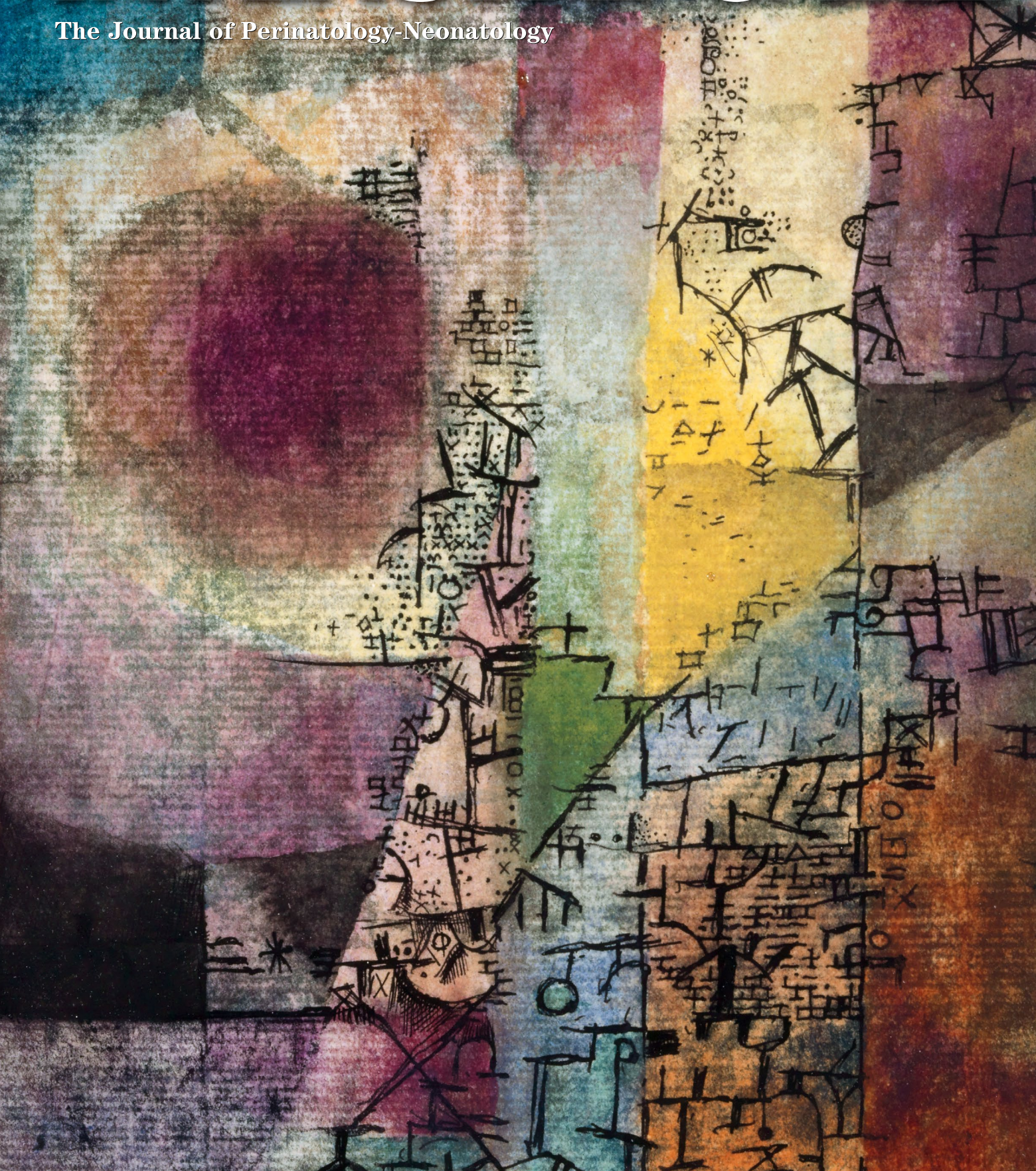


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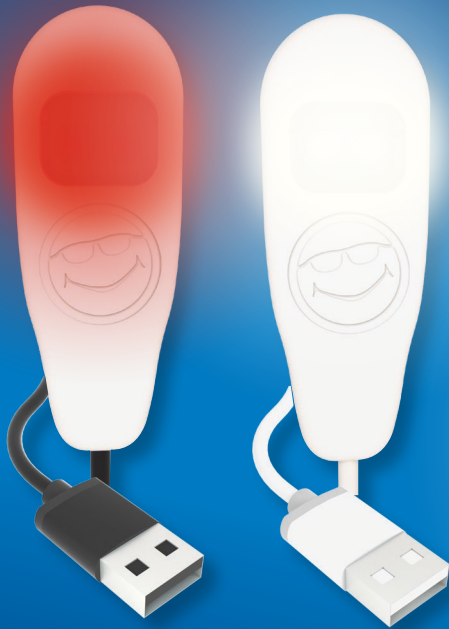
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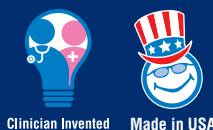
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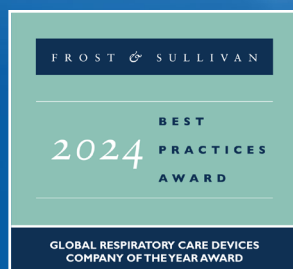
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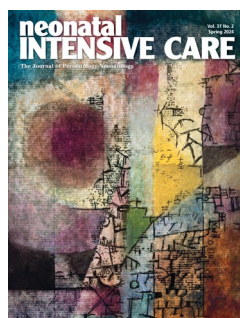


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Prenatal Prescription Opioids Tied to Increased Risk for Preterm Birth

Taking a prescription opioid for pain management during pregnancy is associated with an increased risk for spontaneous preterm birth, data from a new case-control study of over 25,000 Medicaid patients showed. Researchers retrospectively reviewed data on pregnant patients enrolled in Tennessee Medicaid who experienced birth of a single baby at ≥ 24 weeks gestation (25,391 with opioid use disorder and 225,696 without). Median age of participants was 23 years; 58.1% were non-Hispanic White, 38.7% Black, 2.6% Hispanic, and 0.5% Asian. Controls were matched based on pregnancy start date, race, ethnicity, age at delivery (within 2 years), and history of prior preterm birth. Sensitivity analysis included the exclusion of opioid prescriptions dispensed within 3 days of the index date to account for potential opioid prescribing associated with labor pain. A total of 18,702 patients (7.4%) filled an opioid prescription during the 60 days prior to the index date. Each doubling of opioid morphine milligram equivalents (MMEs) prescribed during the 60 days was associated with a 4% increase in the odds of spontaneous preterm birth compared with no opioid exposure in the matched controls (adjusted odds ratio [aOR], 1.04; 95% CI, 1.01-1.08). Overall, 1573 pregnancies filled prescriptions for 900 MMEs

or greater, which was associated with at least a 21% increased risk for spontaneous preterm birth compared with no opioid exposure (aOR, 1.21; 95% CI, 1.10-1.33). Researchers found no significant difference in odds of spontaneous preterm birth among included opioid types after adjusting for confounders and opioid MMD. "This association may appear modest, especially considering that common, one-time prescriptions often fall in the 150-225 MME range, but these findings may provide more caution when prescribing multiple, higher strength opioids," the authors wrote. "We also caution against the conclusion that lower doses, especially those below 100 MME, are safe; the confidence bands over the low dose range still include odds ratios that are consistent with meaningful harm." Sarah S. Osmundson, MD, MS, of the Department of Obstetrics and Gynecology, Vanderbilt University Medical Center, Nashville, Tennessee, was the senior and corresponding author on the study. The study was published online on February 14 in *JAMA Network Open*.

New Product Released

Sylvan Fiberoptics now offers the N103-90 fiberoptic cable, with a 90-degree distal tip, as the lightpipe attachment to the hand-held Neoscan Neo2-W neonatal transilluminators. This provides improved ergonomics while keeping the same four-foot length, functionality, and light output as the straight tipped on-point fiberoptic cables. The design is the direct result of input from nurses and neonatologists. The optical grade glass-silica fibers are bent 90-degree through the stainless-steel distal tip to offer the same on-point transillumination qualities used for decades to help find veins and illuminate chest cavities. Bending the fibers rather than cutting and creating a new connection keeps the light loss at a minimum to maintain the incredibly bright white LED light output being produced. The N103-90 fiberoptic lightpipe is effective, durable, and stays cool. Free trials for the Neoscan Neo2-W with the N103-90 are available. The 90-degree distal tip fiberoptic cables are not currently available for the Pediascan Model 5000 or the Maxiscan Model 1000LEDW transilluminators, however prototypes are being designed. Contact Sylvan Fiberoptics for a quote, literature, or free trial information. email: info@sylvanmed.com; phone: 724-864-9350; website: www.sylvanmed.com.

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AHA: Urgent Need to Reduce Maternal Postpartum CVD Risk

Complications during pregnancy may be a wake-up call pointing to a higher risk for cardiovascular (CVD) and other diseases later in life. Therefore, the postpartum and inter-pregnancy periods are opportune windows for reducing CVD susceptibility and providing preventive care, especially for mothers with a history of adverse pregnancy outcomes (APOs). To that end, the American Heart Association recently released a scientific statement in *Circulation* outlining pregnancy-related CVD risks and reviewing evidence for preventive lifestyle strategies based on the AHA's Life's Essential 8 recommendations. The Life's Essential 8 encompass healthy eating, sleeping, and activity patterns; controlling weight, blood pressure, cholesterol, and blood sugar; and avoiding tobacco use. "The motivation behind this statement was that complications in pregnancy are becoming more common and we now have more understanding that these serve as important risk factors for heart disease later in life," said Jennifer Lewey, MD, MPH, director of the Penn Women's Cardiovascular Health Program and an assistant professor of medicine at the University of Pennsylvania Perelman School of Medicine in Philadelphia.

National Rapid Genome Testing Program Benefits NICU Care

A national study in Israel demonstrates the feasibility and diagnostic benefits of rapid trio genome sequencing in critically ill neonates. Researchers conducted a prospective, multicenter cohort study from October 2021 to December 2022, involving all Israeli medical genetics institutes and neonatal intensive care units. A total of 130 critically ill neonates suspected of having a

genetic disorder were enrolled, with rapid genome sequencing results expected within 10 days. Rapid trio genome sequencing diagnosed 50% of the neonates with disease-causing variants, including 12 chromosomal and 52 monogenic conditions. Another 11% had variants of unknown significance that were suspected to be disease-causing, and 1% had a novel gene suspected of causing disease. The mean turnaround time for the rapid reports was 7 days, demonstrating the feasibility of implementing rapid genome sequencing in a national healthcare setting, the researchers said. Genomic testing led to a change in clinical management for 22% of the neonates, which shows the clinical utility of this approach to diagnosis, they said. Genetic testing may identify patients who are candidates for precision medical treatment and inform family planning, which is "critical for families with a severely affected or deceased child," the study authors wrote. The corresponding author for the study was Daphna Marom, MD, Tel Aviv Sourasky Medical Center, Tel Aviv, Israel. It was published online on February 22, 2024, in *JAMA Network Open*.

Exposure to Phthalates Increases Risk for Premature Birth

Phthalates are chemical compounds found in many everyday consumer products, such as plastic food packaging, polyvinyl chloride (PVC) articles, and certain cleaning or cosmetic products. They are considered endocrine and metabolic disruptors, and their use is regulated in toys, electronic devices, food packaging, medical devices, and cosmetics. Some phthalates are classified as toxic to reproduction. Prenatal exposure could disrupt the development of certain tissues or organs, thus promoting potential health consequences in adulthood that could persist over several generations through epigenetic mechanisms. Numerous studies have also suggested that phthalates influence the course of pregnancy and may lead to premature birth. However, the proportion of the risk for premature birth attributable to these chemical compounds has not yet been quantified. That is why a prospective study was conducted in the United States, involving > 5000 women in whom phthalate metabolites were found in urine samples. The concentrations of phthalate metabolites are roughly the same, regardless of the stage of pregnancy. The data confirm the link between phthalate concentration in urine and the risk of premature birth. Bis(2-ethylhexyl) phthalate (DEHP) was the most widely used phthalate in PVC objects before it was regulated. DEHP is associated with a 45% increase in the risk for premature birth. The most significant increase in risk is associated with urine levels of phthalic acid, diisodecyl phthalate, di-n-octyl phthalate, and diisononyl phthalate. These compounds replaced DEHP after the establishment of regulations limiting the use of the latter. The contribution of phthalates to the occurrence of premature births is far from negligible. Nearly 57,000 preventable premature births occur each year in the United States, with an associated cost of \$3.84 billion. Safer alternatives exist, but the barrier to their use seems to be cost. Therefore, the authors attempted to estimate the environmental burden and health cost of phthalate use, including not only the short- and medium-term consequences of premature births but also child obesity and chronic diseases related to phthalates, such as adult obesity and diabetes, endometriosis, male infertility, and cardiovascular mortality. They estimated that for the United States, this total cost amounts to approximately \$100 billion annually, in addition to the cost of the environmental impact of plastic in the United States, which was recently estimated at \$250 billion each year. The authors encouraged individual initiatives to reduce exposure to phthalates. They

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particularly recommended choosing cosmetics labeled as phthalate-free and replacing plastic-wrapped foods with fresh products.

Dräger receives Frost & Sullivan's 2024 Best Practices Company of the Year Award

Dräger, an international leader in medical and safety technologies, announced that Frost & Sullivan has selected the company for its 2024 Best Practices Company of the Year Award in the global respiratory care devices industry. Frost & Sullivan's selection process

involves identifying companies that consistently develop growth strategies based on a visionary understanding of the future and effectively address new challenges and opportunities employing best practices and strategic analytics across a value chain. "Today's healthcare decision makers are looking beyond devices to determine the value a product brings to their critical care environments," said President and CEO for Draeger, Inc., Lothar Thielen. "This award validates Dräger's approach of combining best-in-class products, cost-effective accessories, and service solutions – which together deliver unmatched value to the hospitals we support."

Addressing hospital needs by offering easy-to-use and cost-conscious solutions According

to Utkarsha Soundankar, senior research analyst at Frost & Sullivan, "Dräger has become one of the leading respiratory device vendors for its enhanced clinical outcomes, product quality, longterm customer support, and ongoing education tools, all of which assist in offering patient safety and enhanced care." Dräger developed its new Evita V600, V800 and Babylog VN800 ventilators based on customer requirements for improving patient safety, patient outcomes, and hospital workflow. These devices can provide various modes of ventilation – such as

high-flow O2 therapy, non-invasive ventilation, and invasive ventilation modes – using the same accessories. This eliminates the need to use multiple devices for critically ill patients who require different types of respiratory support, thereby streamlining workflow and reducing equipment costs. Providing visionary scenarios through mega trends Frost & Sullivan salutes Dräger for introducing first-to-market solutions and continually investing in the development of new technologies. One such example is Dräger's research collaboration with STIMIT for the investigation of ventilator-induced diaphragmatic dystrophy

(VIDD). STIMIT is developing noninvasive diaphragm stimulation for preserving diaphragm thickness. An FDA-approved clinical trial for this emerging technology began in January 2024. Fostering excellent customer ownership and service experiences Used by leading hospitals worldwide, Dräger's respiratory devices are clinically validated, with detailed consideration for the hospital's specific application. To support hospital infection control protocols, Dräger designs its devices with smooth services and minimal nooks that can harbor infectious agents. The company has also developed an extensive line of single-patient use and reusable valves. Frost & Sullivan cites Dräger's best-in-class services, a network of over

3000 technicians, remote service, 24/7 hotline support, and exceptional service follow up. The company also offers webinars and training classes for healthcare facilities that want to manage their own programs. Dräger has a strong leadership team and actively supports the respiratory care community. As of 2023, Dräger donated more than 150 ventilators to respiratory schools in the United States to train the next generation of therapists and will donate another 185 ventilators in 2024.

Continued on page 9...

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Nurturing Peace of Mind: How AI is Supporting Caregivers of Patients in Critical Care

Chelsea Adams, MHA, BSN, RN, CCRN

True story: A young patient was admitted to an intensive care unit and needed to stay for several months. The patient was deemed eligible for discharge several times but could not successfully bridge to a less-invasive medication regimen and thus there were several failed discharge attempts. When the patient was again eligible for discharge, the child's parents were understandably anxious, as they would now be in charge of their little one's care delivery and monitoring at home.

Being a caregiver for a loved one in a medical setting can be an emotionally challenging journey. The constant worry about a patient's well-being, coupled with the complexity of medical data, often leaves caregivers feeling overwhelmed. However, advancements in technology, particularly in the realm of artificial intelligence, are offering peace of mind to caregivers as their loved ones transition back to the home setting.

Clinicians are utilizing Etiometry, an AI-based clinical intelligence platform for critical care, as a visual tool to help families and caregivers better understand the patient's medical conditions, response to treatment, and ideally their clinical improvement over time.

Caregiver Challenges

Caregivers face numerous challenges while navigating the healthcare landscape, from attempting to understand complex medical information, to dealing with emotional stress of relying on others to care for their critically ill family member. In many instances, they find themselves questioning the stability of their loved one, even when medical professionals assure them of the patient's well-being. This uncertainty and lack of clarity can lead to heightened anxiety and strained communication between caregivers and healthcare providers.

Etiometry's Unique Approach

Etiometry addresses these challenges by providing a visual representation of historical patient data, allowing the medical professionals to help caregivers better comprehend their loved ones' medical journey. The platform can serve as a visual cue to signify that the patient is well within acceptable limits. This not only aids caregivers in understanding the current condition, but also fosters trust in the medical team's decisions as both the clinicians and a patient's family are viewing the same clinical information in a singular view.

Unlike traditional monitors that might be ambiguous to non-clinicians, Etiometry's platform aggregates all available patient data onto one screen and incorporates visual cues and trend lines that clearly illustrate a patient's trajectory. When clinicians use Etiometry as a family education tool, it fosters a sense of empowerment and understanding with caregivers.

Real-life Scenarios

The power of Etiometry becomes evident in real-life scenarios, where caregivers have experienced moments of anxiety and uncertainty.

In one case, a concerned parent persistently raised alarms about their child's vital signs, despite reassurances from the clinical team. Etiometry's visual representation of the vital sign trended over several days helped the parent see the stability, alleviating her anxieties.

Similarly, a parent worried about a perceived change in their child's blood pressure was comforted when the physician used Etiometry to demonstrate that the values had remained consistent for more than 24 hours.

The Impact on Emotional Well-being

Etiometry is not just about data; it is about the emotional well-being of caregivers. In a poignant scenario, a mother in the cardiac intensive care unit (CICU) struggled with the frustration of not being able to hold her fragile child due to fluctuating conditions. The bedside nurse utilized Etiometry to visually explain the changes in the patient's condition, offering the mother a clear understanding of the situation. This not only diminished her frustration but also deepened her trust that the medical decisions being made were for the benefit of her child.

Etiometry's AI-based clinical intelligence platform is not just a technological innovation used by clinicians. Leveraging data visuals and trend lines, Etiometry empowers caregivers, quelling concerns, and allowing them to go home with their loved ones with confidence.

As for the pediatric patient who experienced numerous discharge attempts during an extended stay in the pediatric ICU, when the time for discharge arrived, the pediatric intensivist used Etiometry to showcase the patient's stable condition over time. This visual representation reassured the parents and facilitated a smooth transition home for both the parents and the child.

Chelsea Adams, MHA, BSN, RN, CCRN, VP of Customer Success, Etiometry.

News...continued from page 7

Notice Issued for Ventilators

Valued Customers, Bunnell Incorporated hereby announces the Model 203 LifePulse High Frequency Jet Ventilator will be rendered obsolete as of July 1, 2026. The aging ventilators have been used in the critical care of neonates for 36 years. Bunnell intends to service and support these neonatal ventilators until the date of obsolescence. Hospitals are encouraged to migrate to the newer Model 204 LifePulse High Frequency Jet Ventilator, which has been on the market since 2017. The Model 204 LifePulse HFJV provides the same therapy and utilizes the same disposables. Model 203 ventilators may be traded in towards the purchase of the Model 204 LifePulse HFJV. To learn more about the enhanced features of the new LifePulse High Frequency Jet Ventilator Model 204, visit www.bunl.com. For inquiries call 800-800-4358 or email info@bunl.com.

Newborn Recipient of Partial Heart Transplant Doing Well

A first-of-its-kind partial heart transplant in a neonate delivered valves that continue to grow and function beyond 1 year of age, researchers said. The surgery was performed on the 18th day of life of a 5-pound newborn boy diagnosed prenatally with persistent truncus arteriosus and severe truncal valve dysfunction. The procedure involved transplantation of the part of the heart containing the aorta and pulmonary valves from an infant donor upon cardiac death. The standard of care for neonatal heart valve implants are cadaver grafts. But these grafts are not viable and can't grow or self-repair. Therefore, recipient neonates need to undergo repeated implant-exchange surgeries until an adult-sized heart valve can fit. Clinical outcomes generally are poor. The donor was a 2-day-old female weighing 8 pounds. Delivery had been complicated by hypoxic ischemic brain injury, but echocardiography showed structurally normal, functioning outflow heart valves. The heart

was donated after cardiac death and procured using standard surgical techniques. The recipient infant's operation involved sternotomy, cardiopulmonary bypass, and cardioplegic arrest of the heart. The pulmonary artery ostia and coronary artery buttons were dissected, and the infant's irreparable truncal valve was excised. The donor aortic root was transplanted first, using donor tissue to close the ventricular septal defect. Then, the coronary artery buttons were reimplanted; the right ventricular outflow tract was enlarged; and the pulmonary root was transplanted. Postoperative immunosuppression followed. On the follow-up at age 14 months, the transplanted valves showed

no obstruction or insufficiency on echocardiography.

500-mg Calcium Pill Protects Against Preeclampsia, Researchers Say

Taking 500 mg of calcium a day reduces the likelihood of developing preeclampsia in pregnant women as much as higher doses, according to a study in *The New England Journal of Medicine*. The study also shows that the lower dose of calcium protects against preterm birth almost as well as the higher dose recommended by the World Health Organization (WHO). Preeclampsia complicates up to 8% of pregnancies and may contribute to 45,000 maternal deaths globally every year. The US Centers for Disease Control and Prevention estimates that preeclampsia

occurs in about 1 in 25 pregnancies, and Black women are 60% more likely to develop the condition than are White women. Calcium supplementation reduces the risks for preeclampsia, per WHO guidelines. The WHO has recommended between 1500 mg and 2000 mg of calcium supplementation daily along with one 30- to 60-mg iron pill for pregnant women who receive insufficient calcium in their diets, which the WHO says generally occurs in lower-income nations and not wealthier nations, such as the United States. This dosage amounts to a minimum of

Continued on page 18...

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LungFit PH: Transforming iNO Assumptions and Possibilities

Shelly Brown, MBA, RRT-NPS



Shelly Brown, MBA, RRT-NPS

Tell us about your background.

I've spent the last 34 years as a respiratory therapist (RT) in clinical settings that include neonatal, pediatric, and adult populations. My experience with inhaled nitric oxide (iNO) predates a commercialized delivery system and I've had the benefit of using many of the systems currently on the market.

Later in my career, I learned the business side of nitric oxide purchasing as the Director of Respiratory Care for Baptist Health in Arkansas, overseeing the operations and management of respiratory care departments across 10 hospitals. There, I experienced the frustrations of iNO contracting and cost management firsthand.

This background has given me an appreciation for the day-to-day challenges of an RT, and a breadth and depth of understanding for the business decisions hospitals are faced with.

You previously worked at Baptist Health in Arkansas as the Director of Respiratory Care, why did you choose Beyond Air and LungFit PH?

When I discovered Beyond Air (at that time AIT Therapeutics) at the AARC meeting in 2018, I was instantly intrigued by their sign, "Ask Me About Tankless Nitric Oxide," and had a brief conversation about their product. At the 2019 AARC meeting, I sought them out to learn more about their ionizing technology and the benefits the Lung Fit PH could bring to the NICU. I was frustrated with the control that cylinder-based systems had on the market and saw (1) the value of being able to generate iNO from room air and (2) the positive impact it would have on operational efficiency and pricing.

In early 2020 I participated in a pilot study with Beyond Air related to nitric oxide therapy for COVID-19 patients using their LungFit PRO system. Seeing and experiencing the ease of delivering nitric oxide using a device that doesn't rely on tanks

cemented my appreciation for the technology and company.

In 2022, I joined the Beyond Air team as a Clinical Specialist for their FDA-approved LungFit PH device. The reasons are wide-ranging and include:

The LungFit PH device is safe, easy to use, quick to set up, and completely tankless with no cartridges.

The opportunity to develop a partnership with RT departments, show them I understand the frustrations of their work, and build trust to help them navigate delivery of iNO therapy.

Beyond Air's extensive research for nitric oxide therapeutic use outside of PPHN and the potential for commercialization of other devices in the future.

How is LungFit PH changing the expectations for contracting, operations, and inventory management?

Beyond Air has set out to redefine the iNO experience, from demo to delivery. Currently, hospitals are faced with hidden contracting and operations obstacles, we've worked to create a customer experience that's more transparent.

Our agreements are straight-forward

Respiratory departments don't have to worry about stringent cost control measures; our competitive offering allows the flexibility to deliver therapy without micromanaging budget.

We've eliminated cylinder and cassette supply demands

Respiratory therapists can shift their focus from device management to delivering therapy. Additionally, LungFit PH consumables can easily be stored at the point of care. No bulky cylinder management or inconvenient storage requirements.

How have you seen the industry transform over the past 34 years?

The use of surfactants, new modes of ventilation, and iNO have benefited newborns all over the world. Advances with non-invasive ventilation have also greatly enhanced care in the NICU. It is so rewarding to see how these advancements in neonatal care have benefited these tiny babies as they begin their life journey.

However, while clinical care is advancing, a lot of outdated assumptions exist in our industry about what to expect from your iNO supplier and devices.

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net

Assumption 1: iNO is cost prohibitive

iNO is an expensive line item in a hospital's budget. I found many contract structures require estimating an entire year's worth of use, penalize you for exceeding anticipated use, have unanticipated costs, lock you into long-term contracts, and limit competition, including new/advanced technology. It's not transparent and it's not a partnership.

Beyond Air's straight-forward partnership model ensures you have everything you need, without the worries of constant cost management. We're not looking to lock our customers into multi-year agreements that prohibit them from accessing new advances in technology.

Assumption 2: iNO use should be left to Level 3 & 4 NICUs

In instances that a state doesn't regulate what's allowed by NICU level, iNO has been limited to Level 3 & 4 NICUs due to cost, staff proficiency, and the demands of cylinder management. LungFit PH is easy to handle and initiate iNO therapy, so the healthcare teams in smaller NICUs and birthing centers can confidently initiate therapy. This means mom and baby can be kept together.

Assumption 3: A hospital can only contract with one iNO supplier

iNO is one of the few drugs where hospitals are forced to choose just one supplier. That's bad for the healthcare system and bad for the patient. Beyond Air recognizes the value in having the flexibility to use more than one iNO supplier and that technology is always advancing, we won't contractually obligate you to have us as your sole supplier.

Where do you see opportunity to have an impact on an RT's day to day?

Speed to care has so many benefits when managing these fragile lives. LungFit is quick and easy to set up at the bedside, generates and delivers iNO from room air within seconds, and can be stored with all accessories at the point of care.

Storage and handling requirements place a significant burden on RT teams, including monitoring, management, and storage. I worked with one hospital who estimates they dedicate ~2000 hours annually to RT and tech staff time for cylinder management.

LungFit PH is easy to use. The complicated and time-consuming setup process required by cylinder and cassette-based systems has been eliminated.

Where do you see the future of iNO treatment?

I see NICUs that don't currently provide iNO adding it to their treatment protocol so they can treat or initiate treatment prior to transport. This has the added benefit of keeping moms and babies together and, hopefully, avoiding transport.

I also see iNO becoming accessible to patients without significant expense or stress on RT staff. RTs can stop spending so much time managing system use and reallocate it to delivering more care.

What has the response been from customers using the LungFit PH?

I've found the ease of use and the speed to treatment has helped

many RTs overcome their anxiety around iNO. This, in turn, has helped them spend more time on patient care rather than device management and setup.

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INDICATIONS FOR USE

The nitric oxide from the LungFit PH System is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents. Refer to the full Prescribing Information within the LungFit PH System Operator's Manual before use.

Visit www.LungFitPH.com for full Important Safety Information.

Reference: 1. Data on file. Beyond Air Inc. 2021. 2. LungFit PH System Operator's Manual. Garden City, NY: Beyond Air Inc. 2022.



Best Practices in Thermoregulation in the NICU

Liz Drake MN, RNC-NIC, NNP, CNS, C-ELBW

Heart rate, SPO2 and respiratory rate are all critical vital signs to manage in any critical care patient, including low birth weight babies. And yet, there is another “vital” sign that also has a significant impact on the care of these fragile patients. Temperature.

Clinical research has shown low birth weight babies are prone to hypothermia, and within the Golden Minute and Golden Hour, hypothermia can decrease their survivability up to 28%.¹

As caregivers, we continuously monitor temperatures, attempting to manage and correct them; however, this can be a challenge when faced with premature physiology, non-optimal environmental factors, and some ambiguity as to how to prevent and correct thermal stress.

Preventing hypothermia of the premature baby from the moment of birth reduces the risk for morbidity and mortality and can establish a healthy foundation for their care in the neonatal intensive care unit (NICU).

The first article of this series explored the challenges of temperature management in low-birth-weight babies, examining physiology, methods of heat production, impacts of thermal stress, and the importance of thermoregulation to positive short- and long-term outcomes.

This article offers some best practices for temperature measurement and management in the NICU, including:

- Temperature probe placement
- The importance of dual temperature monitoring (skin and axillary)
- The information each mode (skin and axillary) conveys to the baby's caregivers
- Considerations for monitoring during incubator care (skin versus air temperature)
- Three steps for establishing thermoregulation as a priority in your NICU



Liz Drake is a NICU Clinical Nurse Specialist at CHOC Children's at Mission Hospital, Mission Viejo, CA. Liz and Dräger worked in collaboration to develop this article as part of Dräger's continuing efforts to advance neonatal care through the sharing of insights, knowledge and best practices within the neonatal community.

Probe placement: the story of dual monitoring

While the axillary and rectal temperatures can be quite similar, skin temperature is unique and can provide early indication of thermal stress. Normothermia in the preterm infant is evidenced by a skin temperature range of 36.2-37.2 degrees Celsius and an axillary temperature range of 36.4-37.4 degrees Celsius. While we have normative ranges for each site, a significant deviation between skin and axillary temperatures can provide us with valuable intel and be an early indicator of thermal stress.

Continuously monitoring skin temperature is helpful as the axillary temperature can be quite misleading. As described in the first article in this series, brown fat metabolism (non-shivering thermogenesis) is the process infants use to produce heat when they are cold. One of the places brown fat is stored in the premature infant is in the axilla.

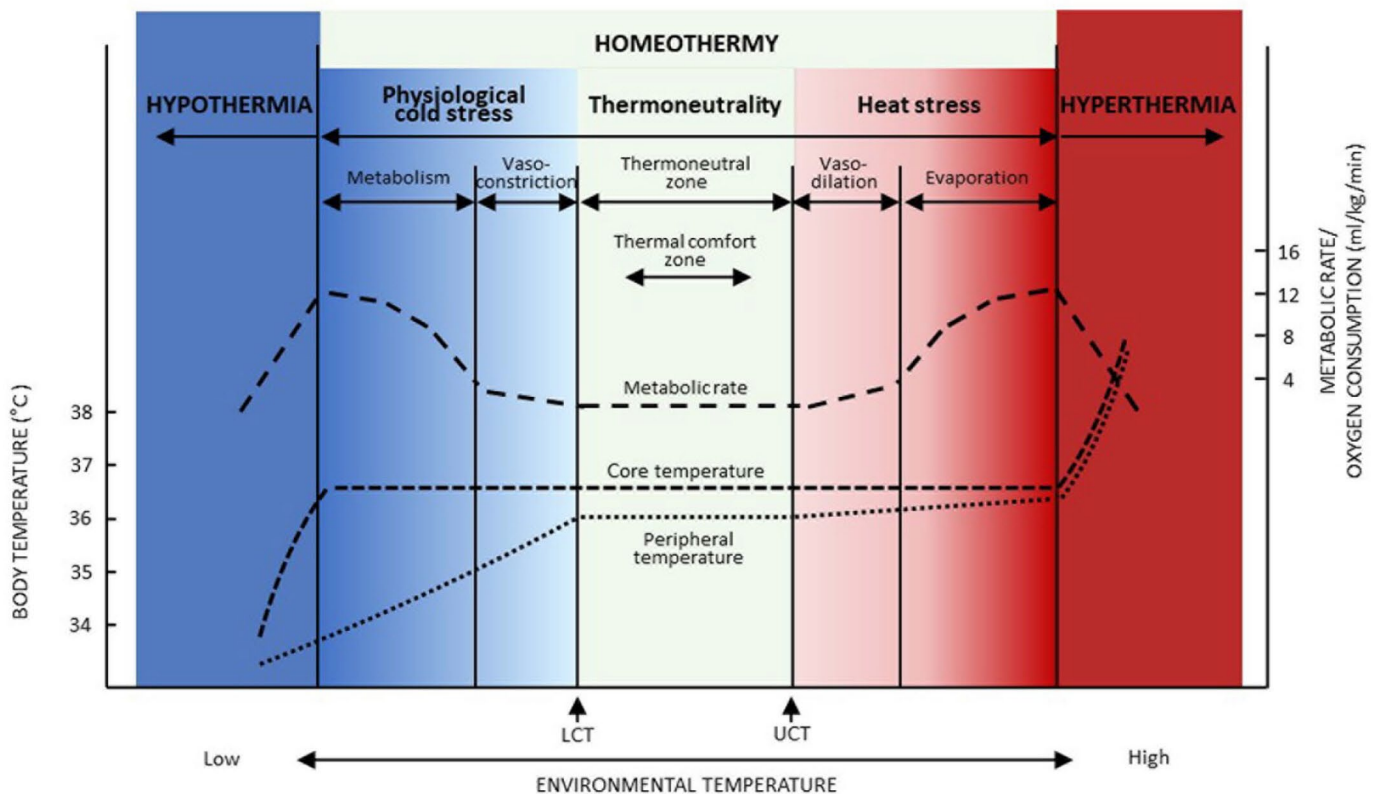
As a cold-stressed baby is burning fat, their axillary temperature increases. Therefore, relying on axillary temperature monitoring alone could lead a clinician to believe a baby was hot/feverish when they are experiencing thermal stress and trying to get warm.

Brown fat in the axilla should lead us to think very differently about axillary temps and where we place our probes. If a baby's axillary temperature is high, assuming that baby is hyperthermic can lead to interventions that are the opposite of what the baby needs. That is why monitoring the skin and axillary temperatures together is a vital part of assessment.

Both the National Association of Neonatal Nurses (NANN) and Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) recommend the skin probe be placed on the baby's abdomen because this is the first place perfusion changes when a baby is cold stressed.² By continuously monitoring skin temperature with a probe on the abdomen, clinicians can see changes second to second, minute to minute and hour to hour. Skin temperature provides a very early indication that a baby is getting sick.

In 1997, the World Health Organization (WHO) set criteria for assessing hypothermia in pre-term infants based on core temperature and we still use it today.³

- Mild hypothermia: 36-36.4 degrees Celsius
- Moderate hypothermia 32-35.9 degrees Celsius
- Severe hypothermia: less than 32 degrees Celsius



LCT: lower critical temperature, UCT: upper critical temperature.

Graphic Source: Kyokan M, Bochaton N, Jirapaet V, Pfister RE. Early detection of cold stress to prevent hypothermia: A narrative review. SAGE Open Medicine. 2023;11. doi:10.1177/20503121231172866

Taking an axillary temperature during care times (every 3-6 hours) while the skin probe remains in place allows the clinician to compare the two temperatures and use this information to assess the baby's state. It is when baby is sick that we see the gap in these values widen and need to determine the root cause. (See graphic: *What are skin and axillary temps telling us?*)

What are skin and axillary temps telling us?

Dual temperature monitoring, skin and axillary, provides a complete assessment of thermoregulation status of the infant.

- If axillary temperature is high and skin temperature on the abdomen is low (below 36.2), the baby is most likely cold stressed
- If axillary temperature and skin temperature are low, the baby is likely hypothermic
- If axillary temperature is high and skin temperature on the abdomen is high, the baby is most likely too warm

Warming methodologies

NICU teams have a variety of techniques and solutions at their disposal to help keep tiny babies warm, including pre-warmed towels, polyethylene caps, polyethylene bags, and incubators with heat shields and touch times mattresses. If the baby is on Bubble CPAP, the Bubble CPAP cap can be used in place of the polyethylene cap.

According to the research, the most effective approach to warming is a bundled approach. One bundling study found mortality of babies less than 29 weeks fell from 252/1,000 down to 175/1,000 when babies were placed in polyethylene bags and on heated mattresses.^{4,5}

Temperature monitoring during incubator care: skin versus air

During incubator care, there are two options to continuously measure and maintain a baby's temperature: skin mode and air mode. With skin (servo) mode, the incubator adjusts air temperature based on the baby's skin temperature, while in air mode, the incubator adjusts air temperature based on the set temperature of the air in the incubator.

- Skin mode: regulates air temperature to preset skin temperature
- Air mode: regulates air temperature to preset air temperature

Let's say a nurse sets the incubator in skin mode at 36.5 degrees Celsius, and the baby's temperature changes due to environmental factors (e.g., nurse opens incubator and unwraps baby). That incubator will keep changing temperature to keep that baby at 36.5 degrees Celsius, which is not a neutral thermal environment.

Furthermore, the incubator's continuous temperature fluctuations can mask if the baby is experiencing issues that are causing skin temperature to fluctuate. For example, one of the first subtle signs of necrotizing enterocolitis (NEC) is temperature instability.⁶

While skin mode for incubator temperature regulation is not an incorrect mode, the baby's care team must think logically about what this mode of measurement and regulation means. They must be aware of whether there are swings in the baby's temperature that indicate underlying issues.

The optimal way to measure baby's temperature during incubator care is using a skin temperature probe on the abdomen while the incubator is in air mode. That way, you know minute-by-minute the baby's temperature and whether there are fluctuations signally issues. If within 10 minutes a baby's temperature drops and then it drops again at 30 minutes and that skin probe has not moved, those are indications that there could be an issue with the baby.

With the incubator in *air mode*, the set temperature remains the same. If the baby gets a little cool based on the skin probe reading, instead of modifying the environment by raising the incubator temperature, put a blanket on the baby or a cap. That way, you are maintaining a true neutral thermal environment.

The Touch Time function of an incubator will minimize nuisance alarms when activated and works to stabilize air temperature in the compartment during care times when portholes are opened. When Touch Time is activated, the incubator fan rotation is accelerated for 20 minutes and the warm air curtain in the patient compartment is intensified.

When care time is completed and portholes are closed, Touch Time will need to be manually deactivated and the bed will return to the previous air temperature or skin temperature setting.

Finding the sweet spot

As described in the first article, the “sweet spot” in thermoregulation of the premature infant refers to when the baby's heart rate is stable, they are sufficiently gaining weight, dual temperatures (axillary and skin temperatures) are each in their own range, and there are minimal temperature fluctuations. Research has established the sweet spot as the range of 36.8 to 36.9 degrees Celsius, and indicates it takes three days of temperature monitoring to identify each individual baby's sweet spot.⁷

Thermoregulation: not just reducing heat loss but preventing heat gain

When managing temperature of the preterm infant, caregivers must consider both hypothermia and hyperthermia. While hyperthermia is rarer in the pre-term baby, heat stress can be just as harmful as cold stress.⁸

What is the difference between hyperthermia and a fever? When in a state of hyperthermia, the body temperature rises above a certain “set-point” that's controlled by hypothalamus. Conversely during fever, the hypothalamus intentionally increases the body's set-point temperature to fight off an illness or infection.⁹

Hyperthermia (skin temperature higher than 37.5 degrees Celsius) can be iatrogenic or symptomatic of a disease process. And as noted earlier in this article, increased axillary temperature can also be symptomatic of cold stress (burning of brown fat generating heat in axilla). Comparing axillary to skin temperature is essential to helping find the root cause of a high axillary temperature.

Thermoregulation means reducing heat loss and heat gain in the baby. With regards to hyperthermia, caregivers must be aware of how interventions can impact a baby's temperature. Research has shown that use of a thermal hat, polyethylene wrap and a heated mattress simultaneously can result in heat

stress.¹⁰ Positioning aids can also increase a baby's temperature. Adding or taking away insulating tools can significantly impact body temperature.¹¹ Therefore, it is important to pace the use of interventions to see how the baby will react.

An important note on skin probe placement with the use of developmental supports: Avoid insulating the probe as that will result in inaccurate temperature readings.

Signs of Cold Stress	Signs of Heat Stress
<ul style="list-style-type: none">• Increased axillary temperature with decrease in skin temperature• Increased O2 demand• Apnea and bradycardia• Lethargy• Feeding Intolerance• Heat stress• Increased heart rate• Tachypnea	<ul style="list-style-type: none">• Tachycardia• Tachypnea in attempt to release excess heat• Hypotension and dehydration from vasodilation and insoluble water loss (IWL)• Seizure activity• Apnea• Poor feeding• Poor weight gain• Increased O2 demand

3 Steps to Enhance Thermoregulation Management in Your NICU

Successfully prioritizing thermoregulation in the NICU requires nurses to think differently, be passionate about temperature management, and educate other stakeholders on its importance and best practices around it.

Here are three steps to help enact change in your NICU.

1. Think differently

Take a step back from how you have always performed care and approach it in a baby-driven, tolerance-driven manner by understanding what a baby's temperature is telling you. As the caregiver at the baby's bedside 12 hours a day, thermoregulation is vital for the bedside nurse to understand.

Incubator tips to decrease heat loss during procedures

- Consider increasing mattress temperature prior to procedure
- During procedure, adjust vertical height of the mattress to bring baby closer to or further away from radiant heater
- Keep hood closed whenever possible to avoid sudden changes to the baby's micro environment influenced by ambient temperatures and changes in humidity
- Position bed away from outside walls, windows and draft
- Consider using plastic wrap, warm hats and warm dry blankets during care times to reduce evaporative heat loss
- Check temperatures prior to opening hood or side panels for an extended period of time; if baby's temperature is stable, determine if additional heat support is indicated

When caring for a baby who is not eating well or seems lethargic, a nurse who is not focused on thermoregulation might overlook temperature and assume the baby is sick. That could lead to unnecessary interventions, such as blood tests, that stress the baby. But if the nurse understands thermoregulation and determines the baby has been cold, simply warming up the baby could increase their energy and improve feeding.

A key question to keep in mind while performing non-emergency care for NICU babies is, “what’s the rush?” Many NICUs have become task oriented, with nursing working off a checklist for a baby’s care as opposed to performing thoughtful care. What is best for fragile babies is to let them stabilize, rest and keep warm.¹²

Too much sound, touch, movement or light can cause a number of physical reactions in the preterm infant, including a drop in oxygen, increase in apnea and bradycardia, a rapid heart rate tachycardia, disrupted sleep cycles and delayed growth.¹³

Maintain a neuroprotective environment with limited stimulus by considering what you absolutely must do in that moment to care for that baby, and delaying those tasks that will cause unneeded stimulation and disruption.

By clustering care, you can minimize disruption to the baby’s environment and episodes of stress. Instead of opening and closing the incubator multiple times to perform different tasks, prepare ahead of time and get everything ready to perform tasks together (change diaper, feed baby, etc.). A baby probably won’t tolerate care if they are being interrupted all the time. Preemptively think about the baby’s needs and this will promote temperature management, sleep and growth.

And always keep thermoregulation as the focus. When taking assessments or administering care, unwrap the baby one area of the body at a time to minimize heat loss and keep temperature regulated.

2. Make it your passion and educate others

A successful thermoregulation strategy requires a champion in the NICU who understands its importance, wants to share their knowledge and passion with others, and is determined to keep temperature management as a focus among their team when caring for babies.

Thermoregulation must be a nursing driven policy because nurses are the ones caring for NICU babies around the clock and therefore will be the first to detect any changes in temperature.

For nurses looking for autonomy, a NICU-wide thermoregulation strategy is a great initiative to spearhead. Be passionate about it, teach others and get them passionate so you are all working toward providing the best care for babies.

3. Take a multidisciplinary approach

If every discipline that cares for the baby doesn’t understand the importance of thermoregulation to their area expertise, they will not focus on it. Therefore, take a multidisciplinary approach to thermoregulation in your NICU, educating all caregivers on how temperature impacts the growth and survival of preterm babies in their care.

For dietitians, understanding thermoregulation will help them determine the best nutrition strategy for baby. If a baby hasn’t been gaining weight, the dietitian with thermoregulation in mind will question the nurse on whether baby has been too hot or too cold. For example, if the baby has been cold, their metabolic rate will increase, and they will burn more calories. Warming the baby should help with feedings and result in better weight gain.¹⁴

If a baby is cold, their motor ability will be compromised; therefore, developmental specialists should have a basic understanding of thermoregulation and its impact on babies.¹⁵ If they are performing exercises with a baby and that baby’s temperature starts to drop, they should know to tuck them back in so they can stabilize to avoid heart rate drops or desaturations.

Doctors tend to be focused on absolutes: if a baby reaches a certain age (32 weeks), weight (1,500 grams) or temperature, it is time to take them out of the incubator. But research shows that thermoregulation should never be based on those factors because there are so many other variables to consider. A doctor who understands the critical importance of temperature management will look to the nursing team to provide evidence that the baby’s temperature is stable enough for life outside of the incubator.

Conclusion

Maintaining a healthy body temperature is as important as monitoring other vital signs for preterm and low-birth-weight babies. Hypothermia can have a significant impact on the survival rates of these babies, especially in the Golden Minute and Golden Hour. Therefore, monitoring and managing the temperature of premature babies from the moment of birth is crucial to reduce morbidity and mortality.

To learn more about the importance of thermoregulation in NICU babies, visit: <https://engagegrowthrive.com>.

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three calcium pills per day because the dietary supplements generally come from suppliers in 500-mg doses. Researchers say the supplements are too expensive for many health authorities of low- and middle-income nations to provide, and that taking so many pills presents a barrier to use even if they were plentiful. In countries such as Tanzania and India, study author Christopher Sudfeld, ScD, associate professor of global health and nutrition at Harvard University's T.H. Chan School of Public Health, in Boston, Massachusetts, explained, governments generally distribute supplements like calcium for free at health clinics. Due to the cost, Tanzania has never implemented WHO's calcium recommendation, Sudfeld said, providing only the iron pill. The randomized double-blinded study included 11,000 pregnant women in Tanzania and 11,000 pregnant women in India. None had yet given birth, which increased their risk for preeclampsia. All participants were older than 18 years and were less than 20 weeks pregnant, according to their most recent menstrual date. Half of participants received the three daily 500-mg calcium pills recommended by WHO; the other half received a single calcium pill and two placebo pills. Researchers measured blood pressure and urine protein levels starting at 20 weeks of gestation, at delivery, and 6 weeks after giving birth. Regardless of how much calcium people consumed daily, preeclampsia occurred approximately 3% of both the 500-mg and 1500-mg groups. Similar rates of preterm births occurred in both groups, although in Tanzanian, women in the 500-mg arm were somewhat more likely to give birth early.

Nellcor™ Pulse Oximetry Performance in Challenging Conditions

Clark R. Baker, BS and Scott McGonigle, MEng

Background

Pulse oximetry noninvasively measures blood oxygenation by estimating the fraction of hemoglobin bound to oxygen in pulsing arterial blood (SpO_2). This parameter primarily reflects oxygen transfer from the lungs to tissues via the blood and provides an early indication of oxygenation issues. Pulse oximetry is quantitative, accurate, continuous, and convenient.¹ Today, pulse oximetry is considered a standard of care and is often relied upon to ensure patient safety.^{2,3}

Pulse oximetry performance and reliability is necessary across patients with diverse demographics and challenging physiological conditions and co-morbidities. Common challenging conditions for pulse oximetry include low sensor-site perfusion and motion artifact. Low perfusion is often encountered in patients with sepsis, shock, and other vascular conditions, and motion artifact can occur in a variety of circumstances, ranging from the involuntary movement of a neonate to a hospitalized adult eating lunch.³⁻⁵ These conditions can occur in all care settings (ED, OR, ICU, GCF, L&D, NICU, etc.), and can impact clinical workflow due to difficult sensor placements and nuisance alarms. A pulse oximeter that can accurately measure pulse rate and SpO_2 is necessary in cases in which a patient presents with one or more conditions that make pulse oximetry challenging, both to ensure patient safety and to maintain efficient clinical workflow.

The purpose of this paper is to review key literature examining Nellcor™ pulse oximetry performance in challenging clinical conditions. Key technical features important in challenging clinical conditions include pulse rate accuracy, SpO_2 accuracy, and alarm management.

Low Sensor-Site Perfusion

Patients with low sensor-site perfusion have a smaller pulse amplitude, due to vasoconstriction or hypotension, that can result in artifact and inaccurate readings.³

Low sensor-site perfusion is common in patients with peripheral vascular disease, sepsis, hypothermia, or shock, making pulse oximetry more challenging.^{3,5} To evaluate pulse oximetry performance during low sensor-site perfusion, both clinical studies and healthy volunteer studies have been performed. While controlled volunteer studies often create low sensor-site

perfusion using cold temperatures or partial arterial occlusion, prospective clinical studies have focused on critically ill patients and transport conditions in which low perfusion occurs.

Healthy Volunteer Pulse Oximetry Low Perfusion Studies

Oximetry performance during low sensor-site perfusion has also been evaluated in volunteer studies of diverse designs, using reproducible protocols and distinct challenges, such as cold or occlusion, to represent non-ideal pulse oximetry conditions. In this section, we summarize the results of several healthy volunteer pulse oximetry studies.

Study 1

In one prospective study, 18 anesthetized volunteers underwent induced apnea, along with reduced finger perfusion by compressing the axillary artery.⁶ Circulatory delay was evaluated using Nellcor™ pulse oximetry monitors connected to Nellcor™ pulse oximetry digit (MAXA) and forehead (MAXFAST) sensors. The forehead is a uniquely robust pulse oximetry site, for which the Nellcor™ MAXFAST pulse oximetry sensor was designed. Because forehead arterial supply also feeds the brain, this site is not susceptible to vasoconstriction.⁷ However, because veins in the head lack one-way valves, the forehead may be prone to venous pulsation, particularly if the head is below the heart (Trendelenberg) or the patient condition or surgical procedure impedes venous return.⁵ The primary mitigation is proper headband application to provide ample pressure to restrict venous pulsation, with secondary mitigation in the monitor's signal processing that was designed for such conditions.

In their low perfusion study, Sugino et al found that, as hypothesized, axillary compression induced a modest incremental circulatory delay for digit SpO_2 relative to forehead SpO_2 (6.3 ± 4.9 seconds), whereas the response at both sensor sites was essentially equal before axillary compression.⁶ Therefore, the forehead sensor demonstrated reduced time to detect the changes caused by induced apnea.

Study 2

In another prospective, healthy volunteer, low perfusion study, Addison et al performed a cold-room (13°C) motion hypoxia study with 12 volunteers of varied skin pigmentation.⁸ This study was conducted and sponsored by Medtronic. The study demonstrated excellent pulse rate accuracy versus ECG (1.6 per minute) on the non-motion digits using Nellcor™ pulse oximetry, indicating that during reduced perfusion with no motion, the pulse oximeter is accurate.

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Table 1. Response times (seconds) of pulse oximeters during hypoxic challenge in healthy volunteers.

Site and Monitor:	Forehead Nellcor™ MAXFAST	Earlobe Masimo	Finger Mean of 4 vendors	p-value
Normothermia	41±14 sec	60±16 sec	130±44 sec	p<0.001
Hypothermia	40±11 sec	60±36 sec	215±67 sec	p<0.001
Hypothermia + glyceryl trinitrate	22±11 sec	33±14 sec	188±77 sec	p<0.001

Study 3

In contrast to studies using a cold room or axillary artery compression to simulate low perfusion, MacLeod et al used a mild hypothermia model (water mattress 14°C, core temperature 36°C) to induce vasoconstriction.⁹ In this prospective study of 10 volunteers, the mean finger circulatory delay was 215 seconds relative to co-oximeter with blood drawn from a radial artery catheter, while head sites demonstrated a fraction of this delay.⁹ Out of 6 pulse oximeter sensor types evaluated (forehead, ear, and finger sensors), a statistical test of rank order found that the Nellcor™ MAXFAST sensor ranked first in response time in 28 of the 30 hypoxic challenges, and the four digit sensors showed equivalent digit circulatory delay, confirming that this delay is a function of physiology.⁹ Table 1 shows the response times to hypoxic challenge (3 minutes at 11% FiO₂).⁹

Study 4

Although circulatory delay due to low sensor-site perfusion may not be readily apparent, a pulse oximeter cannot monitor a drop in oxygenation at the lungs (e.g. apnea) until blood reaches the sensor site. To evaluate the performance of Nellcor™ pulse oximetry during low perfusion, the data from 12 Medtronic-internal motion hypoxia studies performed with room temperature 13-15°C were retrospectively pooled and analyzed.¹⁰

Among 369 forehead-digit sensor pairings (114 healthy volunteers), we observed an incremental circulatory delay for non-motion digit SpO₂ relative to forehead SpO₂ of 74±19 seconds. In response to cold, digit pulse signal amplitude varied by over an order of magnitude across the volunteer pool, as well as compared to normothermic studies on different dates (example: 4.18% in normal conditions and 0.11% in cold room). In this retrospective analysis, we found that digits with the smallest pulses had up to a two-minute circulatory delay compared to forehead pulse oximetry.¹⁰

Study 5

The Nellcor™ MAXFAST forehead sensor provides robust, accurate and timely oximetry monitoring with appropriate headband application. Table 2 shows the results of an 11-volunteer Medtronic-internal room- air study in Trendelenberg position, creating a venous pulsation challenge at the forehead.¹¹ It shows the bias and posting of the Nellcor™ MAXFAST sensor compared to the mean of four digits with Nellcor™ MAXA sensors. With the headband, the Nellcor™ MAXFAST sensor provided reasonable SpO₂ accuracy for tilts down to 20 degrees. However, without the headband, bias ± precision relative to digits at -20 degrees tilt was 6.40±8.38.¹¹

Clinical Pulse Oximetry Low Perfusion Studies

Pulse oximetry performance during low sensor-site perfusion has been evaluated across multiple clinical settings. In this section, we summarize the results of several clinical studies that examined pulse oximetry performance.

Study 1

In a prospective study performed at a large university- affiliated medical center, Schallom et al measured SpO₂ accuracy in 30 critically ill surgical/trauma patients, versus co-oximeter.⁵ Table 3 summarizes results for Nellcor™ pulse oximetry with OxiMax™ technology, which found that Nellcor™ pulse oximetry has low mean error and precision, particularly when using the Nellcor™ MAXFAST sensor.

Study 2

In a separate prospective clinical study, 52 patients were evaluated with Nellcor™ and Masimo pulse oximetry monitors, using both sensors on the same hand, with randomized digit selection, during ambulance transport in cold weather (Vienna, Austria, October-November).¹² Twenty patients had blood pressure ≤ 100/60. The incidence of “malfunctions” (no reading) was 0.13 and 0.21 per patient for Nellcor™ and Masimo pulse oximetry, respectively, which was statistically equivalent. Root-mean-square difference (RMSD) between the two oximeters was 1.69% SpO₂ and 4.48 BPM, implying acceptable accuracy and performance for both monitors. Overall, a systematic review of pulse oximetry accuracy in adult patients with low site perfusion at digit and forehead sensor sites concluded that “Oximeters are accurate in poorly perfused patients, especially newer oximeter models.”³

Study 3

Consider the following case report, which exemplifies the robustness of the forehead site: A coronary artery bypass graft (CABG) surgery was performed in 2002 on a 106 Kg dark-pigmented patient.¹³ As seen in Figure 1, the combination of the Nellcor™ MAXFAST sensor and Nellcor™ pulse oximetry with OxiMax™ technology provided the earliest indication that the patient's heart had been restarted. Pulse amplitudes (normally 0.5 – 2.0% for the forehead) were 0.04%, increasing to 0.06% when pulse beeps became regular. When blood pressure display resumed, pulse pressure was still only 3 mm Hg, compared to normal pulse pressure of 40 mm Hg. This example is consistent with the high sensitivity and accuracy of Nellcor™ pulse oximetry across multiple clinical studies.^{5,6,8,9,12}

Table 2. Bias, precision, and posting of the Nellcor™ MAXFAST sensor in Trendelenberg position with and without a headband.

Patient Position	SpO ₂ Bias vs finger	SpO ₂ Posting %
0 degrees, with headband	1.09±1.85	100%
-10 degrees, with headband	-0.17±2.30	100%
-15 degrees, with headband	-0.59±3.07	100%
-20 degrees, with headband	-1.28±3.61	100%
-20 degrees, without headband	-6.40±8.38	97%
-20 degrees, re-apply headband	-1.39±3.75	96%
Back to 0 degrees, with headband	0.05±1.85	100%

Table 3. Nellcor™ pulse oximetry performance in critically ill surgical/trauma patients.

Site	Forehead	Digit	Digit
Monitor	Nellcor™	Nellcor™	Philips
Technology	OxiMax™	OxiMax™	OxiMax™
Sensor	MAXFAST	MAXA	MAXA
Measurements	89	89	89
Measurement failures	1 (1%)	6 (7%)	9 (10%)
Mean error ± precision	-1.39±1.28	-2.61±3.61	-3.84±6.91
R² versus catheter	0.834	0.433	0.254

Motion Artifact

A second key challenge for pulse oximetry is motion artifact, which occurs in all areas of care. In a review of pulse oximetry and the effect of motion, Petterson et al recognized that the invention of pulse oximetry was based on two principles:¹⁴

1. The light absorbance of oxygenated hemoglobin is different from that of reduced hemoglobin at the two wavelengths used in pulse oximetry (red and infrared).
2. The absorbances at both wavelengths have a pulsatile, or oscillating (AC) component, which is the result of the volume change, normally from arterial blood, occurring between the emitter and the detector of the sensor.

Petterson et al then enumerate the following implicit assumptions:¹⁴

1. All the hemoglobin present is either oxyhemoglobin or reduced hemoglobin.
2. There are no other absorbers between the emitter and detector other than those present during the empirical calibration. The absorption characteristics of these “other absorbers” are the same as during the empirical calibration.
3. All the blood that “pulsates” is arterial blood.

Motion artifact violates the second and third assumptions, both

through the movement of venous blood and by modulating non-blood tissue and its physio-optics.

Squeezing a fingertip visibly changes its optical characteristics, resulting in modulations that are much larger than those caused by arterial pulses. Pulse oximetry studies focused on motion artifact are often healthy volunteer studies, with heterogeneous methods and results.

Healthy Volunteer Pulse Oximetry Motion Studies

Healthy volunteer studies have evaluated oximeter performance during motion artifact, often including low sensor-site perfusion as part of the study design. Table 4 summarizes several pulse oximetry motion studies on digit sensors and illustrates the heterogeneity of both the study designs and the results. One common feature is that all adult studies included controlled hypoxia. In one study, Townsend et al noted, “All new generation pulse oximeters tested performed well to within 20 mmHg of total brachial artery occlusion, mimicking poor perfusion. Only the Nellcor™ 595 [with OxiMax™ technology] with finger sensor met all predefined criteria for accuracy during movement.”¹⁵

One important aspect of healthy volunteer studies examining pulse oximetry accuracy relates to the type of motion utilized in the study. While some studies utilize mechanical, repetitive movement to estimate the accuracy of pulse oximetry during motion, these results are not reflective of real-world conditions, in which patient movement is not mechanical, but random and unpredictable.⁸ Pulse oximetry algorithms may be better equipped to adjust pulse rate and SpO₂ values measured during mechanical motion, making the results of these studies appear accurate, but in reality may be less applicable to real world conditions. In contrast, the healthy volunteer studies in which random motion is utilized generate data more reflective of real-world patient monitoring circumstances.⁸ Importantly, out of the five pulse oximetry with motion studies summarized in Table 4, one prospective volunteer study sponsored by Masimo found equivalence between Nellcor™ and Masimo pulse oximetry performance,¹⁶ two prospective volunteer

Figure 1. Nellcor™ pulse oximetry during coronary artery bypass graft surgery.

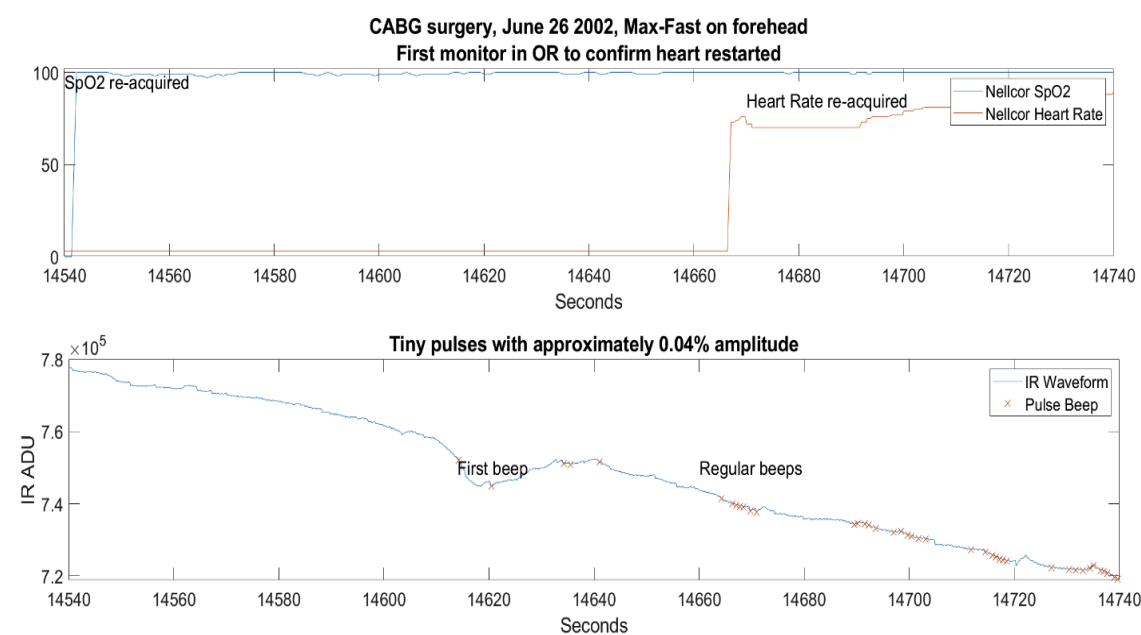


Table 4. Summary of health volunteer pulse oximetry study designs and results.

Study Design	Population	Vendor	SpO ₂ or Pulse Rate reference and results		Conclusions	Reference
20 body turns Room air	18 children Ages 6-10		SpO ₂ change during turn	ECG	Both Nellcor™ and Masimo pulse oximeters report accurate heart rates, but Nellcor™ pulse oximetry had more stable SpO ₂	Townshend 2006 ¹⁵
		Nellcor™	0.07±0.98 ^a	1.11±4.08 ^a		
		Nellcor™ forehead	-0.74±2.33	-0.46±7.40		
		Masimo	-0.04±2.25	0.53±8.94		
Voluntary motion + cool room (16-18°C)	10 adults		Within 7% of non-motion digits	Within 10% of non-motion digits	Using a performance index, both SpO ₂ and HR measurements were not significantly different between Nellcor™ and Masimo pulse oximetry. Masimo had no dropouts.	Shah 2012 ¹⁶
		Nellcor™	73.1% ^b	60.3% ^c		
		Masimo	98.5% ^b	88.5% ^c		
Periodic and aperiodic voluntary motion + cold room (13°C)	12 adults		ECG		Across 5 types of voluntary motion, Nellcor™ pulse oximetry reported pulse rate error > 25 BPM 3.4% of the time, compared to Masimo, which exceeded the error threshold 27.6% of the time. The HR reported by Nellcor™ pulse oximetry was significantly superior to Masimo.	Addison 2013 ⁸
		Nellcor™	RMSD = 8.6			
		Masimo	RMSD = 25.2			
Motion + hypoxia, normal room temperature (28°C) Low perfusion categorized as Masimo PI<2% on non-motion hand	10 adults		SpO ₂ vs co-oximeter RMSD (95% CI)		All pulse oximetry performed well during normal perfusion with motion, but only Nellcor™ and Nihon Kohden pulse oximetry performed well during low perfusion with motion	Louie 2018 ¹⁷
			Low perfusion	Normal perfusion		
		Masimo, non-motion hand	2.2 (1.9-2.6)	1.1 (1.0-1.3)		
		Masimo	7.4 (5.4-9.3)	3.1 (2.0-4.2)		
		Nellcor™	5.1 (3.5-6.8)	3.4 (2.5-4.3)		
		Nihon Kohden OxyPal Neo	2.3 (1.8-2.7)	2.2 (1.7-2.8)		
Voluntary motion + cold room (13-15°C)	115 adults 244 motion digits & 248 non-motion digits	Nellcor™	SpO ₂ Reference: Mean of non-motion digits		Nellcor™ pulse oximetry is very consistent during low perfusion and has more variability during episodes of motion artifact with low perfusion.	Internal Medtronic studies ¹⁰
			Low perfusion	Low perfusion + motion		
			RMSD=1.64	RMSD=7.68		

^aPrecision calculated from the 95% limits of agreement

^bDifference between Nellcor™ and Masimo not statistically significant

^cDifference between Nellcor™ and Masimo not statistically significant

studies concluded that Nellcor™ pulse oximetry provides superior SpO₂ measurements compared to Masimo,^{15,17} and two Medtronic-internal studies, one prospective and one retrospective, concluded that Nellcor™ pulse oximetry has high accuracy in heart rate measurements, including superiority to Masimo in one study.^{8,10} Together, these findings from a broad set of studies highlight that Nellcor™ pulse oximetry is accurate and reliable during motion.

Clinical Pulse Oximetry Motion Studies

Motion is to be expected in L&D and the NICU.⁴ In a single-center prospective clinical study independent of manufacturers, Khoury et al monitored sixty newborns (55 with ECG, mean age 4 minutes) delivered by C-Section with Nellcor™ pulse oximetry with Nellcor™ MAXN sensors and Masimo Radical-7 with M-LNCS Neo sensors.¹ SpO₂ readings were defined as stable when consistent for at least three beats, as well as consistent with clinical appearance and ECG, if available. Nellcor™ pulse oximetry had a shorter time to stable reading and no false bradycardia episodes, as seen in Table 5.¹

For adult and pediatric patients, motion artifact is typically episodic restlessness, such as scratching or tapping, rather than continuous motion.⁴ This still creates the possibility of

Table 5. Performance of Nellcor™ and Masimo pulse oximetry in newborns.

	Nellcor™ pulse oximetry	Masimo pulse oximetry
Stable SpO ₂ reading achieved	60 / 60 (100%)	55 / 60 (92%)
Mean time to stable reading	15 seconds	27 seconds
Median time to stable reading	8.5 seconds	12 seconds
False bradycardia compared to ECG	0 / 55 (0%)	18 / 55 (35%)

false alarms that can interrupt clinical workflow. Nellcor™ pulse oximetry system with OxiMax™ technology includes Nellcor™ SatSeconds alarm management, to suppress audible alarms that are too shallow or transient (in combination) to result in

interventions. After comparing Nellcor™ pulse oximeter alarms with and without Nellcor™ SatSeconds, Brostowicz concluded that “application of an integrated alarm system at 50 SatSeconds reduces the clinically insignificant pulse oximetry alarms by 40% and allows for a new alarm management feature to aid caregivers to respond to potentially clinically relevant alarms.”¹⁸

Conclusion

The truly challenging patients are the “corner cases” in the patient population that interrupt clinical workflow with difficult sensor placements and nuisance alarms. For example, a sensor on the oversized dark-pigmented foot of a NICU patient who frequently vasoconstricts during neonatal abstinence syndrome may pose a triple challenge to the pulse oximeter, and the scenario in which a patient presents more than one challenge for pulse oximetry is quite realistic.

Nellcor™ pulse oximetry is consistently tested, using over 2,000 unique test conditions (infrared and red signal levels, pulse amplitude, SpO₂ and pulse rate) representing a full range of physiological conditions. Nellcor™ pulse oximetry can often acquire saturation and pulse rate for test points having a pulse amplitude of 0.03%, which is very difficult to create in a volunteer study, given that normothermic pulse amplitudes typically range from 0.5-2.0% on forehead and > 2% on digit sites. For low signals (e.g. dark pigment or thick sensor site), our systems can typically acquire pulses with amplitudes under 100 pico-amperes, which is 1000-fold smaller than the average pulse amplitude. Our extensive internal clinical data evaluation, along with independent clinical studies of Nellcor™ pulse oximetry performance, provide evidence that Nellcor™ pulse oximetry can provide reliable pulse rate and oxygen saturation readings in challenging monitoring conditions.^{1,5,6,8-11,15}

Nellcor™ pulse oximetry with OxiMax™ technology demonstrates strong monitoring performance for patients with low sensor-site perfusion, and Nellcor™ pulse oximetry offers the Nellcor™ SpO₂ forehead sensor (MAXFAST) and headband as an alternative to a digit sensor. Nellcor™ pulse oximetry with OxiMax™ technology has a record of accurate, reliable monitoring during motion and low perfusion, as well as reducing nuisance alarms, which combined, can limit consequent disruption to clinical workflow while providing the critical information needed to support decision-making for patient care, even in the most challenging patient conditions.^{1,4,5,8,15,17,18}

The Nellcor™ pulse oximetry monitoring system should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment.

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Angiotensin II Therapy: A Novel Vasoactive for Infants With Bilateral Renal Agenesis

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Congenital bilateral renal agenesis occurs in ~4,000 births.¹ Although renal agenesis was previously considered a lethal condition because of the severity of associated pulmonary hypoplasia, survival has been reported after advances in fetal and neonatal therapies, leading to a trial of serial amniotomies prenatally and novel adaptations of kidney replacement therapy (KRT) in the postnatal period.²⁻⁷

Despite these advances, infants experience complications, including hypotension refractory to traditional vasopressors. The etiology of hypotension in infants with congenital bilateral renal agenesis may be attributed, at least in part, to impaired activation of the renin-angiotensin-aldosterone system. We describe the use of a novel vasoactive, angiotensin II (Giapreza), to treat refractory hypotension in a premature infant with congenital bilateral renal agenesis.

Born with bilateral renal agenesis requiring kidney replacement therapy

A male infant was cared for in our subspecialized NephroNICU program in the Neonatal Intensive Care Unit at Stanford Medicine Children's Health—a multidisciplinary program for babies born with complex kidney birth malformations, kidney failure that occurs after birth, and other kidney-related conditions.

The newborn with bilateral renal agenesis was delivered at Stanford Medicine Children's Health following a pregnancy treated with serial amniotomies. The child required high-

frequency oscillatory ventilation and nitric oxide administration for pulmonary hypoplasia, pulmonary hypertension, and respiratory distress syndrome. The course was complicated by a left grade III intraventricular hemorrhage. Intermittent KRT was initiated, and respiratory status was stabilized, as the infant was extubated and in room air in the second week of life. Nonetheless, the child continued to demonstrate episodes of hypotension during procedures, with infections, or at times of significant negative fluid balance. The infant intermittently received dopamine and vasopressin infusions as well as midodrine to manage hemodynamic instability.

At 3 months, while still intermittently hypotensive on midodrine and daily KRT, the infant developed worsening hypotension and focal seizures that progressed to status epilepticus. Various tests and treatments were given, including an MRI, which showed ex vacuo hydrocephalus without evidence of progressive hemorrhage or infarct. During this episode, the child's previously intermittent hypotension became persistent, and we provided fluid resuscitation and re-initiation of hydrocortisone and infusions of dopamine, vasopressin, and epinephrine.

Using synthetic angiotensin II to treat refractory hypotension

Infants with bilateral renal agenesis may episodically develop severe hypotension that can be refractory to traditional vasopressors. Synthetic angiotensin II is approved by the US Food and Drug Administration for treatment of septic or distributive shock in adults. Synthetic angiotensin II has been successfully used in adults and a few pediatric patients with refractory hypotension but has not been extensively studied in infants.

Because of refractory hypotension, the infant was started on an angiotensin II infusion at 1.25 ng/kg/min that was titrated up to 40 ng/kg/min over four days. A renin level before initiation was 8.6 pg/mL (reference range, 3.2-52.2 pg/mL).

The infant's blood pressure stabilized, and all other vasopressors were discontinued within 26 hours of angiotensin II initiation. The patient briefly required vasopressin re-initiation for 25 hours for transient hypotension after receiving boluses of phenobarbital, fosphenytoin, and fentanyl. Within 48 hours, the child no longer required other vasopressors. Angiotensin II was slowly weaned and discontinued over the course of 10 days, with continued blood pressure stability.

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Earlier reports of angiotensin II were associated with an increased risk of thrombosis.⁸ During angiotensin II administration, the patient was maintained on a continuous heparin infusion. The infant did not develop bleeding or thrombosis, and platelets remained >100,000/μL throughout this acute illness. The child did not experience any arrhythmias.

Synthetic angiotensin II has been reported as a rescue therapy in children with septic shock.⁹⁻¹⁰ Limited information is available on angiotensin II in infants or for specific use in infants with bilateral renal agenesis. Renin, which catalyzes the conversion of angiotensinogen to angiotensin I, is primarily produced by the kidneys, so it is plausible that patients with renal agenesis may have a relative angiotensin II deficiency, particularly during periods of clinical illness.

Infant discharged and awaits transplant

With continued clinical stability and growth, the infant was transitioned to peritoneal dialysis. At approximately 6 months of age, the child was transferred to a hospital closer to his family's home, subsequently discharged on peritoneal dialysis, and is currently undergoing evaluation for kidney transplantation.

"We are learning about the unique physiology of this patient population that previously did not survive, and we have had to rapidly adapt our care paradigms in response," says Sheila Razdan, MD, MPH, first author and Neonatal-Perinatal Medicine fellow. "Although this case demonstrates that angiotensin II was helpful in treating vasoplegic hypotension in an infant with bilateral renal agenesis, it is not clear at what point in the escalation of vasoactive management that angiotensin II should be used. There is so much more to learn about how Giapreza can optimally be used in the NICU population."

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Understanding Feeding Tube Risks Associated with Necrotizing Enterocolitis

Constance Girgenti, MSN, RN, VA-BC and Jennifer Hyde, RD, CNSC

The danger of necrotizing enterocolitis (NEC) continues to be a significant concern in neonatal intensive care units (NICUs) around the world. The risk of NEC continues to contribute to morbidity and mortality for our tiny preterm neonates. As healthcare providers, it is our responsibility to fully understand the factors contributing to NEC and prevent any and all risks when possible. We must implement effective preventative measures that are critical in improving outcomes for our tiny nonverbal vulnerable neonates. This paper explores factors that contribute to NEC. Including the potential danger of implementing ENFit, an adult feeding system in the NICU as it relates to NEC rates. Lastly, it will address some unintended consequences and challenges related to the cleaning protocols required when using ENFit an adult feeding system in the NICU and the associated risk of NEC.

NEC is a complicated and multifactorial disease. There are a number contributing factors to NEC. These factors can include prematurity, enteral feeding, intestinal dysbiosis, and ischemia-reperfusion injury (Neu and Walker, 2011). The preterm neonate has an immature gastrointestinal tract that makes them particularly susceptible to NEC. One of the risks of NEC is enteral feeding. Yet, enteral feedings are critical for the neurological growth and development of the preterm neonate. If these feedings are introduced too rapidly or in large volumes the risk increases even more (Neu and Pammi, 2017). Additionally, preterm neonates also experience alterations in gut microbiota and compromised mucosal barrier function. Thus, further predisposes neonates to NEC (Mai et al., 2020). Extrinsic factors, such as bacterial growth in the lumen of feeding tubes, can also contribute to the development of NEC (Hunter et al., 2020).

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Table 1. Protocol A Cleaning Procedure: The More-Diligent Cleaning Regimen

- Supplies needed:
 - Gauze pad
 - Sterile waler
 - Enteral syringe - 3 or 6 ml
 - Brush for cleaning ENFit connector
 - ENFit commercial cleaning brush
 - Firm-bristled toothbrush
 - Cotton-tipped applicator
- Perform hand hygiene.
- Uncap the ENFit connector and clean the cap with a sterile water-soaked gauze pad.
- Plug the stem of the ENFit connector with the cotton-tipped applicator end (not the end with the cotton attached).
 - This will prevent residue from entering the tube during flushing.
- Flush the moat of the ENFit connector with 2-3 ml of sterile water using a pulsating motion.
- Flick the remaining water out of the moat.
- Remove the cotton-tipped applicator from the stem.
- Using a brush dipped in sterile water, clean the grooves and bottom of the moat using a vigorous rotating motion for 10-15 seconds.
- Rinse the brush in sterile water.
- Replace the cotton-tipped applicator end into the stem.
- Flush the moat with 2-3 ml of sterile water using the same pulsating motion.
- Remove the cotton-tipped application.
- Replace the brush dipped in sterile water and clean with the same vigorous rotating motion.
- If there is visible residue remaining, repeat the process until the residue is gone.
- Remove excess water from the moat and cap.
- Rinse the brush in sterile water.
- Dry the ENFit connector with gentle tapping, drying with washcloth, and allow to air dry.

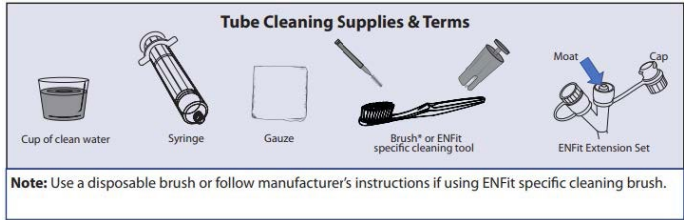
ENFit is an adult standardized design for enteral feeding connectors. The aim is to improve patient safety and reduce the risk of tubing misconnections. ENFit connectors offer advantages in terms of safety and compatibility in the adult patient population. The mitigation of misconnections in the adult patient population created unintended consequences in the NICU. Implementing the ENFIT feeding system in the NICU may inadvertently increase NEC rates. Studies have suggested that the design of ENFit connectors leads to the need to clean the moat and inadequate cleaning, increasing the risk of microbial colonization and contamination (Raad et al., 2018). The meticulous cleaning required for ENFit devices poses challenges in the NICU setting. There are time constraints and workload

Table 2. Protocol B Cleaning Procedure: Less-Diligent Cleaning Regimen

1. Supplies needed:
 - Gauze pad
 - Sterile water
 - Enteral syringe - 3 or 6 ml
 - Brush for cleaning ENFit connector
 - ENFit commercial deaning brush
 - Firm-bristled toothbrush
2. Perform hand hygiene.
3. Uncap the ENFit connector and clean the cap with the water-soaked gauze.
4. If using a firm-bristled toothbrush, make sure some of the center bristles are in the lumen (or stem) of the ENFit connector to block it.
5. Using a brush dipped in sterile water, clean the groves and the bottom of the moat using a rotating motion for 10 seconds.
7. Dip the brush in sterile water and clean the groves and the bottom of the moat using a rotating motion for 10 seconds.
8. Dip the brush in sterile water and clean the groves and the bottom of the moat using a rotating motion for 10 seconds.
9. Remove the excess water from the moat and re-cap.

demand that may compromise adherence to the recommended cleaning protocols (Jackson et al., 2019). The cleaning protocols include: “The More Diligent Cleaning Regimen” and “The Less-Diligent Cleaning Regimen” (see Table 1 and Table 2). In cases where cleaning protocols are implemented, the moat is still not free of bacteria (Jackson et al., 2019). Implementing cleaning regimens that include 9 to 17 steps face challenges for the bedside nurses’ workflow. Not to mention the additional products that will need to be purchased, stored, and maintained (see Table 3). There is evidence that nursing continues to struggle with hand hygiene, adherence to scrubbing the hub, and good practices for central venous catheter maintenance (Dias et al.,2022). Implementing ENFit in the NICU will create more time constraints for nurses. Creating an increase in the risk of NEC in this venerable patient population.

Table 3



Efficient cleaning of ENFit devices will be vital in the NICU for preventing microbial buildup. Having clean tubing reduces the risk of NEC. However, studies have demonstrated that both diligent and less diligent cleaning protocols can fail to adequately clean ENFit connectors. This failure leaves behind residual bacteria (Neu et al., 2019). The design of adult ENFit connectors makes them particularly susceptible to bacterial growth if not cleaned carefully. There can also be variations in cleaning practices among healthcare providers. These variations can further intensify the danger of contamination and NEC in the NICU (Gregory et al., 2021).

Addressing the risk of NEC in the NICU requires advocating for our tiniest of patients. As well as understanding and implementing a multifaceted approach. One that encompasses both clinical interventions, workflow, and system-level improvements. The adult feeding system ENFit offers benefits

in terms of standardization and safety for adults. ENFit poses risks in the NICU. If the cleaning protocols fail, one risk is exchanged for another potentially fatal risk. Ongoing monitoring and retrospective reviews must be done to mitigate the risk of NEC when implementing ENFit in the NICU. Healthcare facilities must invest the time to understand the impact of ENFit in the NICU. The increase in workflow and the additional cost associated with cleaning tools may be futile, research has shown them to be ineffective. Additionally, understanding the benefits of a feeding system that is specifically made for this tiny patient population can mitigate misconnections and not increase workflow, cleaning protocols, and bacterial growth. By prioritizing patient safety and implementing evidence-based strategies, NICUs will continue to reduce the incidence of NEC and improve outcomes for our vulnerable neonatal patients.

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Practical Use of Transcutaneous CO₂ Monitoring in the NICU

Anne M Geistkemper, MSc, RRT, RRT-NPS

Summary

Anne M Geistkemper, MSc, RRT, RRT-NPS discusses the practical applications of transcutaneous CO₂ monitoring in the NICU, its integration into neonatal care practices, and the evolution of this technology's adoption in the Rush University Children's Hospital NICU.

The following has been adapted from its original presentation for clarity and brevity.

Why Use Transcutaneous CO₂ Monitoring in the NICU?

The NICU admission process is fairly invasive for infants: lights, sounds, sticking for lab tests. So, the less invasive we can be within the NICU, the better. If we can introduce something that minimizes invasiveness, especially in those first 72 hours of a neonate's life, it's a valuable addition to our care regimen. Transcutaneous CO₂ monitoring, because it's noninvasive, is one such addition.

Transcutaneous monitoring provides continuous, real-time measurements of CO₂, allowing us to closely observe changes and trends. This becomes crucial when considering hypercapnia (elevated CO₂ levels) and hypocapnia (low CO₂ levels). Research has demonstrated that both hypercapnia and hypocapnia heighten the likelihood of injury to the brain, including intraventricular hemorrhage (IVH).¹ Because of this risk, we want to make sure that we're closely monitoring CO₂ to maintain levels within a safe range. Transcutaneous monitoring facilitates continuous monitoring of CO₂, providing greater visibility to support its effective management.

Clinical Applications of Transcutaneous Monitoring for Neonates

Reducing Iatrogenic Blood Loss

The most common reason for blood sampling is arterial blood gases (ABGs), which account for about 47% of neonatal blood samples.² One study found that neonates lost approximately a third of their blood volume within the first month of life, which is significant especially if you consider micro-preemies.³ This blood loss can have implications for things like anemia and infection.⁴

At Rush, we're frequently getting labs, especially in the first

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Rush University Children's Hospital NICU: An Overview

- Part of a large teaching hospital
- 60-bed level III NICU
- 700 admissions per year | 17% are very low birth weight (VLBW) infants
- Unit comprised of neonatologists, fellows, advanced practice providers (physician assistants and nurse practitioners), nurses, respiratory therapists, and ancillary staff

36 to 72 hours of life, as we strive to stabilize neonates and adjust ventilator settings in a timely fashion. If we can reduce the frequency of these blood gases, while also improving the monitoring of ventilation, that's ideal—something that transcutaneous monitoring can help us accomplish by providing continuous visibility into CO₂.

Continuous Monitoring on Mechanical Ventilation

Titration of mechanical ventilation is important for neonates due to their immature respiratory system. This is especially vital during the "honeymoon period," a well-known concept in the NICU, particularly for micro-preemies. It refers to the period following their birth, often after they've been given a surfactant, where settings are titrated down to minimize support. However, they can abruptly exit this honeymoon phase due to a large cytokine release, requiring prompt adjustment of settings to ensure adequate ventilation.

Because a neonate's status can constantly change, frequent adjustments are often needed. In these cases, having the option to continuously monitor CO₂ can be extremely beneficial. Instead of depending on scheduled blood gas draws to drive care decisions, continuous transcutaneous monitoring can offer greater visibility for enhanced titration support. The goal is to decrease our use of the ventilator while ensuring proper gas exchange; transcutaneous technology can give us continuous visibility into ventilatory status to help support this goal.

Continuous Monitoring on High-Frequency Oscillatory Ventilation

High-frequency oscillatory ventilation is highly effective in removing CO₂, but consequently, there's the potential for rapid fluctuations. We want to prevent these fluctuations as they can impact an infant's cerebral blood flow, which can put their brain

at risk for injury, including IVH.¹ The use of transcutaneous monitoring is helpful because we can closely monitor CO₂ and catch these fluctuations, allowing for proactive management of levels in real time.

Reducing Neonatal Pain

Research has shown that in newborn infants, a high number of early-life skin breaks correlate with worse mental development when examined at both 8 and 18 months.⁵ Furthermore, more frequent invasive procedures early in life have been associated with decreased white matter at 7 years old.⁶

We’re drawing labs, we’re getting gases, and maybe even placing lines. What can we do to help reduce the frequency of painful stimuli?

To minimize pain, we can employ noninvasive methods like transcutaneous CO₂ monitoring. This approach offers continuous CO₂-level visibility, helping to reduce the need for frequent heel sticks. There are also some developmentally appropriate strategies that can help reduce pain and stimuli. This includes swaddling, prone positioning, kangaroo care, or utilizing anesthetic cream or short-acting systemic analgesia for skin-breaking procedures.

Managing Specific Disease Processes

Table 1 outlines recommended CO₂ targets for neonates based on their specific disease process, as well as recommended interventions for neonates experiencing severe hypocapnia or severe hypercapnia. The use of transcutaneous CO₂ monitoring is valuable as we address the unique needs of each patient, providing enhanced titration support to maintain CO₂ levels within the targeted range.

When effectively managing CO₂, observing a reduction in CO₂ levels throughout making adjustments to ventilator settings

is important. Transcutaneous monitoring provides instant visualization of the impact of our titrations. We can see the changes happening, and that can help guide effective titrations and drive care.

Special Considerations

Edema

Edema can lead to altered capillary hemodynamics and cause an increase in the blood-skin barrier due to excess fluid. As a result, transcutaneous readings can be inaccurate, making it important to avoid edematous areas when monitoring. Avoiding areas of edema can be challenging, particularly for infants who are fluid-overloaded. In these cases, however, we can still leverage transcutaneous monitoring to track the trend of CO₂ over time rather than using it for precise values.

Premature Skin

For neonates, especially in 22- and 23-weekers, the skin is thin and fragile, something we want to make sure we consider when using our transcutaneous monitor. To prioritize skin integrity, we should ensure the sensor is at the appropriate temperature (41°C) and that we’re not leaving it on for too long (no more than 8 hours at a time). While the transcutaneous monitor will automatically apply appropriate settings, it is crucial to be aware of this consideration, so you can promptly identify deviations and take action if needed.

Note

It is recommended that the site time be evaluated and adjusted more frequently on premature skin to reduce the risk of skin injury.

Shunting and Low Perfusion

Correct sensor placement is crucial for patients with a shunt. As per AARC Clinical Practice Guidelines, it is recommended to place the transcutaneous sensor on the same side as a shunt.⁷ In

Table 1. Recommended CO₂ targets for neonates based on disease process and recommended titrations of ventilatory settings for severe hypocapnic and severe hypercapnic infants

← SEVERE HYPOCAPNIA 30 mmHg	NORMOCAPNIA 45 mmHg	PERMISSIVE HYPERCAPNIA 65 mmHg →	SEVERE HYPERCAPNIA →
CONSIDER: <ul style="list-style-type: none">↓ Respiratory Rate (RR)↓ Tidal Volume (VT)↓ Peak Inspiratory Pressure (PIP)↓ Amplitude (HFOV)↑ I:E Ratio (increase inspiratory time)	Transient Tachypnea of Newborn (TTN) <ul style="list-style-type: none">Assess & maintain normal ventilationFollow institutional protocol & best practices Respiratory Distress Syndrome (RDS) <ul style="list-style-type: none">Assess & maintain normal ventilationFollow institutional protocol & best practices Persistent Pulmonary Hypertension of Newborn (PPHN) <ul style="list-style-type: none">Routine use of TCM to assess and maintain normal ventilation because hypercapnia and acidosis increase pulmonary vascular resistance (PVR)	Congenital Diaphragmatic Hernia (CDH) <ul style="list-style-type: none">Allow permissive hypercapnia (PCO₂ 45-65 mmHg)PCO₂ > 60mmHg is associated with decreased survival¹¹⁻¹³ Bronchopulmonary Dysplasia (BPD) <ul style="list-style-type: none">Allow permissive hypercapnia (PCO₂ 50-55mmHg) as long as pH remains in normal rangeIn severe disease, PCO₂ up to 70mmHg may be tolerated¹⁴ Meconium Aspiration Syndrome (MAS) <ul style="list-style-type: none">Allow permissive hypercapnia (PCO₂ 50-55mmHg) as long as pH remains in normal range	CONSIDER: <ul style="list-style-type: none">↑ Respiratory Rate (RR)↑ Tidal Volume (VT)↑ Peak Inspiratory Pressure (PIP)↑ Amplitude (HFOV)↓ I:E Ratio (decrease inspiratory time)

these cases, arterial sampling should also be done on the same side, as having these two monitoring methods aligned will allow for an accurate correlation.

Low perfusion may cause transcutaneous CO₂ values to be falsely high. In this situation, similar to the case of edema, it may be more helpful to utilize the monitor to trend CO₂ in order to observe patterns and track progress during care.

Hypothermia

Hypothermia is something we see often in NICUs, especially with hypoxic-ischemic encephalopathy (HIE) or post-cardiac arrest patients undergoing cooling therapy. HIE, hypovolemia, reduced myocardial contractility, and bradycardia can all lead to decreased cardiac output. Consequently, if the region experiences hypoperfusion, it is important to note that the correlation between the transcutaneous and arterial CO₂ may be poor. In this situation, establishing a correlation between the two values, rather than focusing on the exact values, becomes more clinically valuable. Again, this can be used for tracking the trend in CO₂ throughout care.

AARC Clinical Practice Guidelines

The AARC Clinical Practice Guidelines (shown in part in Figure 1) provides recommendations for the effective use of transcutaneous CO₂ monitoring in clinical care.⁷ If you're not fully utilizing your transcutaneous monitors, haven't developed guidelines or implemented it into any protocols, or don't have devices at all, the AARC Clinical Practice Guidelines can guide you. I encourage you to develop a process for your NICU. It can be difficult to get started, but aligning with the AARC guidelines is going to create a standard practice. By adopting this approach, you can foster growth within your team, encouraging increased utilization of the technology. We have a great opportunity especially as respiratory therapists, to help drive care in an efficient, noninvasive manner.

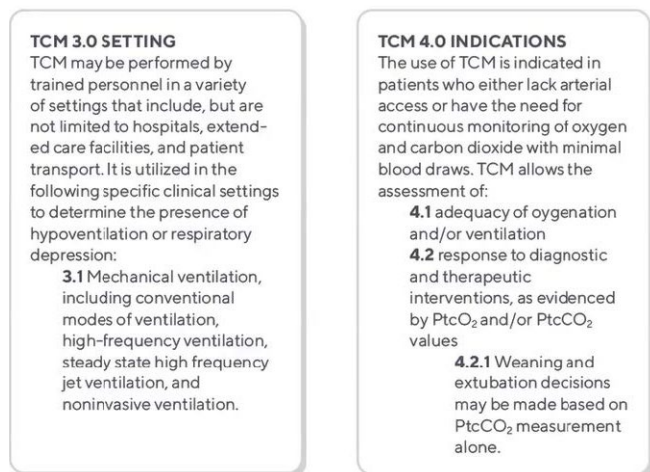


Figure 1. 2012 AARC Clinical Practice Guidelines for Transcutaneous Monitoring of Carbon Dioxide and Oxygen⁷

Benefits of Transcutaneous CO₂ Monitoring in the NICU

Transcutaneous CO₂ monitoring offers a noninvasive method to continuously analyze CO₂ levels in all modes of ventilation. With continuous monitoring, we're able to get real-time values for instant visualization of a patient's response to care strategies. This newer technology preserves skin integrity for delicate patients and helps reduce the need for frequent blood draws.

Additional benefits of transcutaneous CO₂ monitoring in the NICU:

- Provides accurate measurements
- Compatible with any ventilation strategy
- Supported by AARC guidelines
- Supports cost reductions
- Supports neuroprotective care
- Simplifies workflows
- Enables lung-protective ventilation strategies

Tips for Selecting a Monitoring Site

Choosing the ideal site for transcutaneous monitoring depends on your patient. The main determinant for location is perfusion, so the sensor is often placed on the thighs. This is a particularly good choice when swaddling, as there's less of a risk of the sensor falling off. However, in a 22-, 23-, 24-weeker, you might not have the real estate available in these areas, given the presence of a peripheral intravenous line (PIV) and/or other lines they may have.

In the past, we utilized the upper chest and thigh areas at our institution, but encountered challenges in achieving good correlation with these sites. In discussion with the manufacturer, we were advised to try the forehead. While some caregivers initially had concerns, once everyone embraced the idea, we saw remarkable improvements.

In most scenarios, the forehead is well-perfused, making it a great location for monitoring. For us, we keep our preemies midline for 72 hours, which also means there's typically nothing obstructing this area. And when they are being repositioned, we don't have to worry about the sensor as much, and whether there will be pressure placed on it. It's an easy-access area where we found much better correlation, and for my staff, it was less stressful to manage the sensor and troubleshoot appropriately. If you're not using the forehead yet, I challenge you to try it.

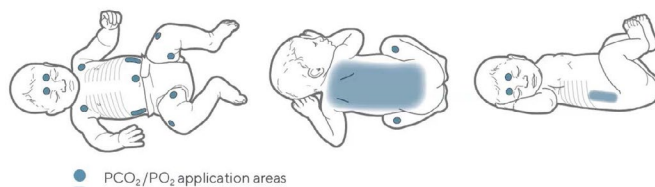


Figure 2. Recommended sensor sites for transcutaneous monitoring include the thorax, the abdomen, the back, the area low on the forehead, the temples, and the inner or anterior aspect of the thigh.

Using Contact Gel: How Transcutaneous Monitoring Use Transformed at Rush

Our facility got by without using contact gel with our transcutaneous sensors for a long time. However, we were having correlation issues. We were experiencing frequent sensor errors and doing a lot of troubleshooting.

We learned from our clinical specialist that by using normal saline in place of contact gel, it meant that we were putting salt on an electrode—no wonder our membranes were struggling. When we replaced the saline with contact gel, we found our sensors were providing much better correlation. In addition, it was more cost-effective because our machines required less maintenance and troubleshooting, and we didn't have to replace membranes as frequently.

Table 2. Five S's of troubleshooting a transcutaneous monitoring device: sample, site, seal, sensor, and status.

Sample	Site	Seal	Sensor	Status
Record the tcPCO ₂ value when you draw the sample, not when results are read.	Check for external pressure on the sensor.	Verify attachment ring is secure on the skin.	Verify correct sensor temperature.	Shock, sepsis, and edema can impact the local perfusion.
Verify proper lab draw technique and operation of blood gas analyzer.	Check perfusion at measurement site. Sampling site and sensor should be on same side of shunt.	Use 1-2 drops of contact gel during application. Ensure sensor is clipped into the ring.	Check the quality of the sensor membrane. Check when the sensor was last calibrated.	Consider the effect of vasoactive medications. Decreased perfusion may cause falsely high tcPCO ₂ .

Present day, our correlation has improved significantly, and I attribute that to using contact gel, as well as using the forehead as a monitoring site. Before, we owned 6 devices and had an average of about 3-4 in use. Now, while we still own 6, we are renting additional units because our usage has increased after gaining the trust of not only the RTs, but also complete medical teams. If you are struggling with usage, I encourage you to reach out to your vendor's support team to see if there is any education to help you along the way.

The Five S's: Troubleshooting Tips for Your Transcutaneous Monitoring System

When it comes to troubleshooting your transcutaneous monitoring device, I like to refer to the Five S's: sample, site, seal, sensor, and status. When you're trying to figure out why your transcutaneous readings aren't correlating as well as you'd like, figuring out which issue you're dealing with can help you troubleshoot appropriately.

Integrating Transcutaneous Monitoring Into NICU Protocols

At Rush, we implemented transcutaneous monitoring within our unit protocols, not only to increase the usage of the devices that we bought, but also to showcase its value and get everybody on the unit more comfortable with the technology.

If you don't have protocols in your unit yet, that's okay. You can use the AARC Clinical Practice Guidelines to start utilizing the technology and building trust. If you do have protocols, there are simple ways to implement the usage of transcutaneous monitoring in your unit, just by adding it to your existing processes.

NICU Conventional Ventilation Protocol

As part of our NICU conventional ventilation protocol, patients who are born at less than 35 weeks get a transcutaneous sensor placed on them for the first 72 hours of life, which allows us to start trending our gases with our tcPCO₂. Because there is a high volume of gases and labs being drawn in the first 24 to 36 hours, we're able to lay a good foundation for our correlation. This protocol also gets everybody more comfortable with transcutaneous monitoring in the NICU.

High-Frequency Jet Ventilator Protocol

As part of our care goals for our high-frequency jet ventilator protocol, any patient who goes on a jet ventilator must have a transcutaneous monitor.

Other Cases to Integrate Transcutaneous CO₂ Monitoring

Other cases where we use transcutaneous monitoring are

BPD and noninvasive ventilation (NIV). While we don't necessarily have these protocolized yet, we still utilize transcutaneous monitoring to continuously monitor ventilation in these patients.

Bronchopulmonary Dysplasia (BPD)

Although gases are not frequently obtained from patients with BPD, their status can change quickly. These patients are often sweaty, which can make finding the proper transcutaneous sensor placement difficult. However, transcutaneous monitoring is a useful tool for this population, providing continuous CO₂ visualization when gas sampling is infrequent.

Noninvasive Ventilation (NIV)

Patients on noninvasive mechanical ventilation are often teetering on the verge of needing an escalation of care, perhaps requiring intubation. Or, they may have just been extubated, and there is uncertainty about their ability to thrive. To be able to have constant CO₂ monitoring in these cases is helpful in guiding our management strategies.

Summary

Transcutaneous monitoring provides clinicians with a noninvasive method to monitor CO₂. This isn't just beneficial for patients in terms of lessening pain; it has the potential to yield benefits for your hospital in terms of cost-effectiveness by supporting the reduction of blood draws. And importantly, as a respiratory therapist, it offers valuable insights into the efficacy of ventilation strategies, which helps guide care.

The more you use transcutaneous monitoring, the more comfortable you're going to be and hopefully the better you'll become at it. In the Rush University Children's Hospital NICU, we already had active protocols, so we took the opportunity to integrate transcutaneous monitoring. This not only got our staff more comfortable using it, but also allowed our bedside caregivers to begin to trust the technology and rely on it during care.

As we continue utilizing transcutaneous CO₂ monitoring, keeping up with current research remains valuable. However, actively engaging with other facilities, who are utilizing devices even more than we are, has also proven significant for our hospital. If you're looking to embrace this technology, or increase its usage, consider reaching out to your colleagues at other hospitals to gain valuable insights on successful implementation. This has played a vital role in our adoption of transcutaneous monitoring in the NICU, and our progress towards utilizing its fullest potential for our patients.

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WHITEPAPER

Balancing Brain & Lung Protection in the NICU with Transcutaneous CO₂ Monitoring

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The very same ventilatory support that can help keep CO₂ within safe ranges for brain protection can also damage the lungs without careful consideration. Failing to deliver enough volume can result in derecruitment and atelectasis. Delivering too much risks overdistension and volutrauma.

In this way, the brain and the lungs are in constant tension – what protects one can harm the other. To prioritize lung protection and avoid potentially harmful airway pressures, respiratory teams may employ a strategy of permissive hypercapnia, which can help keep plateau pressures within a safe range, but could put the brain at risk. Prioritizing the brain may require increased ventilator settings that damage the lungs. In these scenarios continuous visibility to CO₂ can be a powerful, even vital, tool to balance both priorities.

Continuous CO₂ monitoring can be a valuable tool when care teams employ permissive hypercapnia, as it can allow them to keep a close eye on how the patient is responding and to react quickly to unexpected changes or spikes.

Preventing Stillbirth: Large Private Community Practice Experience

B Petrikovsky, MD PhD, M Terrani, MD, C Frankowski-Szymczak, MD, V Gardner, PA-C

Stillbirth is one of the most common adverse pregnancy outcomes, occurring in 1 in 160 deliveries.¹ Approximately 23,600 stillbirths are reported annually.¹ Risk factors include nulliparity, advanced maternal age, diabetes, chronic hypertension, smoking, alcohol use, assisted reproductive technology, multiple gestation, male gender and obstetric history of prior stillbirth, among others.^{2,3} Obesity is a significant risk factor that is associated with an increased risk of stillbirth as well as early fetal loss. Maternal obesity is associated with a 5-fold increased risk of stillbirth.⁴ In vitro fertilization (IVF) pregnancies are associated with a 2 to 3-fold increase of stillbirth rate, after controlling for age and parity.⁵ Even with identifying these risk factors, in many cases, stillbirths are happening in women without identifiable risk factors.⁶

Causes of Stillbirth

Recent research supports premature placental aging as an etiologic factor in many cases of stillbirth.⁶ Histopathologic study of placentas in cases of unexplained stillbirth revealed that 91% of placentas showed thickening of the maternal spiral artery walls, 54% of placentas contained infarcts, and 13% of placentas demonstrated placental vascular occlusion.⁷ However, these placental abnormalities are also seen in live born neonates.

Fetal Testing and Stillbirth Prevention

In March 2001, a workshop on *Setting a Research Agenda for Stillbirth* was held by the National Institute of Child Health and Human Development (NICHD).^{8,9} A questionnaire study of 1,200 ACOG fellows demonstrated that the causes of fetal demise are poorly understood even by the experts, and there are no known preventative tactics. Today, fetal testing remains the only reliable means to address stillbirth prevention. Each test (non stress test (NST), biophysical profile (BPP), oxytocin challenge test (OCT), etc.) when normal, has been shown to correlate well with live birth, normal umbilical artery cord pH, and Apgar score above 8.¹⁰ These tests, when abnormal, have a less reliable correlation with adverse neonatal outcomes.¹¹ Recently Stallmach et al¹² postulated that abnormal placental maturation and placental dysfunction are the major causes of preventable stillbirth. The risk of stillbirth in such cases is 70-fold that of fetuses with normal placentas. The risk of recurrent stillbirth

in cases with abnormal placental maturation and placental dysfunction is tenfold above baseline.¹² These authors divided placental dysfunction into two types: acute and chronic. In the cases of acute placental dysfunction, placental pathology reveals abnormal vascularization of the chorionic villi and lack of syntiocapillary membranes. The chronic dysfunction comprises conditions where fetal growth restriction was noted before fetal demise. Placental pathology in such cases revealed abnormal acceleration of chorionic villi maturation.¹³

Rainbow Stillbirth Clinic

The concept of Rainbow Clinic was developed by Dr Alex Heazell in the UK in 2013. The Rainbow Clinic caters to pregnant women who have experienced a stillbirth in the past. Clinical protocols call for additional testing to identify early signs of fetal growth restriction and placental dysfunction. The multidisciplinary staff of such clinics underwent training to better respond to the emotional needs of these affected families. The clinic's care plans are customized around the needs of the family based on pre-conception date, review of past medical history and their current pregnancy management. Mount Sinai Medical Center in New York City is one of the first OB/GYN departments to open such a clinic in the USA. Each year, about 900 babies are stillborn in NYC alone. About two-thirds of those families will be pregnant again within a year from their loss.

Stillbirth Collaborative Network (SCRN)

Using conservative criteria, 25% of stillbirths in the United States are preventable.¹⁴ The most common causes of stillbirths are placental insufficiency, followed by maternal complications of pregnancy (hypertensive disorders, spontaneous preterm birth among others.) These conditions can also be targeted for stillbirth reduction.¹⁵ Out of 512 stillbirths, the causes were placental insufficiency (12.7%); medical complications of pregnancy (6.1%) hypertensive disorders of pregnancy (3.9%); preterm labor (3.1%); and multiple gestations (0.8%).¹⁵ The newly released report, entitled *Stillbirth A Major Public Health Concern*, was the result of a congressional mandate that instructed the Department of Health and Human Services to develop a Stillbirth Task Force. In the meantime, every obstetrical practice should develop its own strategy on determining stillbirth risks and methods to reduce rates of stillbirth based on its patient population, percentage of high risk patients and available resources.^{16,17}

In a study published in 2016,¹⁸ our practice concluded the benefits of weekly intrapartum surveillance including full

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biophysical profile (BPP) weekly starting at 36 weeks for a cohort of 6900 women over a 10 year period from 2006-2016. Patients were excluded from the study who experienced stillbirth prior to onset of testing, patients with stillborn associated with congenital anomalies and lethal chromosomal and genetic syndromes. The results identified without a strategy of weekly antepartum fetal surveillance between 36 and 41 weeks, women of all age groups experienced 1.6 stillbirths per 1000 pregnancies. Women undergoing weekly testing had a stillbirth rate of 0.9 per 1000 pregnancies. The evidence of the study concluded the overall benefits in decreasing still rate compared to the national average at near term and term stillbirth by applying weekly antepartum surveillance for all age groups.

Stillbirth and Maternal Morbidity

Nyarko et al¹⁸ conducted a retrospective cohort study of 8,694,912 deliveries using birth and death certificates from California, Missouri, Michigan, Pennsylvania and South Carolina. The prevalence of severe maternal morbidity in cases of stillbirth was 791 per 10,000 deliveries compared with 153 per 10,000 deliveries for women with live births. The prevalence of non-transfusion maternal morbidity with stillbirths was 502 per 10,000 compared with 68 per 10,000 deliveries for women with live births.¹⁸

Stillbirth and Maternal Mental Health

The event of a stillbirth can also be detrimental to maternal mental health. In the hospitals, caregivers have been trained to attend to the affected family members.¹⁸ For instance, if there was a name already picked out for the baby, it will be referred to by that name. Having parents connect with their stillborn child has shown to help the living deal with the loss. Parents are given the choice about viewing and/or holding the baby in order to help personalize the birth and help connect with the baby. Most studies have shown that viewing and holding the stillborn helps with the grieving and mourning process, which in turn reduces the long-term psychological problems.²⁰ However, there are studies that have shown that encouraging direct contact with the baby actually increases the rate of posttraumatic stress, anxiety and depression in subsequent pregnancies.^{21,22} The grief and bereavement that occur after a major traumatic event like this can lead to increased rates of mental disorders like complicated grief, major depression, anxiety disorders, and posttraumatic stress disorder. There are support groups available for these parents.²³ These can be found in many communities, hospitals, as well as numerous online organizations and platforms.²⁴

Conclusive Remarks

C. Spong recently published an editorial entitled *The Impact of Stillbirths on Patients and Providers*.²⁵ She stated that stillbirths are one of the most tragic situations we encounter as obstetricians. Unlike deaths later in life, stillbirth results in a lack of shared memories that can help in the healing process. The absence of tangible moments spent with the baby, combined with hesitations to discuss the topic openly, can lead to a sense of isolation and severe emotional pain.²⁴ Therefore, investment in research is essential. Building on the legacy work of the Stillbirth Collaborative Research Network, and in-depth studies into the causes and risks factors of stillbirth can potentially lead to preventative measures that save lives.²⁴ Meanwhile, our link between increased frequency of fetal testing with a decreased rate of stillbirths should be considered until new research data becomes available.

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Engagement Solutions for Families in Neonatal and Pediatric Settings

In this feature, Neonatal Intensive Care interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Robert White, MD, Director and Christopher Rand, CEO of AngelEye Health.

Could you give us an overview of AngelEye, its services, and the key features of the recent platform upgrade?

Christopher Rand: AngelEye Health, the leading technology provider for neonatal and pediatric family engagement solutions, deeply understands the value that family engagement and family-centered care bring to the neonatal and pediatric intensive care environment. We provide HIPAA-compliant family engagement solutions to integrate parents or caregivers simply and seamlessly into the child's care team. From admission to discharge, AngelEye Health's bedside cameras with messaging capabilities and feeding management solution deliver a proven, positive impact on care delivery workflows for the dedicated bedside team, the quality of the family experience, and a successful transition home.

Our platform is used by more than 200 NICUs nationwide, and data reveals that when installed, AngelEye's solutions result in remarkable daily parent usage, with 95% of NICU families actively engaged with more than 10 million virtual visits to date.

During 2024, the company will unveil considerable enhancements to its existing suite of technology, which will then

Robert White, MD, Director, Regional Newborn Program, Mednax, Robert.White@mednax.com: Robert White, MD is a graduate of the Johns Hopkins School of Medicine and has been Director of the Regional Newborn Program at Beacon Children's Hospital since 1981. His primary interest has been in advancing structural and operational strategies to provide the optimal NICU environment of care for babies, families, and caregivers.

To this end, he has written many papers and co-founded the Consensus Committee to Establish Recommended Standards for Newborn ICU Design, the Gravens Conference on the Physical and Developmental Environment of the Newborn, and the International Newborn Brain Conference.

Christopher Rand, CEO, AngelEye Health, crand@angeleyehealth.com: Christopher Rand is the Chief Executive Officer of AngelEye Health. Since assuming the leadership role in 2019, Rand has built a team, created a culture based on collaboration and innovation, and focused on empowering neonatal and pediatric intensive care units with the most advanced family engagement technologies available today. Rand is committed to delivering engagement solutions designed to bridge the gap between families and hospital care teams to ease workflows and offer a more positive hospital stay while elevating patient outcomes. In addition to his role at AngelEye Health, Rand has advised over 50 healthcare companies. He also serves as a partner for a venture investment firm, Tristar Health Partners. Rand received his MBA from Vanderbilt University's Owen Graduate School of Management and his Bachelor's degree from The University of Notre Dame.

enable the introduction of new patient coordination solutions. AngelEye understands the obstacles families and care teams face. AngelEye's platform can be uniquely leveraged to support the patient, their family, and the care team to improve outcomes, efficiency, and satisfaction.

"Today, NICUs nationwide are embracing transformation to forge deeper connections with families. They require innovative technology that empowers families throughout their NICU journey," said Christopher Rand, CEO of AngelEye Health. "By providing round-the-clock virtual access and facilitating crucial information sharing, caregivers can deliver transformative care that leaves a lasting impact on outcomes. Our next step is to turn our active family engagement and empowerment into meaningful workflow improvements for caregivers and ultimately into even greater financial returns with enhanced quality of care for our hospital partners."

New software advancements that are slated for the existing AngelEye portfolio include an extensive refresh to the Iris Camera System, a secure, live video stream enabling families to connect with their infant at any time from their devices, and significantly improved functionality to MilkTracker, a feeding management solution for families and clinicians. In addition to these major enhancements to existing products, AngelEye will introduce new services that redefine NICU navigation and discharge coordination, equipping care teams with integrated technologies that cultivate confident families.

Can you share some insights into the user feedback that influenced the latest upgrades? How does this feedback guide the development of new solutions?

Christopher Rand: AngelEye Health's platform advancements are deeply influenced by feedback from NICU clinicians and families, underscoring its customer-focused product development.

The company employs diverse feedback mechanisms, including technology-enabled surveys, data analytics, personal interactions, and a Clinical Advisory Board, to understand and address the unique challenges of NICU environments.

This approach has led to the creation of targeted solutions and enhancements, such as the development of our newest NICU navigation/discharge coordination solution, a novel NICU groundbreaking tool (assistant) that seamlessly integrates assessments (robust surveys), education, scheduling, and transparent communication, demonstrating how user feedback drives innovation. AngelEye Health's commitment to continuous

education and improvement, evidenced by its extensive support resources and monthly updates, ensures its solutions remain relevant and effective for healthcare providers and families.

In summary, AngelEye Health's dedication to listening to its users has cemented its position as a neonatal and pediatric care technology leader, continually adapting its offerings to meet the evolving needs of its hospital partners and their patients.

In what ways does integrating technology like AngelEye's platform transform the NICU experience and workflows compared to environments that have yet to adopt digital solutions?

Robert White, MD: In the pre-tech era, family interaction with their baby in the NICU consisted of their personal presence or brief phone conversations with their baby's providers. AngelEye has changed that paradigm, especially for those families who are not able to be with their babies most of the time—which, in the US, is the vast majority of parents. The original AngelEye feature, the camera, allowed a parent to observe their baby anytime from anywhere—the mother's hospital bed in the same or an outlying hospital, the father at home or work, the grandparents who might be living on the other side of the country. The camera quickly became a valuable tool to promote family bonding and to alleviate parental anxiety about the status of their baby.

Over the ensuing years, many features have been added to the capability of the AngelEye system, allowing it to become a portal of parent-care team communication, pre-discharge education of families, and support for optimizing breast milk nutrition in high-risk newborns.

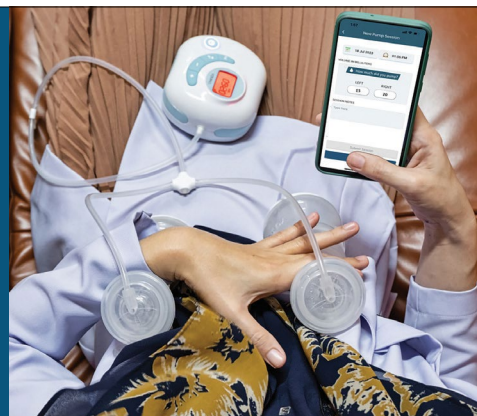
AngelEye now facilitates nearly continuous family engagement with their NICU baby and care team even when they are separated so that at discharge, families are more familiar with and bonded to their babies than has been possible in the past when transportation or time limitations only permitted brief, intermittent interactions.

AngelEye has revolutionized NICU family engagement, transforming intermittent, in-person visits and phone calls into a nearly continuous, intimate connection between families, their babies, and healthcare teams, ensuring that distance and time no longer hinder the crucial bonding and communication essential for the early stages of life.

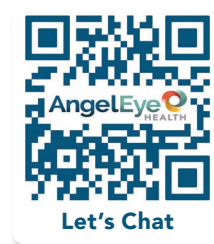
What are some of the primary challenges staff experience in the NICU, and how does AngelEye's platform address these issues?

Christopher Rand: Caring for young patients, especially vulnerable infants and neonates, presents unique challenges for healthcare teams. The high dependency of these young patients places an immense strain on nursing and clinical teams, who are already navigating the pressures of a demanding healthcare landscape. In addition to caring for the patient, clinical teams must keep guardians up to speed on their infant's health. To support their care teams effectively, clinical leaders must equip nurses with the tools needed to endure shortages and the high demands of the job. Innovative solutions can alleviate the workload of the current staff, enhance engagement with patients and families, streamline workflows, and contribute to better patient outcomes.

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Advanced technology platforms can provide invaluable support to their NICU teams in several key areas:

Enhance Family Engagement and Reassurance: Bedside cameras and messaging systems offer real-time visual access to NICU infants, enabling parents to stay connected with their babies even when they cannot be physically present. Beyond just providing life support, NICUs play a crucial role in fostering healthy parent-infant relationships. Real-time visual access and continuous communication enhance engagement between parents and healthcare teams, promoting transparency and trust while creating a collaborative care environment and alleviating parental anxiety.

Advanced Feeding Management: One of the most significant burdens on NICU nurses is meticulously managing feedings. Modern tracking systems streamline nutrition management in the NICU, offering real-time updates on breastmilk availability and aiding in inventory control within the hospital and at home. These platforms optimize feeding schedules and ensure timely delivery of nutrients while empowering healthcare teams to make data-driven decisions to support the nutritional needs of each infant. By automating these processes, nurses can focus their time and attention on other critical aspects of care, thus improving efficiency and patient outcomes.

Educational Support: NICU care extends beyond the hospital walls. Educating families about post-discharge care is crucial for a smooth transition and optimal recovery—technology offers a treasure trove of educational resources conveniently accessible at parents' fingertips. Technology solutions provide families access to abundant educational resources, empowering them with the knowledge and skills to participate actively in their baby's care journey. These resources, from online modules to interactive tools, facilitate learning and enable families to track their progress seamlessly. Also, these platforms eliminate the need for time-consuming manual distribution of printed materials, allowing nurses to allocate their time more effectively and focus on direct patient care.

Support Discharge Coordination: The journey does not end at discharge. Digital tools for discharge planning play a crucial role in empowering families to manage care post-discharge confidently. These platforms provide comprehensive guidance on medication schedules, feeding routines, and follow-up appointments, ensuring a smooth transition from hospital to home. By equipping families with the necessary resources and support, health systems can reduce the burden on nurses during busy shifts and streamline discharge workflows, improving continuity of care and patient outcomes.

In what ways does AngelEye Health's platform facilitate a more holistic approach to neonatal care?

Christopher Rand: AngelEye Health facilitates a more holistic approach to neonatal care through a multifaceted strategy emphasizing comprehensive family involvement and enhanced communication between families and healthcare providers. Here are several key ways AngelEye contributes to a more holistic neonatal care experience:

Continuous Remote Access: The core feature of the AngelEye system, a live-streaming camera system, allows families to visually connect with their infant in the NICU anytime, from anywhere. This constant visual connection supports emotional

bonding between parents, extended family, and their newborns, even when physical presence in the NICU is not possible.

Enhanced Communication: AngelEye offers secure, direct communication between the care team and the family. This allows for timely updates, educational content sharing, and the ability to ask questions and receive answers, facilitating a transparent and inclusive care process.

Pre-Discharge Education: Through the AngelEye platform, families can access educational resources and content specifically designed to prepare them for the care needs of their infant upon discharge. This education is crucial for ensuring a smooth transition home and empowering parents with the knowledge and confidence to care for their high-risk newborns.

Breast Milk Nutrition Support: Recognizing the importance of breast milk in the development of high-risk newborns, AngelEye provides tools and resources to support and optimize breast milk nutrition. This includes educational materials and communication channels that encourage and facilitate breastfeeding and the use of breast milk.

Integrated Care Team Collaboration: AngelEye's newest offerings will enhance the collaboration between different members of the care team, including doctors, nurses, lactation consultants, and other specialists involved in the infant's care, along with the caregivers. This integrated approach ensures that all aspects of the infant's health and well-being are addressed in a coordinated manner to prepare families and the infant for a successful transition from NICU to home.

Family-Centered Care: By placing the family at the heart of the neonatal care process, AngelEye supports a family-centered care model. This approach recognizes the family's integral role in the healing and development of the infant, promoting practices that involve and support the family in care decisions and activities.

In summary, AngelEye Health's technology and services foster a holistic approach to neonatal care by ensuring continuous family engagement, enhancing communication between families and healthcare providers, providing comprehensive pre-discharge education, supporting optimal nutrition, encouraging collaborative care team efforts, and prioritizing family-centered care practices. These elements are essential for improving patient outcomes, reducing parental anxiety, and ensuring the infant's and their family's well-being.

How does AngelEye measure the impact of its platform on NICU outcomes, and what improvements have you observed or anticipated with the recent upgrades?

Christopher Rand: AngelEye actively works with its hospital partners on Quality Improvement Initiatives to validate the impact of virtual engagement solutions on staff productivity, family and staff satisfaction, and reduction in feeding errors that can occur in the inpatient setting. The platform also includes robust reporting features to keep NICU leaders informed with rapid insights on consolidated engagement metrics.

Why should health system leaders consider NICU technology a critical investment for their NICU operations, particularly in terms of patient care and outcomes?

Robert White, MD: System leaders have a keen interest in

becoming the “go-to” hospital for maternal care because of the trickle-down effect of care opportunities for the extended family. To that end, NICUs that are perceived in the hospital’s service area as “high-tech, high-touch” help foster an impression of that facility as a caring, highly competent provider, attracting maternity patients and, ultimately, their extended families at all stages of life. This patient-capture strategy ultimately benefits the bottom line of the hospital organization.

From an outcomes perspective, as everyone is aware, family involvement in the care of a NICU baby has been shown to reduce hospital length of stay and drive better patient outcomes. Today, technology, such as bedside cameras, enables more frequent and deeper family connection during the care process, which ultimately leads to better outcomes. Additional technologies, including automated journey-based education and patient communication, help empower parents and provide them with a greater sense of confidence. When parents are more confident and competent in caring for their babies after discharge from the NICU, those children are more likely to do well both medically and developmentally, which benefits not only the baby and family but also the entire community in the form of reduced societal costs.

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Human Milk-Based Nutrition in the NICU: RCTs and Beyond

Dan L Stewart, MD, FAAP, Lance E Wyble, MD, MPH and Jenelle Ferry, MD

Most health care providers consider the randomized controlled trial (RCT) as the gold standard for evidence when selecting what interventions to adopt in the NICU. There is good reason for this, as a properly designed and conducted RCT can help us uncover the actual impact of an intervention in a well-defined patient population, taking great efforts to minimize risk of bias and minimize the impact of confounders. Nevertheless, it is important to acknowledge that solely having an RCT, does not necessarily make it closer to the “truth” than other types of studies. Poorly designed RCTs can produce misleading results. Furthermore, certain interventions, such as those where outcomes depend on broader aspects of care, may not be well-suited for RCTs.

An excellent example of this is evaluating nutrition options for premature infants born very low birthweight (VLBW). Studies directly comparing cow milk-based fortification (CMBF) versus human milk-based fortification (HMBF) typically employ the exact same feeding protocol in both arms, which fails to take advantage of a key benefit of HMBF: the ability to fortify sooner without increasing the risk of complications, notably necrotizing enterocolitis (NEC). There is ample evidence that the best outcomes using HMBF are achieved when fortification begins in the first days of life.¹⁻³

Limitations of Available HMBF RCTs

Two RCTs that failed to show a benefit of HMBF in their primary endpoint did not follow a recommended human milk-based nutrition protocol, which involves earlier and more intensive fortification than is possible with cow milk-based nutrition. O'Connor et al randomized 127 premature VLBW infants to receive HMBF or CMBF using the same fortification protocol.⁴ The primary outcome was the percentage of infants with a feeding interruption for ≥ 12 h or a $>50\%$ reduction in feeding volume. While the two groups were not significantly different in this regard, it is impossible to say what would have happened if the researchers had used an early fortification schedule in the HMBF arm. The study nevertheless demonstrated an adjusted 14.5% reduced morbidity and



mortality index, which narrowly escaped significance ($P < 0.07$) in the HMBF arm.⁴

More recently, a RCT by Jensen et al randomized 228 premature infants born VLBW to fortification using HMBF or CMBF. The rate of NEC and other outcomes was similar between the two groups, but this RCT had a similar design limitation as the O'Connor study. Unfortunately, fortification in the Jensen study did not start early, with fortification designed to begin before infants reached 100 ml/kg/day of feeding volume. In actuality, the volume at start of fortification differed significantly between the two treatment groups.⁵

The Jensen trial was also clearly underpowered even for the primary composite outcome. The original estimate of the primary outcome used for the sample size calculation (47.7%) was much higher than the actual incidence in the control group (34.5%). Thus, a total sample size of about 1,600 infants would have been required, but only 228 infants were included in the study.⁵ Given this lack of adequate sample size, it is no surprise the results failed to find a difference. There also appears to have been deviations from the approved protocol, since one infant in the HMBF arm died at 2 days, but the protocol specified that only infants who lived to the third day of life were eligible for inclusion.⁵

Entire Body of Evidence

It is worth noting that, despite the failure of poorly designed RCTs to demonstrate benefits of HMBF, major medical societies involved in the care of NICU infants agree that donor

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milk (DM) is superior to cow's milk-based nutrition when mother's own milk (MOM) is not available. This includes the American Academy of Pediatrics (AAP), the European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN), and the World Health Organization (WHO). This may be because looking at the entirety of the evidence when considering a feeding strategy for NICU infants, not just two flawed RCTs, clearly reveals the benefits of human milk. There is ample real-world evidence that premature infants given MOM and/or DM with HMBF have better outcomes, which in turn leads to lower costs. More than 20 clinical studies comparing CMBF with HMBF have shown that HMBF is superior with respect to mortality and morbidity,³ feeding intolerance,⁶ growth metrics,¹ a wide variety of complications,^{1,3,4,6} NICU stay duration,⁶ long-term outcomes,² and hospital costs.^{6,7}

As clinicians, we must comprehensively evaluate all the evidence while considering the benefits, potential risks, and the costs to health care systems. While further research is most welcome, the available evidence strongly favors the use of human milk-based nutrition for select vulnerable NICU infants.

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Arterial Catheter-Induced Blanching of the Leg in an Extremely Premature Infant

Shabih Manzar, MD, MPH and Patricia Richardson, NNP

Abstract

Background: Insertion of arterial catheters is a routine procedure in extremely preterm (EP) infants. However, complications include thromboembolic events with ischemia of the digits.

Clinical Findings: We report a case of a 26-week, 550-gram EP infant who developed severe blanching of the lower leg after posterior tibial artery cannulation, followed by a dusky look of the toes.

Primary Diagnosis: Arterial Vasospasm

Interventions: The case was managed by warming the contralateral extremity and applying nitroglycerine to the affected extremity without using pentoxifylline.

Outcomes: A complete resolution was seen with full function of the leg and healing of the toes.

Practice Recommendations:

- Clinicians should know the associated complications of arterial lines in EP infants.
- Clinicians should observe blood flow and perfusion during and after arterial line insertion.
- Any untoward effect of a procedure should be communicated urgently to the NICU team.
- A fast action plan to manage vasospasm in EP infants should be instituted.

Introduction

Insertion of arterial catheters is a routine procedure in extremely preterm (EP) infants. The main indication is to monitor continuous blood pressure and to obtain painless blood sampling. Umbilical arterial catheters (UAC) are preferred over peripheral arterial lines (PAL) due to the ease of the clinical procedure and associated risks and complications. Both UAC and PAL could cause vasospasms in neonates.¹ If not managed appropriately, the vasospasm may lead to severe complications. The management includes warming the contralateral extremity

to produce reflex vasodilation and using nitroglycerine and pentoxifylline to the affected extremity.^{2,3} We report a case of a preterm infant who developed severe vasospasm after a PAL insertion followed by a gangrenous look of the toes. The objective of the case study is to address the role of timely recognition, communication, and treatment plan instituted by the nursing staff in the management of vasospasm associated with PAL insertion.

Case

An extremely preterm female infant was born by cesarean section at 26 weeks' gestation. The pregnancy was complicated by fetal growth restriction, absent end diastolic flow, and middle cerebral artery cephalization. The birth weight was 550 grams (6.38%, Z = -1.52, small for gestational age). There was no maternal history of prothrombic disorders. The infant was intubated at delivery. The umbilical arterial (UAC) and venous catheters (UVC) were inserted in the NICU on admission. Due to malposition, the UVC was replaced by a peripherally inserted central catheter (PICC) line on the day of life (DOL) 3. The trophic feeds were started on the DOL 5. The infant was placed on a high-frequency ventilator on admission. She was extubated to a non-invasive positive pressure ventilator (NIPPV) on DOL 2. On DOL 4, she was placed on bubble CPAP. The UAC was continued for laboratory analysis and BP monitoring (PAL was inserted with the removal of the UAC for the same reason). On day five of life, the infant developed abdominal distension (Figure 1, panel A). The x-ray showed pneumoperitoneum (Figure 1, panel B). To prepare for exploratory laparotomy, the UAC was removed, and a PAL (24-gauge angiocath) was inserted

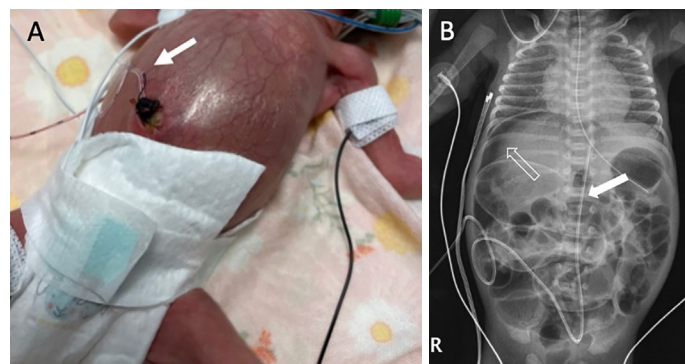


Figure 1. Panel A: Picture showing abdominal distension, an umbilical arterial catheter (white solid arrow). Panel B: X-ray showing pneumoperitoneum (open white arrow) and an umbilical arterial catheter (solid white arrow).

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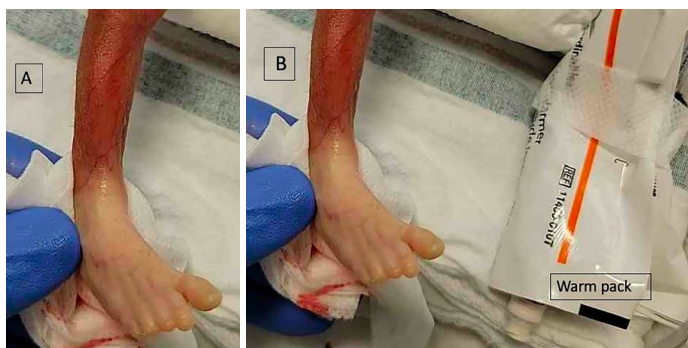


Figure 2. A: Sudden Blanching of the lower right foot extended above the ankle. B: Warmer applied to the Left Leg.

in the right posterior tibial artery. The line flushed well without any signs of extravasation or swelling. An intra-arterial infusion was started with 0.45 normal saline heparinized solution (0.5 Units per mL at 0.5 mL/hr). Within a few minutes of infusion, the bedside nurse noted a sudden blanching of the leg up to the level of the ankle (Figure 2, panel A). The PAL was removed immediately, a warm compress was applied to the contralateral extremity (Figure 2, panel B), and use of 2% nitroglycerine cream application to the affected extremity. An immediate improvement was noted with the restoration of circulation (Figure 3, panel A). However, the rapid improvement in circulation was followed by dusky-looking toes (Figure 3, panel B). A Doppler study was performed the next day that was negative for any thrombus. Over two weeks, the duskiness improved (Figure 3, panel C). At the time of the report (4 weeks), the infant had recovered entirely with some scab formation (Figure 3, panel D). The affected foot has a full range of motion with no deficit, and the infant moves all the toes spontaneously.

Discussion

Complications of PAL primarily occur in the distal extremity of the catheter placement. Most commonly, these are thromboembolic events with ischemia of the digits.^{4,5} The plausible reason for the increased susceptibility of preterm neonates to vasospasm and thrombosis could be the small arterial diameter relative to the catheter size. The other could be the infusion of the wrong fluid; no fluid other than heparinized saline flush solution should be administered into a PAL.

The case was unique as the infant was extremely preterm, with a birth weight of 550 grams, and had vasospasm related to the posterior tibial artery (PTA) managed by warming the contralateral extremity and nitroglycerine without using pentoxifylline. Warm compress on the opposite limb causes reflex vasodilation, while nitroglycerine is a smooth muscle relaxant.²

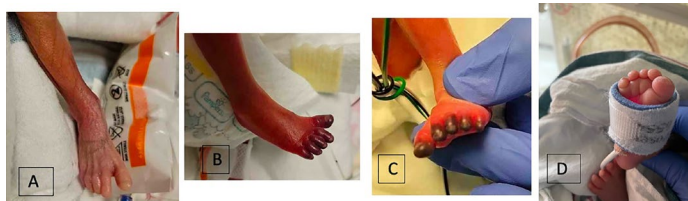


Figure 3. A: Disappearance of blanching with the restoration of blood flow. B: Dusky appearing Toes. C: Dusky Toes (tips only). D: Healed Toes (mild dry scabbing on tips)

Most vascular complications reported in neonates are secondary to brachial artery cannulation.^{2,3} Mosalli et al.² described a case of a critically ill, 520-gram 25-weeker preterm infant with ischemic changes after brachial artery cannulation. Bayraktar and Tanyeri-Bayraktar³ described a case series of nine neonatal vasospasm and thromboembolism. Only one infant was 24 weeks, 870 grams, and that infant had a complication related to the brachial artery cannulation. Similarly, Berzel et al.⁶ found acute brachial artery thrombosis in a neonate. In contrast, Schindler et al.⁷ studied 1473 neonates and reported that cannulation of the brachial artery did not result in permanent ischemic damage. They concluded that the brachial artery could be considered for cannulation in neonates.

Spahr et al.⁸ reported a case series of 15 neonates with 17 cases of catheterizations of the PTA. They found no short-term complications from the procedure. Abrahamson et al.⁹ described a case of a preterm infant with irreversible foot ischemia related to PTA cannulation that unfortunately resulted in a below-knee amputation.

In conclusion, close observation is needed when inserting PAL in EP infants. In the case described, early detection through close monitoring by the nurses and immediate management by the NICU team saved this premature baby from potential complications associated with posterior tibial arterial cannulation.

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Completing Interests Statement

Authors have no competing interests to declare.

Ethical Approval

Parental consent was obtained for the report. No direct patient identifier was used in compliance with the HIPPA.

Acronyms and Abbreviations

NICU	Neonatal Intensive Care Unit
NNP	Neonatal Nurse Practitioner
EP	Extremely preterm
UAC	Umbilical arterial catheters
PAL	Peripheral arterial lines

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Continued on page 47...

Left-Side Neck Mass in a Neonate

Shabih Manzar, MD, MPH

The infant was born by vaginal delivery at a gestational age of 40-3/7 weeks. The prenatal care was limited to two visits during the first trimester. The mother reported no supplemental hormonal therapy during pregnancy. On examination, the infant was noted to have a mass on the left side of the neck (Figure 1). There were no overlying skin changes or color changes. A magnetic resonance imaging (MRI) scan was obtained (Figure 2, panels A and B).

Question

Based on the patient’s history and physical examination, which one is the most likely diagnosis?

- a. Cystic Hygroma
- b. Thyroglossal Duct Cyst
- c. Fetal Goiter
- d. Cervical Hemangioma

See the following table for discussion.

Discussion

The answer is B: thyroglossal duct (TGD) cyst. The mass was excised surgically. During surgery, a stalk of the cyst was noted to be adherent to the thyroid. The pathology showed the cyst wall with fibrosis, acute suppurative inflammation, and minute clusters of thyroid follicles within the wall that was compatible with an inflamed thyroglossal duct cyst. Embryologically, during the sixth week, the thyroid gland descends from the foramen cecum into the pretracheal space through a pathway, the TGD, which degenerates during early pregnancy; however, it may persist at various locations and may present as a cyst at the intralingual, the floor of the mouth, suprahyoid, intralaryngeal, intrathyroidal, and suprasternal areas.^{1,2}

Cystic hygroma would typically show a fluid level within the mass on MRI imaging,³ and tissue biopsy would confirm the presence of lymphatic tissue, which was not the case in the infant. The mass in this patient was on the lateral side, and fetal goiter would present as a midline mass. The mother gave no history of thyroid pathology or replacement hormone therapy. The infant with a cervical hemangioma will typically have overlying skin changes.⁴ Hemangiomas are compressible and

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usually are red or blue in color. None of these findings are noted in the infant.

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Figure 1. Still image of the neck, white arrows showing the extension of the swelling.

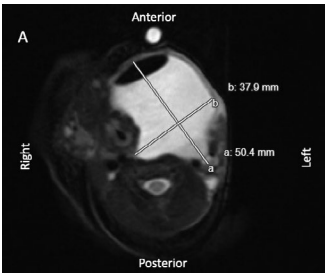


Figure 2. Panel A: Magnetic resonance imaging (MRI), T2 axial image, white lines a and b, showing the extension of the swelling.

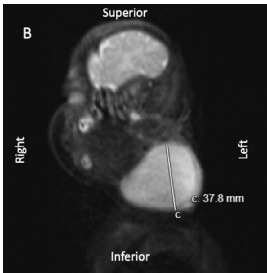


Figure 2. Panel B: Magnetic resonance imaging (MRI), T2 sagittal image, white line c showing the extension of the swelling.

Summary Table

Condition	Characteristics
Cystic Hygroma	Cystic hygroma would typically show a fluid level within the mass on MRI imaging, and tissue biopsy would confirm the presence of lymphatic tissue.
Thyroglossal Duct Cyst	The pathology confirmed clusters of thyroid follicles with acute suppurative inflammation within the wall of the mass compatible with an inflamed thyroglossal duct cyst.
Fetal Goiter	Fetal goiter would present as a midline mass. The mother gave no history of thyroid pathology or replacement hormone therapy.
Cervical Hemangioma	Hemangiomas are compressible and usually are red or blue in color. None of these findings are noted in the infant.

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The Use of Projected Autonomy in Antenatal Shared Decision-Making for Periviable Neonates: A Qualitative Study

Megan J Thorvilson, Katherine Carroll, Bethany D Kaemingk, Karen S Schaepe and Christopher A Collura

Abstract

Background. In this study, we assessed the communication strategies used by neonatologists in antenatal consultations which may influence decision-making when determining whether to provide resuscitation or comfort measures only in the care of periviable neonates.

Methods. This study employed a qualitative study design using inductive thematic discourse analysis of ‘naturally occurring data’ in the form of antenatal conversations around resuscitation decisions at the grey zone of viability. The study occurred between February 2017 and June 2018 on a labor and delivery unit within a large Midwestern tertiary care hospital. Participants included 25 mothers who were admitted to the study hospital with anticipated delivery in the grey zone of viability and practicing neonatologists or neonatology fellows who partnered in antenatal consultation. We used a two-stage inductive analytic process to focus on how neonatologists’ discourses constructed SDM in antenatal consultations.

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First, we used a thematic discourse analysis to interpret the recurring patterns of meaning within the transcribed antenatal consultations, and second, we theorized the subsequent effects of these discourses on shaping the context of SDM in antenatal encounters.

Results. In this qualitative study, that included discourse analysis of real-time audio conversations in 25 antenatal consults, neonatologists used language that creates projected autonomy through (i) descriptions of fetal physiology (ii) development of the fetus’s presence, and (iii) fetal role in decision-making.

Conclusion. Discourse analysis of real-time audio conversations in antenatal consultations was revelatory of how various discursive patterns brought the fetus into decision-making, thus changing who is considered the key actor in SDM.

Background

The anticipated delivery of periviable neonates necessitates supportive counseling of pregnant women by perinatal providers.¹ In the imminent delivery of a neonate at the grey zone of viability, 22 to 24 weeks of gestation, shared decision-making (SDM) among clinicians and parents is the most supported approach.¹⁻³ to determine whether the provision of resuscitation or comfort-focused care is in the best-interest of the newborn,¹⁻⁸ and challenges related to training and communication skills can compromise the encounter.⁹⁻¹³

Further, SDM must account for pluralistic values and preferences among families, providers, and institutions.¹⁴⁻¹⁹ As such, wide variation exists in both clinical practice and antenatal consultation of families^{13,16-18,20} with treatment decisions for extremely preterm infants resulting in long-lasting moral distress for families and providers.²¹

In SDM for periviable infants, neonatologists may play the role of choice architects, tasked with framing parental understanding of the medical decision in the context of clinical facts.¹¹ This role requires neonatologists deliver understandable information while balancing personal beliefs to help parents express their own values towards the formulation of goals of care.^{22,23} As such, decision-making for periviable neonates is subject to significant biases, including framing effects, anchoring, optimism, or implicit prejudgment.^{4,24-26} The use of language in the counseling encounter may play a significant role in shaping understanding, constructing goals, or compelling decision-making.

In this study, we aimed to better understand the communication strategies used by neonatologists which may influence decision-making when determining whether to provide resuscitation or comfort measures only in the care of periviable neonates.

Methods

This study employed a qualitative study design using inductive thematic discourse analysis of ‘naturally occurring data’^{27,28} in the form of antenatal conversations around resuscitation decisions at the grey zone of viability. The objects of investigation are the transcripts derived from 25 real time audio-recorded antenatal consultations between neonatologists and pregnant women within a large Midwestern tertiary care hospital in the USA. The study was approved by Mayo Clinic’s Institutional Review Board (IRB #15-003365).

Antenatal consultations were purposively sampled and audio-recorded according to the following criteria: (1) mothers were admitted to the study hospital with anticipated delivery in the grey zone of viability defined as 22 0/7 to 24 6/7-weeks’ gestation, or when additional factors prompted SDM regarding resuscitation status for an extremely preterm neonate (ii) antenatal consultations were conducted by either practicing neonatologists or neonatology fellows (hereafter “neonatologists”). In the majority of antenatal consultations (22/25), a mother’s partner or other family member was present.

Between February 2017 and June 2018, 25 of 28 families approached by the study team consented to participate. Eligible mothers were not approached for consent in cases of precipitous labor and delivery. Neonatologists started audio-recorders upon commencing the consultation and stopped audio-recorders at the end. Participants were informed they could request the audio-recording be turned off at any time; no recording was interrupted

in our study. The consults were anonymized by the removal of participant names, assigned a randomly-generated reference number, and transcribed by expert qualitative transcriptionists.

Demographic data of the participating pregnant woman including sex, race, age, marital status, pregnancy gestation, and birth outcome were collected. The participating neonatologists were represented by 2 females and 8 males; all identified as white race. One of the neonatologists both designed and participated in the study. That neonatologist removed himself during the teams’ analysis of his two consultations to allow for frank discussion by the research team. Following an interpretivist qualitative methodology, all participants and researchers were cast with active involvement in meaning construction as an interpretive practice during both the recorded antenatal conversation and our research analytic practice.²⁹ Details of consultations were previously published.³⁰

Discourse analysis unpacks the assumptions that underpin what is said,³¹ and the potential consequences for those who are positioned by these discourses.^{32,33} We used a two-stage inductive analytic process to focus on how neonatologists’ discourses constructed SDM in antenatal consultations. First, we used a thematic discourse analysis to interpret the recurring patterns of meaning within the transcribed antenatal consultations, and second, we theorized the subsequent effects of these discourses on shaping the context of SDM in antenatal encounters.^{27,32} The team initially read five transcripts to discuss, determine, and agree upon the major themes in the text that were of interest to clinical practice. One researcher (KC) then returned to the remaining 20 transcripts to complete preliminary coding and develop a code book. Each co-author then reviewed the coded transcripts and code book for accuracy.

Further details on the coding process and the development of themes are published elsewhere.³⁰ This paper examines one theme, entitled Projected Autonomy, that was deemed by the clinical researchers (CC and MT) to be clinically relevant because it was both pervasive in the data set (Table 1) and pertinent to the study focus on SDM. A second researcher (MT) conducted a discourse analysis of this theme across the 20 antenatal consultations where it was present, with a focus on the assumptions embedded in the thematically coded discourse and their effects on establishing antenatal SDM.

Results

In this paper, we focus on the common practice of producing “Projected Autonomy” in antenatal consultations. We use the term projected autonomy to describe the use of language granting the fetus the right of participation or even ownership of decision-making during antenatal consultations. Our discourse analysis revealed that neonatologists used language that creates projected autonomy in 20 of 25 consults recorded in our study, albeit with varying degrees of impact (Table 1).

Projected autonomy changed the role of the fetus from a recipient of medical interventions at birth to an actor within medical decisions in the NICU. Projected autonomy was especially produced by neonatologists when their consultations included descriptions of neonatal physiology, the anticipatory guidance of how the neonate may respond to intensive care, and the baby’s role in decision-making. To examine how projected autonomy features in antenatal consultation, we first explored three analytic categories (i) fetal physiology

Table 1 Distribution of Discursive Strategies that Produce Projected Autonomy:

Consult No.	Fetal Physiology	Development of the Fetus's Presence	Fetal Role in Decision Making
441		*	
180	*		
723	*		
582	*		*
332		*	
611	*		
41			*
118	*		
145		*	*
210	*		
949	*		*
824	*	*	
678	*		
339	*		
393	*		*
714	*		
866	*		
516	*		
728	*		
276	*	*	

Table 2 Categories, Definitions, and Examples of Projected Autonomy

Sub-categories	Definition	Examples
Physiology	Neonatologists describe the complexity of neonatal physiology, making it more accessible by making the fetus the subject of the actions.	<i>Limits</i> <ul style="list-style-type: none">• Won't be strong enough to do it on their own• Don't realize they need to make the transition• Won't be able to breathe on his own.• They don't know how to feed on their own. <i>Responder</i> <ul style="list-style-type: none">• We'll watch and see how he's responding...• Based on how your child's responding• If he doesn't respond, it's just too early for him• We'll see how he responds – how he's growing, how his activity is over time <i>Recipient of Help</i> <ul style="list-style-type: none">• We'll help them breathe, stay warm, support blood pressure <i>Actor</i> <ul style="list-style-type: none">• Baby's job is to grow the placenta.• He's pumping blood through the umbilical cord.• He's still got room to wiggle in there.• Your baby is growing. He's becoming more mature.• Declares it's her turn to come into the world.• He'll figure out how to eat.• They kind of fix themselves.
Development of the Fetus's Presence	Neonatologists refer to the fetus in a future state, beyond the NICU course. Neonatologists use adjectives or nouns to depict strength and vigor.	<ul style="list-style-type: none">• We want him running around terrorizing his brother.• ... keeping up with his brother and sister.• I hope he's not too much trouble.• She's active.• She's strong.• He or she is the boss here.• We are her soldiers, all aligned and listening.• He's got a will to live.• Fighter like his dad.• He's got the highest mountain to climb.

(ii) development of the fetus's presence, and (iii) fetal role in decision-making.

Fetal physiology

The first category of neonatologists' communication contributing to projected autonomy is "fetal physiology" (Table 2) Fetal physiology was the most pervasive discursive device throughout the consults, appearing in 16 of 25 (Table 1).

Discussing limitations in fetal physiology due to extreme prematurity, neonatologists laid the foundation for necessary intensive interventions. One neonatologist stated that neonates "don't realize they need to make the transition" (from in utero to ex utero) to describe the potential for pulmonary hypertension

and its treatment (Consult 393; line 68). Another outlined that a neonate "won't be able to breathe on his own" (Consult 276; line 61), setting up the rationale for intubation and ventilation.

Neonatologists discursively highlighted how they attune to baby's physiological response to initial treatment to assess the efficacy of interventions and further inform SDM. For example, "Let's see how things go when the baby's born, let's see what the data looks like as far as how he is going to respond, what his head ultrasound looks like, and make a decision if we're doing the appropriate thing, you know, after the baby's delivered" (Consult 866; line 513).

Further promoting the role of the neonate's physiology in SDM, some neonatologists described their role as assistants to the baby's physiology. "We do what we need to do to keep them [neonates] be stable — help them breathe, help them stay warm, maybe help their blood pressure" (Consult 723; line 421). This description grants the fetus a more active role in managing their own physiology. With the strongest description of the neonate's responsibility for his/her physiology, one neonatologist shared, "...but they mostly fix themselves" (Consult 714; line 472). This description gives the fetus the primary role in their physiology, minimizing the critical role of medical staff and technologies.

Development of the fetus's presence

The second discursive strategy contributing to fetal projected autonomy is "Development of the Fetus's Presence" (Table 2). During the prenatal consults, neonatologists established the presence of the fetus in two primary ways: future orientation and attribution of characteristics. The neonatologists referred to the imagined life of the fetus beyond the NICU as evidence for the efficacy of medical interventions or as a counter-balance to challenging discussions around potential morbidity and uncertainty in neonatal medicine. As an example, one neonatologist described, "...a baby starts maturing to the point that if he is born early then the medicines and the procedures that we do as physicians and nurses can make a difference and that he can survive and that he can run and play with his brothers, sisters" (Consult 276; line 28). By projecting the future, neonatologists provided a positive glimpse of the child's life beyond the ICU and advanced the premature fetus to a phase of life that is much easier for parents to conceptualize.

Neonatologists also established the neonate's presence through attribution of characteristics. Neonatologists used adjectives or nouns that suggested strength and resilience to describe the neonate or to mirror the parents' descriptions of the fetus. These descriptions included "active," "strong," "a boss," and often appeared near the beginning of the consult or following delivery of challenging information, such as population-based survival statistics for very premature infants and the potential for death during resuscitation. For example, shortly after describing the potential of the baby not responding to resuscitation, the neonatologist asked, "Is he a fighter like his dad?" (Consult 276; line 189). These characteristics begin to define and shape the parents' understanding of the child they have yet to meet.

Through establishing a future orientation of the neonate and attributing character traits, neonatologists shape the neonate's presence and developing autonomy outside the womb, establishing a being who can assume more responsibility in decisions.

Table 3 Fetal Role in Decision-Making

Example 1	<i>Then that's something we would come and we'd talk to you and we'd say, hey listen, this is where things are at, despite all intensive care that we can offer, your baby, you know, we can't get things where we want, and it's basically, that's the sign, that's your baby telling us that, you know, just the lungs are too premature (Consult 41; lines 929–934).</i>
Example 2	<i>If-if find that we are starting resuscitation and that he's just not responding then we come to you and say "you know he's just not responding. I think he is telling us that he wants to be with mom and dad." And literally that's what happens we stop what we're doing and we bring him to you, and you can be a family for a very short period of time (Consult 145; lines 276–278).</i>
Example 3	<i>Because sometimes, babies tell us and, ultimately, they guide the decision-making, and they tell us my body's not ready in this world and you're doing everything, but I'm not responding; I'm not getting better (Consult 949; lines 454–456).</i>
Example 4a	<i>And the other thing I'll tell you that, you know, sometimes I don't, I don't know what moms and dads necessarily feel pressure alleviated, but sometimes it's not even you making the choice; it's your baby (Consult 393; lines 213–214). . . Sometimes after, you know, the first couple days, we have more information regarding bleeding or infection and, or his lungs are really not working for him, and families make the decision to listen to the baby and, and stop the support (Consult 393; lines 225–227).</i>
Example 4b	<i>Your decision, whichever it is, is the right answer, um, and that's something we just want you to know in your heart and your head, whatever you decide is the right decision, and we'll support you. And if your baby, he, if he tells us differently, we'll, we'll let you know (Consult 393; lines 417–419).</i>
Example 5	<i>I think you know one of the challenges of what it can feel like when I come in or when one of my colleagues comes in to talk to you is that you're making a decision whether your child may live or die. And I, my hope is that we can somewhat reframe that question and not take away a little bit about the question of your child is gonna make the decision. He or she is the boss here. We are kind of ah their, his or her soldiers, and we're looking to make sure we're all aligned and, and listening to your baby. And to not feel responsible of that decision because he or she is guiding it. And it's just us listening (Consult 582; lines 345–356).</i>

Fetal role in decision making

The third discursive strategy that enhanced the fetal role in periviable decision-making appeared in five consults (Table 3). While not the most prevalent, we argue it was the most impactful.

With this strategy, the neonatologist included the fetus not only as the individual affected by the decision, but an independent contributor in SMD. In some of the examples, the language used alluded to the fetus providing important information to the neonatologist directly, including that the baby could not survive. In others, the language delegated the sole responsibility for the decision to the fetus. To explore the fetus's role in decision making, we examine five examples in order of increasing authority delegated to the neonate.

Example 1 The parents ask the neonatologist when to expect greater clarity on the severity of illness for the baby, which might prompt a transition to comfort-focused care. The neonatologist grounds the response in the delivery room during the resuscitation. The neonatologist describes that the baby may not respond to resuscitation and is therefore “telling us” that their lungs are too immature. This input from the baby would then inform a recommendation to focus on comfort (Table 3, example 1).

Example 2 The family articulates the importance of quality of life for their child and finds reassurance when the neonatologist describes multiple opportunities to revisit decisions throughout the treatment course. As the consult progresses, the neonatologist describes the initial resuscitation. The family asks, “Are there complications with resuscitation?” The neonatologist describes the possibility of death, prompted by the neonate’s “telling us” that he wants to have time as a family (Table 3, example 2).

Example 3 To frame this consult, the neonatologist sets up two possible paths forward—a comfort-focused or an intensive care plan, and then outlines the common neonatal challenges, including lung disease, necrotizing enterocolitis, intraventricular hemorrhage, and the potential for surgery. The family articulates their decision to “go with the second option where you guys would do everything.” The neonatologist responds with potential roadblocks and how those roadblocks can be the baby “telling us” that their body is not ready, thus participating in the decision (Table 3, example 3).

Example 4 The parent asks specifically about survival rates for preterm infants. The neonatologist goes on to describe the uncertainty inherent in neonatal medicine and introduces the concept of comfort-focused care. The grandmother then states that the choice is the parents’ alone, “No one else can make that choice for you.” The neonatologist subsequently offers that it may not be the parents’ choice and offers the alternative to “listen to” the choice of the baby (Table 3, example 4a).

As the consult progresses, the family considers the difference between starting and stopping interventions. They request specific numbers for the outcome of neonates born at 22 weeks. The neonatologist again refers to the significant uncertainty for neonates at 22 weeks gestation and shares that there is no right answer. The neonatologist then pivots and assures the family that whatever decision they make will be the right one, again referencing the baby as an actor in the decision through his “telling us” of the right decision (Table 3, example 4b).

Example 5 The parents ask, “For me I mean it’s just at what point we have the right to have a decision about things and at what point during the process, weeks wise, what decision do we have” (lines 13–14). The mother draws from the experience of a friend’s premature infant’s death without access to tertiary neonatal care, and how their lack of opportunity “haunts” her. Following this description, the neonatologist shifts the burden of the decision from the parents (“you’re making a decision whether your child may live or die”) to the fetus (“your child is gonna make the decision”), and clarifies that the parents’ responsibility is to listen to their child (Table 3, example 5).

Discussion

With projected autonomy, neonatologists elevated the role of the fetus in prenatal consults, granting the fetus participation in decision-making during antenatal consultations. Projected autonomy appeared in the majority of consultations. Projected autonomy’s use was most prevalent in Fetal Physiology and most impactful in Fetal Role in Decision Making. In the context of SDM, our analysis showed neonatologists used projected autonomy to efficiently convey complicated information, orient parents to the potential challenges ahead, foster a sense of hope and trust, and guide parents to a decision around resuscitation.

Referencing Fetal Physiology allowed neonatologists to distill complex information about neonatal physiology to parents, thus equipping them with information to make informed decisions.^{34,35} Beyond descriptions of physiology, the neonatologists shared how the neonate's physiology and response to interventions could serve as a tool for frequent re-evaluations throughout the NICU course, further informing SDM.

Neonatologists' discursive strategy of Development of the Fetus's Presence infused hope into the prenatal consult. As parents face the potential reality of preterm delivery and the impact for their child and family, they inevitably feel fear and despair.³⁶ The transition from hoping for a "normal" pregnancy to the possibility of morbidity and even death is disorienting for parents.³⁷⁻³⁹ A description of life beyond the NICU may be one strategy that neonatologists use to offset parental anxiety, allowing a moment of decompression in the high-stakes prenatal consult.^{40,41} It may also help parents that neonatologists can envision a hopeful path forward with survival for their child, thereby building trust in the neonatal team.⁴²⁻⁴⁴

Beyond hope and trust, the reference to a child's future may produce bias towards resuscitation as the outcome of the medical decision. The description of a child's future life assumes survival beyond the NICU, and the references to milestones (i.e., running) paint a picture of a normal or near-normal childhood. The attribution of characteristics of "strong" and "a fighter" may also favor resuscitation. These powerful life-assuming adjectives describe a vigorous (yet unknown) child and carry the potential of favoring resuscitation.

The strategy utilized by neonatologists to grant the fetus a role in SDM offers the most powerful example of projected autonomy. Projected autonomy, as seen in the examples of decision-making, may allow neonatologists to offload some of the burden of the decision around resuscitation from both the parents and neonatologist.^{45,46} By introducing a new participant in the decision—the participant most affected by the decision—the decision's weight is distributed across the parent, the neonatologist, and now the neonate. As a result of projected autonomy in SDM in the antenatal consultation, the distribution of the burden includes the neonate and creates more space for parents to attune to the neonate as the newly realized participant in the decision.⁴⁷ Further, it may even suggest that decision-making is no longer necessary if the baby projects self-determination via grave illness that further intensive interventions may no longer be helpful.

Clinically, this transformation of dyadic SDM between the neonatologist and the parents to triadic SDM transforms what was previously a binary decision at the prenatal consult—to resuscitate or not—to one that includes a third option, namely "a trial of intervention".⁴⁸ This transformation ultimately places the response of the infant at the center of the decision and stretches this communicative role of the infant into the NICU course.

One strength of a trial of resuscitation and the extension of the decision is the mitigation of uncertainty around outcomes for extremely premature infants.⁴⁸ The inability to accurately and consistently predict the NICU course and the developmental outcomes can be uncomfortable and unnerving for neonatologists.^{19,45,49} As we saw above, one neonatologist

postponed the decision from the prenatal consult, suggesting they return to the decision in the initial days after birth when they could truly speak to the reality of the head ultrasound, risk of infection, and pulmonary function. Waiting to gather more information after the child's birth, neonatologists create space to move further along the spectrum from uncertainty towards certainty when the stakes are so high.⁵⁰

While we caution against applying projected autonomy broadly beyond the clinical space of SDM, our study suggests that projected autonomy onto the fetus is a distinct discursive strategy that may be commonly utilized by neonatologists. This has the effect of deferring the antenatal decision into the postnatal NICU course in order to incorporate clinical events into SDM. This discursive strategy perhaps also attests to the broader discomfort of proactively discussing care at the margins of life, including the possibility of death, particularly among babies and the young in the culture of acute-care medicine.⁵¹ By its nature, a qualitative study design aims to understand the particulars and the meaning of naturally-occurring data derived from a specific sample of the population.^{28,52} Qualitative discourse analysis of prenatal consults offers clinical staff insight to the content and efficacy of these clinical encounters. This study was conducted at a single Midwestern regional referral center and included neonatologists from a homogenous white racial background. Therefore, the main limitation to the study is transferability to other neonatal treatment locations within the United States and worldwide.⁵² Despite this limitation, this study adds a unique perspective to the medical literature through the utilization of discourse analysis of real-life medical encounters during antenatal consultations.

Conclusion

Discourse analysis of real-time audio conversations in antenatal consultations was revelatory of how various discursive patterns brought the fetus into decision-making, thus changing who is considered the key actor in SDM.

Abbreviations

SDM Shared decision making
NICU Neonatal intensive care unit

Author contributions

MT contributed to data collection, design of the codebook, data analysis, and drafted the initial manuscript; KC contributed to the design of the study, including the codebook, and data analysis; BK and KS contributed to the design of the codebook and data analysis; CC provided direct oversight of each step of the study, including conceptualization and design of the study, design of the codebook, supervision of data collection, and data analysis; and all authors approved the final manuscript as submitted and are accountable for all aspects of the work and accuracy and integrity of all data as presented.

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Data Availability

Data will be kept confidential to protect the confidentiality of the patients in the study.

Declarations

Competing interests

The authors declare no competing interests.

Ethical approval

The study was approved by the Mayo Clinic's Institutional Review Board (institutional review board 15-003365).

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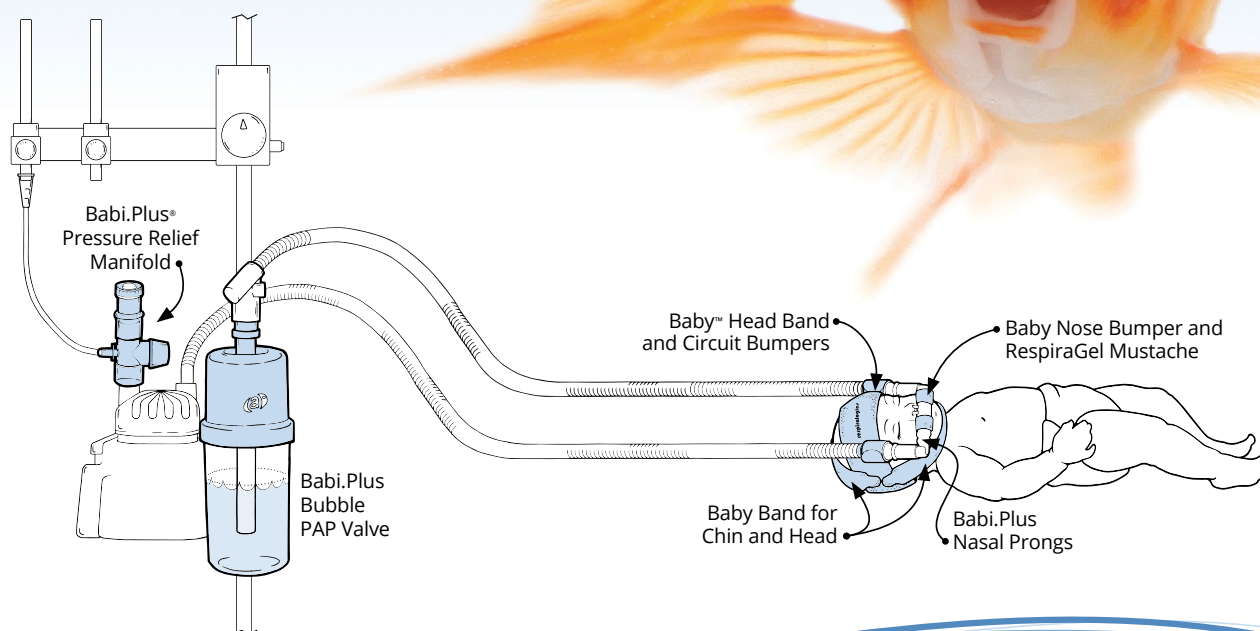
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