong elevated levels of low-density lipoprotein cholesterol (LDL-C). People with untreated homozygous FH rarely survive past the third decade. While homozygous FH is rare, occurring in an estimated 1 in 300,000 persons, heterozygous variants in the LDL receptor or a cholesterol-regulating protein are present in about 1 in 250-300 people. The new study, led by Amy Peterson, MD, MS, director of pediatric preventive cardiology at the University of Wisconsin, Madison, used validated techniques to measure total cholesterol, LDL-C, and apolipoprotein B (ApoB) from 10,000 dried blood spot specimens from newborns. Genetic testing was performed in 768 samples with high LDL-C and ApoB to look for pathogenic variants associated with FH. Variants were confirmed in 16 of these samples, suggesting 1 in 625 newborns in the general population will carry a pathogenic defect for FH. "If implemented, newborn screening for FH would be used to detect homozygous FH and possibly severe heterozygous FH," Peterson said. "It's important to note that newborns with milder heterozygous FH phenotypes — and any child with polygenic hypercholesterolemia or hypercholesterolemia due to other causes — would not be identified through newborn screening." Newborn screening would supplement, rather than replace, cholesterol screening at other times during childhood and adolescence, Peterson added.

Genetically Engineering Babies

A small San Francisco-based startup called Preventive is quietly developing technology to create genetically-engineered babies—despite such procedures being banned in the US and many other countries. The company is backed by prominent tech figures like Sam Altman (of OpenAI) and Brian Armstrong (of Coinbase). Preventive has raised around $30 million and is exploring research opportunities in countries with more permissive regulation than the US—including the United Arab Emirates. Its stated aim is to prevent hereditary diseases by editing embryos before implantation. The company is also mulling "what would

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Reducing Enteral Feeding Misconnections in the NICU: The Role of Dedicated Neonatal Enteral Feeding Systems

Constance Girgenti, MSN, RN, VA-BC

Abstract
Enteral feeding misconnections are rare but potentially catastrophic patient safety events. Neonates are uniquely vulnerable due to multiple access devices, small-bore tubing systems, precise low-volume delivery, and frequent medication administration. Human vigilance alone is insufficient to prevent errors. Engineering solutions, including application-specific connectors and neonatal-specific enteral feeding systems, reduce misconnections, improve dosing accuracy, and optimize workflow efficiency. This article reviews the risk of enteral misconnections in neonatal care and discusses how neonatal-specific feeding systems compliant with ISO standards enhance safety and efficiency in the NICU.

Introduction

Medical tubing misconnections occur when devices intended for one route are inadvertently connected to another, sometimes delivering enteral nutrition intravenously, resulting in severe injury or death (Guenter et al., 2008). Although infrequent, these events are classified as sentinel by accrediting organizations due to their severity (The Joint Commission, 2014).

The NICU presents a high-risk environment: multiple catheters, feeding tubes, and respiratory circuits in confined spaces, compounded by high-acuity conditions and frequent device manipulations. These factors necessitate system-level solutions, rather than reliance on human vigilance alone, to prevent misconnections and medication dosing errors.

Misconnection Risk in Neonatal Care

NICU staff manage frequent line access, device manipulations, and patient transitions, all increasing misconnection risk. Fatigue, shift handoffs, short staffing and look-alike connectors further elevate the risk (Simmons et al., 2016). Historically, widespread use of Luer connectors across multiple applications enabled unintended cross-connections between enteral, intravenous, and respiratory systems.

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The ISO 80369 series was developed to address these risks by creating -specific small-bore connectors, physically incompatible with non-target devices (ISO, 2016). For enteral feeding, these connectors prevent cross-connection with intravenous and other systems, reducing a major safety vulnerability for both patient and nurse.

Neonatal-Specific Enteral Feeding Systems

Neonates—especially preterm or extremely low birth weight infants—require feeding systems specifically designed for their physiology. Devices adapted from pediatric or adult populations may not adequately address neonatal risks such as inaccurate low-volume medication delivery, increased dead space, tube dislodgement, and feeding intolerance (Becker et al., 2021; Guenter et al., 2008).

Neonatal-specific systems deliver very small, precise medication volumes, including a small mote thus not needing a cleaning protocol. Compliance with ISO 80369 standards ensures physical incompatibility with non-enteral devices, further enhancing safety. Standardizing these systems across a NICU improves staff familiarity and consistency of care (Morgan et al., 2014; Simmons et al., 2016).

Medication Dosing Accuracy and Workflow Efficiency

Accurate medication delivery is critical in neonates due to small dosing requirements. Standard enteral systems may introduce dose variability through dead space, residual volume loss, or inconsistent syringe interfaces. In an *in vitro* comparison, neonatal-specific ISO-compliant enteral syringes delivered significantly more accurate doses than ENFit LDT syringes, with only 4.7% of tests exceeding acceptable dosing variance compared with 48% for LDT designs (O'Mara et al., 2023).

Figure 1. ENFit (left) & NS2 (right).

Neonatal-specific systems also improve workflow, requiring no cleaning protocol, reducing nursing workload, and contamination risk. These operational efficiencies support safer, more reliable care and optimize clinician time in high-acuity NICU settings.

Clinical Implications

Adopting neonatal-specific, enteral-only feeding systems aligns with patient safety recommendations and reduces reliance on human vigilance. NICUs implementing standardized neonatal enteral systems can expect:

- Reduced misconnection risk
- Improved medication dosing accuracy
- Streamlined nursing workflow

Integrating these systems into unit protocols represents a practical, evidence-based, system-level intervention to improve safety and operational efficiency in the NICU.

Conclusion

Enteral feeding misconnections and dosing inaccuracies are preventable risks in neonatal intensive care. Neonatal-specific enteral feeding systems with application-specific connectors mitigate these risks by preventing incompatible connections, supporting precise medication and nutrition delivery, and streamlining workflows. Widespread adoption in NICUs enhances safety, efficiency, and quality of care for vulnerable neonatal patients.

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If Fetal-to-Fetal In Utero Kidney Transplantation Was Performed, Why Not Heart Transplantation?

More science fiction than science…

Boris Petrikovsky, MD, PhD, Lev Neymotin, PhD, Arkady Uryash, MD, PhD

Introduction

Congenital heart defects incompatible with postnatal survival occur in approximately 1 in 4,000 births in the United States, representing close to 1,000 affected fetuses annually and more than 40,000 worldwide. Neonatal heart transplantation is rarely feasible in these cases because of donor scarcity, size mismatch, and the profound hemodynamic instability that characterizes severely compromised newborns at birth.[1] This persistent gap between clinical need and available therapy provides the foundation for considering in utero heart transplantation (IUHT) as a technically motivated therapeutic strategy for otherwise lethal congenital heart disease.[2]

Why In Utero Heart Transplantation Now?

IUHT proposes a fundamentally different approach to cardiac replacement by shifting transplantation from the neonatal period to fetal life. The fetal environment offers two biological advantages that cannot be replicated after birth and that directly address the technical limitations of neonatal transplantation:

Placental circulation eliminates the need for a heart-lung machine

During fetal life, oxygenation and carbon dioxide exchange are entirely placental. The placenta functions as a natural cardiopulmonary support system, allowing the fetal heart to be arrested or replaced without the metabolic instability and systemic stress associated with postnatal cardiopulmonary bypass.[3]

The fetal immune system is programmed toward tolerance

Before thymic maturation, the fetal immune system favors tolerance rather than rejection. This principle has been validated in in utero hematopoietic stem cell transplantation and raises the possibility that IUHT could achieve durable graft acceptance with reduced reliance on lifelong immunosuppression—one of the central challenges of pediatric heart transplantation.[4-8]

In contrast to earlier eras, the present clinical environment is characterized by clear determination of death standards, regulated donor authorization pathways, increased consistency regarding anencephalic organ donation, and well-established maternal-fetal surgical safety frameworks.[9,10] In parallel, recent advances in catheter-based fetal cardiac intervention have demonstrated that increasingly complex intracardiac procedures can be performed safely during gestation.[11] Together, these developments create conditions in which the technical feasibility of IUHT can be examined systematically.

Boris Petrikovsky, Professor of Obstetrics and Gynecology, Editorial Board Member.
Lev Neymotin is a former researcher at Brookhaven National Laboratory.
Arkady Uryash is with Mount Sinai Medical Center, Advanced Research Institute, Miami, Florida.

Historical and Ethical Landscape

The concept of IUHT emerges from earlier ethical discussions surrounding neonatal organ donation, particularly from infants with anencephaly.[12] The literature documents the controversies that accompanied early transplantation efforts and the regulatory uncertainty that limited their broader application. These discussions provide historical context but are not the primary focus of the present work.

Lessons from Early Infant Heart Transplants

Infant heart transplants performed in the late twentieth century demonstrated that surgical replacement of a newborn heart is anatomically feasible. At the same time, they revealed fundamental limitations of the neonatal setting: postnatal physiology in critically ill neonates is inherently unstable, donor procurement practices were inconsistently regulated, and mortality frequently reflected systemic constraints rather than surgical impossibility.

Kantrowitz et al. performed the first human heart transplant in America at Maimonides Medical Center in Brooklyn on 12/06/1967, transplanting a brain-dead infant's heart to another neonate. The recipient died 612 hours after surgery due to severe acidosis.[13]

NAFTNet Guidelines and Modern Oversight

Current fetal interventions operate within a defined ethical framework articulated by North American Fetal Therapy Network (NAFTNet) and related professional bodies.[9] This framework emphasizes maternal safety, fetal beneficence, and transparent risk disclosure.[14]

Scientific and Clinical Rationale

Developing a rationale for IUHT begins with an appreciation for the unique biological conditions that exist only during fetal life. The fetus is in rapid transition, supported by physiologic conditions that do not persist after birth.

Fetal Immune Tolerance

One of the most compelling elements of IUHT is the developmental state of the fetal immune system. Before birth, the immune system is not yet fully trained to distinguish "self" from "non-self," and this window of immaturity allows for tolerance pathways that are impossible to replicate later in life. Studies of **in utero hematopoietic cell transplantation (IUHCT)** have shown that donor-derived cells introduced during early to mid-gestation can engraft and persist long-term, with little or no need for postnatal immunosuppression.[4-8]

Although solid organs are more immunologically complex than hematopoietic cells, the underlying principle still applies: the fetal immune environment is unusually receptive. If a donor heart or even a partial cardiac graft were implanted during this immunologic window, the potential for long-term graft acceptance without the burden of lifelong immunosuppression becomes a realistic, if still unproven, possibility.[7]

Placental Physiology as Natural Cardiopulmonary Support

A second advantage unique to fetal life is the extraordinary role of the placenta. In many ways, the placenta functions as a biologic version of cardiopulmonary support—far more stable than any mechanical alternative available after birth.[3] Oxygenation, carbon dioxide exchange, nutrient delivery, temperature regulation, and metabolic waste removal all occur independently of the fetal heart and lungs. This means that during surgery, the fetal heart can be arrested or partially reconstructed **without jeopardizing systemic oxygenation**, something that would be life-threatening in a newborn. Placental support allows the surgical team to operate in a physiological environment that is inherently protected from the hemodynamic collapse that accompanies neonatal procedures. The advantage is not subtle; it fundamentally shifts the technical and physiological limits of what can be done safely.

Advances in Fetal Surgical Technique

Any discussion of IUHT must also acknowledge how dramatically fetal surgery has changed over the past two decades. Procedures that once required hysterotomies and prolonged uterine exposure are now performed with highly refined fetoscopic or hybrid techniques, including complex intrathoracic interventions carried out through minimally invasive access.[2,10] Surgical visualization, microinstrumentation, anesthetic control, and fetal positioning systems have *all* advanced to the point where even delicate operations inside the fetal thorax can be approached with precision.

The Relevance of Partial Heart Transplantation

A particularly meaningful development for the future of IUHT has been the emergence of **partial heart transplantation**, an approach that involves transplanting only selected components of the heart—most often the ventricles or individual valves.

Recent work has shown that these partial grafts can integrate successfully and even demonstrate growth in pediatric recipients.[14] This is significant because many fetuses with lethal congenital heart disease have **normal atria**, with pathology confined primarily to the ventricles or outflow tracts. In such cases, replacing only the affected structures may be more achievable than attempting a full cardiac transplant.

Clinical Relevance of In Utero Kidney Transplantation (IUKT)

Potter sequence, typically resulting from severe bilateral renal agenesis or renal dysplasia, is uniformly fatal without renal replacement therapy.[15] Affected fetuses develop severe oligohydramnios, pulmonary hypoplasia, and limb contractures.

One of the strongest practical precedents for IUHT comes from the only solid-organ transplant successfully performed during fetal life: **in utero kidney transplantation (IUKT)**. Although still investigational, IUKT has demonstrated that a donor organ can be surgically implanted, perfused, and functionally integrated during gestation.[16-18]

Converging Rationale

The arguments for IUHT are not derived from a single discovery but from the alignment of multiple independent scientific observations:

- Immunologic permissiveness of fetal development,
- Stabilizing effects of placental physiology,
- Refined capabilities of contemporary fetal surgery,
- Demonstrated feasibility of partial cardiac transplantation, and
- Precedent of successful in utero kidney transplantation, demonstrating that solid-organ fetal surgery is possible.[3-8,17-22]

Technical Feasibility and Modern Advancements

Although IUHT has never been attempted, the individual technical components required for such a procedure already exist within contemporary fetal surgery, cardiovascular surgery, and transplantation medicine. IUHT requires an exceptionally short warm ischemia interval—ideally under 10 minutes. Several modern innovations directly support this goal, including microsurgical sutures, end-to-end anastomotic couplers, laser-assisted vascular welding tools, and adhesive-assisted vascular fusion technologies.

Recent work by Overbey et al. demonstrates that partial cardiac grafts—particularly involving the ventricular outflow tract and valve complexes—can be implanted successfully with fewer and larger anastomoses than those needed for complete heart replacement.[14] Fetal kidney studies also demonstrated the feasibility of rapid vascular anastomosis.[16,18] For IUHT, this reduction in the number and size of connections significantly decreases the technical complexity of the procedure.

Maternal Risk Profile

Maternal safety remains a prerequisite for any fetal intervention. The risks associated with IUHT are therefore considered here to define feasibility boundaries rather than to provide an exhaustive review of maternal-fetal surgery outcomes.[16,23]

Summary

Although no human in utero heart transplantation has yet been performed, the **surgical, physiologic, and immunologic foundations** required for such a procedure are now sufficiently developed to make IUHT a technically plausible target for translational investigation. Placental circulation provides continuous cardiopulmonary support, and the fetal immune environment offers a unique opportunity for tolerance induction. Advances in fetal surgery and microvascular techniques further support the feasibility of cardiac replacement during gestation.

From a regulatory perspective, contemporary transplant policy recognizes the fetus as a transplant candidate, resolving earlier ambiguities. Historically, IUHT extends a trajectory that began with experimental organ transplantation and progressed through neonatal cardiac replacement and modern fetal intervention. Positioned just beyond current clinical practice, IUHT represents a technically grounded direction for future exploration rather than speculative abstraction.

Limitations and Unresolved Questions

While the theoretical advantages of IUHT are compelling, several limitations must be acknowledged. Many of the physiological and immunological benefits described in earlier sections—although well supported by existing principles—have not yet been validated in the context of a full or partial cardiac transplant performed during fetal life. Practical application may reveal outcomes that differ from what current models predict.

Translational Pathway and Key Takeaways

Although IUHT remains a near-future objective, the sequence of four steps required to move from conceptual work to a carefully supervised first-in-human attempt is already clear:

Step 1. Refinement of animal models, focusing on optimizing surgical access, donor-graft handling, timing of placental support, and techniques for vascular reconstruction.

Step 2. Optimization of perfusion and microanastomosis protocols, including methods for ex-vivo donor-heart preparation, strategies to limit ischemic injury, and workflow models that synchronize implantation with placental physiology.

Step 3. Establishment of donor-eligibility and consent guidelines that align with existing OPTN/UNOS policies on fetal transplant candidates and reflect contemporary standards for ethical use.

Step 4. Implementation of carefully governed pilot feasibility studies, incorporating real-time maternal monitoring, independent ethical review, and stringent eligibility criteria to ensure that maternal safety remains the priority.

As a sequence, the steps outlined above lie just beyond current clinical practice, informed by tools, principles, and experience already in hand.

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Reducing Hypothermia in High-Risk Newborns: What One Quality-Improvement Project Teaches the Rest of Us

Commentary on Andrews C, Whatley C, Smith M, et al. Pediatrics 2018;141(3):e20171214

Hypothermia in fragile newborns has always felt a bit like an "old problem" we assume we've already solved. Modern units are warm, babies wear hats, and early skin-to-skin is standard. Yet when you look carefully at temperature data, a different story often emerges: late-preterm and low birth weight infants are still getting cold, still needing interventions, and sometimes still going to the NICU for an issue that is largely preventable.

In their quality-improvement report in Pediatrics, Christine Andrews, MD, MPH, and colleagues shine a bright light on this gap. Working in a mother–infant unit rather than a NICU, they asked a deceptively simple question: can a structured bundle of basic thermoregulation practices reduce hypothermia in late-preterm infants (LPIs) and low birth weight (LBW) infants who would otherwise be candidates to room-in with their mothers? Their answer, backed by careful data and statistical process control (spc), is a resounding "yes"—and the implications extend well beyond temperature management.

The Problem: Cold Stress in the "Well Baby" Environment

The authors start with a reality many clinicians will recognize. Hypothermia—defined in this study as a rectal temperature <36.0°C—is not limited to extremely preterm babies in the NICU. LPIs (35–36 6/7 weeks' gestation in their unit) and LBW infants (1750–2500 g) cared for on a mother–infant unit had a baseline hypothermia rate of nearly 30%. For all newborns in the same unit, the rate was 9–10%.

These are not trivial events. As Andrews and colleagues remind us, hypothermia is associated with hypoglycemia, respiratory distress, sepsis, metabolic acidosis, and even increased mortality in vulnerable infants. It also consumes nursing and physician time, generates lab testing, and often prompts transfers to the NICU. Each avoidable transfer means maternal–infant separation, parental anxiety, and increased resource use.

The team's working hypothesis was blunt and important: much of this hypothermia was environmental and therefore preventable. The key was to standardize the "small things" that, in aggregate, determine an infant's thermal experience in the first 24 hours.

The Intervention: Three PDSA Bundles, One Clear Goal

Andrews et al. conducted their project on the mother–infant unit of the Children's Hospital at Dartmouth-Hitchcock, a setting familiar to many of our readers: 22 LDRP beds, 19 bassinets, ≈1200 births per year, and an adjacent level III NICU. Otherwise healthy infants ≥35 weeks and ≥1750 g stay with their mothers unless clinical issues arise. A confirmed rectal temperature <36.0°C, per policy, is a reason to transfer to the NICU.

A multidisciplinary team—a pediatric hospitalist, nurse manager, clinical nurse specialist, bedside nurses, and a medical student—met regularly and implemented a series of plan–do–study–act (PDSA) cycles. They rolled out three bundles over time:

1. PDSA 1 – Immediate Towel Drying for All Newborns (July 2015)

   Instead of the soft but relatively non-absorbent blankets used previously, all infants were thoroughly dried with warm towels immediately after birth before skin-to-skin. This simple change targeted evaporative heat loss in the first minutes of life.

2. PDSA 2 – Targeted Bundle for LPIs and LBW Infants (August 2015)

   For the highest-risk babies, the team added a bundle of thermoregulatory measures:

   - A plastic-lined knit hat for occlusive head coverage
   - Delayed bathing until at least 12 hours of life
   - All provider assessments in the first 12 hours performed under a radiant warmer
   - A visual crib card to identify LPIs/LBW infants and cue staff to use the bundle

3. Before this bundle, there were no standardized thermoregulation protocols for these infants, no consistent hat use, and no standardization around bath timing or the location of assessments.

4. PDSA 3 – Delayed, Submersion Bathing for All Newborns (December 2015)

Finally, the team broadened some elements to all newborns: baths were delayed until at least 12 hours of life, and sponge baths were replaced with submersion tub baths, which previous work has shown to better preserve temperature than sponge-bathing under a radiant source.

Throughout the project, a medical student conducted biweekly audits to ensure fidelity, and the team used e-mails, posters, and charge nurse leadership to reinforce practice changes.

The Results: A Two-Thirds Reduction in Hypothermia in the At-Risk Group

Between July 2014 and September 2016, 2161 eligible births remained on the mother–infant unit and were included in the analysis. Of these, 215 (about 10%) were LPIs and/or LBW infants.

The baseline numbers tell the story clearly:

- Preintervention hypothermia:
  - LPIs/LBW infants: 29.8%
  - All newborns: 9.4–9.5%

After the interventions were rolled out, the team saw a stepwise and sustained improvement in the high-risk group:

- Early intervention (PDSA 1 + 2): hypothermia in LPIs/LBW fell from 29.8% to 19.2%.
- Full intervention (all three PDSA cycles): the rate dropped further to 10.0%.

From start to finish, that's roughly a two-thirds relative reduction in hypothermia among LPIs and LBW infants. Statistical process control charts showed a classic "special-cause" signal, with nine consecutive data points below the baseline centerline after the full bundle was in place—a hallmark of real system change rather than random variation.

For the total population of newborns on the unit, the effect was more modest but still significant: hypothermia decreased from 9.4% to 7.1%, about a one-quarter relative reduction.

Equally important, the team monitored for the opposite problem: hyperthermia. Maximum recorded temperatures and the proportion of infants with rectal temperatures >37.5°C did not increase in the postintervention period. In other words, they were able to keep more babies warm without inadvertently overheating them.

Why This Matters: Rooming-In, Value, and Family-Centered Care

The clinical consequences of hypothermia are real, but the downstream system and family impacts are just as important. In many hospitals, a rectal temperature below 36.0°C in an at-risk infant triggers:

- Extra bedside monitoring
- Blood glucose checks and sepsis evaluations
- Radiant warmer or isolette care
- NICU transfer for more intensive observation

Each of these responses is appropriate when clinically needed—but if the initial temperature drop is preventable, all of that extra care is avoidable as well.

Andrews and colleagues make a strong case that targeted environmental strategies can allow otherwise healthy LPIs and LBW infants to safely remain on the mother–infant unit, rooming-in with their parents. This advance is not just about temperature; it's about preserving the benefits of rooming-in: improved breastfeeding, early bonding, parental confidence, and a more family-centered experience.

From a health system standpoint, the project supports a broader conversation about value. Avoiding unnecessary NICU admissions frees scarce intensive care capacity for infants who truly need it, reduces costs, and aligns with emerging data suggesting that NICUs may have been overused in higher-gestational-age, higher-birthweight infants over the past decade.

The takeaway is powerful: if we get the basics of thermal care right, more high-risk infants can safely stay with their families.

The "Small" Practices That Make a Big Difference

One of the strengths of this QI project is that none of the interventions are exotic. They are exactly the things we sometimes think we are doing—but not always, not consistently, and not as a coordinated bundle.

Key elements include:

- Active drying with warm, absorbent towels immediately after birth, not just a quick wipe with a blanket.
- Occlusive head coverage using a hat designed to reduce evaporative and convective heat loss.
- Delaying baths until after the first 12 hours of life, when infants are more stable.
- Submersion tub bathing rather than sponge baths under radiant heat.
- Performing early assessments under a radiant warmer for at-risk infants instead of in an open bassinette.
- Visual cues (crib cards) so every team member recognizes the infant as high risk and applies the bundle automatically.

Are any of these ideas new in isolation? Not really. What's novel here is the disciplined combination, the attention to implementation, and the insistence on measuring outcomes rigorously over time.

For respiratory and neonatal clinicians, this is a familiar theme. We see the same pattern in sepsis bundles, ventilator bundles, and feeding protocols: no single intervention is magic, but when you combine small evidence-based steps, the cumulative effect is substantial.

Strengths, Limitations, and What to Watch For

The authors are appropriately cautious about their findings. This is a single-center project in a relatively small children's hospital with a cohesive team of pediatric hospitalists and mother–infant nurses. That made it easier to communicate and sustain changes than it might be in a large, complex perinatal center.

They also did not attempt to control for secular trends beyond looking for obvious demographic shifts (there weren't any) or large changes in room temperature (also absent). Seasonal variation, staffing changes, or subtle shifts in practice could theoretically have contributed, but the timing and pattern of improvement strongly support the interventions as the primary driver.

One particularly thoughtful aspect of the study is the way the team defined and verified hypothermia. They only counted events confirmed by rectal temperature, acknowledging that axillary measurements in newborns can underestimate or misclassify thermal status. This attention to measurement detail strengthens the validity of the results.

Implications for Your Unit: How to Get Started

For readers of Neonatal Intensive Care and Respiratory Therapy who are caring for late-preterm and small infants on mother–infant units, the questions practically ask themselves:

- What is your current hypothermia rate in LPIs and LBW infants in the first 24 hours?
- Do you know how often hypothermia contributes to NICU transfers?
- Are your thermoregulation practices standardized or left to individual preference?
- Do you differentiate protocols for the higher-risk group (35–36 6/7 weeks, 1750–2500 g)?

The Andrews et al. project offers a practical blueprint:

1. Measure your baseline. Start with a three- to six-month lookback using rectal temperatures and clear thresholds.
2. Build a small, empowered team. Include bedside nurses, a physician champion, and a QI-minded analyst or educator.
3. Pick a simple first PDSA cycle. For example, standardize immediate towel drying and hat use, or delay baths in high-risk infants.
4. Add visual cues. A crib card or color-coded identifier for LPIs/LBW infants can make practice consistent.
5. Monitor, adjust, and expand. Use run charts or SPC methods to track progress, then broaden successful strategies to all newborns.

The beauty of this approach is that it doesn't require new technology, special staffing, or major construction. It requires focus, discipline, and a willingness to treat thermal care as a core safety process, not a background detail.

Where Thermoregulation Devices Fit In: The Role of Occlusive Hats

A central component of the PDSA 2 bundle was the use of a plastic-lined knit hat to provide occlusive heat protection for high-risk infants. The physiology behind this is straightforward: newborns lose a disproportionate amount of heat through the head, and when that heat loss is reduced—especially in small or late-preterm infants—the overall thermal balance is easier to maintain.

For clinicians and hospitals seeking to replicate this success, there are two broad pathways:

- Develop an in-house protocol using whatever hats are available and focus primarily on process (consistent drying, early hat placement, delayed bathing, etc.).
- Partner with companies that specifically design thermoregulation products for fragile infants to ensure consistent, high-performance occlusion and fit.

This is where industry innovators such as Respiralogics enter the picture. Although the Pediatrics study itself used a different brand of hat and does not evaluate specific commercial devices, its findings strongly support the concept of purpose-designed, occlusive headgear as part of a bundled thermoregulation strategy.

Products like Respiralogics' Preemie Beenie™ are engineered with the challenges of LPIs and LBW infants in mind: maintaining coverage during skin-to-skin care, avoiding pressure points, accommodating respiratory interfaces, and supporting stable temperature in environments that don't have the tight thermal control of a NICU.

When integrated thoughtfully into a QI bundle similar to that described by Andrews and colleagues, such devices can help units move from "we use hats most of the time" to "we deliver consistent, high-reliability thermal protection for every at-risk infant."

The key is to keep the evidence and the product strategy aligned: hats are not a stand-alone solution, but an important element in a broader, bundle-based approach that includes timing of baths, assessment practices, and environmental control.

Connecting Thermoregulation and Respiratory Stability

For the respiratory therapy audience, it's worth underscoring how tightly temperature regulation and respiratory status are linked in high-risk newborns. Cold stress increases oxygen consumption, raises metabolic demand, and can unmask or worsen respiratory distress in late-preterm infants whose pulmonary reserve is already limited.

Hypothermia may also contribute indirectly to escalation of respiratory support, from extra oxygen to CPAP or intubation, particularly when combined with hypoglycemia or sepsis.

By preventing hypothermia up front, we are often preventing a cascade of downstream problems:

- Less shivering and metabolic acidosis
- Less pulmonary vasoconstriction
- More stable glucose levels
- Fewer episodes that trigger sepsis evaluations and respiratory escalation

In that sense, thermoregulation is not just a nursing detail—it's an upstream respiratory intervention. For companies like Respiralogics that specialize in respiratory support solutions, aligning respiratory care with thermal protection is a natural extension of their mission to keep fragile infants stable, supported, and as close to their mothers as safely possible.

Final Thoughts: Back to Basics, Forward to Better Care

The quality-improvement work by Andrews, Whatley, Smith, Brayton, Simone, Holmes, and their colleagues is a reminder that meaningful advances in neonatal care do not always require new drugs, new machines, or new units. Sometimes the biggest gains come from returning to basics—drying, covering, bathing, and assessing babies in a more deliberate, evidence-based way.

For clinicians and administrators, the message is clear: if your unit cares for late-preterm and small infants outside the NICU, your hypothermia rate is a quality metric worth knowing, tracking, and improving. For industry partners such as Respiralogics, the study underscores an important opportunity—to design and provide products that fit seamlessly into these bundles and help make best practice easier to deliver, every time.

Most of all, for families, the payoff is profound but simple: more babies staying warm, stable, and right where they belong—at their mother's bedside, not behind NICU glass.

News…continued from page 31
amount to a biological first" with a (yet unconfirmed) couple identified for embryo editing. Preventive and other startups are pushing boundaries in two related areas: Embryo gene-editing (changing DNA in sperm, eggs or embryos) to "prevent" disease or enhance traits; polygenic screening of embryos: using advanced algorithms to analyse DNA from embryos and estimate probabilities for traits like disease-risk, IQ, height, mental-health risks, etc. For example, companies such as Orchid, Nucleus and Herasight are already marketing polygenic screening services, with costings of thousands of dollars per embryo analysis (e.g., Orchid charging ~$2,500; Nucleus ~$9,999 for up to 20 embryos). Embryo editing is *very* controversial—there's only one known case (in China, 2018) of children born from edited embryos, and that sparked global condemnation. Scientists say our understanding of the human genome and gene interactions is still incomplete, so editing embryos carries significant risks including unintended mutations, long-term heritable changes, and unpredictable effects. The screening-for-traits companies face criticism for promoting "baby optimization" rather than strictly medical disease prevention. The American College of Medical Genetics and Genomics concluded that polygenic screening offers *no proven clinical benefit* yet. Some observers see this as a new form of eugenics—"corporate eugenics" in the words of the article. The idea of selecting embryos for higher IQ, certain physical traits or lower disease risk raises profound societal questions. The US Food & Drug Administration (FDA) cannot currently review human-trials applications involving embryo editing—making operating in the US difficult. Preventive notes it may have to conduct research abroad. The embryo-editing industry is still nascent, expensive and shrouded in uncertainty regarding returns, uptake and regulation. Meanwhile, the IVF market is growing (from ~$3.5B in 2023 to projected ~$5B by 2028), offering context to why investors are interested. In short: a new frontier in biotech is emerging, led by well-funded tech-backed startups, aiming not just to prevent genetic disease but to *enhance human traits*. The science is still immature, the regulation unclear and the ethical stakes high. As the article says, "the field will be watching" to see whether these ventures proceed responsibly—or spark unintended consequences.

Thermal Management Solution Released

Respiralogics, a Global Respiratory Solutions, Inc. company, announced the release of the Preemie Beenie Poly-Lined Knit Hat, an innovative thermal management solution designed to reduce cranial heat loss in extremely low birth weight (ELBW) and full-term infants. Newborns, particularly those born prematurely, are highly vulnerable to heat loss, especially through the head. The Preemie Beenie addresses this critical challenge with a specially engineered polyurethane liner placed between two layers of soft, stretchable cotton knit, offering a snug, skin-friendly fit that helps maintain optimal body temperature during the earliest, most vulnerable stages of life. Key Features and Benefits: Poly-lined design reduces evaporative and conductive heat loss. Soft, stretchable cotton knit ensures easy application and a secure fit. Latex-free, DEHP-free materials for gentle skin contact. Color-coded sizing system for fast identification. Available in three sizes to fit infants from ≤25 weeks to full term. Single-patient use to support infection control protocols. The Preemie Beenie Poly-Lined Knit Hat joins Respiralogics' growing portfolio of neonatal and pediatric respiratory care products, all designed to meet the highest standards of clinical effectiveness and patient comfort.
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Reframing Bedside Cameras as a Standard of Care in the NICU: Evidence, Outcomes, and Imperatives for Adoption

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Executive Summary

This white paper presents a comprehensive, evidence-based case for establishing live-streaming bedside cameras with secure, one-way digital communication (photo, video, and text) as a standard of care in Neonatal Intensive Care Units (NICUs). While historically considered a family engagement amenity, the integration of bedside cameras is increasingly supported by clinical, operational, equity, and economic data. Evidence indicates associations with improved parental mental health, stronger bonding and confidence, sustained lactation behaviors, more transparent staff-family communication, fewer reassurance phone calls, and measurable gains in participation among families facing structural barriers to presence (Hoyt-Austin et al., 2022). Importantly, when implemented equitably with mobile-first access, multilingual support, and streamlined onboarding, camera programs can reduce disparities in bedside access for families who are at a distance, publicly insured, or have limited English proficiency. Against the backdrop of workforce constraints and family integrated care goals, extending meaningful presence virtually, without adding burden, is no longer discretionary but aligned with clinical quality, safety, and equity aims (Chant et al., 2023, Gallagher et al., 2023, Klawetter et al., 2019, Patel et al., 2022, Stefanescu et al., 2023).

Introduction: Rethinking the Role of Cameras in Modern NICU Care

The NICU is among the most technologically advanced and emotionally taxing settings in healthcare. Parents routinely experience separation due to infant acuity, infection control policies, logistics, and competing family or work obligations. Live-streaming bedside cameras, paired with secure one-way team to family messaging, have emerged as a way to bridge this gap by providing real-time visual reassurance and concise, consistent information. Despite demonstrated value, adoption remains inconsistent, with cameras still often viewed as "nice-to-have" rather than essential.

This perspective is increasingly out of alignment with current evidence and standards. The family integrated care literature demonstrates that parent engagement and participation are associated with better infant and parent outcomes (Gooding et al., 2011; Liu et al., 2022; O'Brien et al., 2018). Telehealth and equity research show that virtual participation options increase attendance, reduce barriers, and can narrow disparities when designed intentionally (Patel et al., 2022; Rosenthal et al., 2024). Operational studies and reports from frontline staff indicate that well-implemented camera programs reassure families at their most vulnerable time, reduce miscommunication, and improve trust (Gallagher et al., 2023; Stumpel et al., 2023). While initial costs and resource needs are important, evidence suggests that the long-term benefits, such as improved family engagement, reduced staff workload from fewer calls, and enhanced equity, justify investment. Including a dedicated section on cost analysis and resource planning can help decision-makers evaluate financial feasibility and prioritize implementation (see section on Cost and Resources). This proactive approach addresses common concerns about budget constraints and demonstrates the program's value.

Evidence of Impact: What Bedside Cameras Change

Parental mental health, bonding, and confidence

Separation in the NICU elevates parental stress and anxiety; qualitative and cohort evidence indicate that real-time video access and consistent, brief visual updates mitigate distress, improve perceived presence, and strengthen trust in the care team (Gallagher et al., 2023; Klawetter et al., 2021; Pajak et al., 2023). These effects align with foundational family integrated care principles and interventions (e.g., Family-Integrated Care, FICare) that increase parental participation and are associated

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with better infant growth and parent outcomes (Gooding et al., 2011; O'Brien et al., 2018; Waddington et al., 2021). Parents who receive reliable, visually anchored updates report greater confidence in caregiving and a clearer understanding of the plan of care, factors tied to safer transitions at discharge (Lucile et al., 2025)

Lactation and breastfeeding trajectories

Visual connection supports oxytocin-mediated letdown and motivation to sustain pumping when parents cannot be present at the bedside (Weber et al., 2021). Camera-enabled connection and micro-updates on feeding milestones are consistent with the literature for maintaining milk supply during separation (Hoyt-Austin et al., 2022). In parallel, FICare trials link enhanced parental participation to improved feeding trajectories and earlier readiness for discharge, outcomes plausibly supported by consistent visual coaching and reinforcement (O'Brien et al., 2018; Waddington et al., 2021). Given the high downstream costs of neonatal morbidities, interventions that protect lactation and caregiver competence carry strategic value (Johnson et al., 2015).

Communication quality, trust, and fewer interruptions

A frequent concern is that cameras will increase call volume. Multiple studies report the opposite: reassurance-seeking calls decrease when families can see their infant or receive concise, accurate updates via secure one-way messaging; staff report fewer repetitive interruptions and clearer communication across shifts (Stumpel et al., 2023). Qualitative studies show that when cameras are framed as a connection (not surveillance) and paired with norms such as pausing during hands-on care, trust and satisfaction improve for families and staff (Gallagher et al., 2023; Rhoads et al., 2012). Messaging also helps teams batch communication efficiently and maintain consistency day to day.

Equity and Access: Making Presence Predictable

Digital realities and onboarding

Families with limited financial resources are less likely to have broadband access but often own smartphones and seek digital health information, underscoring the need for mobile-first, low-bandwidth design to promote fairness (Weems et al., 2016). In a 357-infant cohort, families engaged with cameras on a median of 86% of hospitalization days (165,795 total logins). Publicly insured families experienced longer consent times and fewer logins, underscoring the importance of supportive onboarding to foster trust and inclusivity (Stefanescu et al., 2023).

Language and distance as structural barriers—and opportunities

Use of remote infant viewing is markedly higher among families who do not require an interpreter, underscoring language access as a pivotal equity lever (Patel et al., 2022). Families living farther from the NICU were also more likely to use remote viewing, indicating that cameras help mitigate distance-related limitations (Bourque et al., 2023; Patel et al., 2022). Evaluations from the COVID-19 era found heterogeneous uptake by insurance and room type, reinforcing the need to standardize equitable workflows and actively track disparities (Mangla et al., 2022; Patel et al., 2023).

Parallel evidence from virtual family-centered rounds

Randomized and quasi-experimental studies of virtual family-centered rounds (V-FCR) demonstrate substantial participation gains, with particularly large relative improvements among families facing structural barriers (e.g., racial/ethnic minority status, lack of a college education) (Rosenthal et al., 2024). These findings translate conceptually to NICU camera programs: when virtual presence is easy to access, linguistically inclusive, and proactively offered, engagement disparities narrow rather than widen.

Equity blueprint for camera programs

1. **Mobile-first UI and low-bandwidth streaming** with plain-language design (Weems et al., 2016).
2. **Proactive enrollment at admission** (not passive opt-in) with translated, pictorial instructions (Stefanescu et al., 2023).
3. **Translation integration and multilingual messages** for one-way updates (Patel et al., 2022).
4. **Equity monitoring** (activation/use by language, insurance, distance) with device/hotspot support and navigator outreach where needed (Patel et al., 2022; Stefanescu et al., 2023).

Operational Value and Health System Impact

Throughput and discharge readiness

FICare trials demonstrate improved parent participation and infant growth with operational implications for length of stay and discharge readiness (O'Brien et al., 2018; Waddington et al., 2021). Cameras extend participation beyond physical visiting hours and enable micro-learning (e.g., cue-based feeding, safe positioning) that families can revisit, thereby smoothing the path to discharge.

Workforce efficiency and experience

Concise updates reduce phone tag and repeated explanations; alignment of multidisciplinary messaging improves consistency across disciplines (Joshi et al., 2016). Program maturity, with clear expectations and privacy protective pausing during hands on care, is associated with greater staff comfort and fewer complaints (Gallagher et al., 2023; Rhoads et al., 2012).

Strategic and financial rationale

The costs of neonatal morbidities are substantial; interventions that strengthen breastfeeding, improve caregiver confidence, and enhance discharge readiness plausibly yield meaningful value, even when gains accrue across multiple small improvements (Johnson et al., 2015; Weber et al., 2021). Camera programs can also improve patient-family experience narratives, which supports community trust and public perception (Gallagher et al., 2023; Weber et al., 2021). The telemedicine literature further supports its value, as it improves access to specialty care and follow-up for rural and socioeconomically constrained families (Sauers-Ford et al., 2019).

Common Concerns—Aligned With Evidence

- **"Families will call more often."** Evidence shows reassurance calls decline when families can visually check the infant or receive concise updates (Stumpel et al., 2023).
- **"I feel like I'm being watched."** Modern programs employ one-way video (no audio), pause during hands-on care, and display a "care in progress" banner, norms associated with staff comfort and family trust (Rhoads et al., 2012).
- **"This adds to my workload."** Digital updates and parental reassurance by viewing the camera typically *reduce* time on the phone and the need for repetitive explanations (Kubicka et al., 2021., Muller et al., 2024, Stumpel et al., 2023).
- **"We offer 24/7 visitation—cameras are unnecessary."** Distance, work, illness, and childcare make continuous

presence unrealistic for many families; cameras transcend these barriers and enable uninhibited connection (Patel et al., 2022; Weems et al., 2016; Saito et al., 2024).

- **"Critically ill infants shouldn't be on camera."** Parents of the sickest infants often benefit most from connection; privacy rules and expectation-setting protect dignity while decreasing distress (Reimer et al., 2021).

Implementation Guidance for Leaders (Burden-Light, Equity-First)

1. **Integrate enrollment with admission (ADT/SSO)** and provide translated, plain language "first use" guides; enroll proactively (Stefanescu et al., 2023; Weems et al., 2016).
2. **Normalize privacy protective operations:** camera paused during hands-on care, on-screen "care in progress" message, no audio recording (Rhoads et al., 2012).
3. **Train for consistency and speed:** 20–40-second photo/video/text updates; batch when feasible; align messages across disciplines.
4. **Language access by design:** translated User Interface messages in families' preferred languages(Patel et al., 2022; Weems et al., 2016).
5. **Measure equity and iterate:** monitor activation/use by language, insurance, distance; offer devices/hotspots, technical support, and navigator outreach to close gaps (Patel et al., 2022; Stefanescu et al., 2023).
6. **Align with FICare and discharge pathways:** use cameras to reinforce kangaroo care, feeding plans, and discharge education (O'Brien et al., 2018; Waddington et al., 2021).

Ethical Imperative

Minimizing the harm of separation is integral to safe, family-integrated neonatal care. Default, privacy-respecting virtual visibility, implemented with cultural humility, upholds partnership, reduces preventable distress, and operationalizes equity (Gooding et al., 2011).

Future Directions for Broader Clinical Application

Cameras already deliver value as connection tools, but they are increasingly knit into broader digital ecosystems that support parent education, quality improvement, and regional tele-consultation (Sauers-Ford et al., 2019; Weber et al., 2021). As integration expands (e.g., with discharge education platforms and interpreter services), leaders should evaluate cameras with the same rigor applied to other standards (e.g., kangaroo care, structured discharge) and treat them as core infrastructure for modern neonatal care (O'Brien et al., 2018; Waddington et al., 2021).

Conclusion

The convergent evidence, qualitative experience, implementation cohorts, randomized family integrated care trials, and telehealth equity studies support reframing bedside cameras with secure one-way messaging from "amenity" to standard infrastructure in NICUs. Programs that enroll families proactively, protect privacy during hands-on care, provide succinct multilingual updates, and monitor equity demonstrate improved trust, fewer reassurance calls, stronger engagement in feeding and discharge planning, and better alignment with institutional quality and equity goals (Gallagher et al., 2023; Joshi et al., 2016; O'Brien et al., 2018; Patel et al., 2022; Rosenthal et al., 2024; Stefanescu et al., 2023). The question is no longer whether cameras have a place in the NICU; it is how rapidly we can implement them effectively, equitably, and at scale.

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Neonatal Complications and Referral Practices at Birth: Insights From a Population-Based Study in the Indian State of Bihar

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Abstract

Objectives To explore neonatal survival by type of neonatal complications at birth and referral pattern for these complications by place of delivery.

Setting Bihar, India.

Participants Women aged 15–49 years who had given live birth between July 2020 and June 2021.

Primary and secondary measures Prevalence of neonatal complications at birth, referral pattern by complication and neonatal deaths by type of complication.

Results Data were available for 6,767 (81.8%) newborns including 717 neonatal deaths. The prevalence of at least one neonatal complication at birth was reported for 32.9% (95% CI 32.4 to 33.4) newborns, with the most common complications including difficulty in breathing (21.9%), high fever (20.7%), low birth weight (12.5%) and jaundice (13.2%). A total of 578 (26.6%; 95% CI 25.8 to 27.4) neonates with complications at birth were referred to another health provider, predominantly to private sector (68.1%, 93% and 78.7% from public facility, private facility and home). The complications with high referrals included meconium aspiration syndrome (64.1%; 95% CI: 61.1 to 67.1), inability to pass urine (54.7%; 95% CI: 42.1 to 67.2), difficulty in suckling (49.7%; 95% CI: 46.9 to 52.5), cold to touch (48.5%; 95% CI: 43.5 to 53.6), inability to cry (47.2%; 95% CI: 44.2 to 50.1), pneumonia (45.6%; 95% CI: 42.0 to 49.1), difficulty in breathing (44.0%; 95% CI: 42.5 to 45.6) and lethargy (43.5%; 95% CI: 38.4 to 48.6). Referrals were linked to higher neonatal deaths, in particular, among neonates born at home and referred for complications (84.7%; p<0.001) compared with those born in public facilities (59.8%) or private facilities (47.3%) and referred for complications.

Conclusions With one-third of the neonates reported to have complications at birth and those referred more likely to die, critical gaps in addressing neonatal complications at birth and improvement in the referral services are urgently needed to reduce neonatal mortality.

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Introduction

The global neonatal mortality rate (NMR) was estimated at 17.1 per 1,000 live births in 2021, with the majority of the neonatal deaths in developing countries.[1] Neonatal disorders, congenital anomalies and lower respiratory infections were reported as the leading causes of neonatal deaths world-wide.[2,3] Furthermore, with an estimated 13.4 million babies born preterm,[4] small size at birth or small-for-gestational-age (SGA) acts as the leading risk factor for over 80% of neonatal deaths.[5] Many of these neonatal deaths are preventable at large through access to skilled birth attendants and emergency healthcare services during and after the delivery.[6–8] Concerted efforts focused on the type of neonatal complications are required to achieve the Sustainable Development Goal 3 by 2030 to reduce preventable newborn deaths.[9]

The estimated NMR in India for 2021 was 21.2 per 1,000 live births.[10] Several initiatives have been put in place in India with the focus on improving neonatal survival, including setting up of the Newborn Stabilization Units to deliver immediate care to sick and small newborns at subdistrict level.[11–17] An effective referral system is an essential component to enhance the neonatal outcomes,[16,18–20] but gaps in the execution of a quality referral system have long been identified in India.[21–24] The lack of knowledge and skills among healthcare professionals to manage major causes of neonatal deaths has also been described as potential factors affecting quality of neonatal care and outcomes.[25–27] In this context, we explore neonatal survival by type of neonatal complications at birth and referral pattern for these complications by place of delivery in a study in the Indian state of Bihar, which is the third most populous state in India with one of the highest rates of neonatal mortality.[28,29]

Methods

Study population and design

Detailed methods for ENHANCE 2020 have been published previously.[30,31] ENHANCE 2020, a cross-sectional study, was designed to determine the change in NMR in Bihar between 2016 and 2020 as compared with the 23.3% decline in NMR documented in Bihar during 2011 to 2016.[32] Assuming a similar trend, to detect an expected decline in NMR of about 18%, with

85% power and 95% precision, 30,000 live births were estimated as the target sample size for the study, further assuming a 10% refusal rate.

The study population was usual resident women aged 15–49 years, and the inclusion criteria for ENHANCE 2020 was women who reported a birth (live birth and/or stillbirth) between July 2020 and June 2021. By defining the study population as women who had given birth during a set time period, we ensured that all neonates and stillbirths were captured. Defining neonates as the study population would have resulted in a biased sample with underreporting of neonates who did not survive and of stillborn babies. A usual resident woman was defined as a woman living in the sampled household for at least 6 months prior to the data collection. To ensure a robust estimation of total births in this population, births were documented also for women who had died during or after delivering the baby and those who had migrated out.

We used a multistage sampling design to obtain a representative sample of women with these births from all the 38 districts of Bihar. Each district of Bihar is divided into 5–27 blocks, giving a total of 534 blocks in the state, and we considered 50% of these blocks for the survey. We stratified the 534 blocks as those having only rural population (70.2%) and those with both rural and urban populations (29.8%); and sampled 267 blocks for the survey which included 187 (70%) blocks with only rural population and 80 (30%) blocks with both rural and urban populations. Within these 267 blocks, the secondary sampling units (SSUs) were villages in rural areas and urban frame survey blocks in urban areas as defined by the Census 2011.[33] Thus, a total of 1,340 SSUs were sampled in proportion to the number of villages from each block using systematic random sampling.

Data collection

Methods relevant to the analysis presented in this paper on live births are described. After the selection and mapping of SSUs, all the households (a household was defined as all the people eating from the same kitchen) of each SSU were enumerated. Trained interviewers captured the information on sociodemography of the household and birth outcomes in usual resident women aged 15–49 years in each household between July 2020 and June 2021 from the head of the household after seeking informed consent. Date of birth and sex of the baby born were documented for each live birth. Following initial documentation, all women with neonatal death and 25% of the women with live births (selected using systematic random sampling in each cluster) were considered eligible for a detailed interview. Informed consent was sought from the sampled women for detailed interview after seeking permission from the head of the household to contact them. The interview captured information on the sociodemography including woman's age, place of residence, Wealth Index; information related to the focal child including age, sex, birth weight, if the child was currently alive; pregnancy duration for the focal child and the place of delivery were captured. Whether the focal child had any complications at birth was enquired from all the respondents. Those who responded as yes were asked what the complications were using a question with precoded response options. The response options included symptoms (difficulty in breathing, high fever, baby drank dirty water in the womb (meconium aspiration syndrome (MAS)), spasm/convulsion, chest indrawing, cold to touch, vomiting and difficulty in suckling) and also names of some common conditions (low birth weight, jaundice, pneumonia, diarrhoea) to accommodate for responses given by respondents who may or may not be aware of the clinical diagnosis. All symptoms and conditions indicated by the respondents were captured. The symptoms or clinical diagnosis not in the list were captured in full under 'others', which were reviewed by MA and SPD and categorised into meaningful categories (unable to cry, congenital anomalies, infection, measles and lethargy). Furthermore, if the focal child was treated at the place of delivery or was referred for treatment elsewhere for the reported neonatal complications, it was documented, including the type of referral facility referred to.

Data were collected between August 2021 and April 2022. The interview questionnaire was developed in English and then translated into the local language (Hindi) and then again translated back to English to ensure the accuracy and relevant meaning of the questions, without diverging from the intent of the questions. Interviews were conducted by the trained data interviewers using Computer Assisted Personal Interview software in handheld tablets. A pilot testing of the questionnaire was also carried out to test the logistics and the quality of data collection, and appropriate modifications were made to the questionnaire as required before the start of the survey. A total of 10% of the enumeration data were checked from 50% of the sampled clusters, which translated into 670 clusters. Similarly, a total of 20% of interviews were checked in 50% of the 1,340 sampled clusters to ensure data quality.

Data analysis

We present the findings in two ways—by the type of complications at birth and by neonates with at least one complication at birth. For the type of complications at birth, we considered each episode of complication reported for every neonate as unique to determine the distribution of the reported complication episodes. We present the distribution of the type of reported neonatal complications at birth, overall and by the place of delivery, and also report the prevalence of referral and proportion of neonatal deaths by type of complication.

For findings by neonate, we estimated the prevalence of any reported complications at birth among the live births by select characteristics, overall and disaggregated by place of delivery. We report on the distribution of referral for complications at birth by neonate, the referral pattern by the place of delivery and the care given before referral. The proportion of neonatal deaths overall and by top referred complications is reported among neonates by place of delivery. We report the distribution of overall neonatal deaths and neonatal death disaggregated by age at death (0–2 days, 3–7 days and 8–27 days) and by the single or multiple neonatal complication and its referral status.

As the sample was a multistage stratified cluster sample, sampling weights were calculated based on the sampling probabilities separately for each sampling stage for each study cluster. We calculated the selection probabilities for a cluster from the sample and the birth outcomes; then obtained the overall probability as the product of both of these; sampling weight was estimated by taking the reciprocal of this overall probability. The design weight was then adjusted for household non-response and individual non-response to obtain the final sampling weight. In-transit deliveries were considered as home deliveries. The Wealth Index was calculated using the standard methods used in the National

Table 1 Weighted prevalence of reporting of at least one neonatal complication at birth by place of delivery among live births born between 2020–2021 by select characteristics.

Variable	Variable categories	Weighted prevalence of at least one neonatal complication at birth by neonate (95% confidence interval)			
		All live births irrespective of the place of delivery	Public facility delivery	Private facility delivery	Home delivery
Overall		32.9 (32.4 to 33.4)	30.4 (29.7 to 31.0)	44.3 (43.2 to 45.4)	25.7 (24.7 to 26.6)
Urbanicity	Rural	29.9 (29.4 to 30.4)	29.7 (29.0 to 30.4)	40.4 (39.2 to 41.5)	22.8 (21.9 to 23.7)
	Urban	42.6 (41.3 to 43.9)	34.0 (32.4 to 35.7)	48.5 (46.6 to 50.5)	40.2 (36.8 to 43.6)
Wealth index quartile	I (lowest)	31.0 (30.1 to 31.9)	30.5 (29.2 to 31.8)	48.5 (45.5 to 51.4)	25.6 (24.2 to 27.1)
	II	29.7 (28.7 to 30.6)	28.4 (27.3 to 29.6)	41.8 (39.4 to 44.2)	24.5 (22.4 to 26.5)
	III	33.4 (32.4 to 34.3)	29.4 (28.2 to 30.6)	45.5 (43.6 to 47.5)	29.1 (26.8 to 31.4)
	IV (highest)	37.6 (36.5 to 38.7)	34.5 (33.0 to 35.9)	43.3 (41.5 to 45.1)	22.0 (19.9 to 24.2)
Gestation period (months)	<8	88.2 (86.5 to 90.0)	80.6 (76.5 to 84.6)	97.1 (96.2 to 98.1)	81.2 (76.8 to 85.5)
	8	31.4 (30.5 to 32.3)	29.3 (28.2 to 30.5)	43.4 (41.5 to 45.4)	19.8 (18.5 to 21.1)
	More than 8	31.5 (30.9 to 32.1)	29.9 (29.2 to 30.7)	40.9 (39.5 to 42.3)	25.3 (24.1 to 26.6)
Sex of the baby	Boy	37.3 (36.6 to 38.0)	33.4 (32.5 to 34.3)	46.9 (45.3 to 48.4)	33.3 (31.8 to 34.8)
	Girl	28.2 (27.5 to 28.9)	27.2 (26.3 to 28.1)	40.7 (39.2 to 42.3)	19.2 (18.0 to 20.4)
Birth weight	Not weighted	28.8 (27.6 to 30.1)	53.2 (47.3 to 59.0)	43.6 (39.5 to 47.7)	26.8 (25.5 to 28.2)
	Do not know	38.0 (35.5 to 40.6)	33.8 (30.5 to 37.0)	47.8 (43.1 to 52.4)	25.7 (20.0 to 31.3)
	< 2.5 kg	56.3 (54.9 to 57.7)	48.4 (46.8 to 50.1)	75.4 (72.7 to 78.1)	42.9 (38.2 to 47.7)
	>= 2.5 kg	28.5 (27.9 to 29.1)	26.0 (25.3 to 26.7)	36.9 (35.7 to 38.1)	20.5 (19.2 to 21.8)
Referred delivery	No	31.3 (30.8 to 31.8)	30.1 (29.5 to 30.7)	40.9 (39.6 to 42.2)	25.2 (24.3 to 26.2)
	Yes	55.9 (54.1 to 57.7)	47.4 (42.7 to 52.1)	56.9 (54.9 to 58.9)	62.5 (50.8 to 74.2)

Family Health Survey (NFHS) to calculate the Wealth Index as detailed by the Demographic and Health Survey (DHS) programme for India.[34,35] We have reported a 95% CI for all estimates as relevant. SAS V.9.4 was used for the analysis.

Patient and public involvement statement

Patients were not involved in the design, conduct, reporting or dissemination plans of our research.

Results

A total of 261,124 households were enumerated (91.5% participation) covering a population of 1,260,984 and a total of 30,412 birth outcomes were reported by 29,517 women between July 2020 and June 2021. Of the 30,412 birth outcomes, 29,830 (98.1%) were live births, including 831 (2.8%) neonatal deaths. Of the 8,271 eligible women for detailed survey, 6,767 (81.8%) women participated, including 717 women with a neonatal death.

Prevalence of at least one neonatal complication at birth among neonates

Out of 6,767 live births, 2007 (32.9%; 95% CI 32.4 to 33.4) neonates were reported to have at least one neonatal complication at birth. Irrespective of the place of delivery, reporting of at least one neonatal complication was significantly higher in neonates with a gestation period of <8 months, whose mother was referred for delivery, those belonging to the highest wealth quartile, in boys and among neonates with a birthweight of <2.5 kg (Table 1). The reporting of at least one neonatal complication was significantly higher in newborns delivered at private facilities (44.3%; 95% CI, 43.2 to 45.4) as compared with public facilities (30.4%; 95% CI 29.7 to 31.0) and home deliveries (25.7%; 95% CI 24.7 to 26.6). A similar pattern of prevalence of reporting of at least one neonatal complication was seen by the different places of delivery (Table 1).

Type of neonatal complications at birth

A total of 3,324 complications were reported for 2007 neonates (32.9%), including 963 (47.4%) cases with a single complication and 1,044 (52.6%) with multiple complications. Among the 3,324 complications, the most commonly reported neonatal complications included difficulty in breathing (21.9%), high fever (20.7%), low birth weight (12.5%) and jaundice (9.8%) as shown in online supplemental Table 1. A significantly higher reporting of low birth weight (16.2%; p=0.009), jaundice (13.2%; p=0.009) and MAS (9.6%; p=0.001) was in neonates born in private facilities as compared with those born elsewhere, and high fever (26.3%; p<0.001) and pneumonia (5.3%; p=0.042) were reported significantly more among home births as compared with facility births.

Referral of neonates for neonatal complications at birth

Among the 2007 neonates with at least one complication, 578 (26.6%; 95% CI 25.8 to 27.4) were referred to another facility or provider for their complications (online supplemental Table 2). Overall, referral was significantly higher among neonates from rural areas (p=0.029), with gestation period <8 months (p<0.001), boys (p=0.006) and among neonates whose mother was referred for delivery (p=0.001). The prevalence of referral for complication was the highest in private facility births (36.0%; 95% CI 34.4 to 37.6) as compared with public facility (21.2%; 95% CI 20.1 to 22.2) and home births (22.3%, 95% CI 20.4 to 24.3) but the pattern of referral by select characteristics was similar by place of delivery. Overall, irrespective of the place of delivery, the majority of the referrals was to a private facility—68.1% from public facility, 93.0% from private facility and 78.7% from home (online supplemental Table 3). Among the public facility births, referral was higher (though not significant) to a private facility in urban areas (72.4%) and in boys (69.5%), whereas referral to a private facility was

Table 2 Weighted prevalence of referral for the type of reported neonatal complications at birth by the place of delivery

Neonatal complication at birth	All live births irrespective of the place of delivery		Live births in public facility		Live births in private facility		Live births at home	
	Number with complications (N)	Prevalence of referral for complication (95% CI)	Number with complications (N)	Prevalence of referral for complication (95% CI)	Number with complications (N)	Prevalence of referral for complication (95% CI)	Number with complications (N)	Prevalence of referral for complication (95% CI)
Any complication	3324	33.1 (32.4 to 33.8)	1637	28.7 (27.8 to 29.6)	1112	42.9 (41.6 to 44.1)	575	25.2 (23.7 to 26.7)
Difficulty in breathing	740	44.0 (42.5 to 45.6)	343	38.5 (36.3 to 40.8)	280	53.3 (50.8 to 55.7)	117	40.6 (36.6 to 44.7)
High fever	615	11.5 (10.6 to 12.5)	343	11.1 (9.8 to 12.5)	138	19.3 (17.0 to 21.5)	134	4.4 (3.2 to 5.7)
Low birth weight	400	37.2 (34.9 to 39.5)	204	25.9 (23.4 to 28.4)	139	45.6 (41.6 to 49.6)	57	40.5 (34.7 to 46.4)
Jaundice	319	24.7 (22.8 to 26.5)	147	30.3 (26.9 to 33.7)	130	21.0 (18.8 to 23.2)	42	21.4 (16.8 to 26.0)
Difficulty in suckling	193	49.7 (46.9 to 52.5)	94	49.6 (45.3 to 54.0)	55	60.2 (55.4 to 65.0)	44	35.8 (30.2 to 41.4)
Meconium aspiration syndrome*	192	64.1 (61.1 to 67.1)	80	60.2 (55.9 to 64.4)	109	63.8 (59.6 to 68.1)	3	100.0 (100.0 to 100.0)
Unable to cry	170	47.2 (44.2 to 50.1)	86	37.3 (33.2 to 41.3)	61	56.9 (52.1 to 61.8)	23	60.8 (52.4 to 69.3)
Pneumonia	137	45.6 (42.0 to 49.1)	56	49.6 (43.7 to 55.5)	43	63.1 (57.4 to 68.9)	38	21.5 (17.0 to 26.1)
Vomiting	111	8.8 (7.1 to 10.5)	60	6.4 (4.4 to 8.4)	22	15.7 (10.4 to 21.0)	29	7.0 (4.2 to 9.8)
Diarrhoea	85	3.4 (2.3 to 4.5)	47	0.7 (0.3 to 1.2)	22	5.3 (3.0 to 7.5)	16	7.6 (2.8 to 12.5)
Congenital anomalies	73	35.7 (30.9 to 40.4)	36	35.9 (28.9 to 42.9)	23	44.3 (34.4 to 54.1)	14	15.8 (9.7 to 21.9)
Chest in drawing	68	35.7 (31.2 to 40.3)	32	24.2 (19.0 to 29.3)	20	68.2 (57.6 to 78.8)	16	21.1 (14.4 to 27.9)
Cold to touch	63	48.5 (43.5 to 53.6)	26	26.7 (20.9 to 32.5)	19	76.8 (70.3 to 83.4)	18	15.5 (9.9 to 21.0)
Measles	46	19.2 (13.5 to 24.9)	26	9.8 (5.4 to 14.1)	16	27.5 (16.9 to 38.1)	4	17.9 (0.0 to 36.6)
Infection	43	14.5 (11.1 to 18.0)	24	7.5 (4.5 to 10.6)	12	24.4 (15.6 to 33.1)	7	17.1 (4.6 to 29.6)
Lethargic	42	43.5 (38.4 to 48.6)	20	36.8 (28.8 to 44.8)	16	56.0 (46.5 to 65.6)	6	41.6 (23.6 to 59.6)
Unable to pass urine	19	54.7 (42.1 to 67.2)	9	62.9 (46.3 to 79.5)	4	100.0 (100.0 to 100.0)	6	0.0 (0.0 to 0.0)
Spasm/ convulsion	8	27.7 (14.9 to 40.5)	4	0.0 (0.0 to 0.0)	3	100.0 (100.0 to 100.0)	1	100.0 (100.0 to 100.0)

All percentages are weighted while the numbers are unweighted.
*Reported as ‘drank dirty water in the womb’.

significantly higher among girls (95.9%; p=0.022) than boys in home births (online supplemental Table 3).

Among the 516 deliveries where neonates were referred, 263 (52.1%) neonates were provided with pretreatment or stabilisation, 82 (13.6%) were put in an incubator, and 175 (31.0%) were provided with oxygen before referral (not mutually exclusive). Pretreatment or stabilisation (63.1%; p=0.014) was reported significantly higher in public facility as compared with private facility and home. Incubator services (27.4%; p<0.001) and oxygen provision (43.4%; p=0.014) were reported significantly higher in public facility as compared with private facility before referral (online supplemental Figure 1).

Referral by type of neonatal complication

Considering the 3,324 reported complications irrespective of the place of delivery (Table 2), the highest proportion of referrals was for MAS (64.1%; 95% CI: 61.1 to 67.1), followed by inability to pass urine (54.7%; 95% CI: 42.1 to 67.2), difficulty in suckling (49.7%; 95% CI: 46.9 to 52.5), cold to touch (48.5%; 95% CI: 43.5 to 53.6), inability to cry (47.2%; 95% CI: 44.2 to 50.1), pneumonia (45.6%; 95% CI: 42.0 to 49.1), difficulty in breathing (44.0%; 95% CI: 42.5 to 45.6) and lethargy (43.5%; 95% CI: 38.4 to 48.6). Referral was significantly higher for high fever (19.3%; p=0.012), pneumonia (63.1%; p=0.024), chest indrawing (68.2%; p=0.024) and cold to touch (76.8%; p<0.001) in private facility delivery as compared with public facility delivery and home delivery.

Neonatal complications at birth and neonatal deaths

Irrespective of complications, 715 (10.5%) neonates died during the neonatal period, among whom 451 (61.6%) died during 0–2 days, 147 (18.8%) during 3–7 days and 117 (19.7%) during 8–27 days after birth. The proportion of neonatal deaths was significantly higher among neonates born at home and referred elsewhere for complications (84.7%; p<0.001) compared with those born in public facilities (59.8%) or private facilities (47.3%) and referred for complications. While neonatal death proportions were comparatively lower in the non-referred cases across all settings, the difference in neonatal mortality by the place of delivery remained statistically significant (p=0.019, Figure 1).

Regardless of the place of delivery, neonatal deaths were more prevalent among the referred neonates with multiple complications (61.7%), followed by those with single complications (43.1%) as compared with those with no reported complications at birth (Table 3). The majority of the neonatal deaths were within 0–2 days of birth irrespective of place of delivery or complications. Figure 2 shows the survival by referral for the top 10 neonatal complications at birth by the prevalence of referral as identified in Table 2 (complications not mutually exclusive). The proportion of neonatal deaths was higher among the referred cases irrespective of the type of complication and place of delivery. On the other hand, the proportion of neonatal deaths was also higher among the non-referred complications in private facilities for most complications as compared with the non-referred neonates for complications in public facilities.

Discussion

One-third of all newborns were reported to have complications at birth, of whom one-fourth were referred to another provider for the complication management in this population, with private sector providers preferred for referral. The neonatal survival in referred newborns with complications was lower than those who were not referred irrespective of the place of delivery. These findings underscore the critical need to strengthen the management of neonatal complications at birth to reduce neonatal mortality in the state.

At least one neonatal complication at birth was reported for one in three newborns in this study, with half of them reported to have more than one neonatal complication. Extrapolating this finding to the estimated 2,560,000 live births in Bihar annually,[1] 84,750 newborns in the state would likely have at least one neonatal complication at birth. Difficulty in breathing, high fever, low birth weight and jaundice were the most commonly reported neonatal complications at birth with some variation reported by the place of delivery. With the high proportion of facility births in this population, there is a great opportunity for providing essential newborn care and identifying and managing high-risk newborns. Significant investments have been made in India to strengthen care around the time of birth and the first week of life, including expanding services for small and sick newborns and setting up Special Newborn Care Units (SNCUs) in almost all districts of India.[11–13,15–17] Several initiatives have been undertaken in Bihar to improve neonatal survival by addressing skills, capacity and infrastructure-related challenges in the public sector facilities, including for addressing neonatal complications.[36,37] Logistical, cultural, monitoring and supervision and skill retention barriers have also been identified as challenges to address neonatal complications appropriately and in a timely manner.[38–40] This population-level assessment highlights the magnitude of these challenges, as a significantly higher proportion of neonatal deaths occurred in those newborns with complications than without.

The increased risk of neonatal complications at birth with preterm birth, low birth weight and sex of the neonate found in our study has also been reported previously.[4,41–44] Gestational age at delivery is considered among major determinants of neonatal survival and morbidity, and low birth weight neonates are more prone to complications,[45,46] as also observed in our study.[45–47]

The significantly higher proportion of neonatal deaths among the referred newborns with neonatal complications in this population is concerning. The majority of these deaths were in 0–2 days, with the most on day 0, highlighting issues with quality, timeliness and appropriateness of referral and of the critical components of management of the neonate.[24,48,49] Reported complications of MAS, inability to pass urine, difficulty in suckling, cold to touch, inability to cry, pneumonia and difficulty in breathing and lethargy were the complications that resulted in most referrals in this population, which are mostly linked to respiratory distress or prematurity.[50–54] Furthermore, the distribution of referral pattern by the type of complications and by the place of delivery in this study generates important insights both for designing targeted programmes to strengthen the skills and capacity by the place of delivery and to improve on the referral system to reduce neonatal mortality. The majority of the referrals from the public sector facilities was made to the private facilities, highlighting the continued challenges that need to be addressed to strengthen the public sector facilities in the state.[38–40] This brings forward the need for further deep dives to explore how an adequate and comprehensive approach to neonatal care can be provided, addressing not only the infrastructural challenges but also trained workforce and organised referral protocols and systems to ensure timely and effective care for small and sick neonates.

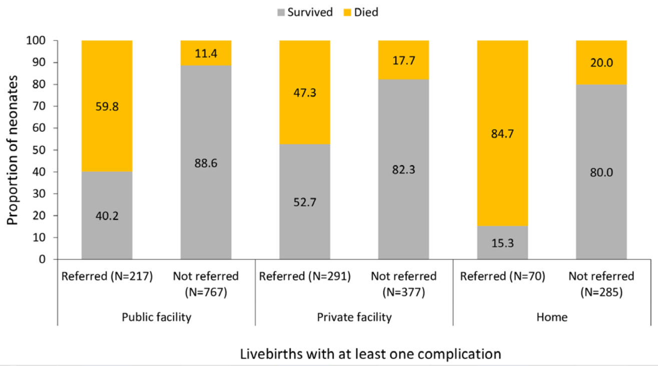

Figure 1. Weighted survival in the neonatal period for neonates with at least one complication at birth by referral and place of delivery.

Interestingly, the proportion of referrals for neonatal complications was higher from the private sector than public sector facilities, and these referrals were also predominately to another private sector facility. Also, the proportion of neonatal deaths was higher among the non-referred complications in private facilities for most complications as compared with the non-referred neonates for complications in public facilities. These findings need to be interpreted with caution. The private sector health facilities in Bihar are not a homogenous group and range from tertiary care hospitals to nursing homes with varied levels of infrastructure, capacity and skills.[55] Newborn survival in India is known to be influenced by the place of delivery, with the private sector performing poorly for early neonatal deaths in comparison to the public sector, including in Bihar.[56] It is also important to interpret the higher neonatal mortality in private sector facilities within the context of referral for delivery in this population, where most deliveries that were referred were from the public sector to the private sector facilities. It is well known that the private sector in India provides most of the emergency obstetric care and also serves as a referral facility for the public sector for complicated deliveries.[57,58] Better engagement with the private sector in improving and sustaining quality of care for mothers and newborns is desired under the India Newborn Action Plan.[14] In view of these findings, appropriate engagement with the private sector in the state is much needed to improve neonatal survival.

Prereferral care was limited in this population irrespective of the type of facility, highlighting the gaps in timely and adequate prereferral management. Inadequate prereferral care for neonatal complications contributes to poor conditions at arrival with subsequent poor outcome,[19] whereas neonatal outcomes improve when prereferral care such as administration of intravenous fluid, provision of warmth and/or oxygen

Table 3 Weighted distribution of overall neonatal deaths, disaggregated by neonatal death period of 0–2 days, 3–7 days and 8–27 days, among all live births by complication and referral

Place of delivery	Complication at birth	Referred for complication	Number of live births (N)	Neonatal deaths			
				Total (% of N)	**0–2 days (% of N)**	**3–7 days (% of N)**	**8–27 days (% of N)**
Overall	None	Not applicable	4760	142 (2.7)	81 (1.6)	31 (0.5)	30 (0.6)
	Single	Yes	167	65 (43.1)	42 (27.9)	14 (9.3)	9 (5.8)
		No	796	90 (8.0)	73 (6.3)	7 (0.9)	10 (0.7)
	Multiple	Yes	411	247 (61.7)	141 (35.4)	67 (13.7)	39 (12.6)
		No	633	171 (24.1)	114 (15.2)	28 (3.5)	29 (5.4)
Public facility	None	Not applicable	2595	66 (2.2)	28 (0.9)	18 (0.5)	20 (0.8)
	Single	Yes	55	21 (49.7)	13 (25.9)	4 (14.4)	4 (9.5)
		No	423	31 (6.4)	26 (4.5)	2 (1.0)	3 (0.8)
	Multiple	Yes	162	106 (62.6)	56 (32.5)	29 (14.3)	21 (15.8)
		No	344	68 (18.3)	45 (12.9)	11 (2.0)	12 (3.3)
Private facility	None	Not applicable	960	28 (2.6)	20 (1.7)	4 (0.6)	4 (0.3)
	Single	Yes	95	29 (22.4)	21 (18.3)	6 (2.5)	2 (1.6)
		No	215	33 (7.9)	28 (7.0)	2 (0.5)	3 (0.3)
	Multiple	Yes	196	98 (54.1)	59 (28.6)	29 (14.5)	10 (11.1)
		No	162	53 (31.2)	32 (16.0)	10 (5.4)	11 (9.8)
Home	None	Not applicable	1205	48 (3.9)	33 (2.8)	9 (0.5)	6 (0.7)
	Single	Yes	17	15 (87.3)	8 (60.5)	4 (17.3)	3 (9.6)
		No	158	26 (13.0)	19 (10.5)	3 (1.5)	4 (1.0)
	Multiple	Yes	53	43 (83.8)	26 (64.8)	9 (9.5)	8 (9.5)
		No	127	50 (27.5)	37 (19.3)	7 (4.3)	6 (3.9)

All percentages are weighted while the numbers are unweighted.

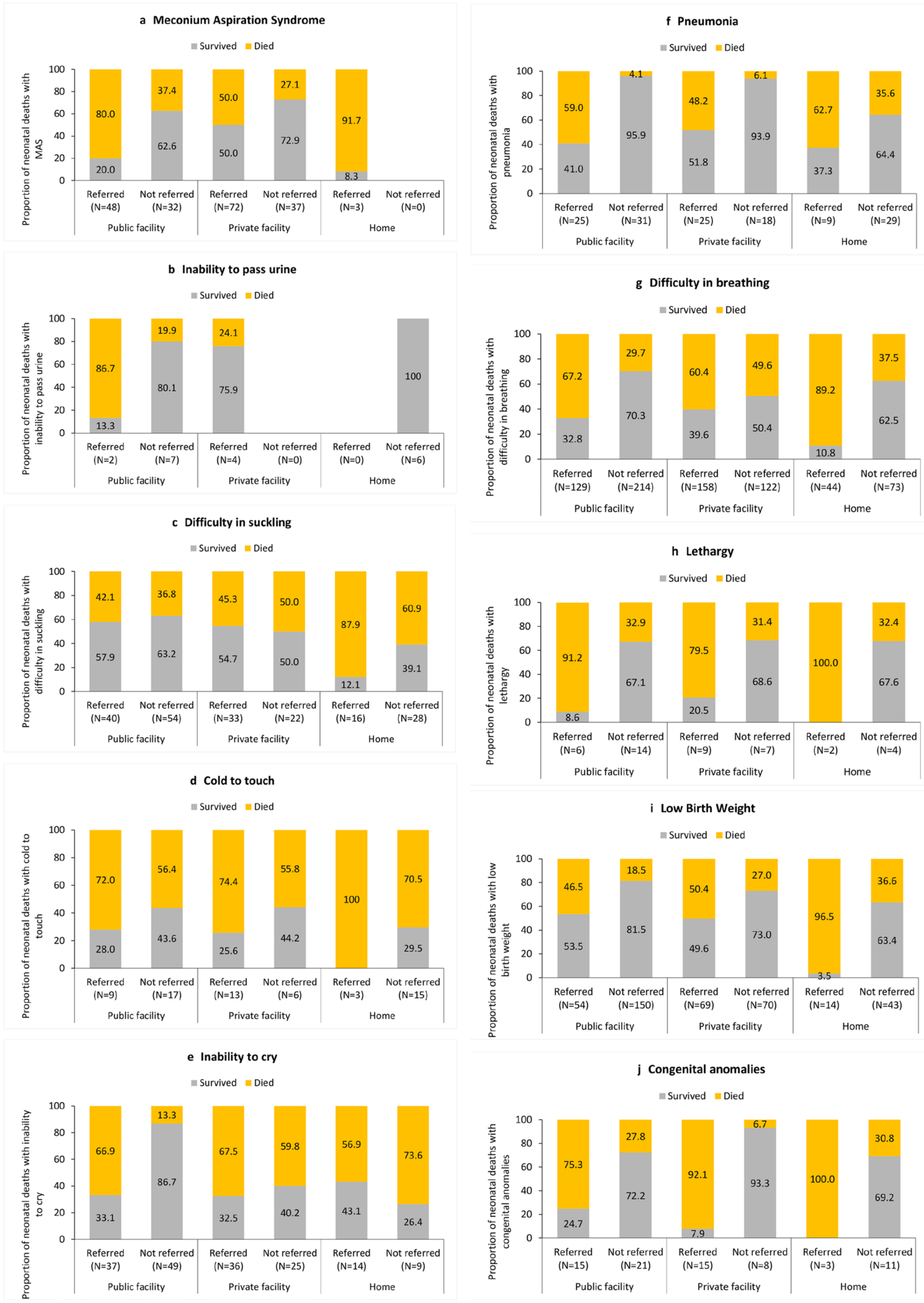

Figure 2. Weighted proportion of survival in the neonatal period for neonates by place of delivery for the top 10 complications at birth based on the prevalence of referral. The complications are not mutually exclusive.

administration is provided before referral.[59] This calls for improved resources and protocols across all facility types to ensure better neonatal outcomes within the referral system. The components include prereferral management, information about availability of facilities for specifically required advanced care, reaching those health facilities without delay with continued care during transit and immediate provision of required treatment including care at SNCU in the referred centre.[19,22,24,60,61]

Several approaches are available towards appropriate care of sick neonates, such as an emergency call and ambulance dispatch centre; mobile application for initiating referral, tracking and deployment of ambulances can improve coordination and efficiency in emergency case referral and transport and an e-referral system to strengthen the health system gaps by streamlining the referral process for timely management of cases.[49,62] An e-referral system called 'Jiyyo Innovations e-Referral System' in India has shown its impact on streamlining the referral process and improved outcomes, by addressing the communication gap between referring and referred facility and by ensuring the timely provision of requisite information about every referral.[61]

The strength of this study lies in the state-wide representative sample of live births capturing the prevalence of neonatal complications, referral patterns and neonatal survival. This large-scale study allows for a detailed understanding of neonatal complications by place of delivery in a low-resource region, which can be generalised for other similar settings as well. Some limitations are to be considered as well. Analysis relies on self-reported data regarding neonatal complications at birth, which may be subject to recall bias, though we only dealt with the recent incidences and the recall period was short. Additionally, the accuracy of the reported complications could be influenced by the respondents' understanding of the medical condition of the neonates or the severity of the conditions and may not always accurately align with clinical diagnoses. The gestational age was captured in months instead of weeks as the pregnancy length in India is reported in months. The last menstrual period forms the basis for most gestational age estimates and is considered a reliable estimate for measuring gestational age in both developing and developed country settings.[63,64]

Conclusion

With neonatal complications being reported for one-third of newborns and a significant number of neonatal deaths among those who are referred, the findings call for urgent strengthening of the referral process, ensuring timely access to skilled care and improving the prereferral care to reduce neonatal mortality both in the public and private sector facilities.

Contributors. RD and GAK had full access to data in the study, take full responsibility for the integrity of data and accuracy of the data analysis and had final responsibility for the decision to submit for publication; RD and GAK conceptualised the study; RD guided the data analysis and drafted the manuscript; GAK undertook data analysis with contributions from IB, MA and SPD; GAK and IB contributed to drafting of manuscript; MA, MM and SPD guided data collection; TM contributed to interpretation; all authors approved the final manuscript. RD is responsible for the overall content as the guarantor.

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Competing interests. None declared.

Patient and public involvement. Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication. Not applicable.

Ethics approval. This study involves human participants and the study protocol and procedures for Every Newborn Health Assessment and Neonatal Care Evaluation (ENHANCE) 2020 were reviewed and approved by the Institutional Ethics Committee of the Public Health Foundation of India (TRC-IEC 462/21). Participants gave informed consent to participate in the study before taking part.

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Data availability statement. All data relevant to the study are included in the article or uploaded as supplementary information. Not applicable.

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Lung Aeration Patterns in Chest Radiographs Tied to Surfactant Treatment in Premature Infants With Respiratory Distress Syndrome

Computerized chest radiograph analysis revealed that the surfactant treatment led to better aeration in the right lung than in the left lung among infants born extremely preterm with respiratory distress syndrome (RDS). Basal regions showed improved aeration compared to apical regions regardless of surfactant treatment, suggesting anatomical influences on distribution patterns. Researchers conducted an observational study of 66 newborns with extremely low gestational age (22-27 weeks; 42% girls) at Uppsala University Children's Hospital, Sweden, between January 2021 and December 2022. The analysis included chest radiographs taken within 6 hours after surfactant administration in the surfactant-treated group (n = 52) and at matched timepoints before treatment in the pre-surfactant group (n = 8). Infants in the surfactant-treated group received a median of two doses of surfactant, whereas those in the pre-surfactant group received a single dose, both prophylactically immediately after birth. Digital images of the chest radiographs were obtained from the database (Telerad) and processed using ImageJ software in which 12 regions of interest were selected manually in the intercostal segments two to seven bilaterally. Outcomes included changes in the mean pixel intensity (MPI) that described the focal lung density and the focal heterogeneity in pixel intensity (FHPI) that estimated variation in the distribution of air in the regions of interest. Additionally, an independent visual grading of RDS was performed by two radiologists and compared with the computerised image analysis. The MPI was higher in the left lung than in the right lung for infants in the surfactant-treated group (P = .008) but not for those in the pre-surfactant group, indicating lower aeration in the left lung after surfactant administration. The MPI was significantly higher in apical than in basal regions bilaterally for infants in both the surfactant-treated group (right lung, P = .024; left lung, P = .015) and the pre-surfactant group (right lung, P = .047; left lung, P < .001), showing that this distribution was not influenced by the treatment.

Determinants of Neonatal Near Miss Among Newborns Admitted to SOS Mother & Child Hospital, Benadir Region, Somalia: A Case-Control Study

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Background

The arrival of a neonate evokes profound love and anticipation, as families eagerly await their beloved new addition.[1] However, this joyous occasion may sometimes be overshadowed by concerns stemming from critical life-threatening challenges for both the mother and the neonate. During this journey, many infants tragically lose their lives, while others experience near-miss events, narrowly escaping severe health complications.

Annually, 135 million newborns enter the world, commencing their journey in an identical state of vulnerability.[2] Yet, their prospects for survival and flourishing diverge markedly depending on the global context of their birth.[3] This spectrum ranges from high-income nations equipped with universal neonatal intensive care to environments where births occur at home, devoid of midwifery support, medical provisions, or institutional healthcare assistance.[4]

Globally, 2.3 million children died in the first month of life in 2022, equating to approximately 6,300 neonatal deaths every day.[5] Sub Saharan Africa accounted for 57% of these deaths, despite only having 30% of global live births. This disparity resulted in the region having the highest neonatal mortality rate in the world, with 27 deaths per 1,000 live births. Somalia remains one of the countries with the highest neonatal mortality rates worldwide, with approximately 37 deaths per 1,000 live births, reflecting substantial gaps in maternal and child health services.[7]

Although neonatal mortality is an indicator of neonatal health, it only reveals the tip of the iceberg, as most neonates who survive complications remain unnoticed.[3] Understanding the full extent of neonatal ill-health requires studying neonates who survived from severe complications (neonatal near miss) in addition to neonatal deaths.[8] Neonatal near miss is defined as a condition of newborn infant characterized by severe morbidity (near miss) of pragmatic and management criteria but survived these conditions within the first 28 days of life.[9] Like the concept of maternal near miss, neonatal near miss (NNM) is gaining prominence as an emerging methodology and is increasingly recognized as a critical indicator for evaluating the quality of neonatal care.[10-12] This approach plays a pivotal role in efforts to mitigate preventable neonatal morbidity and mortality.

Somalia experiences one of the highest neonatal mortality rates globally, with 37 deaths per 1,000 live births,

reflecting significant public health challenges. This crisis is compounded by limited access to quality healthcare and inadequate maternal health services, as only 24% of pregnant women receive at least four antenatal care visits, and just 32% of deliveries are attended by skilled birth attendants.[13,14] Prolonged conflict and instability have further weakened the country's health infrastructure, leaving maternal and child healthcare services severely under-resourced and unable to meet the growing needs of the population.[15] Globally, neonatal near miss (NNM) prevalence remains a significant concern, with survival rates among newborns with severe complications ranging from 37.1 to 45.3%. In Africa, the pooled prevalence of NNM is approximately 30%, though this figure varies across regions and time periods.[7,16] This relatively lower prevalence in Africa can be attributed to the high neonatal mortality rates, where many sick neonates do not survive due to limited healthcare access and resources. Data on NNM in Somalia remains scarce; however, studies from the Banadir region identify critical factors contributing to NNM, such as inadequate antenatal care, short birth intervals, and low maternal education.[17] Therefore, the study examined the determinants of neonatal near miss among neonates born in major public hospitals in the Banadir Region, Somalia.

Methods

Study design

This was a hospital-based unmatched case-control study designed to assess neonatal near-miss events by comparing affected neonates (cases) with healthy neonates (controls).

Setting

The study was conducted at SOS Mother and Child Hospital in the Banadir region, Somalia, from December 2024 to April

2025. This facility is a major maternal and child health hospital, offering comprehensive neonatal care with approximately 200 beds and admitting an average of 65 newborns monthly.

Participants

The study participants consisted of neonates admitted to SOS Mother and Child Hospital during the study period, classified into two groups: cases and controls. Cases included neonates who experienced at least one neonatal near-miss event within the first 27 days of life but ultimately survived. Identification of neonatal near-miss cases was based on criteria established by the Latin American Centre for Perinatology (CLAP), which include both pragmatic and management criteria. Pragmatic criteria were neonates born weighing less than 1750 g, delivered before 33 weeks of gestation, or with an Apgar score of less than 7 at five minutes. Management criteria encompassed neonates who required critical clinical interventions such as therapeutic antibiotics, nasal continuous positive airway pressure (NCPAP), neonatal intubation, phototherapy initiated within 24 h of birth, cardiopulmonary resuscitation, administration of vaso-active medications, anticonvulsants, surfactants, blood products, steroids for refractory hypoglycaemia, or surgical procedures during their neonatal period.[10,11]

Controls were healthy neonates selected from the hospital's postnatal wards. These neonates were born without complications, did not require any specialized medical interventions, and were discharged in stable condition. To enhance comparability, for every neonate identified as a near-miss case, three control neonates were carefully selected on the same day the near-miss event occurred.[18]

Table 1 Socio-demographic characteristics of respondents

Variables	Neonatal Near Miss		Total *N* (%)	*P*-value
	Case *n* (%)	Control *n* (%)		
Residence				***0.000***
Urban	183 (75.3)	644 (88.2)	827 (85.0)	
Rural	60 (24.7)	86 (11.8)	146 (15.0)	
Maternal Age				***0.421***
< 25 years	131 (53.9)	383 (52.5)	514 (52.8)	
26–35 years	97 (39.9)	315 (43.2)	412 (42.3)	
> 35 years	15 (6.2)	32 (4.4)	47 (4.9)	
Maternal Marital Status				***0.002***
Married	226 (93.0)	711 (97.4)	937 (96.3)	
Unmarried	17 (7.0)	19 (2.6)	36 (3.7)	
Maternal education				***0.000***
No formal education	194 (79.8)	437 (59.9)	631 (64.9)	
Formal education	49 (20.2)	293 (40.1)	342 (35.1)	
Paternal education				***0.000***
No formal education	197 (81.1)	365 (50.0)	562 (57.8)	
Formal education	46 (18.9)	365 (50.0)	411 (42.2)	
Maternal working status				***0.993***
Working	199 (81.9)	598 (81.9)	797 (81.9)	
Not working	44 (18.1)	132 (18.1)	176 (18.1)	
Family size				***0.893***
< 5 Individuals	101 (41.6)	307 (42.1)	408 (41.9)	
≥ 5 Individuals	142 (58.4)	423 (57.9)	565 (58.1)	
Monthly family income				***0.000***
< 100 USD	168 (69.1)	293 (40.1)	461 (47.4)	
≥ 100 USD	75 (30.9)	437 (59.9)	512 (52.6)	

Neonates were excluded from the study if they had an unknown or incomplete birth history, belonged to multiple gestations, experienced maternal absence during admission, possessed incomplete medical records, or were initially categorized as controls but subsequently reclassified as cases during the study period.[19]

Sampling procedures

Cases were selected using consecutive sampling. All neonates admitted to the newborn unit who met the neonatal near-miss (NNM) criteria during the study period were included as cases at the time of discharge. This ensured that every eligible case was captured without omission until the required sample size was achieved. For each case included in the study, three controls were randomly selected from among neonates who were born healthy and discharged without complications. A list of all eligible healthy neonates admitted to the postnatal ward was compiled using their registration numbers. From this list, controls were selected using computer-generated simple random sampling, maintaining a 1:3 case-to-control ratio.

Sample size determination

The sample size for this study was calculated using the double population proportion formula through the Epi Info 7 StatCalc program. The calculation was based on the following assumptions: a 95% confidence level, 80% power, and a case-to-control ratio of 1:3. The percentage of cases exposed to lack of ANC (12%) and the percentage of controls exposed to lack of ANC (5.7%) were taken from a study conducted in Northeast Ethiopia.[20] Based on these parameters, the required sample size was calculated to be 824 participants. After adjusting for an 18% non-response rate, the final sample size increased to 973 participants (243 cases and 730 controls).

Data collection method

Data was collected from the mothers of the neonates using a structured and pretested questionnaire, administered by trained interviewers. The questionnaire was carefully adapted from relevant literature to ensure its validity and relevance.[19,21,22] The data collectors used face-to-face interviews and client record review techniques to collect data. Structured interviews with mothers of newborns were conducted in private settings, primarily at the time of patient discharge, ensuring that cases had recovered from their illnesses and controls were physiologically stable and ready for discharge. In addition to interviews, relevant clinical data were extracted from hospital records with appropriate permissions. This dual approach enhanced data richness by providing objective clinical information alongside maternal reports.

Study variables

Neonatal near miss was defined as a neonate who experienced a severe, life-threatening condition during the neonatal period (0–28 days) but survived, as per established clinical or management criteria. This outcome variable was coded as 1 = 'Yes' and 0 = 'No'.

Independent variables included socio-demographic characteristics such as maternal age, education and occupation of both parents, marital status, household size, income, and residence. Obstetric history covered gravidity, parity, previous stillbirths, abortions, neonatal deaths, and birth intervals.

Maternal health conditions during pregnancy such as anemia, hypertension, diabetes, heart disease, and infections were considered, along with health service factors like ANC attendance, number of visits, and complications during labor and delivery.

Newborn-related variables included sex, gestational age, birth weight, APGAR score, and presentation. Critical interventions such as use of antibiotics, CPAP, intubation, phototherapy, CPR, and presence of congenital anomalies were also assessed to identify near-miss cases.

Data quality control

The data were collected by ten qualified midwives fluent in both English and Somali. Prior to data collection, they received an intensive two-day training that covered data collection procedures, the objectives of the study, questionnaire content, participant interaction, and ethical considerations such as confidentiality and privacy.

One week before data collection began, a pretest was conducted on 5% of the sample to assess the clarity, validity, and usability of the questionnaire. Feedback from the pretest informed necessary revisions to enhance accuracy and ease of understanding for respondents.

To ensure high data quality throughout the study, supervisors carried out random checks of completed questionnaires to verify adherence to the study protocol and maintain consistency and accuracy in data collection.

Table 2 Maternal obstetric history and newborn characteristics

Variables	Neonatal Near Miss		Total *N* (%)	*P*-value
	Case *n* (%)	Control *n* (%)		
Parity				***0.000***
≤ 3	52 (21.4)	422 (57.8)	474 (48.7)	
> 3	191 (78.6)	308 (42.2)	499 (51.3)	
Short birth interval				***0.000***
Yes	116 (47.7)	194 (26.6)	310 (31.9)	
No	127 (52.3)	536 (73.4)	663 (68.1)	
ANC attendance				***0.000***
Yes	52 (21.4)	464 (63.6)	516 (53.0)	
No	191 (78.6)	266 (36.4)	457 (47.0)	
History of Stillbirth				***0.000***
Yes	51 (21.0)	33 (4.5)	84 (8.6)	
No	192 (79.0)	697 (95.5)	889 (91.4)	
Obstetric Complications				***0.000***
Yes	83 (34.2)	76 (10.4)	159 (16.3)	
No	160 (65.8)	654 (89.6)	814 (83.7)	
Premature Rupture of Membranes				***0.853***
Yes	42 (17.3)	130 (17.8)	172 (17.7)	
No	201 (82.7)	600 (82.2)	801 (82.3)	
Gestational Age at Birth				***0.000***
Preterm (< 37 weeks)	80 (32.9)	125 (17.1)	205 (21.1)	
Post-term (≥ 42 weeks)	5 (2.1)	37 (5.1)	42 (4.3)	
Term (37–41 weeks)	158 (65.0)	568 (77.8)	726 (74.6)	
Prolonged labour				***0.000***
Yes	54 (22.2)	54 (7.4)	108 (11.1)	
No	189 (77.8)	676 (92.6)	865 (88.9)	
Place of Delivery				***0.000***
Health Facility	52 (21.4)	356 (48.8)	408 (41.9)	
Home	191 (78.6)	374 (51.2)	565 (58.1)	
Mode of Delivery				***0.287***
SVD	152 (62.6)	484 (66.3)	636 (65.4)	
Non SVD	91 (37.4)	246 (33.7)	337 (34.6)	
Chronic Medical Conditions				***0.000***
Yes	168 (69.1)	293 (40.1)	461 (47.4)	
No	75 (30.9)	437 (59.9)	512 (52.6)	
Baby sex				***0.000***
Male	160 (65.8)	372 (51.0)	532 (54.7)	
Female	83 (32.2)	358 (49.0)	441 (45.3)	
Birth weight				***0.000***
Low birth weight	110 (45.3)	60 (8.2)	170 (17.5)	
Normal birth weight	133 (54.7)	670 (91.8)	803 (82.5)	

Data analysis and processing

All collected data were reviewed for completeness, accuracy, and consistency prior to analysis. Data cleaning was conducted to address any missing or inconsistent entries. The cleaned dataset was then analyzed using SPSS version 25. Descriptive statistics were used to summarize participants' background characteristics. To assess associations between the dependent variable (neonatal near miss) and independent variables, Chi-square tests were employed. Variables showing a statistically significant association ($p < 0.05$) in the Chi-square test were included in a binary logistic regression model to identify independent predictors of neonatal near-miss events. The strength of associations was quantified using adjusted odds ratios (aORs) with 95% confidence intervals (CIs). A p-value of less than 0.05 was considered statistically significant in the final model.

Ethical considerations

The study received ethical clearance from the Research Ethics Committee of SOS College of Health Science (Reference: SOSCHS/REC/2025/015), underscoring adherence to the highest standards of ethical conduct and research integrity. Informed consent was obtained from all participants before data collection, with strict measures in place to safeguard their privacy and confidentiality. Participation was fully voluntary, and individuals retained the right to withdraw from the study at any point without any form of penalty or disadvantage.

Results

Socio-demographic characteristics

The study included 973 participants, with 243 neonatal near miss (NNM) cases and 730 controls. Most participants (85%) lived in urban areas, though a higher proportion of cases (24.7%) were from rural areas compared to controls (11.8%). Maternal age was similar across groups, with over half of mothers under 25 years. The majority of mothers were married (96.3%), but unmarried mothers were slightly more common among cases (7%) than controls (2.6%).

A large portion of mothers lacked formal education (64.9%), with this proportion higher among cases (79.8%) than controls (59.9%). Similarly, more fathers of cases had no formal education (81.1%) compared to controls (50%). Maternal employment status and family size were comparable between groups, with about 82% of mothers working and roughly 42% of families having fewer than five members. Regarding income, nearly half of all families earned less than 100 USD monthly, with a notably higher percentage among cases (69.1%) versus controls (40.1%) (Table 1).

Table 3 Factors associated with neonatal near miss among neonates

Characteristics	*N* (%)	Neonatal Near miss		AOR 95%(CI)
		Yes = 243	No = 730	
Residence				
Urban	827 (85.0)	183 (75.3)	644 (88.2)	1.24 (0.714–2.158)
Rural	146 (15.0)	60 (24.7)	86 (11.8)	1
Marital status				
Married	937 (96.3)	226 (93.0)	711 (97.4)	2.59 (0.978–6.863)
Unmarried	36 (3.7)	17 (7.0)	19 (2.60)	1
Maternal education				
No formal education	631 (64.9)	194 (79.8)	437 (59.9)	2.61 (2.004–2.412)*
Formal education	342 (35.1)	49 (20.2)	293 (40.1)	1
Paternal education				
No formal education	562 (57.8)	197 (81.1)	365 (50.0)	3.64 (2.448–5.419)*
Formal education	411 (42.2)	46 (18.9)	365 (50.0)	1
Monthly family income				
< 100 USD	461 (47.4)	168 (69.1)	293 (40.1)	2.82 (1.968–4.046)*
≥ 100 USD	512 (52.6)	75 (30.9)	437 (59.9)	1
Parity				
≤ 3	474 (48.7)	52 (21.4)	422 (57.8)	0.26 (0.179–0.392)*
> 3	499 (51.3)	191 (78.6)	308 (42.2)	1
Short birth interval (< 24 Months)				
Yes	310 (31.9)	116 (47.7)	194 (26.6)	1.97 (1.349–2.854)*
No	663 (68.1)	127 (52.3)	536 (73.4)	1
ANC attendance for last pregnancy				
Yes	516 (53.0)	52 (21.4)	464 (63.6)	0.16 (0.100–0.240)*
No	457 (47.0)	191 (78.6)	266 (36.4)	1
History of Stillbirth				
Yes	84 (8.6)	51 (21.0)	33 (4.5)	4.35 (2.870–6.606)*
No	889 (91.4)	192 (79.0)	697 (95.5)	1
Obstetric Complications				
Yes	159 (16.3)	83 (34.2)	76 (10.4)	4.46 (3.127–6.373)*
No	814 (83.7)	160 (65.8)	654 (89.6)	1
Gestational Age at Birth				
Non-term (pre & post)	247 (25.4)	85 (35.0)	162 (22.2)	1.89 (1.375–2.588)*
Term (37–41 weeks)	726 (74.6)	158 (65.0)	568 (77.8)	1
Prolonged labour				
Yes	108 (11.1)	54 (22.2)	54 (7.4)	3.58 (2.373–5.391)*
No	865 (88.9)	189 (77.8)	676 (92.6)	1
Place of Delivery				
Health Facility	52 (21.4)	356 (48.8)	408 (41.9)	0.21 (0.053–0.817)*
Home	191 (78.6)	374 (51.2)	565 (58.1)	1
Chronic Medical Conditions				
Yes	78 (8.0)	52 (21.4)	26 (3.60)	3.37 (4.484–12.120)*
No	895 (92.0)	191 (78.6)	704 (96.4)	1
Baby sex				
Male	532 (54.7)	372 (51.0)	532 (54.7)	1.86 (1.371–2.510)*
Female	441 (45.3)	358 (49.0)	441 (45.3)	1
Birth weight				
Low birth weight	170 (17.5)	110 (45.3)	60 (8.2)	9.34 (6.408–13.310)*
Normal birth weight	803 (82.5)	133 (54.7)	670 (91.8)	1

Maternal obstetric history and newborn characteristics

The study also assessed various obstetric and neonatal variables in relation to neonatal near miss (NNM) outcomes. Regarding parity, a larger proportion of NNM cases (78.6%) had more than three children, compared to 57.8% of controls, highlighting higher parity among cases. Short birth intervals were more common in NNM cases, with 47.7% having intervals shorter than 2 years, compared to 26.6% of controls. Similarly, antenatal care (ANC) attendance was significantly lower in NNM cases (21.4%) than in controls (63.6%), indicating a notable gap in maternal healthcare utilization.

In terms of history of stillbirth, 21.0% of NNM cases had a previous stillbirth, compared to only 4.5% of controls. Obstetric complications were more prevalent among women whose neonates experienced a near-miss (34.2%) compared to those whose neonates did not (10.4%), indicating that such complications are more common in pregnancies resulting in near-miss neonatal events. Premature rupture of membranes (PROM) did not show a significant difference between the groups, with 17.3% of cases and 17.8% of controls affected.

Regarding gestational age, a higher proportion of NNM cases (32.9%) were preterm (< 37 weeks), compared to 17.1% of controls. In contrast, term births (37–41 weeks) were more common in controls (77.8%) than in cases (65.0%). Prolonged labor was more frequent in NNM cases (22.2%) compared to controls (7.4%), suggesting a link between prolonged labor and NNM.

Concerning place of delivery, a higher proportion of NNM cases (78.6%) delivered at home, compared to 51.2% of controls. No significant difference was found in the mode of delivery, with 62.6% of NNM cases and 66.3% of controls delivering vaginally. Chronic medical conditions were more common among NNM cases (69.1%) compared to controls (40.1%), suggesting that underlying health issues may contribute to NNM. In terms of baby sex, 65.8% of NNM cases had male babies, compared to 49.0% of controls. Finally, birth weight was significantly associated with NNM, as 45.3% of NNM cases had low birth weight, compared to only 8.2% of controls, with most controls (91.8%) having normal birth weight (Table 2).

Determinants of neonatal near miss identified through multivariable analysis

Variables that showed statistical significance in the chi-square analysis were further examined using multi-variable logistic regression. The multivariable analysis identified several factors significantly associated with neonatal near miss. These included maternal and paternal education, low monthly family income, high parity, short birth interval, lack of antenatal care (ANC) attendance, history of stillbirth, obstetric complications, non-term gestational age, prolonged labor, place of delivery, chronic medical conditions, male sex of the newborn, and low birth weight. In contrast, variables such as residence did not show a statistically significant association with neonatal near miss after adjusting for potential confounders.

Mothers without formal education had higher odds of neonatal near miss compared to those with formal education (AOR: 2.61; 95% CI: 2.004–2.412). Likewise, paternal lack of formal education was significantly associated with near miss events (aOR: 3.64; 95% CI: 2.448–5.419). Similarly, families with a monthly income of less than 100 USD were nearly three times more likely to experience a neonatal near miss (AOR: 2.82; 95% CI: 1.968–4.046). Having more than three children was associated with increased risk, while having three or fewer children was protective (aOR: 0.26; 95% CI: 0.179–0.392). A short birth interval of less than 24 months also significantly raised the odds (AOR: 1.97; 95% CI: 1.349–2.854).

Notably, mothers who attended antenatal care (ANC) during their last pregnancy were approximately 6 times less likely to experience a neonatal near miss compared to those who did not attend (aOR: 0.16; 95% CI: 0.100–0.240), highlighting ANC as a strong protective factor. In contrast, mothers with a previous history of stillbirth had more than 4 times higher odds of experiencing a neonatal near miss (aOR: 4.35; 95% CI: 2.870–6.606). Similarly, the presence of obstetric complications significantly increased the odds by over fourfold (AOR: 4.46; 95% CI: 3.127–6.373). Additionally, neonates born outside the term gestational window (preterm or post-term) were nearly 2 times more likely to experience a near miss compared to those born at term (AOR: 1.89; 95% CI: 1.375–2.588). On the other hand, prolonged labor was associated with a more than 3.5-fold increase in risk (aOR: 3.58; 95% CI: 2.373–5.391), underscoring the importance of timely obstetric care.

Delivering at a health facility significantly reduced the odds of experiencing a neonatal near miss by approximately five times (AOR: 0.21; 95% CI: 0.053–0.817), underscoring the protective role of institutional delivery. In contrast, mothers with chronic medical conditions had more than three times higher odds of experiencing a neonatal near miss compared to those without such conditions (aOR: 3.37; 95% CI: 4.484–12.120), indicating a strong association between maternal health status and neonatal outcomes. Moreover, male neonates were nearly twice as likely to be classified as near miss cases compared to females (aOR: 1.86; 95% CI: 1.371–2.510). Above all, low birth weight was the most significant predictor of neonatal near miss, with affected infants being over nine times more likely to experience life-threatening complications than those with normal birth weight (aOR: 9.34; 95% CI: 6.408–13.310) (Table 3).

Discussion

The study examined the determinants of neonatal near miss among neonates born or admitted to SOS Mother & Child Hospital in Mogadishu. The findings revealed that neonatal near miss remains a significant public health concern, influenced by a range of maternal, socio-economic, obstetric, and neonatal factors. Key determinants identified in this study include lack of maternal and paternal formal education, low household income, high parity, short birth interval, lack of antenatal care (ANC) attendance, history of stillbirth, obstetric complications, non-term gestational age, prolonged labor, home delivery, chronic maternal medical conditions, male sex of the newborn, and low birth weight.

Mothers who attended ANC were approximately 6 times less likely to experience a neonatal near miss. A similar protective effect was reported in Ethiopia, where ANC attendance reduced the odds of neonatal near miss by 73%.[23] This could be explained by the fact that antenatal care provides an essential opportunity to identify and manage maternal and fetal complications early, promote birth preparedness, and ensure timely referral for high-risk pregnancies. The study also reported that low birth weight increased the odds of neonatal near miss more than 9-fold. This aligns with studies in India, where low birth weight was a key criterion for NNM.[24] This might be due to the fact that low birth weight neonates often suffer from immature organ development, reduced immunity, and poor thermoregulation, making them more susceptible to life-threatening conditions such as infections, respiratory distress, and feeding difficulties—especially in low-resource settings where access to neonatal intensive care may be limited.[25]

Regarding the institutional delivery, the study found out that health facility delivery reduced the odds of neonatal near miss by about five times. This can be explained by the fact that institutional deliveries are attended by skilled health professionals who are equipped to manage labor complications, provide timely neonatal resuscitation, and ensure immediate postnatal care.[26] In line with this, the study found that women who experienced obstetric complications had a 4.5-fold increased risk of neonatal near miss compared to those without such complications.[27] More specifically, prolonged labor—one of the most common obstetric complications—was associated with over a 3.5-fold increase in the odds of neonatal near miss. Almost similar findings were reported in a study conducted in Ethiopia, where obstetric complications were significantly associated with increased odds of neonatal near miss.[23]

With respect to gestational age, non-term neonates (preterm and post-term) had 1.9 times higher odds of neonatal near miss. In the light of the fact that preterm infants are more vulnerable to complications such as respiratory distress, hypothermia, and infections due to organ immaturity, while post-term births are often associated with increased risk of birth asphyxia, meconium aspiration, and placental insufficiency—all of which contribute to adverse neonatal outcomes. Studies in India and Ghana identified non-term gestational age as a critical criterion for neonatal near miss. These studies highlighted that both preterm and post-term births are associated with increased risks of severe neonatal complications.[24,28]

It was shown that chronic maternal conditions (e.g., anemia, hypertension) were linked to 3.4 times higher odds of neonatal near miss (NNM). A similar study conducted in India found that 74.5% of NNM cases involved maternal comorbidities.[24] This is attributable to chronic maternal health issues, such as hypertension, diabetes, and anemia, can significantly impair the physiological processes necessary for a healthy pregnancy.

Finally, regarding the sex of the newborn, the study revealed that male neonates had nearly double the odds of experiencing a neonatal near miss compared to females. This can be explained by the biological vulnerability of male infants, who are more prone to respiratory distress, infections, and slower lung maturation during the neonatal period. Although not conclusively evidenced by this study, existing literature suggests that male neonates generally have a higher risk of adverse outcomes due to these physiological factors.[29,30]

Strengths and limitations

A key strength of this study is the use of standardized neonatal near miss criteria based on internationally recognized CLAP guidelines, which ensured consistency in case identification. The relatively large sample size and use of both structured interviews and medical record reviews enhanced the reliability of the findings. Additionally, the multivariable analysis allowed for adjustment of confounding variables, strengthening the validity of the associations identified.

Despite its valuable contributions, the study has certain limitations. Although it included a relatively large sample size, it was conducted in a single hospital, which may not capture the full variability of neonatal care practices. In addition, some variables were based on maternal recall, which may have introduced recall bias and affected the precision of the data collected.

Conclusion & recommendation

The burden of neonatal near miss remains a critical public health concern in Somalia. This study identified several factors significantly associated with neonatal near miss among neonates in Mogadishu. These included lack of formal maternal and paternal education, low household income, high parity, short birth interval, absence of antenatal care (ANC), history of stillbirth, obstetric complications, non-term gestational age, prolonged labor, home delivery, maternal chronic illnesses, male sex of the newborn, and low birth weight.

Addressing these factors is essential to reducing neonatal morbidity and improving survival. Interventions that promote ANC attendance, safe delivery practices, maternal education, and early identification of high-risk pregnancies should be prioritized by both governmental and humanitarian actors. Strengthening facility-based care and improving access to skilled birth attendants can play a pivotal role in preventing life-threatening neonatal complications and achieving better outcomes for newborns in resource-limited settings.

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Author contributions

Hassan Abdullahi Dahie: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. Falis Ibrahim Mohamud: Writing – review & editing, Writing – original draft, Supervision. Mohamed Abdullahi Osman: Supervision, Methodology, Data curation. Abukar Abdi Osman: Writing – original draft, Data Collection. Yusuf Ali Jimale: Visualization, Supervision, Investigation. Hamdi Ahmed Hussein: Supervision, Investigation, Formal analysis. Mohamed Osman Alasow: Visualization, Software. Abukar Abdi Osman: Writing – original draft. Abdirahman Mohamed Abdullahi: Writing – review & editing, Writing – original draft. Mohamed Maalin Dakane: Writing – review & editing, Writing – original draft, Formal analysis. Dek Abdi Hussein: Writing – review & editing, Writing – original draft, Formal analysis. Abdihakin Mohamed Hassan: Writing – review & editing, Writing – original draft, Supervision.

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Data availability

No datasets were generated or analysed during the current study.

Ethics approval and consent to participate

The study was approved by the SOS College of Health Science Research Ethics Committee (Ref: SOSCHS/REC/2025/015). Informed consent was obtained from all participants, with strict confidentiality maintained. Participation was voluntary, and respondents could withdraw at any time without consequence.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Neonatal Intensive Care Unit to Pediatric Intensive Care Unit Transfers: A Critical Juncture in the Trajectory of Neonatal Critical Illness

Sarah Mahdally, MD, and Conrad Krawiec, MD

Critically ill neonates represent some of the most challenging patients encountered in clinical practice. While most infants recover sufficiently to be discharged directly from the neonatal intensive care unit (NICU), others require ongoing specialized care, beyond the NICU.[1,2] In these cases, neonatologists and pediatric intensivists collaborate closely to make the difficult decision to transfer care, often after months of dedicated treatment, vigilance, and hope.

The decision to transfer care is a particularly stressful period for both teams. The neonatologist, deeply familiar with the patient and family, must weigh whether the timing of transfer is appropriate: Is it in the patient's best interest? Will it disrupt the progress they are making? Will it create added stress for the family? Conversely, the pediatric intensivist must quickly grasp a complex medical history, absorb the nuances of the prior NICU course to ensure continuity of care, and establish rapport with a family who is abruptly transitioned to a new environment.[3]

All of this must occur while managing both neonatal and pediatric intensive care unit (PICU) capacity, balancing unit-level acuity, and evaluating the safety and appropriateness of transfer—bearing in mind that some patients require only brief PICU support, while others may need extended intensive care. These considerations are central to the decisions both neonatologists and pediatric intensivists face particularly amid fluctuating census and acuity across both units.

In light of these challenges, Cohen et al, in this issue of *Journal of Pediatrics: Clinical Practice*, conducted a multicenter study using data from the Pediatric Health Information System to better characterize NICU-to-PICU transfer patterns and examine associations between patient characteristics, transfer timing, and post-transfer outcomes.[4]

The study found that approximately 5% of NICU encounters involved transfer to the PICU, most commonly among infants younger than 10 days and those older than 100 days.[4] Timing of transfer and length of PICU stay were associated with markers of technology dependence and severe morbidity.[4] Notably, post-transfer mortality rates exceed those seen in the general NICU population, underscoring the clinical complexity and vulnerability of these infants.[4]

This study offers one of the first estimates of NICU-to-PICU transfer rates, addressing a gap in the existing literature. The findings have important implications for resource planning and system-level coordination. Large children's hospitals often have between 20 and 40 PICU beds[5] and annual admission volumes—depending on the hospital's level of care—can range from 600 to 1000 patients.[6] Extrapolating these estimates suggests that as many as 4000 children nationally could be transferred from the NICU to PICU each year. This figure may only represent the beginning. As technology advances and evidence-based practices continue to evolve, more neonates will survive the acute phase of their NICU stay,[1] and depending on their comorbidities, may subsequently require critical care services in the PICU. As such, these numbers are likely to rise over time, creating additional pressure on pediatric critical care systems.

Approximately 40% of transfers occurred during the early neonatal period, the authors suggest many early transfers reflect PICU-specific needs, such as postoperative care after cardiac surgery or other specialized interventions.[4] Conversely, transfers occurring later in the neonatal period, >100 days, were associated with prematurity, technology dependence, and illness severity.[4] However, the study did not distinguish between emergent and nonemergent transfers or planned transfers, limiting insight into transfer context. Many transferred patients had relatively lower medical complexity, with few requiring extracorporeal life support or cardiopulmonary resuscitation. Although mechanical ventilation was common, it is a nonspecific marker encompassing a broad range of clinical situations, not all warranting emergent transfer. Thus, while some transfers may reflect clinical deterioration, others may have been driven by census pressures, advancing age of patients, subspecialty access, or other operational factors not captured in the study. Future studies should better differentiate emergent from nonemergent transfers, as these distinctions may impact short- and long-term outcomes, particularly when comparing early and late transfers.

The authors unexpectedly discovered that transfer timing may have been influenced by sociodemographic factors or external stressors. They appropriately suggest that this may reflect healthcare access disparities that contribute to greater medical complications or potential biases in care delivery. However, another important consideration is potential ongoing lack of access and support some families face even during

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the NICU stay itself.[7] For example, structural challenges like work obligations, lack of paid leave, transportation barriers, or competing caregiving responsibilities,[7] may prevent parents from consistently being at the bedside. Parents often experience significant emotional challenges of their own, which may impact their ability to cope and support their child, further limiting their ability to participate in their child's care or fully engage in shared decision-making.[8] Language barriers further complicate communication and create misunderstandings that affect care planning.[9] These challenges may delay certain interventions or extend NICU stays, particularly in complex decision-making processes such as the timing of tracheostomy for infants with bronchopulmonary dysplasia. As neonatal survival rates continue to improve,[10,11] a growing proportion of NICU patients may emerge from medically and socially vulnerable populations, often requiring robust family-centered support throughout both the NICU and PICU care. Future studies will need to address these issues directly, as they may have lasting implications for both transfer practices and long-term outcomes.

This study also highlights that both the timing of transfer and the post-transfer length of stay were associated with clinical features such as technology dependence and greater medical complexity.[4] This finding is significant, as it reinforces that transfer is not without consequence. Prolonged PICU stays may result, placing additional strain on PICU resources.[12] Given the observed higher mortality rates following NICU-to-PICU transfer, and the known association between prolonged PICU stays and increased mortality, these realities demand careful decisionmaking and deliberate coordination.[2,12] Successful transfer depends on close collaboration between neonatologists and pediatric intensivists to ensure that the complex medical needs of these fragile patients are thoroughly understood, communicated, and managed. Furthermore, the elevated mortality risk must be weighed carefully, particularly in an era where ICU quality metrics and hospital performance indicators are under increasing scrutiny.[13] Higher than expected mortality rates can carry broader implications not only for institutional reputation but also for parental trust, raising uncomfortable but real questions about families' confidence in entrusting transferring their critically ill child into such a system.

This study by Cohen et al adds meaningfully to the growing body of literature surrounding NICU to PICU transfers.[4] They have established an estimated prevalence rate that can inform future decisions regarding resource allocation and bed capacity in the setting of increasing ICU demands. The study also highlights the influence of medical and sociodemographic factors that may place certain patients at elevated risk for comorbidities, and it reaffirms the higher mortality risk associated with these transfers. Moving forward, all large children's hospitals with NICU and PICU capabilities—both existing and those under development—should leverage studies like this to create formalized protocols that go beyond managing acute illness alone. Protocols must foster early multidisciplinary discussions, promote seamless collaboration between intensive care units, and minimize the emotional and logistical burdens faced by families who have already invested so deeply in their child's care. NICUs were established envisioning a future where advances in neonatal care would allow most infants to eventually go home. For many of these complex patients, transferring to the PICU and ultimately being discharged home still fulfills that goal. Such transfers should not be seen as an afterthought or as reactive decisions driven by system-level pressures. Rather, they should be recognized as a deliberate and integral part of care planning for our most vulnerable and underserved patients. Only when this mindset becomes embedded in our culture can we fully realize the optimal health outcomes that these patients and their families deserve.

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