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- Easy to clean for infection control [15,16]
- Disposable liners for each infant bath [15,16]
- Decreased risk of hypothermia and hypoglycemia [2,3,4,6,8,9,10]

Supports Developmental Care

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- Parents can do the bathing [11,12,13]
- Facilitates parent bonding [13]
- Supports breast feeding [9,10]

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- Less time and less steps than sponge bathing [9]
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- Increase Patient Satisfaction
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- Research based best practice for bathing. [1, 5,14]
- Swaddle bathing is recommended by AWHONN and NANN [1, 14]

References available upon request

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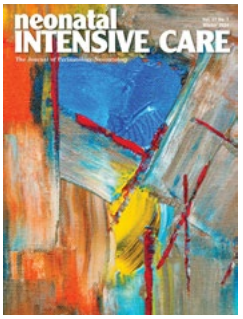

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DEPARTMENTS

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Physical Strength Recovery After Birth

BM Petrikovsky, MD, PhD

The earliest recommendations for exercise reflect the cultural and social norms of the time. In the 18th century, doctors promulgated numerous limitations such as instructing patients to avoid strenuous exercise and dancing or horseback riding, among others. The first studies on physical activity and its effect on birth outcomes were published in the late 19th and early 20th centuries. These studies attributed lower infant birth weights to increased levels of occupational and household work. In the beginning of the 20th century, 'moderate activity' was defined as a daily walk of at least 2-6 miles.[1] In 1949 the US Children's Bureau issued the first standard recommendations for prenatal exercise which concluded that pregnant women can continue housework, gardening, daily walks of up to 1 mile and swim occasionally but should avoid active participation in sports (Federal Security Agency and Social Security Administration, 1949).

In 1985 ACOG issued the first guidelines for prenatal exercise based on a consensus opinion of a panel of obstetricians. The opinion instructed pregnant women to exercise caution with high impact activities and included restrictions on duration (e.g., no activity longer than 15 minutes for strenuous exercise) and heart rate (e.g., heart rate should be no greater than 140 beats per minute).[1]

In 2002, ACOG updated its guidelines and recommended 30 minutes of moderate intensity physical activity ("PA") during most days of the week for women without medical/obstetrical complications. The guidelines also suggested that participating in a wide range of recreational PA is safe. (ACOG, 2002).

Recent WHO guidelines state that all pregnant and postpartum women without that contraindication should do at least 150 minutes of moderate intensity aerobic PA of varying muscle strengthening type throughout the week.

We proposed a new test to assess placental reserves by measuring fetal heart rate ("FHR") responses to maternal exercise. A cohort of 640 term patients underwent an exercise test for accepted clinical indications. A total of 1680 tests were performed using a motorized treadmill in a moderate exercise regimen. Abnormal FHR responses to maternal exercise (late decelerations, fetal bradycardia) were associated with adverse neonatal outcomes. Overall, positive test results were associated with 29% of category III FHR tracing.[1] With regard to adverse neonatal outcomes, 1.6% of 5 minute Apgar scored less than 7, and there were only 9.8% admissions to the intensive care nursery, 2.2% of growth restrictions, and 1.2% of fetal or early neonatal demises.[2]

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

Postpartum Physical Fitness

Despite the importance of knowledge on the timing and progress of postpartum physical recovery, there is a paucity of quality research in this area. Therefore, a recent study from a number of medical hospitals including Walter Reed Medical Center deserves special attention.[3] In February 2016, the US army increased their postpartum leave policy from 6 to 12 weeks.[4] Previously, all female soldiers had returned to physical fitness training 6 weeks after delivery. All study subjects underwent the following exercise regime: push-up exercises to assess muscular endurance of their chests and upper arms, as well as sit-ups to assess muscular endurance of their core and hip flexors. The women were permitted to rest during push ups with their arms fully extended, and during sit ups only when their spines were perpendicular to the ground. They then completed a 2-mile run to assess aerobic fitness. Walking was permitted but discouraged.[3] Postpartum female soldiers has a 10% drop in push-up and sit-up repetitions. Similarly, smaller studies reported failure rates between 7 to 25% on fitness assessments in the first year postpartum (4-6). Results showed that chest, shoulder and upper arm strength is less likely to be adversely affected by pregnancy than are abdominal muscles. Recovery of physical strength after cesarean section was no different from the one after vaginal birth.

Summary

Pregnancy poses challenges for a woman's physical fitness. Women who are granted 12 weeks of maternity leave had no adverse outcome on physical fitness at 9 months postpartum.

- Postpartum recovery of physical strength requires further study.
- Upper body strength recovers faster than the strength of the abdomen and low extremities.
- Physical strength recovery after cesarean delivery is the same as after vaginal birth provided both are uncomplicated.
- All conclusions can be used when counseling women who are not in active army duty but who were fit and/or in good physical shape prior to the onset of pregnancy.

References upon request. The author wants to thank Adina Feder, Esq. for valuable editorial comments.

News

☐ Winter 2024

Pandemic Drove Premature Births Up, Vaccinations Brought Numbers Down: Study

The number of premature births in California jumped during the first year of the COVID-19 pandemic and came back down after vaccinations became widely available, new evidence reveals. For example, researchers found that during that year, there was a 29% increase in deliveries before 37 weeks of gestation. In absolute percentages, rates increased from 7.3% to 8.7%. When they accounted for maternal social, demographic, and other factors, there remained a 15% increase in the likelihood of preterm births, from 7.3% to 8.4%. This increased rate that was associated with the pandemic in 2020 disappeared completely by 2022. But not all areas of the state returned to baseline quickly. "One finding that was surprising is the sharp decline in the impact of maternal COVID-19 infection on preterm birth in areas with high vaccination rates compared to areas with low vaccination rates," said lead investigator Florencia Torche, PhD, professor of sociology at Stanford University in California. "This sharp decline supports the claim that it was vaccination—rather than alternative health-protecting behaviors among pregnant people—that accounts for the reduction in preterm risk," Torche said. Rates of premature births did not differ significantly until May 2021, the point that vaccines became more widely available. However, in comparing babies born to women who tested positive at birth from July 2020 to February 2023 to siblings not exposed to COVID, they found "marked differences." COVID vaccination helped avoid thousands of preterm births and related complications, the authors note. It was also cost saving. Research shows that each preterm birth was estimated to cost more than $80,000, they added. "A critical implication of this study is that vaccination provides an effective protective mechanism for the health of the newborn, substantially reducing the risk of preterm and other adverse infant health outcomes," Torche said. The observations are "not necessarily surprising, given that some studies had proposed that COVID was associated with preterm birth, while others, carried out in the late period when the majority of women were vaccinated, no longer found this association," said Emmanuel Bujold, MD, full professor of maternal and fetal medicine in the Faculty of Medicine, Laval University, Quebec, Canada, who was not affiliated with the study. "But these were only indirect scientific evidence, whereas the study proposed today represents direct evidence of the benefit of vaccination." Bujold said this scientific approach confirms the hypotheses from some smaller studies and helps to reassure pregnant women about vaccination. "Personally, I feel that these data, combined with previous studies on the safety of vaccination, are sufficient to recommend vaccination against COVID-19 to pregnant women." Torche cautioned that even though the news from this study is positive, there is no guarantee that preterm birth rates related to the pandemic will remain at baseline. "The consequences of COVID-19 infection might increase in the future as viral variants change and immunity conferred by vaccination or prior infection wanes." Moving forward, Torche and her colleague Jenna Nobles, PhD, hope to drill down deeper into the data beyond preterm rates based on ZIP code to evaluate the effects of COVID vaccination for individual pregnant women.

AHA, AAP Update Neonatal Resuscitation Guidelines

The American Heart Association (AHA) and American Academy of Pediatrics (AAP) have issued a focused update to the 2020 neonatal resuscitation guidelines. The 2023 focused update was prompted by four systematic literature reviews by the International Liaison Committee on Resuscitation (ILCOR) Neonatal Life Support Task Force. The groups noted that

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effective positive-pressure ventilation (PPV) is the priority in newborn infants who need support after birth. And while the 2020 update provided some details on devices to be used for PPV, the 2023 focused update gives guidance on use of T-piece resuscitators for providing PPV, which may be particularly helpful for preterm infants, and the use of supraglottic airways as a primary interface to deliver PPV, he explained. Specifically, the updated guidelines state that use of a T-piece resuscitator to deliver PPV is preferred to the use of a self-inflating bag. Because both T-piece resuscitators and flow-inflating bags require a compressed gas source to function, a self-inflating bag should be available as a backup in the event of compressed gas failure when using either of these devices. Use of a supraglottic airway may be considered as the primary interface to administer PPV instead of a face mask for newborn infants delivered at 34 0/7 weeks' gestation or later. The updated guidelines continue to emphasize delayed cord clamping for both term and preterm newborn infants when clinically possible. There is also a new recommendation for nonvigorous infants born 35-42 weeks' gestational age to consider umbilical cord milking. Specifically, the guidelines state: For term and late preterm newborn infants ≥34 weeks' gestation, and preterm newborn infants <34 weeks' gestation, who do not require resuscitation, delayed cord clamping (≥30 seconds) can be beneficial compared with early cord clamping (<30 seconds). For term and late preterm newborn infants ≥34 weeks' gestation who do not require resuscitation, intact cord milking is not known to be beneficial compared with delayed cord clamping (≥30 seconds). For preterm newborn infants between 28- and 34-weeks' gestation who do not require resuscitation and in whom delayed cord clamping cannot be performed, intact cord milking may be reasonable. For preterm newborn infants <28 weeks' gestation, intact cord milking is not recommended. For nonvigorous term and late preterm infants (35-42 weeks' gestation), intact cord milking may be reasonable compared with early cord clamping (<30 seconds). The guidelines also highlight the following knowledge gaps that require further research: Optimal management of the umbilical cord in term, late preterm, and preterm infants who require resuscitation at delivery. Longer-term outcome data, such as anemia during infancy and neurodevelopmental outcomes, for all umbilical cord management strategies. Cost-effectiveness of a T-piece resuscitator compared with a self-inflating bag. The effect of a self-inflating bag with a positive end-expiratory pressure valve on outcomes in preterm newborn infants. Comparison of either a T-piece resuscitator or a self-inflating bag with a flow-inflating bag for administering PPV. Comparison of clinical outcomes by gestational age for any PPV device. Comparison of supraglottic airway devices and face masks as the primary interface for PPV in high-resourced settings. The amount and type of training required for successful supraglottic airway insertion and the potential for skill decay. The utility of supraglottic airway devices for suctioning secretions from the airway. The efficacy of a supraglottic airway during advanced neonatal resuscitation requiring chest compressions or the delivery of intratracheal medications.

Saving Preterm Babies: Research Shows Deferred Umbilical Cord Clamping Works

For preterm babies, delaying umbilical cord clamping after birth reduces the risk of mortality by around 30% in comparison with immediate cord clamping, according to a new meta-analyses published in *The Lancet.* Researchers also assessed the efficacy of cord milking, the practice of pumping blood to

the baby through the cord, and found no statistically significant improvement in the rate of deaths before discharge compared to immediate or deferred cord clamping. While a large body of research shows that deferred cord clamping and cord milking improve infant survival rates, until now, researchers had not reached a clear consensus on which strategies work best, according to Anna Lene Seidler, PhD, senior research fellow at the Clinical Trials Center of the National Health and Medical Research Council at the University of Sydney in Australia. "We brought together this really large database to be able to ask the question, 'What actually works best? How can we improve survival for preterm infants?' " Seidler, the lead author of both studies, said. Previous studies have shown that waiting to clamp the umbilical cord improves circulation, increases iron storage, and lowers rates of brain bleeding. "But to show a decrease in overall mortality is impressive," said Ilina Pluym, MD, assistant clinical professor of obstetrics and gynecology at the David Geffen School of Medicine at University of California, Los Angeles. Although "before practice change can be recommended widely, I would want to see the results repeated among a broader general population." In 2022, 1 in 10 babies in the United States were born preterm. The rate of infant mortality due to prematurity or low birthweight was 87.1 per 100,000 live births in 2020.

Are We Ready for Systematic Newborn Genome Sequencing?

Will the traditional newborn screening program developed 60 years ago by Dr Robert Guthrie soon be superseded by genome screening at birth? Routine sampling and analysis of newborn DNA would allow us to screen for many hundreds of childhood genetic diseases. This is the claim made by David Geneviève, MD, PhD, chair of the French Association of Clinical Geneticists and lecturer at the University of Montpellier, France, at the 9th annual conference of the French Society of Predictive and Personalized Medicine (SFMPP). To date, newborn screening has consisted of taking a drop of blood from a newborn's heel. In the future, DNA samples could be taken from babies for whole genome sequencing to look for diseases that are likely to crop up later in life. "In France, nearly all of the 720,000 babies born each year undergo newborn screening (only 300 refuse)," said Geneviève. For 60 years, newborn screening has tested for phenylketonuria, congenital hypothyroidism, congenital adrenal hyperplasia, sickle cell disease, cystic fibrosis and medium-chain acyl-coenzyme A dehydrogenase (MCAD) deficiency. On January 1, 2023, France's national newborn screening program added seven new diseases, bringing the number of rare diseases screened for to 13. The new diseases are homocystinuria, maple syrup urine disease, tyrosinemia type 1, isovaleric acidemia, glutaric aciduria type I, long-chain 3-hydroxyacyl-coenzyme A dehydrogenase deficiency, and carnitine deficiency. "There aren't just 13 childhood diseases," continued Geneviève. "There are several hundred rare diseases, and genome sequencing tools allow us to broaden our screening capabilities. It's inevitable that the ability to sequence your child's genome at birth will become a possibility. It's highly likely that within 10 to 15 years, all newborns will have their genome determined at birth for screening purposes." Genome sequencing has already been studied for several years in multiple countries. New York's Guardian study requires all newborns taking part to undergo genome sequencing. "Our English-speaking colleagues use the genome to screen for childhood diseases that would benefit from treatment (235 can be treated) but also as a preventive measure and a way of providing early therapeutic education," said Geneviève. In 2016, American researchers launched the BabySeq Project, which was conducted at several sites (Boston, New York, Birmingham, Detroit, and Philadelphia). One of its aims is to assess the medical, psychological, and financial impact of screening via genome sequencing at birth, compared with conventional screening.

Masimo Receives FDA Clearance for Baby Monitoring System

Masimo, a global leader in innovative monitoring technologies used in top hospitals, announced today FDA clearance of Stork, a revolutionary baby monitoring system, for prescription use with healthy and sick babies 0-18 months of age. Leveraging the same Masimo sensor technology that monitors more than 10 million babies in hospitals every year, Stork provides continuous, accurate monitoring of a baby's health. Stork is available at retailers nationwide as a non-medical device for general health and wellness purposes. With this clearance, Stork is now available for prescription use to continuously monitor babies at home as a medical device for healthy or sick babies. "When my son was born, we were concerned about his breathing. Our doctor prescribed pulse oximetry monitoring for a week for him. A therapist arrived at our home with a large standalone pulse oximeter made for hospitals, with cables and wires everywhere and tethered to our son, and charged us $5,000 for a week of monitoring," said Joe Kiani, Founder and CEO of Masimo. "I know how important it is for parents to better understand their baby's physiological well-being, especially when they are sick, and it's our privilege to provide them with an easy-to-use, accurate product that allows them to continuously monitor key vital signs for less than one tenth of the cost I paid, and also includes video surveillance." When prescribed, parents and family members will now be able to receive alarms regarding their baby's oxygen saturation (SpO_2), pulse rate (PR), and skin temperature. They will be able to share these vital signs data remotely with clinicians. In addition, Stork alerts parents if their baby turns over and is sleeping face down, which can be dangerous for babies. Stork leverages the same technology that has been used on babies in the neonatal intensive care unit (NICU) for years, helping to improve health outcomes for the youngest and most vulnerable patients. Known as Signal Extraction Technology, or SET, this technology has helped clinicians reduce the incidence of neonatal blindness from retinopathy of prematurity[1] and has led to significant improvements in screening newborns for critical congenital heart disease. Stork's SpO_2 performance specification is industry-leading, at 1.5% A_{RMS}* at one standard deviation, even during motion. This patented sensor technology nests within the Stork boot, which is made from an ultra-soft, medical-grade silicone that conforms gently to the baby's skin and is available in three sizes to ensure a perfect fit as the child grows. The sensor embedded in the boot is the product of meticulous engineering that harnesses decades of expertise in non-invasive monitoring to detect babies' SpO_2, PR, and skin temperature continuously with unprecedented accuracy and dependability. With a sleek, minimalistic design ideal for any nursery aesthetic, the Stork Vitals+ bundle includes the boot with sensor that monitors baby's skin temperature, pulse rate, and oxygen saturation, and a 2K Quad High-Definition (QHD) capable camera with technology supported by the TODA platform from Like Minded Labs. The camera hardware and software architecture are designed to leverage and be compatible with future edge AI-based features, in development. For those who do not require

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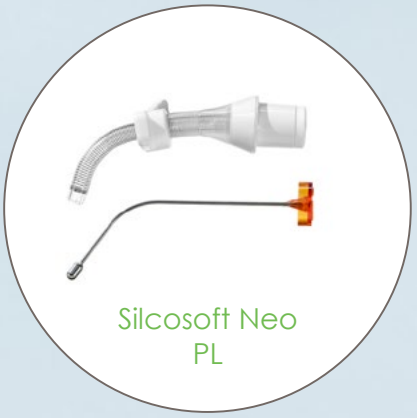

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Nellcor™ pulse oximetry with OxiMax™ technology meets six key challenges in neonatal monitoring.

Speed to Post
Seconds count in neonatal care decisions.[1] Don't lose them waiting for an accurate vital signs reading. Nellcor™ pulse oximetry has been shown to post on average up to 12 seconds faster than Masimo.[3]

Accurate Pulse Rates
Inaccurate pulse rate readings may guide clinicians to inappropriate or unnecessary interventions.[4] Nellcor™ pulse oximetry showed no clinically significant difference from ECG reference.[3,4]

Motion
Neonate motion can cause irregular venous blood flow that affects accurate monitoring.[4] Nellcor™ pulse oximetry was the first motion tolerant technology to comply with ISO 80601-2-61.2011.6

Low Saturation
Saturation rates as low as 66% in the first minutes of life may make neonates difficult to assess.[4,7] Nellcor™ pulse oximetry has demonstrated best-in-class accuracy at saturation rates as low as 60%.‡

Skin Sensitivity
Monitoring may be unavoidable, even though attaching a sensor may pose a risk to the fragile skin of a newborn.[9] Nellcor™ non-adhesive sensors use the patients' own skin moisture to secure sensor, while comparable in accuracy to adhesive sensors.[10]

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Alarm fatigue can negatively impact your workflow and your ability to provide the best possible care. Nellcor™ SatSeconds alarm management may reduce alarms in neonates by 40 percent.[11,12]

Discuss your company's R&D efforts relevant to oximetry.
Being a leading manufacturer and brand in pulse oximetry, we continue to make technical improvements, as seen with the recently released Nellcor™ OxySoft™ neonatal adult SpO2 sensor.

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Some companies may provide initial product training but charge for ongoing education — requiring more of your budget. We offer clinical education support with field-based product specialists at no extra charge. Our clinical field team of experienced clinicians includes many former nurses and respiratory therapists — who can directly relate to your daily challenges. They'll work with you to tailor education and training programs. Because they are located throughout the US, they can respond and assist you in different areas including:
- Alarm management tools and settings to help reduce nuisance alarms
- Proper sensor placement and application
- Knowledge of specialty sensors and their uses
- Effective and accurate monitoring in difficult patient situations such as motion and poor perfusion
- New or updated industry guidelines

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Our goal is to make technical support as easy and efficient as possible. Our US-based technical service support center has been around since the inception of our Nellcor™ pulse oximetry more than 40 years ago.

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Customer support resources are in one location to help save you time. The Nellcor™ pulse oximetry support website offers:
- FAQs and links to educational courses
- Product manuals
- Sensor application guides and hang tags
- Hardware user guides
- Add-on software

Nellcor™ pulse oximetry offers a five-year warranty
We believe in protecting your investment from the start. That's why Nellcor™ pulse oximetry monitors have a five-year warranty. Other manufacturers typically offer one year.

More value for Nellcor™ pulse oximetry customers
Delivering excellent patient care depends on a lot of things, including efficient workflows, timely information, and flexibility. Our investments in technology, services, and partnerships are designed around these priorities:
- Nellcor™ pulse oximetry analytics tool. Data insights can enhance your research, clinical studies, and education. This complimentary tool, which you can download, allows you to transfer patient data from your Nellcor™ pulse oximetry monitors to a computer. Then you can view and analyze data for one or more patients, as well as customize data displays, graphs, and reports. The data insights can help you make even more informed patient care decisions, like identifying who

may need a sleep study or home oxygen support.
- Alarm analysis program. By analyzing the frequency of device alarms under your current settings, we can work with you to optimize alarm settings. That helps to create better focus without missing any clinically significant alarms. This program may considerably reduce your alarms. If you are interested in participating in an alarm analysis, please contact your Nellcor™ pulse oximetry representative.
- Nellcor™ SatSeconds alarm management. Controlled through monitor settings, Nellcor™ SatSeconds alarm management is engineered for simple workflow integration. It differentiates between serious hypoxemia and minor transient events — so you can have peace of mind when responding to alarms for patients most in need.
- OEM solutions. We integrate our pulse oximetry technology into most multiparameter monitors (MPM) — allowing many hospitals to have Nellcor™ pulse oximetry technology no matter which MPM provider is used. Ultimately, this is a way for more clinician and patient needs to be met. Partnerships with other companies ensure your flexibility and ability to use accurate, consistent pulse oximetry monitoring. You'll receive the same Nellcor™ pulse oximetry training that every customer receives. OEM partner solutions are backed by a global team of clinical, engineering, and marketing professionals, ensuring advanced technology and collaboration with people you know and trust.

What type of training and user support programs do you have in place?

Our clinical education and training programs are designed to help you provide innovative solutions and improve patient care. We are committed to delivering targeted educational solutions aimed at helping you achieve procedural and clinical proficiency. Stay on track with training courses, downloads, and other educational materials that fit your needs and equip you with the tools to succeed.

Build your knowledge and skills with free learning opportunities. Our professional and clinical education (PACE) program includes:

- Online Education (Accredited) Online Education (Non-Accredited)
- Peer-to-Peer Events
- Educational Grants
- MedEd Learning Experience podcast

References

1 Wyckoff MH, Aziz K, Escobedo MB, et al. Part 13: neonatal resuscitation: 2015 American Heart Association guidelines update for cardiopulmonary resuscitation and emergency cardiovascular care. Circulation. 2015;132(suppl 2):S543–S560.

2 Wyllie J, Perlman JM, Kattwinkel J, Atkins DL, Chameides L, Goldsmith JP, et al., 2010 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. Resuscitation. 2010;81(Suppl 1): e260–87.

3 Khoury R, Klinger G, Shir Y, Osovsky M, Bromiker R. Monitoring oxygen saturation and heart rate during neonatal transition. comparison between two different pulse oximeters and electrocardiography. J Perinatol. 2020 Nov 30. doi: 10.1038/s41372-020-00881-y. Epub ahead of print. PMID: 33250516.

4 Rabi Y, Dawson JA. Oxygen therapy and oximetry in the delivery room. Semin Fetal Neonatal Med. 2013;18(6):330-5. doi: 10.1016/j.siny.2013.08.007.

5 Louie A, Feiner JR, Bickler PE, Rhodes L, Bernstein M, Lucero J. Four types of pulse oximeters accurately detect hypoxia during low perfusion and motion. Anesthesiology. 2018;128(3):520-530. doi: 10.1097/ALN.0000000000002002.

6 Source (RE10052121 - PRD / TRACE MATRIX, OXIMAX SENSORS) -Motion Studies: 10035078, 10047614, 10011350 Clinical motion performance was evaluated for the Max A and rationalized to be equivalent to the Max N. -Max N: Clinical functionality of the MAXN sensor has been demonstrated on a population of hospitalized neonate patients. Source (10018923, Clinical Evaluation Report).

7 Dawson JA, Kamlin CO, Vento M, et al. Defining the reference range for oxygen saturation for infants after birth. Pediatrics. 2010;125(6):e1340-e1347. doi: 10.1542/peds.2009-1510.

8 Nellcor Oxygen Saturation Accuracy Specification Grid. Part No. 10091796 Rev B 01/2013.

9 Widiati E, Nurhaeni N, Gayatri D. Medical-device related pressure injuries to children in the Intensive Care Unit. Compr Child Adolesc Nurs. 2017;40(sup1):69-77. doi: 10.1080/24694193.2017.1386973.

10 10077105 -SoftCare Sensor Peer Review includes verification that the patient contact material is a 1/32" PVC closed cell, polyvinyl chloride foam material, 3M 9777L. The Sensor Face drawings (064923 REV B (SC-A), 066042 REV C (SC-PR), 066819 REV D (SC-NEO) and 'where used' reports from Agile demonstrate that the patient contact surface is specified in 901813 REV A. A BOM report from Agile is included for each sensor face to coordinate between the face assembly drawing and the patient contact material. 10077105 -SoftCare Sensor Peer Review includes verification that the sensor is secured to the patient using an integral Velcro closure, a Velcro cable wrap is included for anchoring the cable, and that the sensor does include additional adhesives or sticky rings to extend the use of the sensor. The peer review references the following IFU process instructions (see attachments to RE10077105 for details).IFU: 10035575 rev C (SC-A/SC-A-I), 10056240 rev B (SC-NEO/SC-NEO-I), 10035647 rev B (SC-PR/SC-PR-I) – for attachment methodPI065868 rev L: Process Instruction, SoftCare Sensor – verification of package content specification. Product samples: SC-A: lot # 0123072, SC-NEO: lot #8144035, and SC-PR: lot #8032039 – verification of package content

11 Brostowicz HM. Oxygen Saturation in the Neonatal Intensive Care Unit: Evaluation of a New Alarm Management. American Academy of Pediatrics National Conference and Exhibition. October 2009.

12 Stefanescu BM et al. Improving Filtering of Pulse Oximeter Monitoring Alarms in the Neonatal ICU: Bedside Significance. Resp Care. 2016;61(1):85-89.

Neotech Bridge – A Bridge Toward Breastfeeding Success

Kathi Salley-Randall, MSN, CNS, NNP-BC

Human milk (HM) is the ideal nutrition for infants of all gestational ages, and particularly, for those infants born prematurely or critically ill and who required prolonged hospitalization in the neonatal intensive care unit (NICU) or other pediatric areas.[1,2] Premature infants and their parents face several obstacles to the initiation and maintenance of successful breastfeeding. The most common obstacles to breastfeeding while in NICU stem from the infant's age, neurological maturity, and severity of illness. These factors result in limited time that a sick or premature infant can spend directly nursing at the breast which ultimately impacts the establishment of an adequate milk supply. This situation is further complicated with the fact that neurologically immature or injured infants have difficulty latching on to and feeding from the breast directly due to their small size, lack of strength, poor endurance, and insufficient suck-swallow coordination. Bottles are often used to deliver supplemental nutrition to premature infants, which further reduces time spent at the breast.

Breastfeeding assistance systems have been designed to deliver supplemental nutrition to infants while keeping them at the breast and are not dependent on a bottle. When used in the hospital and NICU setting, breastfeeding assistance systems may reduce the time for premature infants to achieve exclusive breastfeeding which ultimately can impact the infant's length of stay in the NICU.[1,4]

The Neotech Bridge ("the Bridge") is an easy-to-use breastfeeding assistance system that enables nursing parents to use the device independently (saving nursing and lactation consultant time) and is more developmentally supportive and safer than legacy systems since the parent can control the rate, timing, and amount of supplementation their infant receives. With the Bridge, parents of infants in the hospital can be empowered to overcome many of the common hurdles to establishing a positive and long-lasting breastfeeding relationship with their baby.

Benefits of Breastfeeding

For babies in the NICU, HM is more than nutrition—it is a vital component of medical care.[1] HM has many well-known benefits derived from its unique composition of anti-microbial, anti-inflammatory, and immunoregulatory agents, and it is particularly beneficial for infants born prematurely.[2] Receiving HM decreases the risk for necrotizing enterocolitis, late-onset sepsis, lower respiratory tract infections, severe diarrhea, and ear infections.[1] An exclusively HM diet also decreases feeding intolerance, time to full feeds, length of NICU stay, and hospital and physician charges for very low birth weight infants.[3,4] Given these benefits and more, both the World Health Organization (WHO) and the American Academy of Pediatrics (AAP) recommend all babies, including those born prematurely, receive an exclusively HM diet for the first 6 months of life.[5,6]

Barriers to Breastfeeding

Although the AAP and WHO recommend an exclusive HM diet, many premature infants do not receive this standard of care. Parents of infants in the NICU are faced with challenges both initiating breastfeeding during their hospital stay and continuing breastfeeding after the infant is discharged home. Infants born prematurely have decreased breastfeeding rates 1 month postpartum compared to term newborn infants.[7,8]

There are several factors that can lead to difficulties with breastfeeding and milk production in the hospital setting. In the NICU there is delayed opportunity for the infant to latch on the breast due to acuity of illness, neurologic injury, developmental immaturity, as well as oral-motor strength and endurance challenges. The lactating parent is often left to pump

Kathi Randall is a Clinical Nurse Specialist and board-certified Neonatal Nurse Practitioner with more than 20 years of neonatal clinical expertise. She is also the founder of Synapse Care Solutions, an education and consulting company dedicated to supporting Neonatal Neuro-Critical Care Units.

their breasts to maintain their milk supply but this results in decreased milk emptying which further reduces milk production. Lastly, the necessary separation of infants in the NICU from the lactating parent significantly interferes with successful breastfeeding initiation and continuation.[1]

Milk supply is a major hurdle to breastfeeding success for parents of infants of any gestational age. Most nursing parents report feeling as if they are not making enough milk to meet the demands of their baby.[9] Inadequate milk supply is perceived as a major barrier for breastfeeding success for both term and preterm infants, and a top reason why parents stop nursing.[10-12] Strategies to address milk supply and weight loss issues often involve supplementation typically using a bottle, which can further hinder successful breastfeeding.[13]

Supplementation & Breastfeeding Assistance Systems

Depending on their gestational age at birth, premature infants are often fed through a gavage tube before attempting to feed at the breast. It is not uncommon for infants to receive supplementation with donor human milk or formula as a stopgap measure until their lactating parent's milk supply increases. Furthermore, premature infants may need even more volume than their parent is producing due to hypoglycemia (low blood sugar), jaundice, micronutrient deficiency, or weight loss.

Supplementation is often delivered by bottle. Bottle-feeding can interfere with breastfeeding success by decreasing time spent at the breast stimulating milk production and may cause nipple confusion as infants may prefer the faster and easier flow of bottles, and become frustrated when switching back to the breast.[13] Given these issues, other methods of supplementation have been developed to ensure that premature babies get the nutrition they need while not interfering with breastfeeding skills.

Breastfeeding assistance systems are devices designed to supplement infants with milk or formula while keeping the infant at the breast. By providing supplementation at the breast the baby may receive enough nutrition from both the breast and the device to feel satisfied and reduce the need for gavage or bottle feeding. In a randomized control trial of preterm infants, oral stimulation and a breastfeeding assistance system shortened the transition period to full breastfeeding and increased breastfeeding rates.[14]

Existing breastfeeding assistance systems can be difficult to use, requiring the help of hospital staff to attach the device to the nursing parent, and then to deliver the supplemental nutrition to the baby while latched on the breast. Additionally, in many of these systems, the tube used to deliver supplemental nutrition is taped to the breast and can disrupt a baby's latch and seal around the nipple. Furthermore, the flow rate of these systems is difficult to control. Babies may receive milk or formula too quickly, which can overwhelm the infant with more volume than they can swallow safely, or too slowly, which can frustrate the infant resulting in agitation and crying instead of nursing.

An intuitive breastfeeding assistance system is needed to solve these issues and allow the nursing parent to use the device independently and simultaneously control the amount, rate, and timing of the supplementation.

A New Solution: The Neotech Bridge

The Bridge is an easy-to-use breastfeeding assistance system that allows babies to latch to the breast while receiving supplementation. It consists of a silicone nipple cover with a built-in channel system that attaches to a syringe filled with colostrum, expressed milk, donor milk, fortified human milk, or formula. Syringes of variable size are held by the person breastfeeding, giving them full control over the amount, flow rate, and timing of supplementation. With this control, the baby can be encouraged to work at the breast, maximizing output from the breast and stimulating the wearer's milk supply.

Unlike other options, the Bridge can be attached to the breast and used by the person nursing with ease. The Bridge requires no tape and less than a minute of set-up time. Given that the inconvenience of breastfeeding supplemental systems is a major impediment to nursing success,[15] the ease of use of the Bridge is a major asset.

The Neotech Bridge is the first breastfeeding assistance system available that provides a latching surface as part of the device. The nipple piece can help overcome the difficulties many premature infants experience with achieving and maintaining attachment to the breast.[16] The 23.8mm silicone piece has one large center and five smaller outer holes that mimic the breast. For infants who prefer the bottle, the thin silicone nipple piece feels similar to a bottle nipple, which may also encourage latching on at the breast.

For parents aiming to overcome two of the most common impediments to nursing - milk supply and latching issues, the Bridge offers a simple solution. Its easy-to-use design and silicone nipple piece are intended to minimize frustrations for both the nursing parent and the baby, respectively. Implementation of the Neotech Bridge may help parents and providers successfully establish breastfeeding for infants of any gestational age.

References

1 Meek JY, Noble L. Technical Report: Breastfeeding and the Use of Human Milk. Pediatrics. 2022;150(1):e2022057989. doi:10.1542/peds.2022-057989

2 Goldman AS. Evolution of immune functions of the mammary gland and protection of the infant. Breastfeed Med. 2012;7(3):132-142. doi:10.1089/bfm.2012.0025

3 Cristofalo EA, Schanler RJ, Blanco CL, et al. Randomized Trial of Exclusive Human Milk versus Preterm Formula Diets

in Extremely Premature Infants. The Journal of Pediatrics. 2013;163(6):1592-1595.e1. doi:10.1016/j.jpeds.2013.07.011
4 Assad M, Elliott MJ, Abraham JH. Decreased cost and improved feeding tolerance in VLBW infants fed an exclusive human milk diet. J Perinatol. 2016;36(3):216-220. doi:10.1038/jp.2015.168
5 WHO. Breastfeeding. Published 2023. Accessed July 17, 2023. https://www.who.int/health-topics/breastfeeding
6 Meek JY, Noble L, Section on Breastfeeding. Policy Statement: Breastfeeding and the Use of Human Milk. Pediatrics. 2022;150(1):e2022057988. doi:10.1542/peds.2022-057988
7 Hackman NM, Alligood-Percoco N, Martin A, Zhu J, Kjerulff KH. Reduced Breastfeeding Rates in Firstborn Late Preterm and Early Term Infants. Breastfeeding Medicine. 2016;11(3):119-125. doi:10.1089/bfm.2015.0122
8 Noble A, Eventov-Friedman S, Hand I, Meerkin D, Gorodetsky O, Noble L. Breastfeeding Intensity and Exclusivity of Early Term Infants at Birth and 1 Month. Breastfeeding Medicine. 2019;14(6):398-403. doi:10.1089/bfm.2018.0260
9 Bazzano AN, Cenac L, Brandt AJ, Barnett J, Thibeau S, Theall KP. Maternal experiences with and sources of information on galactagogues to support lactation: a cross-sectional study. International Journal of Women's Health. 2017;9:105-113. doi:10.2147/IJWH.S128517
10 Alves E, Magano R, Amorim M, Nogueira C, Silva S. Factors Influencing Parent Reports of Facilitators and Barriers to Human Milk Supply in Neonatal Intensive Care Units. J Hum Lact. 2016;32(4):695-703. doi:10.1177/0890334416664071
11 Gianni ML, Bezze EN, Sannino P, et al. Maternal views on facilitators of and barriers to breastfeeding preterm infants. BMC Pediatr. 2018;18(1):283. doi:10.1186/s12887-018-1260-2
12 Brown CRL, Dodds L, Legge A, Bryanton J, Semenic S. Factors influencing the reasons why mothers stop breastfeeding. Can J Public Health. 2014;105(3):e179-185. doi:10.17269/cjph.105.4244
13 Zimmerman E, Thompson K. Clarifying nipple confusion. J Perinatol. 2015;35(11):895-899. doi:10.1038/jp.2015.83
14 Çelik F, Sen S, Karayagiz Muslu G. Effects of Oral Stimulation and Supplemental Nursing System on the Transition Time to Full Breast of Mother and Sucking Success in Preterm Infants: A Randomized Controlled Trial. Clin Nurs Res. 2022;31(5):891-900. doi:10.1177/10547738211058312
15 Li R, Fein SB, Chen J, Grummer-Strawn LM. Why Mothers Stop Breastfeeding: Mothers' Self-reported Reasons for Stopping During the First Year. Pediatrics. 2008;122(Supplement_2):S69-S76. doi:10.1542/peds.2008-1315i
16 Geddes D, Hartmann P, Jones E. Preterm birth: Strategies for establishing adequate milk production and successful lactation. Seminars in Fetal and Neonatal Medicine. 2013;18(3):155-159. doi:10.1016/j.siny.2013.04.001

Value of Lateral Film in Diagnosing Malposition of a Central Catheter

Archana Bottu, MD, Lakeya O'Neal, MD, Shabih Manzar, MD, MPH

The value of obtaining lateral film in diagnosing the malposition of a central catheter is highlighted in this report. In the case (Figure 1), a peripherally inserted central catheter (PICC) was inserted using the left femoral vein. On the anterior-posterior (AP) view, the catheter was noted to take an unusual course on the left side of the abdomen (Figure 1 A). A lateral film (Figure 1 B) showed that the catheter was not traversing any major vessel but was subcutaneous. The PICC was removed immediately.

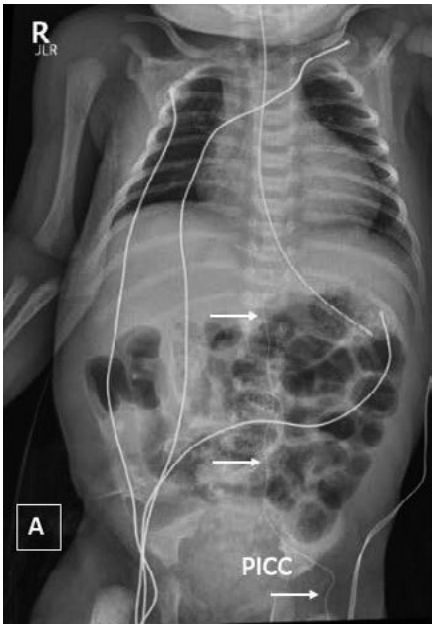

Figure 1 A. An anterior-posterior film shows an unusual course of peripherally inserted central catheter (PICC) on the left side of the abdomen.

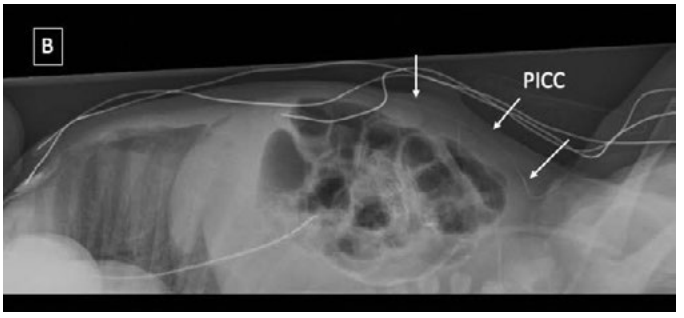

Figure 1 B. Lateral film showing a subcutaneous placement of the PICC. The thoracoepigastric vein runs along the lateral aspect of the trunk between the superficial epigastric vein below and the lateral thoracic vein above and establishes an important communication between the femoral vein and axillary vein.

PICC: Peripherally inserted central catheter

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Archana Bottu, Resident, Department of Pediatrics at Louisiana State University Health Sciences Center at Shreveport.
Lakeya O'Nealis, Fellow, Division of Neonatology at Louisiana State University Health Sciences Center at Shreveport.
Shabih Manzar, Attending, Division of Neonatology at Louisiana State University Health Sciences Center at Shreveport.
Corresponding author: Shabih Manzar, MD, Louisiana State University Health Sciences Center at Shreveport, 1501 Kings Hwy, Shreveport, LA, 71103, Phone: 318-675-7275, Fax: 318-675-6059, Email: shabih.manzar@lsuhs.edu

Swaddle Bathing with the TurtleTub

In this feature, Neonatal Intensive Care adapts educational webinars delivered by clinicians and healthcare providers about the actual application of specific products and therapies. The webinar adapted below was presented by Catapult Products, LLC.

I think we'll go ahead and get started. First, I'd like to thank you all for joining us this afternoon as we talk about swaddle bathing, and in particular, swaddle bathing with the TurtleTub. My name is Dana Denton, and I am the clinical specialist for Catapult Products. I'm also a neonatal physical therapist. I've been working in the NICU for over 15 years, so I have years of experience with swaddle bathing. What I'd like to do this afternoon is start with a quick PowerPoint presentation, and then after the PowerPoint I'll briefly show you how to do a swaddle bath. As a reminder, be sure that you're on mute, and if you have any questions, please just drop it in the chat or unmute yourself and fire away. So, we will go ahead and get started with the PowerPoint.

Okay, so our objectives for today are first to understand what swaddle bathing is and why it's beneficial, and then to know who would be appropriate for swaddle bathing. The final objective is to have a basic understanding of how to do a swaddle bath. Before we get started, I would like you to take an assessment of how bathing is done in your unit.

What is your current bathing practice? Does the infant enjoy the bath that you're giving them now? Does it cause stress to the baby? Are they crying or are they hypothermic after the bath? Is there consistency in your bathing practices? Is it easy for the nurses or the parents to give a bath in the unit? And most importantly, are the parents able to participate in the way that you're giving the bath now? Would you be happy and satisfied for the parents to bathe the infant at home with the same technique that you're doing in the hospital? Those are just some questions to start out with on how your bathing practice is done.

Here are some pictures of how babies may be bathed in hospitals. One is using a pink basin in which it's hard to hold the baby, and it's hard for the families to be involved. A sponge bath can lead to hypothermia and a very stressed baby. In the sink oftentimes we have difficulty keeping the sinks clean and keeping them warm. And finally, there are a couple other options at the bottom of the slide.

What I'd like to talk with you today is about what immersion swaddle bathing is and why using the TurtleTub can make it easy for you to do swaddle bathing. There are two types of bathing: immersion bathing and immersion swaddle bathing. Immersion bathing is when you just place the infant in warm water. Swaddled immersion has the added benefit of containment. The infant is swaddled then placed in the warm water.

So how do you do a swaddle bath? In a nutshell, you fill the tub with warm water, swaddle the infant, put them in the TurtleTub, and take out one extremity at a time for bathing.

But again, I will show you a little bit more detail on how you do a swaddle bath at the end of this presentation.

So, who can be swaddle bathed? Certainly, infants in the NICU would enjoy and benefit from being swaddle bathed, as would full-term, well babies and babies going through neonatal abstinence syndrome. Let's talk first about why it's important to do a swaddle bath on a preterm infant.

A preterm infant is not just a small version of a full-term infant, even though it's easy to assume they can do the things that a full-term infant can. If you look at brain growth in the pictures at the bottom of the slide, you can see how much brain development occurs even between 35 and 40 weeks of gestation. The experiences an infant has during that time in the NICU influences the structure and the function of the brain. So anytime we can change a medical procedure or a medical process to be a little bit less stressful and a little bit more enjoyable, we have an impact on the developing brain. So changing bathing to a positive experience is going to help with development. Preemies have less fat, so it's harder for them to maintain their body temperature. They are also easily overwhelmed by sensory stimulation. So swaddling them when putting them in a warm bath helps them regulate their sensory processing.

So, what about well babies? Why would it be important to do a swaddle bath for the well babies? The two primary reasons are to decrease the risk of hypothermia and decrease their motor stress cues. When we do that, when we decrease hypothermia and motor stress cues, we have less recovery to do after the bath. The infant doesn't have to spend time under the warmer. The infant can go directly to skin-to- skin holding, directly to feeding, and we don't have to spend all that time helping them recover from the bath. During a swaddle bath is a nice time for education on this appropriate technique for bathing your infant at home. There's no difference in umbilical cord healing or colonization with an immersion bath. And now that many hospitals are doing delayed bathing, waiting six to 24 hours after birth, we have this beautiful opportunity to teach the families

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

and involve the families on how to bathe their infant. You can wheel the TurtleTub cart right to the bedside, educate the family, and they can do the bath right there. If we can decrease the risk of hypothermia, we can have an impact on hypoglycemia as well. And swaddle bathing is a very well-researched and evidence-based practice.

So, what about infants with neonatal abstinence syndrome?

Swaddle bathing is a calming strategy for this population, and it's a nice way of bringing families in and giving them an activity that leads to a calm and happy infant. If you choose to do swaddle bathing daily for calming and for parent interaction, be sure not to use cleanser every day, it can be drying on the skin.

This slide is a clinical practice guideline. It is primarily used in the NICU or special care nursery. It outlines in a flow chart, which infants would be appropriate for swaddle bathing. As you can see, we start with 32 weeks gestation and move on through older infants. The criteria needed to justify the clinical decision-making processes for those younger, more fragile infants goes beyond the scope of our guideline.

For those infants over 32 weeks gestation, you work your way down into the diamond shape. And there we identify safety parameters such as babies don't have IVs, and they have stability in their thermal and cardiorespiratory systems. Since we're going to be taking the infant off their monitors for about 10 minutes, you also want to be sure that you feel comfortable with that infant not being monitored for 10 minutes. And then we'd like for those infants to weigh over 1500 grams. At the bottom of the flow chart, you can see the decision making on whether the umbilical cord has fallen off or not. AWHONN has stated that it is okay to do an immersion bath with the umbilical cord still on, but if your hospital policy states that the umbilical cord should be off before doing an immersion bath, don't worry, you can still do a swaddle bath. Just keep the water level lower in the tub so the umbilical cord stays above the waterline.

We would now like to talk a little bit about family involvement. Swaddle bathing is a very typical parent activity, and for those of you that are in the NICU or special care nursery, you know that there are not many typical parenting activities in the NICU. Feeding is hard, holding your infant is hard with lines and cords. So, swaddle bathing is a nice, typical parenting activity. And whether your baby is in the well baby unit or in the special care nursery, the first bath is a strong emotional memory. We'd really like to make sure that the strong emotional memory is a positive one.

So let's talk about the benefits for nurses. When you do a swaddle bath, it takes less than 10 minutes. And like we mentioned before, you don't have to chase the baby's physiologic stability. The babies are warm, they're happy, they're content.

Oftentimes they're showing feeding cues once they get done with the swaddle bath, so you can put them directly to skin-to-skin holding, or you can put them directly to breastfeeding. It's nice, because you don't have to spend that recovery time after the bath. Parents can be educated to do the bath, and they can take on some of that care.

And just as a reminder, nursing associations recommend swaddle bathing, NANN for example. The AWHONN skincare guidelines state that ideally infants should be bathed with immersion tub bathing or with immersion swaddle bathing.

Now that we've talked about why it's important to do swaddle bathing and immersion bathing, I'd like to just touch on a few features and benefits of the TurtleTub that will help implement swaddle bathing in your unit. First, we'd like to talk about the tub itself. The temperature indicator is at the bottom of the tub. We would like the water to be around 101 degrees, where the research has been done. As you fill the tub with water, oftentimes you're adding a little bit of hot water and a little bit of cold water, so there are pockets of hot and cold water. Be sure you use your hand and swirl the water to mix the hot and cold pockets, so the temperature indicator has a consistent temperature to read. Other features, as you can see in the tub, are the high sides and deep seat so when the infant sits in the TurtleTub, they are stable. The stability makes bathing more friendly for parent involvement.

Other accessories we offer to make swaddle bathing easier include a cart with wheels for a mobile bathing station. You can then do the bath at the bedside with the parents. We have different types of blankets for swaddle bathing, and we also have full accessory kits, so you don't have to spend time wandering around the unit trying to assemble all the supplies you need for a bath. Everything is combined in one simple and easy to use pack.

So just a quick discussion about different types of swaddle bathing blankets. Our warmest option is the fleece blanket, and that one would be ideal for the infants in the NICU where temperature regulation is more of a concern. It also absorbs the water for a nice, heavy feel on the babies. The fleece is a reusable blanket, and as you can see by the yellow line on the chart, it is the warmest option. The other two options are a flannel and a disposable blanket. These two, as you can see, also help to keep the infant warm. The bottom line on the chart is no blanket. It would mimic more like a sponge bath where the infant is exposed to the cold air.

We offer different options on how you want to use the TurtleTub in your unit. Ideally, each infant would have their own tub and then it is gifted to them at discharge. They would learn how to swaddle bathe and then the practice would carry to home. If that's not a possibility, then you can reuse the TurtleTub on multiple infants. For multi-use, a disposable liner is placed on the tub before each bath. We don't want any type of cross-contamination with the infants during bathing. And then finally, some hospitals will do a combination of both. Perhaps you have some infants that are in the unit longer, and it would make more sense for them to have their own tub. But the infants in the well baby unit, who get only one bath, would use the disposable liner.

Here is a brief discussion on the importance of how you clean the TurtleTub. When you're doing single patient use, you can just wash it with soap and water and dry. If you're using it for multi-patient use, you will discard the liner and then wipe down the TurtleTub and any surface of where you've been bathing with one of our approved wipes. Here is a list of the approved wipes.

So hopefully with this short PowerPoint presentation we've shown you why it's important to do swaddle bathing and in particular swaddle bathing with the TurtleTub. First of all, we want to avoid any adverse clinical outcomes associated with bathing in the hospital, and we want time savings for you as the

caregiver. Swaddle bathing supports developmental care, and it's a great hospital marketing advantage. The first bath, and bathing in general, is a real parent pleaser when it's done in a way that the baby has a positive experience.

Alright, are there any questions I could answer before I move on to show you how you do a swaddle bath? Looks like there were a few in the chat, but they have been answered. So, we'll just go ahead and switch cameras so I can show you how you do a swaddle bath.

This is the TurtleTub. You can see how nice and deep the seat is, so the infants aren't going anywhere. The temperature indicator is at the bottom. The cart has drawers, so you can put your supplies here. This is an individually wrapped liner, but I'll go ahead and use one that we already have open. Remember to put on gloves prior to bathing.

We start by putting the liner on the TurtleTub. Simply drape the liner over the tub, then push it down. Make sure the plastic is flat on the temperature indicator so the indicator can read the water temperature more accurately. You can then wheel the cart over to the sink, and fill the tub with water. I usually like to fill to the height of the seat. You can adjust the water depending on the size of the baby, but that's a good place to start.

If your infant has monitors, remove the oxygen monitor off their foot and disconnect all the other leads before you put them into the tub. I like to remove the sticky part from the chest in the tub, because they become slippery and slide off. It's easier to take them off in the water. Then swaddle the infant and place them in the tub. All right, so now we have our infant in the TurtleTub. Other supplies include: washcloths for the baby's face and bottom; a rinse cup for clean water to wash the baby's face and head; baby wash; and a couple of different options for washing the baby's head. The brush and comb set works well for older infants that may have more hair. This smaller brush is a little easier to manage on those small infant heads. All right, so we're ready to do the swaddle bath. If you're helping a family, I usually just like to keep my hands up here at the head and talk them through how to do a swaddle bath.

We start by taking a washcloth to wash the face. Wash from the inside out on one of the eyes. Use a different part of the cloth and go inside out on the other eye. Then wash the baby's face, neck, and behind their ears. Discard the washcloth.

Next you can unswaddle one of the baby's extremities and put just a little bit of cleanser on your hand. Wash the baby's arm using a firm, but gentle pressure. I usually like the families to use their hands when washing the baby, because skin to skin contact and a little bit of a massage is nice sensory exposure for the infant. You do not need to scrub. The vernix can stay on the skin and certainly those infants that are in the NICU don't need that extra sensory exposure of being scrubbed.

Wash and rinse the extremity, then tuck the arm back in the swaddle. Do the same with the other arm. Take out a little bit of cleanser, wash the baby's arm with a nice firm pressure, and then tuck the baby's arm back in the swaddle. You're keeping the infant swaddled the whole time to keep them warm and contained. Moving on to the baby's chest. Open a little bit of the swaddle and put cleanser on your hand. Wash the baby's chest. This is a good time to put water underneath the leads and slide them off the baby's chest. Re-swaddle the infant.

Now we work our way down to the lower extremities. Take out one leg, put a little cleanser on your hand, and use a nice firm pressure to wash the baby's leg. You can spend time on the baby's feet for some positive sensory exposure. If the infant has had multiple heel sticks, for example, or infant is in the NICU where the oxygen monitor is taken off frequently, it's nice to give a little bit of positive impact to their feet. Do the same with the other leg and then rinse. To do the infant's back, you just turn the baby to the side and remove the back part of the swaddle. You can use the front side to keep the baby warm and contained. Wash and rinse the baby's back. If the baby is very small or you are concerned about their temperature, you can wash through the blanket, give a little rinse, then you're done.

Transition the infant to their back and use either the scalp brush or one of the other brushes to wash the baby's head with a little bit of cleanser. To rinse, you can either pour the water on their head or just squeeze the water from a couple washcloths. If you feel that the baby needs a full rinse at the end of the bath, you can open the blanket and rinse before you take them out of the tub.

I'll show you how you take the infant out of the tub. I take a nice, warm blanket and put it on my chest with my arms on top so your hands are free and the blanket is secured under your arms. Then you just lean over the tub and lift the infant onto your chest, over the tub. After you have the baby in the blanket, bring the bottom part of the blanket up to make a little pocket. The baby is not going anywhere. Then you can pat them dry, and place the infant on their bed. So that's how you do a swaddle bath.

Once you're finished, you clean the TurtleTub. This fleece blanket is re-usable, so it can just be put into the laundry. Wheel the cart over to the sink, pour out the water, discard the liner with all of the items used during bathing. Finally, wipe down the TurtleTub, all the surfaces that you were using, including the cart and caddy. Alright, that is how you do a swaddle bath.

Can I answer any questions?

Do you see improvements in pulse oximetry and heart rates after the swaddle bath?
There has been research that addressed those issues, and yes, they did find improvements or they remained the same.

Could you show the slide with the approved products to clean the TurtleTub?
We can email that to you. Just put your email in the chat, then we can email you that slide.

With the approved wipes, do you have to use the disposable liner if you are wiping it down between uses?
Yes. You need to use the liner. This method of cleaning is compliant with FDA's disinfection requirements for multi-patient use medical products. Our cleaning method with the liner has been tested and validated which gives us the confidence that you won't have cross-contamination when the tub is cleaned according to our IFU. Secondly, we don't want residue left on the

tub that can contact the infant's skin. So yes, the liner must be used for multi-patient use.

Can you send the whole PowerPoint?
Yes. You're welcome to use the PowerPoint for education. And we have videos on our website on how to do a swaddle bath, in the special care nursery and in the well-baby nursery.

It was really helpful.
Well, thank you. Looks like more of you interested in the PowerPoint and yeah, hopefully the PowerPoint gives the background of why it is important to consider how we do medical procedures for the infants, whether they're in the well baby unit or when they're in the NICU.

There is a question about the cost for the TurtleTub.
If you're interested in the tub, then depending on where you are geographically, we have distribution that helps with sales. We would put you in contact with your local rep, and then they can help you with the cost of the options that will work best for your unit.

How long does the tub last?
We guarantee the tub for a year. With normal wear and tear, little scratches may appear on the TurtleTub which may affect cleanability. The temperature strip will also fade over time. So, we highly recommend that you replace the tubs once a year.

Does the temperature need to be a certain reading prior to performing the bath?
Yes. We recommend the water temperature to be around 101, and the indicator will turn green. The infant's temperature should be within normal range, 36.5°C to 37.5°C, prior to bathing. There are special considerations for younger infants, infants under 32 weeks gestation. What I would recommend for that population is to keep in mind the principles you're learning here to minimizing stress and decreasing hypothermia by swaddling them during their bath. We do not recommend that you take the infants out of their isolette and use the TurtleTub for infants under 32 weeks gestation.

Do you advise we put the blanket in the warmer prior to using for the bath?
You do not need to put the swaddle blanket in the warmer. However, I would recommend that the drying blanket or towel be warmed. And if temperature regulation is one of your primary concerns, then I would definitely recommend that you use the fleece blanket because that one will keep the infant the warmest. The other options, like I mentioned, this one is the disposable blanket and it's made out of a non-woven material and it's super soft. So if laundry is an issue for you, then definitely consider using the disposable. It can be thrown away at the same time that you dispose of the liner. These are good questions. This is fun.

Alrighty. Okay, I think we're good. Thank you again for joining us this afternoon to learn about swaddle bathing. I hope that we've convinced you that swaddle bathing is a great way to bathe your infants in the hospital, to keep them warm, to keep them contained, to involve parents, and to help infants go directly to skin-to skin-holding and/or feeding. Thanks again. If you have any further questions, please contact us through our website. Have a great afternoon.

Optimizing Temperature Management of the Infant

Thermoregulation is a cornerstone of neonatal care and continues to be a challenge in the extremely low birth weight (ELBW) population. Temperature instability can lead to a cascade of other sequelae detrimental to the infant. In this webinar, Dr Jessica M Jones, DNP, APRN, NNP-BC will go through the basics of heat loss and the challenges associated with it, as well as the importance of nursing care in the management of thermoregulation and what can be done now and into the future.

Our objectives today are several. First, I want to define the mechanisms of heat loss. I'm sure it's a review for many of you. And we'll discuss the concept of thermoregulation in a thermoneutral environment. Second, we're going to describe the pathophysiologic characteristics of the ELBW baby and those things that complicate temperature regulation in that population. Third, we're going to discuss delivery room management of thermoregulation principles and things that we can do to help the infant's temperature on admission. Fourth, we're going to identify nursing interventions that contribute to euthermia. Fifth, we will identify specific challenges to maintaining stable temperatures in our ELBW population, and finally, we will discuss the future of temperature regulation, which I'm really excited to talk about.

First things first, why are we here? Why is this important? Once you read these slides and you see the statistics, it really should hit all of us, the importance of maintaining a stable temperature in these infants. Studies have shown that for each one degree Celsius and admission temperature below that 36-degree Celsius threshold, there is an increase in mortality by 28% and in late onset sepsis by 11%. So right off the bat, that admission temperature that we take one degree Celsius off from 36 degrees increases your baby's chance of mortality by 28%, and that is staggering. When we really contemplate that number, we should be really honed-in and focused on what that admission temperature is going to be in our NICU babies. Additionally, the mortality rate for newborns who become hypothermic is fivefold higher when it happens within the first five days of life. And that's just general newborn population. That's not even talking about the preterm infant.

Additionally, hypothermia is associated with hypoglycemia, respiratory distress, metabolic acidosis, coagulopathy, and death. Temperature instability and poor humidity control lead to increased trans epidermal water loss. Those increased losses lead to hypernatremia, which is also associated with IVH, BPD and mortality. Those are major benchmarks that we look at in the NICU as far as outcomes. And then lastly, studies that have shown for every milliliter of water loss from evaporation, there's a loss of 560 calories of heat, which is a significant expenditure for these ELBW babies. These six little statistics that we're sharing have a significant impact on our infant population and really shines a light on the importance of thermoregulation in our patient population.

To go into a little bit of embryology and a lot of detailed information, let's talk about epidermal development in the fetus. The stratification of the epidermis occurs between 14- and 23-weeks gestational age, and that's followed by a terminal differentiation with the formation of that cornified cell envelope. Between 21 to 22 weeks gestational age, there's a thin layer of compact keratin. That's all. Several years ago, this may not have been as important of a detail, but now when we start talking about the edge of viability and resuscitation of infants at 22, sometimes even 21 weeks gestation, it becomes even more important to focus on that skin development. Between 22 to 23 weeks gestational age, the fetal epidermis is composed of just two to three thin layers of the stratum corneum, and that becomes more morphologically mature via multiple layers by the end of the second trimester, so closer to 28 weeks gestation. And it's fully mature by 34 weeks gestational age. Between 23 to 24 weeks gestation, there is a basket weave keratin that's present in the hair follicles, and that gradually extends along the epidermis.

During our third trimester of development, that's when we see the cornified cell layers increase in number, and that's when we get the addition of a really formed barrier of skin. Finally, that postnatal environment that we're going to talk about a little bit with unification. The postnatal environment of the preterm baby influences their development, and that leads to histological maturation of the epidermis where it resembles that of a term infant. That usually happens by two weeks of age. Regardless of the gestational age at birth, typically by postnatal age of two weeks, your infant is going to have histologically mature skin.

Let's talk about the thermoneutral environment. That's considered an environmental temperature in which the infant's oxygen consumption and their metabolic rate are both at a minimum. The goal is for no additional calories to be used for heat production or loss. These babies are already at significant calorie deficits. There's a lot of caloric expenditure just trying to stay alive and so we don't want to have them work even harder to maintain their temperatures in an environment that does not have a stable temperature. A thermoneutral environment is required for adequate growth and the ambient air temperature required to maintain that thermoneutral environment is going to vary and it's going to rely on factors such as gestational age, corrected age, and weight. Which makes a lot of sense, right?

The smaller the baby as far as birth weight and gestational age, the more is going to be required to maintain a thermoneutral environment.

Let's review mechanisms of heat loss and go back to basics. Evaporation is the major source of heat loss within the first two weeks of life in term and preterm infants. It's water vaporization from the body that requires energy and heat consumption, and that leads to heat loss. That's your main mechanism of heat loss in these infants. Then we have convective heat losses, which can happen when the infant is exposed to cold air flows like airflow through an open door or from air conditioners.

We have conduction, which is the transfer of heat from one solid object to another via surface-to-surface contact. When the baby's placed on a cold scale or a cold bed, we're going to have heat transfer and heat loss from there. And finally, radiation which is a transfer of heat from the core body tissues into the subcutaneous blood vessels, and that leads to the emission of some infrared rays from the skin surface leading to heat loss.

Looking at heat production in the newborn. Infants require temperature homeostasis for survival, and the goal again is to maintain a thermoneutral state. The baby's going to lose about 150 Kcals per minute attempting to maintain euthermia. When a baby that's in a cold environment or has cold stress, they are going to struggle and burn a lot of energy to maintain a stable temperature.

Non-shivering thermogenesis is the main mechanism of heat production for neonates. It's created via the heat oxidation of free fatty acids, and it requires enough brown adipose tissue, the 5'/3'- monodeiodinase, and thermogenin. Now, the importance is that brown fat is highly vascularized. It's found in the neck, the axilla, the interscapular regions, mediastinum, and it also surrounds the major organs and it's near kidneys and adrenal glands as well.

The problem is that preterm infants delivered before 32 weeks gestational age do not really have those adequate brown fat stores, and so they're not able to create that non-shivering thermogenesis, which would help them maintain a stable temperature. Brown fat, when it's metabolized, the heat that's produced warms the organs and the blood directly, and that leads to the elevated body temperature. One important note

is that when brown fat is ultimately converted to glucose and oxygen, once it's depleted, it can't be replaced. So, once you've used that brown fat, there's nothing else to draw from. And again, our very low birth weight infants do not have those adequate brown fat stores to begin with.

Let's see the effect of cold stress on our neonates. As we discussed, brown fat metabolism is inefficient in our extremely low birth weight population due to extreme immaturity. And so, there's not going to be enough brown fat and nonshivering thermogenesis to prevent the baby's temperature from falling. When we have cold stress, that leads to increased metabolism which then leads to increased glucose utilization, depletion of glycogen stores, and hypoglycemia. In the extremely low birth weight infant, they already have minimal energy stores. There's not much to pull from. We already have a baby that's starting from behind the eight-ball, and then we add cold stress to it, that can cause so many more complications.

Additionally, when we have cold stress and increased metabolism, we have increased oxygen consumption, which leads to this cascade of hypoxemia, anaerobic metabolism, metabolic acidosis, pulmonary vasoconstriction, worsening hypoxemia, and worsening respiratory distress.

These extremely low birth weight babies tend to have respiratory distress due to surfactant deficiency and immaturity. Therefore, oxygenation during cold stress is going to be even more decreased. Glucose is consumed during the thermogenesis process, which depletes the baby's already minimal energy stores. These factors lead to the accumulation of lactic acid, which places a greater demand on the cardiovascular system to increase cardiac output. Consequently, the extremely low birth weight infant becomes acidotic. Increased energy expenditure in an already sick and unstable infant could affect their vital signs, pH, glucose homeostasis and oxygenation. Decreased oxygenation leads to increased acidosis, hypoglycemia, and tachycardia. All these things come from cold stress and that can lead to increased morbidity and mortality. While it may be only one vital sign that we think about, it really can affect the baby overall.

One of the things that I love about thermoregulation and when we talk about stable temperatures and temperature management in the NICU is that as NICU nurses, it's really the one variable that nurses have full autonomy over. When we talk about other things like ventilation and blood gases and blood sugars and cardiac output, there's so many different factors that go into that and we can collaborate with our team, we can work together to improve those things, but temperature regulation really is something that the nurses are able to control and have full autonomy over, and it's a great responsibility. It's not just another vital sign. And it's something that we really need to focus in on and pay attention to. And we can see why.

Looking at specific risk factors to the extremely low birth weight infant, there is a disproportionate body mass to surface ratio. There is an increased skin exposure due to their posture and tone. The infants are typically laid out in the bed. They don't have good tone that keeps them curled into themselves. Usually with positioning, we can help that, but we've all seen what those babies look like in admission when everybody's working on them. We're trying to get things done. We have a decreased presence of subcutaneous fat, which we talked about. We have inefficient vasomotor control and nonshivering thermogenesis as well as an immature skin barrier. The larger skin surface area does lead to greater radiant heat loss as well as increased insensible water losses. And as we discussed, brown fat isn't well-developed until the baby gets closer to 26 to 30 weeks gestational age. And then additionally hypoxemia, which again, so many of these babies struggle with, can impair any brown fat metabolism that is taking place. This baby may already have severe RDS and could be struggling with hypoxemia, which just compounds and could make things worse.

Then we get to management of heat loss in the delivery room. Thankfully, there's been a lot of research that has shown various ways to mitigate heat loss when dealing with extremely low birth weight babies, especially in the delivery room. A couple of them include a preheated bed, and that helps to minimize heat loss from conduction radiation. Whenever we know that there's a warmer baby alert, a small baby that's getting ready to deliver, we make sure that we preheat our warmer and that it's ready to

go. Another method is the polyethylene wraps or bags. So those plastic bags that we place the babies in. We make sure that we don't dry them off, but we put them into the bag right away, and that helps minimize heat loss from evaporation and convection. And then we have the heating of respiratory gases, which has shown significant improvement in admission temperatures.

Some of the challenges that we face in the delivery room include the delivery room temperature itself. And this can be very facility dependent. A lot of times when the OR staff are not understanding of the full impact that temperature regulation can have on these babies, it makes it difficult. I really stress having the discussions around the importance of maintaining a stable delivery room temperature. Cold delivery rooms less than 26 degrees Celsius have been associated with colder admission temperatures in the NICU for ELBW babies. 77 degrees Fahrenheit in the ORs or special delivery units, where we have all babies less than 32 weeks gestational age, have been shown to help the baby's admission temperature. Additional challenges include delay cord clamping. So that's the gold standard to have that delayed cord clamping for at least a minute as long as the baby's doing well.

If we think about it, not all the providers are there, especially in the OR to help maintain temperatures. We may have a baby that's pulled straight out and is wet and is not necessarily being dried, so when we talk about all those mechanisms of heat loss that are taking place, they're just lying there for a full minute. I liken that to if you're somewhere in a cold temperature sitting in a hot tub and you get out and you're just standing there. No towel, nothing to dry you off, and you're freezing, right?

You're wet, you're cold. And that's a huge way that babies are losing heat in the delivery room. So, trying to figure out how to work together as a team to minimize those losses during that first minute of life, delayed cord clamping is very important.

Then we have the challenge of just to provide our infant transfer. We're moving the baby from one place to another. We're walking them maybe through a cold OR to a colder special delivery unit. We're delayed in placing a baby on servo mode if that's even an option in some delivery rooms. And we've got competing priorities. We want to focus on that airway and breathing, circulation, our ABCs and making sure that we're following NRP. And along with that, sometimes what happens is thermoregulation gets kicked down the road and it's not as much of a focus. Try keeping that in the back of your mind - what are we doing to preserve the baby's temperature during that stabilization process? And then finally just struggles in obtaining a temperature prior to leaving the OR. I know that's a goal of our unit is to attain an ancillary temperature, just to get a baseline and see where we're at and what needs to be done before we even leave the special delivery unit or the OR. We want minimal hands touching the infant. I think we've all seen those infrared pictures where we look at the heat transfer when we stick our cold hands into a warm I-slot, we can see the way that heat is transferred from the baby to hands. We really try to focus on minimal hands touching the baby, which is a challenge because there's a lot of things that need to be done on these tiny patients. We got to move them over to the bed, get leads attached, put on our pulse ox if it's not already there, and everybody wants to help. It's a great team effort. Just knowing for every hand touching that baby, we're increasing the risk of heat loss from the infant.

We want to have a dedicated admission bed with equipment warming. That is super helpful. And again, we don't always know when we're about to get an ELBW baby especially, but if we do know, let's say, there's a 24-week baby that's getting ready to deliver, let's get everything pre-warmed and ready for the baby so it can be admitted to a warm environment. We want to make sure that we have the correct equipment for these infants. One of the things that we found doing some QI projects in our unit was that we didn't have the correct servo probes for our beds, even just having the baseline equipment. We started off with the right probes, and then as ordering got handed off to other people, we went with the cheaper probe. That's what happens sometimes. Well, we can get the same amount for cheaper or really save money here, but making sure that we have the correct equipment for what we want to do. So having the right servo probes for the bed is a huge thing. And then making sure that we're putting them in the right place.

And then finally, being familiar with your equipment and its optimal use. One of the things that we've started doing with our new nurse interns as they come into the unit is let them play with one of our incubator beds. See what capabilities they have, learn about servo mode, learn about the air boost, learn about air control, and all of the different ways that we can maintain temperature in this population using the equipment that we have.

I've also found that it's helpful for the nurses to be able to understand what goes on. Sometimes we just throw them into training and say, 'here's an incubator and baby needs to stay in it', but we don't really go through all the details. That leads to trouble down the road when they don't know how to troubleshoot. And we don't know what's going on and suddenly, we haven't been following it and we didn't notice that things have changed because there's subtle changes with the incubator bed and that gets missed.

What do we do when we get to the NICU as far as managing temperatures? We want a minimum of 70% humidity to minimize trans epidermal water losses. Once the top is down, keep it down. I've noticed before we really got into focusing on thermoregulation in our unit that we were just popping the top of the bed very casually and for unnecessary interventions. Obviously, if you have a baby who's compromised and you need to get to that baby, there's an issue with the airway or something like that, then yes, we need to do what we need to do to resuscitate the infant. But if anything can be done with the top down, that is the goal. The moment you pop the top of that incubator, you're losing the heat, you're losing the humidity, and you really must start all over again.

What we've started doing is using a plastic covering if the incubator is open. When we bring our babies up, our ELBW babies, they're in that polyethylene bag and they stay there until we've achieved adequate humidity. But if we must pop the top of the bed open, we do have another plastic covering available at the bedside and a kit ready to go so that the nurse can cover the baby. And again, minimizes evaporative losses. We try to utilize the patient care portholes with air boost. We're conscious of temperature management during procedures. That was another big thing we noticed when we started our QI projects. And you know so many times how one QI project leads to another and another. We really perfected our admission temperatures. All our babies were now being admitted with stabled, axillary temperatures. It was a huge victory, especially when we look at

that statistic that we shared at the beginning of this webinar, that 28% mortality rate for infants with a one degree Celsius below 36-degree temperature. We were proud of ourselves. But what we found was an hour later, our temperatures were either really low, or they were really high. Either way, the baby was not being maintained in a thermoneutral environment.

And what happens during that golden hour, right? We've got line placement, we've got surfactant, we've got measurements, X-rays. All these different variables that are taking place, which were causing the baby to have unstable temperatures at that one-hour mark. With another QI project, something that we instituted was having one nurse who was there solely responsible for temperature checks every 15 minutes during that golden hour time where they could stop the provider and say, "I know you're putting in lines, but we really need to make sure that we've got a stable temperature on this baby." Because what we don't want is to have access and surfactant but then have a baby whose temperature is way below normal. Another way that we can help minimize losses is through pre-warmed IV fluids and heated and humidified gases. And then just really remembering that every basic nursing intervention such as suctioning, repositioning, obtaining vital signs, all those things, if we're not aware of it, can lead to hypothermia in our patient population.

Humidification. The goal of a humidified environment is to minimize those transdermal water losses and promote skin maturation. As we talked about the embryology of fetal skin development towards the beginning of this, we discussed how those thin layers of skin in our extremely low birth weight infants can lead to evaporative water losses. What we've shown is that higher humidity prevents those losses and is associated with a decrease in insensible water loss, lower rates of hypernatremia, a decreased total fluid intake, and lower urine output. Lower humidity levels lead to a more rapid maturation of the skin barrier. It's a bit of a balance. We want to make sure that we have enough humidity to minimize trans epidermal water losses and all those other things like the hypernatremia, but we also don't want to have such high humidity where we're increasing the risk of bacteria colonization or we're delaying the maturation of the skin.

I love this quote from Sung, et.al. In 2013. And it says, "Maintaining appropriate body fluid metabolism as well as balanced electrolyte levels in the extremely low birth weight infant following delivery is regarded as the most important factor to morbidity such as PDA, bronchopulmonary dysplasia and necrotizing enterocolitis." When we think about all three of those things, we know how difficult it can be to manage and how it can affect our outcomes, our morbidities, and mortalities. We need to make sure that we are maintaining good fluid and electrolyte balance in these babies. One of the ways that we do that, especially in the first week of life to two weeks of life, is through the use of humidification.

Some of the challenges that we look at when we talk about thermoregulation overall as a unit include a lack of local thermoregulation guidelines for preterm infants specifically, a lack of staff awareness and education on the importance of normothermia in preterm infants, and a lack of consistency amongst medical and nursing staff on thermoregulation practices. The question really is what are we doing well, but also what are we doing wrong? I'm sure that most of this information probably is not new to us as NICU providers. So, we need to stop and look and think about what are we doing that can be improved upon? What are the thermoregulation challenges that we continue to see in our unit? Every unit is so different in the things that they do well and in the areas that they struggle in, but thermoregulation is so important to overall outcomes, and it's a great opportunity for QI projects and a QI thermoregulation bundle.

We had our own quality improvement projects that we had chosen, and we worked together with the equipment rep to come up with a troubleshooting guide for our bedside nurses. A few things on there are to continue to preheat those Giraffe beds to 37 degrees. And if you have a non-preheated bed to be used for admission, we're going to preheat that bed then with the top-up on 100% for at least three minutes. We'll use the air boost when those portholes are open for a prolonged time. We're going to utilize the Baby Susans which rotate around for IVs, intubation, and different procedures whenever possible. And then a couple of tips on probe placement.

One simple thing that you can do is look at your equipment. What do we have? How are we not using it correctly? Or what things are we using correctly that maybe other nurses in our unit that are new or come from different locations can be helped with this information and coming up with something like this just as a bedside resource. And every time we have something like this at the bedside, it can just serve as a great reminder to our team.

So, what do we do with all this information that we've been given? Here are a couple of process improvement ideas. I know small baby teams. All the studies are supportive of small baby teams as far as outcomes, but that's one thing that you can do. You can review the implementation and adherence of your thermoregulation guidelines that are particular to your unit. You can have training and accountability among nursing, RTs and providers. And then finally, and to me most importantly is remembering your why's. And that's a big thing for me as a provider and as a NICU nurse is why we are doing what we're doing. Why do we care about thermoregulation? And it all does point back to those statistics that we shared in the beginning. We have the ability to impact outcomes, morbidity and mortality in this patient population and really impact them for the good.

And here's one of the quality improvement projects that I focused on, and that was the use of humidity in our unit. We had already used humidity as a baseline, 80% for the first two weeks of life, and then we would have a general weaning guideline that our nurses followed. And somewhere in the projects that I wanted to look at, which again, opened the door to more projects was what if instead of just following a standardized weaning from humidity, we look at individual weaning of humidity? For example, if you have a two-week-old infant who seems to have increased insensible water losses, their sodium levels are high, they're in the 150s or they've had excessive weight loss and just signs that point to increase insensible water losses, what if we just delayed the weaning of humidity in these patients a little bit?

One of the things that we did find that spurred off from this project was that it really helped to improve physician to nurse communication. We did a lot of education with our nurses about the importance of thermoregulation, the importance of humidity and fluid and electrolyte balance. That education empowered our nurses to have discussions with our physicians and our nurse practitioners about, "Hey, I've noticed the baby may have

some signs of increased insensible water losses and we're due to ween humidity today. Maybe we should delay that ween and keep the baby stable at the current humidity." It was really an interesting project and overall, it helped communication within our unit as well. That's just one example of an idea regarding thermoregulation and a QI project.

Looking at future utilization, specifically central peripheral temperature gradient monitoring for the detection of late onset sepsis. Studies have shown an association between thermoregulatory alterations and sepsis in newborn infants with normal temperatures. Instead of just monitoring a single axillary temperature or having that temperature probe on one specific location, we're looking at the difference between a central and a peripheral temperature gradient. There was a small pilot study by Leante-Castellanos that demonstrated interesting results regarding this thermal gradient alteration. For this study, it was defined as a gradient greater than two degrees Celsius in infants delivered less than 1500 grams or less than 32 weeks gestational age. Late onset sepsis is always a concern and a struggle in our unit. We have babies who are already struggling with respiratory distress or apnea and other soft symptoms where we're not quite sure if they are having increased apnea because they're sick, because they just need an increased dose of caffeine or is there something else going on? Is there a problem with the ET tube? Are they requiring increased FIO tube because they have a PDA and they're getting sick? Etc.

We all struggle with detecting late onset sepsis. So, this study found that there was an alteration in that temperature gradient noted in 12 newborns. In 10 of those infants, the alteration coincided with late onset sepsis. Nine cases were confirmed, one was probable. And in the remaining two patients, one presented with a hemodynamically significant PDA and the other one with NEC. The sensitivity of the gradient for diagnosis of proven or probable late onset sepsis was 90.9% with a specificity of 90%. So pretty great results. In those 10 infants that had the late onset sepsis, labs were drawn within an hour of the gradient alteration and laboratory results were not suggestive in infection in 80% of that population. What do we do the first time the baby is having bradycardia becomes somewhat symptomatic? We send off those labs. And oftentimes they are reassuring. We don't really find anything specific, and that's because CBCs or a CRP in this infant population can be difficult to determine if there is some type of a sepsis process going on. The fact that 10 of those babies did have late onset sepsis and 80% of them did not have any laboratory changes that coincided with that initial gradient alteration, is fascinating.

And then finally, what do we do with what we know? First and foremost, I want you to remember that nurses have impact. With physician providers, the management of the thermal neutral environment and thermoregulation aren't always on the forefront of their minds. They may not be experts as far as how to work your incubator beds, how to change from servo mode to air control, and the differences and the importance of doing each one. This is your vital sign to own and to take accountability for and to be able to impact Run with it. Meet with your NICU leadership. Look at what's going on in your NICU. As bedside nurses I think you all have a great idea and a great pulse for what's going on in your unit. Areas where you're struggling. Where you see, "Wait. The last couple babies I've admitted their temperatures have been on the lower side. What's going on?"

Meet with NICU leadership, garner support. Show them the way that temperature can impact your outcomes. Get into literature views. Search the literature. Look for what evidence-based practice is showing what the best practice is. Chart audits and compliance checks. I know nobody really wants to be that person that's looking at those things sometimes, but even just doing it anonymously and looking and seeing what you're finding regarding temperature and how you're managing it in your unit? Are we adhering to our policies and procedures? Are we doing what we've set in place and what we know to do? The look at those policies and procedures and guidelines. Are they up to date with clinical practice and what the research is showing, or do they need to be reworked? Then, garner some support for that, get your colleagues together, and starting to work on those.

Creating a taskforce or special team. Once you share those statistics and the impact that you can have in maintaining stable temperatures, especially in our extremely low birth weight population and the importance of a thermoneutral environment, it shouldn't be hard to get folks together to work on a project like this. Do retrospective chart reviews. Both to see what you could be doing better, and then looking at what your changes have done as far as results are concerned. Look to see, we've implemented a new guideline or are we making some changes to our initial temperature management during the golden hour. Look back and see, did we make any changes in outcomes? Are we impacting the baby? Are we having better results? And continue to work through that process. Those PDSA cycles, although people don't really enjoy talking about them, they really can make a difference. And they don't have to be difficult. It does not have to be a huge intense project. I think the key is starting somewhere and then going. And I feel like one of the great things about PDSA cycles and quality improvement projects is they continue to cycle through and open the door to further projects and more learning.

I have my references listed here that you'll be able to see. I think there's several great references that you can look through and even as a starting point as far as looking at the research for yourself and making sure that your policies and procedures in your unit are up to date with current practice.

For the full webinar and other resources around thermoregulation, go to: https://clinicalview.gehealthcare.com/webinar/optimizing-temperature-management-infant

References

1 Bissinger, R. L., & Annibale, D. J. (2010). Thermoregulation in very low-birth-weight infants during the golden hour. Advances in Neonatal Care, 10(5), 230–238. https://doi.org/10.1097/anc.0b013e3181f0ae63

2 Çınar, N., & Filiz, T. (2006). Neonatal thermoregulation. Journal of Neonatal Nursing 12(2), 69-74 https://doi.org/10.1016/j.jnn.2006.01.006

3 Evans, N., & Rutter, N. (1986). Development of the epidermis in the newborn. Neonatology, 49(2), 74–80. https://doi.org/10.1159/000242513

4 Fawcett, K. (2014). Preventing admission hypothermia in very low birth weight neonates. Neonatal Network, 33(3), 143–149. https://doi.org/10.1891/0730-0832.33.3.143

5 Knobel, R., & Holditch-Davis, D. (2007). Thermoregulation and heat loss prevention after birth and during neonatal intensive-care unit stabilization of extremely low-birthweight infants. Journal of Obstetric, Gynecologic & Neonatal

Nursing, 36(3), 280–287. https://doi.org/10.1111/j.1552-6909.2007.00149.x
6 Koop LK, Tadi P. Physiology, Heat Loss. [Updated 2022 Jul 18]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK541107/
7 Kurimoto, T., Ibara, S., Ishihara, C., Naito, Y., Hirakawa, E., & Yamamoto, T. (2022). Incubator humidity and temperature control in infants born at 22–23 weeks' gestation. Early Human Development, 166, 105550. https://doi.org/10.1016/j.earlhumdev.2022.105550
8 Leante-Castellanos, J., Lloreda-García, J. M., García-González, A., Llopis-Baño, C., Fuentes-Gutiérrez, C., Alonso-Gallego, J., & Martínez-Gimeno, A. (2012). Central-peripheral temperature gradient: An early diagnostic sign of late-onset neonatal sepsis in very low birth weight infants. Journal of Perinatal Medicine, 40(5). https://doi.org/10.1515/jpm-2011-0269
9 Li, S., Guo, P., Zou, Q., He, F., Xu, F., & Tan, L. (2016). Efficacy and safety of plastic wrap for prevention of hypothermia after birth and during nicu in preterm infants: A systematic review and meta-analysis. PLOS ONE, 11(6), e0156960. https://doi.org/10.1371/journal.pone.0156960
10 Manani, M. (2013). Elimination of admission hypothermia in preterm very low-birth-weight infants by standardization of delivery room management. The Permanente Journal, 17(3), 8–13.
11 Meyer, M. P., Hou, D., Ishrar, N. N., Dito, I., & te Pas, A. B. (2015). Initial respiratory support with cold, dry gas versus heated humidified gas and admission temperature of preterm infants. The Journal of Pediatrics, 166(2), 245–250.e1. https://doi.org/10.1016/j.jpeds.2014.09.049
12 Modi, N. (2004). Management of fluid balance in the very immature neonate. Archives of Disease in Childhood - Fetal and Neonatal Edition, 89(2), 108–111. https://fn.bmj.com/content/89/2/F108
13 Moniaci, V. K., & Bellflower, B. (2021). Nann's thermoregulation in the care of infants guideline for practice executive summary. Advances in Neonatal Care, 21(5), 340–340. https://doi.org/10.1097/anc.0000000000000945
14 Monnikendam, C. S., Mu, T. S., Aden, J. K., Lefkowitz, W., Carr, N. R., Aune, C. N., & Ahmad, K. A. (2019). Dysnatremia in extremely low birth weight infants is associated with multiple adverse outcomes. Journal of Perinatology, 39(6), 842–847. https://doi.org/10.1038/s41372-019-0359-0
15 Singh, T. S., Skelton, H., Baird, J., Padernia, A., Maheshwari, R., Shah, D. M., D'Cruz, D., Luig, M., & Jani, P. (2022). Improvement in thermoregulation outcomes following the implementation of a thermoregulation bundle for preterm infants. Journal of Paediatrics and Child Health, 58(7), 1201–1208. https://doi.org/10.1111/jpc.15949
16 Sodemann M, Nielsen J, Veirum J, Jakobsen MS, Biai S, Aaby P. Hypothermia of newborns is associated with excess mortality in the first 2 months of life in Guinea-Bissau, West Africa. Trop Med Int Health. 2008 Aug;13(8):980-6. doi: 10.1111/j.1365-3156.2008.02113.x.
17 Soll, R. F. (2008). Heat loss prevention in neonates. Journal of Perinatology, 28(S1), S57–S59. https://doi.org/10.1038/jp.2008.51
18 Sung, S. I., Ahn, S. Y., Seo, H. J., Yoo, H. S., Han, Y. M., Lee, M. S., Chang, Y. S., & Park, W. S. (2013). Insensible water loss during the first week of life of extremely low birth weight infants less than 25 gestational weeks under high humidification. Neonatal Medicine, 20(1), 51–57. Retrieved August 16, 2022, from https://doi.org/10.5385/nm.2013.20.1.51
19 Wood, T., Johnson, M., Temples, T., & Bordelon, C. (2022). Thermoneutral environment for neonates: Back to the basics. Neonatal Network 41(5), 289-296. https://doi.org/10.1891/nn-2022-0003

Unplanned Extubation in the Neonatal Intensive Care Unit

In this feature, Neonatal Intensive Care adapts educational webinars delivered by clinicians and healthcare providers about the actual application of specific products and therapies. The webinar adapted below was presented as part of Respiratory Care Week by Brian K Walsh PhD, RRT, RRT-NPS, RRT-ACCS, RPFT, FAARC.

Thanks for that introduction and happy Respiratory Care Week to all you guys out there that are respiratory therapists. I look forward to hopefully seeing you at Congress. If you do, stop by and say hi. Stop me in the hallway, whatever. I'm very approachable and would love to chat with you and meet you.

Today we're going to talk about unplanned extubation, specifically in the neonatal intensive care unit. A lot of these will also fall into the PICU as well, but we'll specifically just talk about the NICU for today.

Let's start with the unplanned extubation definition. The working definition, as you guys probably already know, is an unintentional dislodgement. We used to use self extubation, things like that. We really gotten down to this UE, meaning it's unplanned, whether the patient did it, a healthcare provider, or whatever it may be that it's an unintentional dislodgement of that endotracheal tube and it can be done by several different types of ways of doing it during family-centered care. Obviously, team care like X-rays is a big one that we'll talk a little bit more about, and then also patients unrestrained, also knocking out the ET tube themselves.

Unplanned extubations in the NICU, the prevalence is all over the place. I've never seen a prevalence that is so wide, but it can be as large as 16.1 unplanned per 100. It's different than ventilator associated pneumonia, which is per thousand, as low as 0.54, but very few people are actually able to keep it below one a lot of times.

But that is still our target and if it was easy, everybody would do it, right? It is difficult a lot of times. Anywhere from 14%-41% of infants experience an unplanned extubation during their NICU hospitalization.

When a dislodgement actually occurs, I like to use the DOPE mnemonic. This is something that came from the American Heart Association many years ago, and I really still enjoy today and it helps me think through assessing for an unplanned extubation.

Is it dislodged? Is it obstructed? Is there a pneumothorax or is it equipment failure? Let's step through those.

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

When it comes to displacement, a lot of times you obviously want to do an inspection. Do you have equal chest rise and fall? Vapor in the tube is the classic one for initial intubation. I will say that that gets harder if they were previously intubated and they're extubated now because a lot of times that is already missed in that tubing. It's not like taking a brand new tube and then putting it in and then you can actually see that vapor in the tube pretty readily.

Auscultation, obviously equal breath sounds, maybe louder on the right than the left and so you may have a right mainstem intubation for that. I will say that particularly with the micropreemies auscultation, at least in my hands, is sometimes difficult because I've had patients unplanned extubate and I thought I heard bilateral breath sounds because it radiates across their little body. When they're 500 to 600 grams, auscultation can be a little bit problematic because it seems like the breath sounds are all over the entire body.

As they get older, it's a little bit easier as well. Then of course, end tidal CO_2 is the gold standard to understand whether you use colorimetric or waveform capnography. It's something that we're trying to push people more to capnography the waveform because it can help you with resuscitations as well as whether you're intubated appropriately or not.

When it comes to obstruction, in-line suction catheter is the mainstay, if you will, I think for most neonatal intensive care units. You certainly want to think about do they have a history of secretions, were they tenacious thick, things like that. Then do their saturations improve when you do suction them out when you are looking for an obstruction.

Pneumothorax is obviously one that hopefully happens pretty rare, but when it does happen, you will remember it a lot of times. When you're suspecting a pneumothorax, a lot of times you will have unequal chest rise and fall. You won't necessarily hear breath sounds on that side. Then if you are in a unit that uses transillumination, that's something that you can use to actually determine whether there is a pneumothorax or not.

But remember, it takes cutting out a lot of the lights and things like that and sometimes it's very disruptive to the unit. I also see people using ultrasound nowadays as well as sometimes just blindly tapping the side in which you don't hear breath sounds, which particularly if the patient is in extreme danger of arrest or something like that, you may want to do proactively.

When it comes to equipment failure, obviously bagging is the first thing that you want to do in making sure that it's not an equipment failure from a ventilator perspective or disconnecting the circuit. Then you certainly want to look for improvement. If they do improve with manually ventilating, then you want to probably obviously look at the ventilator to make sure that the circuit has integrity and there's not a disconnect or something like that that may have caused desaturation.

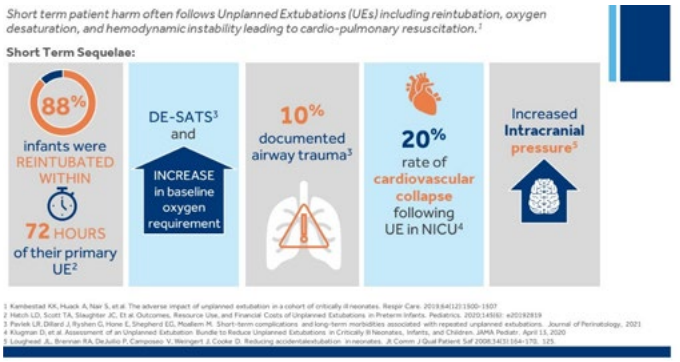
When it comes to clinical outcomes, a lot of times this is something that I've come to more of a realization than I used to have. I used to think unplanned extubation, particularly in the NICU, the NICU is a risky business, right? There should be an acceptable amount of unplanned extubations.

But that's really the false. That's almost like saying there should be an acceptable amount of ventilator associated pneumonia. That's just not really a way to drive quality, is by accepting any standard of UEs in those situations.

But let's talk about why that's so important to keep striving even if you have one of the lowest rates of UEs possible out there, why you need to continue to look at that.

We'll break it down between short-term and long-term. Short-term, 88% of infants are reintubated within 72 hours.

Short Term



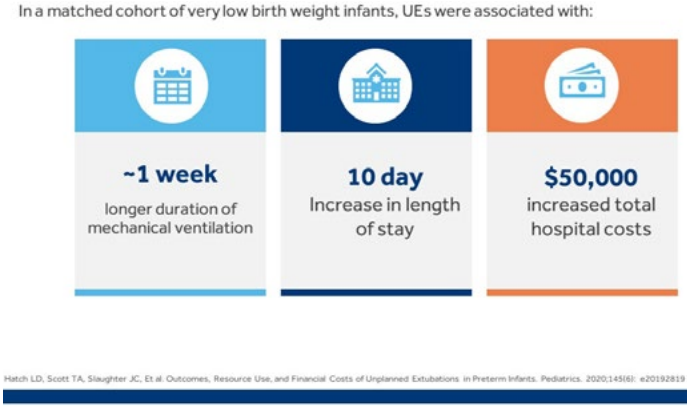
Certainly, they have desaturation, and if they have atelectasis associated with that, they'll have an increase in baseline oxygen requirement, certainly reintubation. You can traumatize the airway by manipulating it or instrumenting it. Then about 20% of those guys actually have cardiovascular collapse.

Either by the time you recognize it, they desaturate it so much that they have difficulties in responding to the replacement of that airway. Then certainly last but not least on this group is increased intracranial pressure.

Now, whether that leads to a bleed or something like that, we can't really say for the short-term. But it's not something that you want, particularly in preterm infants that have a general matrix that can actually be susceptible to bleeding.

When it comes to long-terms, UE is associated with bronchospasms. You can have a pneumonia that came from the aspiration, hypotension that may lead to a lactic acidosis, arrhythmias, CPR event, and even death if not recognized soon enough. Then they also have an increased risk of repeated unplanned extubations. It's almost like they figure it out and you have to check things. But it's probably not the child itself. It's actually what we're doing with that particular patient that probably causes those unplanned extubations or repeated unplanned extubations. Then there's associations with bronchopulmonary dysplasia, tracheostomy, subglottic stenosis, emergent reintubations, laryngeal or tracheal injury or scarring, pulmonary injury from excessive ventilation and interventricular hemorrhage.

Long Term

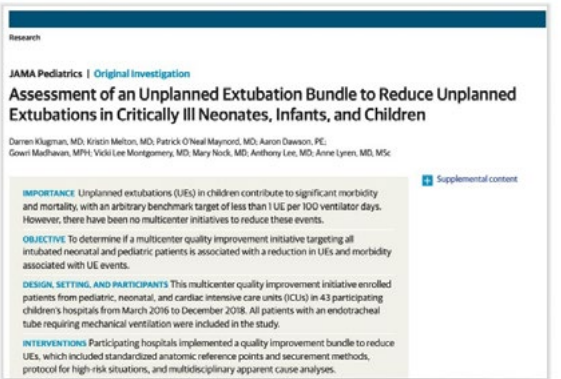


Hatch LD, Scott TA, Slaughter JC, Et al. Outcomes, Resource Use, and Financial Costs of Unplanned Extubations in Preterm Infants. Pediatrics. 2020;145(6): e20192819

You say, "Well, so what?" Let's talk about financial implications. Sometimes this is what administrators like to hear about that want to help you with improving the quality of that is that there can be lots of associated hospital cost with it.

In a matched cohort of very low birth weight infants, where UE was associated with an increased length of stay or duration, sorry, of ventilation, as well as an increased length of stay by 10 days, so one week and 10 days, and then associated about $50,000 in hospital cost. If you have several of those a month, you can imagine how much that adds up if you have a really busy NICU. Let's talk about some evidence-based approaches. What does the current research support?

Certainly, assessment of unplanned extubation bundles can help reduce or decrease your unplanned extubation rate in neonates, in infants as well as children. It applies across the gamut of pediatric respiratory care. When they looked at these standardizing approaches to anatomic reference and points and securement methods like using two licensed clinicians for securing and repositioning, or manipulating the endotracheal tube, looking at anatomic landmarks like gum, teeth, nare, certainly things like that that everyone agrees to, and not use things like lip that can move.


Research

JAMA Pediatrics | Original Investigation

Assessment of an Unplanned Extubation Bundle to Reduce Unplanned Extubations in Critically Ill Neonates, Infants, and Children

Darren Klugman, MD; Kristin Melton, MD; Patrick O'Neal Maynord, MD; Aaron Dawson, PE; Gowri Madhavan, MPH; Vicki Lee Montgomery, MD; Mary Nock, MD; Anthony Lee, MD; Anne Lynen, MD, MSc

Supplemental content

IMPORTANCE Unplanned extubations (UEs) in children contribute to significant morbidity and mortality, with an arbitrary benchmark target of less than 1 UE per 100 ventilator days. However, there have been no multicenter initiatives to reduce these events.

OBJECTIVE To determine if a multicenter quality improvement initiative targeting all intubated neonatal and pediatric patients is associated with a reduction in UEs and morbidity associated with UE events.

DESIGN, SETTING, AND PARTICIPANTS This multicenter quality improvement initiative enrolled patients from pediatric, neonatal, and cardiac intensive care units (ICUs) in 43 participating children's hospitals from March 2016 to December 2018. All patients with an endotracheal tube requiring mechanical ventilation were included in the study.

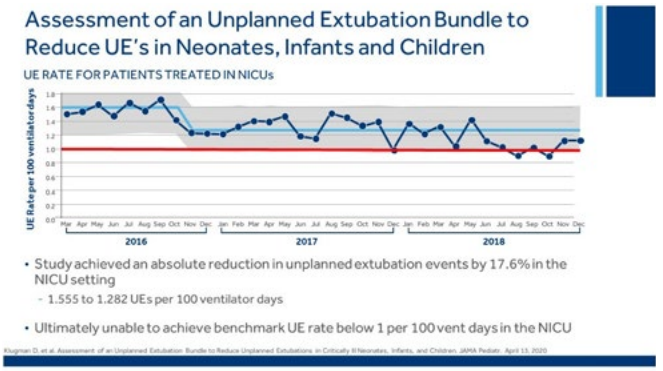
INTERVENTIONS Participating hospitals implemented a quality improvement bundle to reduce UEs, which included standardized anatomic reference points and securement methods, protocol for high-risk situations, and multidisciplinary apparent cause analyses.

Klugman D, et al. Assessment of an Unplanned Extubation Bundle to Reduce Unplanned Extubations in Critically Ill Neonates, Infants, and Children. JAMA Pediatr. April 13, 2020

Then selecting a standardized securing method, whether it's taping, you think, "Well, taping can only be done one way." Well, no, there's actually three different taping methods that you can use. Choosing one, selecting it, and sticking with it is really important. Then for high-risk situations, actually protocolizing what you do. Having two people basically at the bedside for things like rated graphics, images and studies, invasive procedures, kangaroo care, and repositioning, switching beds, weighing, things like that, that we often know is associated with unplanned extubations. You should have two care providers, one dedicated to holding that tube and making sure that it doesn't move while you're moving the child. That's their sole role is to do that.

Then multidisciplinary review of events is something that also should be done so that we're making sure that you do it right in the situation within that current shift so that everyone knows exactly what happened, and where we may actually improve things by having a cause analysis done exactly or as soon as possible right after the event with the people that actually witnessed it. When you do these types of things, you can actually see that you can actually lower your UE rate. Remember, I told you at the beginning, less than one is the preferred unplanned extubation.

In a study, they were able to actually get to under one for a short period of time, but not sustain it. Even though they've made a mark success from 1.5 to 1.2, 1.3 per 100 ventilator days, they were unable to actually get it below that one mark for more than a couple of months there that you'll see.

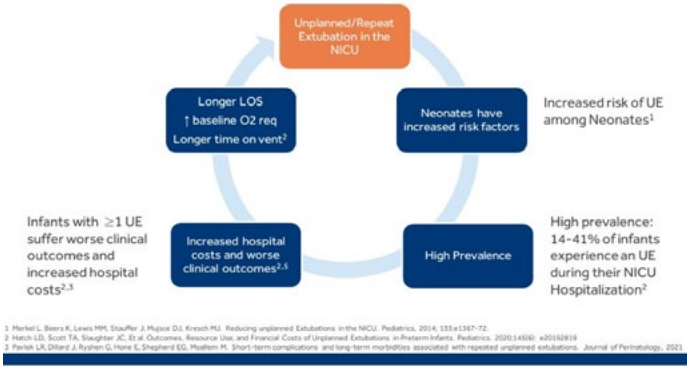


When you're assessing unplanned extubation bundles, a lot of times eliminating unplanned extubation, the harm associated with those events remains achievable and all should try to strive for that zero UEs that we all long to as well. These are folks that have actually worked really hard to get to zero and were unable but still believe that everyone should strive for that zero unplanned extubation. What about the other studies that have been done looking at unplanned extubations and decreasing it in the NICU with looking at just tip positioning? This was one that was published in Respiratory Care. Endotracheal tubes that are high, about to come out kind of thing, are associated with unplanned extubations.

This is a no doubt but it's one of those things that when you focus on it, a lot of times you actually can change the practice. They decided to focus on the endotracheal tip being below T1 and using that as a landmark when they're looking at X-rays to actually make sure that the tip is in the appropriate position during that intervention.

Then there's some review of some technologies that we'll get to here and look at some of the things that we can think about. Let's first pause and talk about the challenges. Obviously, unplanned extubations or repeat extubations in that particular child is associated with increased risk factors such as hospitalization and poor clinical outcomes. Even longer length of stays, more oxygen, as we talked about. That prevalence is anywhere from 14%-41% that experience that, and most units have a rate of greater than one UEs per 100, as we see through the literature.

Current Challenges



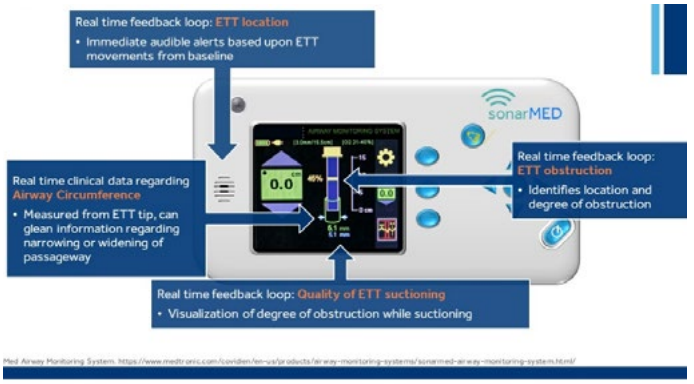
Limitations in current practice is that we focus on X-rays, but if you think about it, we don't often expose our infants to X-rays as often as maybe we used to in the past, and so that sets us up for a potential failure because we're not getting daily X-rays like we used to back in the day and now we're going with as a need.

In other words, if they have more respiratory support or something like that, or maybe once or twice a week, every other day, things like that. Then standardizing that anatomical reference and even teaching the radiologist of where we would like to keep that so that if they read an X-ray in which it's higher than that, that they call and have a checks and balance system.

Certainly, using the DOPE algorithm will help with the process of elimination by looking through these things and not necessarily pulling an endotracheal tube that was maybe obstructed or something like that in which you could have suctioned it out. But if it is obstructed and you can't quickly suction it out, you should definitely pull it. I would side on pulling it always versus leaving a plug endotracheal tube in there, or a dislodged one in the esophagus for a prolonged period of time.

SonarMed has come out and it's actually been out for a while, and most recently has refocused its attention on the neonatal population. Yes, what is SonarMed? It's a small sensor that uses sonar to help acoustic waves to help understand the distance between the carina as well as the diameter of the airway itself.

Applications



This sensor can actually be put on the endotracheal tube as a standard 15-millimeter adapter. It gives you real-time warnings and you can set alarms and things like that to actually be able to utilize that to alert people to the change in positioning of an endotracheal tube. If you look at the device itself, it has lots of things, and so it has audible alarms, obviously, just like a ventilator alarm or something like that, that can alert you to the changes.

You have real time of ET tube obstructions, and so you can see here, it's showing you a 45% obstruction of the endotracheal tube. About midway down, you can see that the quality of ET tube suctioning. If you suctioned and you reduce that by 45%, it'll tell you those types of things or if the tip is now obstructed. Then it also has real time circumference of the endotracheal tube as well of that airway. This is something that I'll talk to you a little bit more about in a second or two.

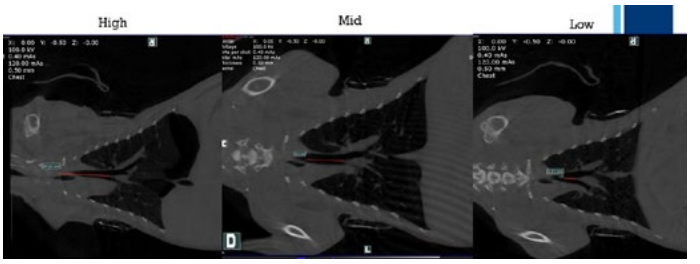
I most recently participated in a translational study in which I was doing a different study in rabbits. But I needed the ability to understand where the endotracheal tube was. I needed to be at the right mainstem, this particular animal, to do a particular study.

I wanted to have something that had real-time feedback, and so I knew about the SonarMed. I reached out and said, "I'd love to use this in my study as an add on study to look at how accurate the device is."

We had pretty small rabbit models, which is our neonatal translational model, and we had endotracheal tubes from 2.5-3.5 in the situations. Prior to lung injury, we actually had what we call a normal lung, and we would right mainstem, as I mentioned before. We would do things like hypoventilation, PEEP titration up and down. You can imagine the airway moves quite a bit as you expand the lung, as you collapse the lung, and so we were able to actually look at that.

Then we also had the injured lung, and so I did a surfactant washout model and we did things like stair step recruitment and decrement PEEP titration. The goal for this particular part of the study was to actually look at the relationship between low, mid, high, and right mainstem. We used CT scans at each one of these events. We considered the gold standard for being able to determine the distance between the carina and the SonarMed's assessment of the distance of the carina. Here's the CT scans, and you can see here that we have one that's high, and so you can see that this is 3.7 centimeters above the carina.

CT Carina Distance Method



This one is mid, and so you can see that it's 2.1 above the carina. Then this one is 0.64, and so just a little over half a centimeter above the carina in these images here. This is what we compared it to. We measured each one of these X-rays and then compared it to the SonarMed, which was actually applied during that same time frame.

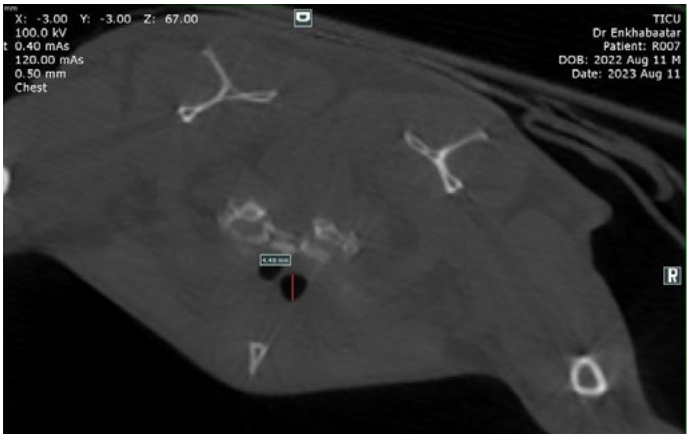
You can see here, we did five different animals, and we did several CT scans, as high as 16, as low as 12. Then you can see the mean carina distance by CT scan as compared to the mean SonarMed carina distance here. You can see that they're really close and they do fairly well. We're walking through the differences here between the two devices, which I found really remarkable.

Carina Distance Results - cm

Animal #	Number of CT scans	Mean CT carina distance (SD)	Mean Sonarmed carina distance (SD)	Mean Diff
R0007	15	3.52 (0.22)	3.54 (0.70)	+0.02
R0008	13	2.62 (0.79)	2.63 (0.76)	+0.01
R0009	16	1.01 (0.23)	1.77 (1.10)	+0.76
R0010	16	1.75 (0.39)	1.96 (1.63)	+0.21
R0011	12	1.89 (0.86)	2.05 (1.18)	+0.16

Additionally, we were able to actually look at the diameter. Because we were doing CT scans, I could actually look at the slice and actually look at the airway.

CT Diameter Methods



We went a few millimeters below the endotracheal tube, which is where the SonarMed is assessing the diameter, and we were able to measure that. A couple of the limitations, and you actually see here, is that the diameter of the airway is not perfect either. In other words, it's not a perfect sphere or circle because we have those cartilages rings and openings and things like that.

It's not super perfect, but it's good enough, I think, to take a shot at measuring those as we go along. You can see here that also when it comes to measuring the diameter by CT scan and then measuring it by SonarMed, that they're really good.

Now, this is in millimeters, and so I want to draw your attention to that. It's not centimeters. These are really representative neonatal airways when it comes to diameters. Then you can see the differences here, but pretty close and pretty similar.

Trachea Diameter Results - mm

Animal #	Number of CT scans	Mean CT diameter (SD)	Mean Sonarmed diameter (SD)	Mean Diff
R0007	15	4.45 (0.29)	4.97 (0.31)	+0.52
R0008	13	5.15 (0.38)	4.74 (0.26)	-0.41
R0009	16	5.41 (0.55)	4.8 (0.46)	-0.61
R0010	16	5.45 (0.33)	4.55 (0.17)	-0.9
R0011	12	5.28 (0.37)	4.93 (0.5)	-0.35

Then when you summarize them, we ended up doing 68 scans in those five animals, and you can see that they're fairly close. It seems that in the distance, the SonarMed overestimates by a little bit less than a half a centimeter and then underestimates the diameter when it comes to that.

Summary

- Still analyzing the data and hope to submit for publication soon.
- Debating the difference between statistical significance and clinical significance.

3. System Accuracy

Indicator	Accuracy (95% Confidence)
ETT Tip Movement	± 1 mm
ETT Obstruction (%)	± 15% [1]
Passageway Diameter (mm)	± 25% [2]

1 - Percentage is absolute. For example, if actual obstruction is 50% of ETT cross-sectional area, then accuracy is 35% to 65%.
2 - Percentage of passageway diameter. For example, if actual diameter is 10.0 mm, then accuracy is 7.5 mm to 12.5 mm.

But remember those limitations that I mentioned about the airway not being perfectly round. Then there's measurement errors that I could even make when I was actually measuring the airways.

Right now, we're looking through and pouring through this data. But I wanted to present it to you guys because I thought it was almost hot off the press, if you will. We're still debating the differences between what is statistically significant versus what is clinically meaningful, and then also understanding the accuracies that are published by SonarMed, for example, of the tip of the movement for example it's plus or minus 0.3 centimeters or 3 millimeters. Obstruction is 15% and then the airway diameter is plus or minus 25% when it comes to those types of things. It's looking like the data has fallen within those well-known accuracies of the device. Next steps for us is that.

We are actually actively evaluating the SonarMed and we're breaking it into three different categories: high risk situations, kangaroo care, skin to skin, those kids that have difficult airways. We want to carefully monitor them even a little bit more closely when there's special manipulations of the endotracheal tube. We had this BPD child in which we had a left large bleb, if you will, and we were trying to deflate it.

The team wanted to right mainstem the infant and so we actually used the SonarMed for us to help guide us into the right mainstem and then also monitor just in case it pops out, because, as you know, it's hard to keep it in the right mainstream because it's a large endotracheal tube and that takeoff is a little bit smaller. We used it to monitor our progress in those situations. Then the last one is one that is coming up is, for me at least, and something I didn't realize until starting to utilize this as the airway diameter.

Sometimes you have those kids that have a large endotracheal tube leak and you want to know, can I upsize them? Being able to estimate the diameter of their airway could be something that this device could be used for, to help give you a little bit more security that, hey, yes, that larger tube will actually fit and fit well in that particular child. Then last but not least is more of a research one, is tracheomalacia, because you can actually see on the device in real time airways opening and closing with positive pressure ventilation.

In those kids with tracheomalacia, I could imagine that it would actually be much more severe, if you will, of opening and closing. Maybe that could help you with positioning the endotracheal tube a little bit beyond, say, the tracheomalacia, or adjusting PEEP to actually help minimize the collapse of that airway in those situations. That's for more to come, if you will, about situations in which I think it might be actually beneficial to utilize this device.

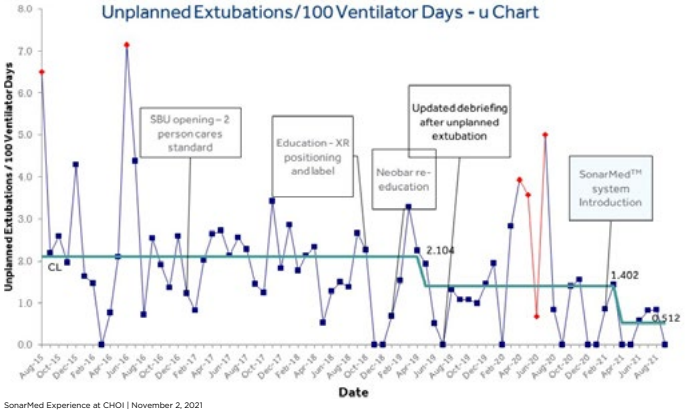
Then we'll end on an experience from a children's hospital in Illinois that looked at using the SonarMed system to actually help them reduce their unplanned extubations. What they started off with is that they had no standardized way of collecting the unplanned extubations.

They discovered that when they did figure it out, how to collect this information, they had a higher rate than they desired. Compared to others, they utilized a neobar in those majority of cases and they didn't routinely do nasal intubations. Their major intervention was doing a root cause analysis on unplanned extubations. They educated all RTs on proper neobar sizing and taping methods.

They did auditing of the bundles that they implemented, and they annotated the ET tube placement by radiology on each chest X-ray and verified that position at the gum. They did mass education to their units on the proper positioning for chest X-ray.

Remember, the head position can really matter of whether that endotracheal tube is low or high. A lot of times they encouraged use of two person in those cares of all intubated patients, and their baseline rate was 2.1 per 100 ventilator days prior to the interventions. They had a historically low chronic lung disease rate compared to other Vermont Oxford groups or centers.

Outcomes



SonarMed Experience at CHOI | November 2, 2021

Unplanned extubations are associated with physiologic changes including hypoxemia, hypercapnia, increased arterial pressure, and increase intracranial pressure that often can lead to emergent less controlled endotracheal intubations. It seems like it always happens in the middle of night when you're at two or three different deliveries. At that same time, then you have one in the unit as well.

Then repeat intubations, especially done emergently increase the risk of airway injury, lung injury, ventilator associated pneumonia, and then non-pulmonary complications such as IVH.

Unplanned extubations is the core measurement of the US News and World Report as a marker of quality. Then last but not least, and maybe probably the important part is that the team knew they could do better. Why SonarMed in that situation? Despite all interventions that they implied they still actually were only able to drop it from 2.1 to 1.4, but they really wanted to continue to strive for that less than one situation.

Noting that unplanned extubations were during cares such as kangaroo time, critical moments despite encouraging two-person cares, the staff not completely bought in in the two-person care.

I can totally feel that because I've tried doing these implementations and they're like, "I've been doing this for 20 years or so in. I've never had an unplanned extubation." It can be tough culturally a lot of times and then presume that the endotracheal tube had tended to move especially during critical moments but no way to actually measure whether it actually moved or not.

I think we see this and know this a lot of times is that their cheeks move quite a bit even with different kind of holders that are out there commercially available or tape jobs. We know that endotracheal tube, even taped to the best of your ability, can move quite a bit.

Then some unplanned extubations also occurred outside of care. Normal respirations, typical movements of an infant, even a hiccup one that they reported and they pushed the tongue to endotracheal tube out a lot of times and they wanted to see if monitoring these movements in real time could help them avoid these unplanned extubations. Their outcome is that they were actually able to achieve their goal of getting below that one at 0.51 per 100 ventilator days for the last six months. They were pretty proud of that and I think they should be. That is a huge accomplishment.

The bedside staff had observed more focused approach to invasive mechanical ventilation. It brought about awareness of typical cares that being provided and how much the ET tube does move and migrate, if you will, during those events. They were able to actually track it really well and so they actually looked at the two-person cares, but again, they're still in this two range education, neobar reeducation.

Updated debriefing after unplanned extubations seemed to help quite a bit but then they're back up again and then the introduction of the SonarMed system was allowing them to actually keep an average down below one for six months, which was pretty awesome. The other outcomes that they had is that during critical transfers there was a strong belief in overwhelming benefits to skin to skin and things like that.

It just helped ingrain in a culture to encourage that special time, but allowed them to actually do that at a higher frequency without having to worry about an unplanned extubation or being able to monitor that kind of high risk procedure, if you will, or critical transfers, as they call it, even on high frequency ventilation, which I think is pretty cool because that can obviously be a very scary time, particularly for parents, and they don't want to move or they freeze and then they get sore from trying to hold the baby in a perfectly still situation.

Having that SonarMed device or monitor was helping to reassure that yes, you can move, get comfortable, things like that, and it would draw attention if that endotracheal tube does move and hopefully provides less anxiety and worry to the caregiver, particularly during that important time.

Eliminating unplanned extubations and harm associated with events remains achievable. Again, this is a repeat from what we talked about earlier and you can see that the Illinois experience was important and so they were able to get below 100, but we still are striving for that zero as we go along. Then I'll be happy to take any questions that the team may have or participants may have as we go along.

The recording of this presentation can be found at https://www.medtronic.com/covidien/en-us/clinical-education/catalog/webinar-wednesdays.html on October 25, 2023.

Whole Genome Sequencing is Driving Improved Health Outcomes for Newborns

Dr Madhuri Hegde, FACMG, SVP and Chief Scientific Officer of Revvity

Millions of people (many of them infants and young children) suffer from misdiagnosed or undiagnosed diseases due to insufficient genetic testing—yet there may be a way to bring those numbers down. Whole Genome Sequencing (WGS) has the potential to streamline genetic assessments and help provide early intervention.

Most people who undergo WGS have already had some genetic testing. The purpose of WGS is to find a genetic cause of a patient's signs and symptoms. WGS is the most comprehensive DNA genetic testing option available and may find a genetic cause when previous testing failed.

WGS has demonstrated its ability to improve the accurate diagnosis of rare diseases by up to 55 percent. In fact, the research that yielded this datapoint showed that of all the genetic diagnoses made, 25 percent of findings immediately impacted healthcare decisions for patients and their relatives.

Unlike Whole Exome Sequencing (WES)—which analyzes only the coding regions of an individual's DNA—WGS examines both coding and non-coding regions of the genome, making it more likely to identify DNA variations that affect gene activity and protein production, which might otherwise go undetected by WES. Other disease-causing changes like copy number variations, repeat expansions and point mutations in difficult gene regions such as for Spinal Muscular Atrophy (SMA) can be identified easier with WGS when compared with WES. Several years ago, WGS cost thousands of dollars and took several months to complete. Fortunately, over time there have been significant improvements that reduce cost and turnaround time for results—making it more accessible and useful than ever before.

Typically, physicians and other healthcare providers rule out causes one at a time until they identify a molecular diagnosis. WGS does this ruling out all at once and has the potential to become the routine, first-line test for many types of patients, which is now reflected in the American College of Medical Genetics and Genomics (ACMG) guidelines. This means you have a higher diagnostic yield, a faster time to diagnosis, and less likelihood of ending up on an ineffective or wrong treatment.

Performing testing using WGS from the beginning of a newborn's diagnostic journey also means patients can undergo fewer tests and avoid the inconvenience of scheduling and traveling to multiple doctor appointments and undergoing multiple pricks for collection of sample that is required for testing. Using WGS shortens a newborn's diagnostic odyssey. This is potentially life-changing for many patients, given that, on average it takes a child four to eight years before being diagnosed with a rare disease. You're potentially improving the patient's quality of life with early intervention while creating more effective long-term treatment plans and implementing them sooner and creating the ability to participate in clinical trials.

The Role of Dried Blood Spots

Dried blood spot (DBS) is a testing methodology that was recently approved in New York State for whole genome sequencing. When we're talking about the newborn population, a dry blood spot sample is routinely collected at birth for newborn screening purposes. In general, the capability to use this minimally invasive sample type to perform WGS means you don't need multiple EDTA blood tubes from a sick baby in order to perform WGS. In addition, a DBS card is easier to store and transport from the collection location to the testing laboratory. Revvity is one of the few companies offering whole genome tests from a simple and easily obtained sample consisting of a DBS.

Impact of Ultrarapid WGS

Ultrarapid WGS (urWGS) can help even more with timely diagnosis and with the implementation of management programs for better prognosis. New urWGS offerings can provide physicians with comprehensive, meaningful results in as little as five days to help inform clinical management and improve outcomes for critically ill patients in neonatal and pediatric intensive care units. With many genetic diseases being chronic and progressive in nature, reducing the time to reaching an accurate diagnosis can eliminate unnecessary procedures, initiate treatment and improve clinical outcomes. As a result of informing and initiating changes in clinical management, rapid WGS tests have been shown to reduce healthcare costs for patients in NICUs and PICUs and reduced length of hospital stays.

Madhuri is a passionate and perpetually curious leader whose team is committed to delivering cutting-edge products to Revvity customers, while keeping a close eye on innovation and bringing those developments to market. Madhuri is energized by bringing people and teams together to make a difference and harness science to positively impact human health. Madhuri currently serves on the board and is an officer of the American College of Medical Genetics and Genomics Foundation (ACMGF), and leads the ACMG's International Outreach and Engagement Committee.

Revvity Study Shows Value of Proactive Genome Sequencing in Newborns

The application and use of various sequencing technologies have dramatically increased, generating large amounts of data that has helped scientists and doctors better understand variations in the human genome, and how they relate to human disease. This data also helps clinicians make more informed decisions about medical management and ultimately the recommended course of treatment for patients. When it comes to newborns, doctors have relied upon insights from genome sequencing to make informed management decisions for critically ill newborns, but what about its utility in screening apparently healthy newborns? This is a question that a team of scientists from Revvity Omics sought to uncover in a study that appeared in *JAMA Network Open.*

Behind the Study

The objective of the study was to assess the clinical utility of genome sequencing versus a gene panel for curated set of medically actionable pediatric-onset conditions in the largest-to-date cohort of apparently healthy newborns and children tested at a single clinical laboratory. Given that the exome-based panel included only a limited number of genes, more findings were expected from genome analysis (including to 6,000 disease-associated genes), however, the extent and landscape of the findings remained unknown. There were 562 apparently healthy children screened by genome sequencing at the Revvity Omics laboratory in Pittsburgh, Pennsylvania: 46 were (8.2%) found to be at risk for pediatric-onset diseases, including 22 (3.9%) at risk for being very likely to develop a disease. In contrast, only 2.1% of 606 children screened with an exome-based panel of 268 genes for well-known medically actionable pediatric conditions were found to be at risk.

The risks uncovered by genome sequencing involved a wide range of pediatric-onset conditions likely to be missed on limited gene panels. Many of these risks involve high-penetrance, often neurodevelopmental disorders that may benefit from early interventions, leading to better prognosis and clinical outcomes.

Future Approach to Newborn Screening

The starkest difference was not so much in the percentage of children with uncovered risk (8% vs 2%), but the heterogeneity of the risks uncovered by genome sequencing, and that close to 50% were associated with high penetrance conditions. A limited-number gene panels, when compared to genome sequencing would have picked up only one-fifth of the high penetrance conditions, many of which are neurodevelopmental disorders that could potentially benefit from early interventions. Discussions are already underway among the medical community on what genes should be included when screening newborns by sequencing, and the study provides real-world data on what can come out of genome sequencing.

Genomic technologies have the power to revolutionize the way we detect diseases in their early stages, as demonstrated by this research. The use of proactive genomic screening would enable healthcare professionals to uncover a wide range of risks for looming pediatric onset conditions allowing for earlier interventions and personalized treatment plans based on individual genetic make-up.

Introducing genome sequencing for newborns universally could have an immense impact in the health of our population heralding a new era of pediatric healthcare and beyond. For one, beyond sequencing at birth, recording genomes allow families to keep going back to the data to look for answers to medical issues as they need it — whether it be for immediate care or family planning. Sequencing at birth also provides a true DNA profile and this data can be used in the future (if needed) as a comparative data set for any somatic oncology testing. The cost of sequencing continues to gradually decrease and soon may be more economical to implement, especially given the costs associated with delayed diagnosis of a rare disease.

Revvity's Impact

Each year, Revvity's solutions help screen approximately 40 million babies for life-threatening disorders. Revvity Omics has established itself in the world of newborn screening and rare disorders testing, and with that as its foundation, have delved into the fascinating field of genomic testing. With access to cutting-edge technologies and experience in offering top echelon testing services, its team of experts are providing the most comprehensive WGS available across the globe via its global network of laboratories, which includes laboratories in China, India, United States, Sweden, and its newest lab in the United Kingdom. Revvity Omics, under the umbrella of Revvity, Inc., is a key player in advancing health outcomes given its expertise in conceiving or ideating, developing, and then manufacturing instruments and kits, testing to assist clinical trials, and navigating the regulatory approvals process.

Looking Ahead

There is no doubt that with technological advancements in the fields of genomics and precision medicine, the rate of detection and introduction of treatments for rare conditions has grown considerably, but there is still more to be done. As genomic sequencing implications in diagnostics is continuously evolving, it's important to conduct studies that expand our knowledge to better inform the development of screening programs and diagnostic tools. But science alone is not enough — continuous collaboration between healthcare system authorities and governments is needed to ensure that real-world practices are in line with new findings as they occur.

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Benefits of an Exclusive Human Milk Diet: Conclusions, Controversies, and a Critical Review of the Evidence

Sandra Sullivan, MD, IBCLC, FAAP and Brian Scottoline, MD

Caring for any patient involves caution, attention to detail, and an understanding of risks, benefits, and limitations of knowledge. It stands to reason that adherence to evidence-based practices, when the evidence is available, should form the backbone of care practices.

Poised near the top of the evidence pyramid is the randomized controlled trial (RCT), which typically aims to evaluate the impact of one variable while keeping all other variables constant, thus providing the opportunity to evaluate the benefits and risks of a specific intervention with minimal risk of bias. All research, whether trials, studies, or experiments, has limitations based on design, endpoints, and outcome measures, and thus we need to carefully consider how that study was designed, analyzed, interpreted, and reported. By no means does this signify that research is inherently flawed; it is just to say that consideration of research should be balanced and impartial.

When applying evidence to clinical practice, new or change, we must look at *all* the available evidence, keeping the relative pros and cons of each type in mind. While RCTs provide high-quality data, medical and biomedical research also recognizes the potential value of non-RCT data: prospective, retrospective, and real-world evidence that can reflect the interventions in neonatal intensive care unit (NICU) settings over long periods of time, with many patients—with, of course, their own limitations in what can be concluded. This data affords the opportunity to evaluate extensive patient populations to several thousand, compared to the typically much smaller numbers of patients in RCTs driven by realities of power calculations and resource limitations.

The role for an Exclusive Human Milk Diet (EHMD) is an example of an intervention for preterm infants in the NICU for which there is both a growing body of published clinical research and increasing controversy over how to apply that research.

Critical Evaluation of the Data Is Essential

Before applying conclusions from RCTs to clinical practice, we must consider the trial design, endpoints, or outcome measures, and the resulting statistical analyses performed. For instance, RCT trial design can be constrained by ethical considerations, as all groups must receive, at minimum, the best level of care available *at the time of trial design lock*.

In addition, confusion regarding the meanings of and differences between clinical and statistical significance can conceal potentially important findings, particularly in the case of studies that are underpowered. Understanding power and how sample sizes were calculated is crucial for interpretation of findings. RCTs generally select for a narrowly defined patient population, which may mean the findings have limited generalizability to specific NICUs or populations of patients.

While RCTs are considered very high level of evidence, it is important to recognize that many practices and interventions have been adopted into NICU practice despite a lack of RCT data showing benefit. One key example is use of inhaled nitric oxide for preterm infants <34 weeks' gestation with hypoxemic respiratory failure and/or pulmonary hypertension.[1]

Design Implications

An EHMD is an example of an intervention for which RCT data has led to incomplete or simplified conclusions. In 2018, O'Connor et al published an RCT in which infants born weighing <1,250 g recruited from neonatal units in Ontario, Canada, were fed mother's own milk (MOM) and donor milk (DM) as required. The infants were randomized to a human milk–based fortification (HMBF, 0.81 kcal/mL) or cow milk–based fortification (CMBF, 0.72 kcal/mL), commencing at ≥100 mL/kg/day and increased at 140 mL/kg/day to 0.88 and 0.78 kcal/mL, respectively.[2]

The study failed to demonstrate benefit of an EHMD compared with a CMBF strategy with regard to feeding tolerance, morbidity, or mortality. However, it was designed in such a

Sandra Sullivan is a clinical neonatologist and breastfeeding medicine specialist currently practicing at HCA Florida Hospital in Gainesville, Florida. She received her MD and completed her pediatrics residency and fellowship in neonatal-perinatal medicine at the University of Florida. In addition to being a member of several neonatal and breastfeeding medicine academies and societies, she has delivered more than 60 lectures and presentations at congresses throughout Europe and North America. She is committed to improving patient safety and satisfaction, especially related to hospitalized newborns and those feeding breastmilk.

Brian Scottoline is an associate professor of pediatrics, surgery, molecular, and medical genetics at Oregon Health and Science University. He received both his MD and PhD from the Stanford University Medical School and did his fellowship in Boston in the Harvard Neonatal-Perinatal Medicine Fellowship program. His research focuses on the biochemistry of human milk and the neonatal intestinal microbiome, as well as necrotizing enterocolitis.

way that made it unlikely to detect other important differences between the interventions, even if one was superior. One of the key benefits of an EHMD is that it allows for earlier fortification without increasing the risk of complications such as necrotizing enterocolitis (NEC), and earlier fortification is associated with improved outcomes.[3-6] As an example, a recent head-to-head RCT involving term babies, who tolerate non-human protein better than premature infants, found improved growth and reduced NEC risk in infants with single ventricle physiology fed an EHMD post-surgery compared to a mixed human/cow milk-based diet.[7]

Ethical Implications

Early fortification could not ethically be attempted in the CMBF arm of the O'Connor study, as the early fortification strategies commonly used with EHMD have not been well-tested with CMBF in very preterm (VPT; <28 weeks gestational age (GA) at birth) infants and thus might have put the infants at risk for undefined complications. To keep the two arms identical for as many variables as possible, early fortification was not part of the trial design for either arm. Therefore, it was highly improbable to see any benefits of early fortification with EHMD that had thus far been demonstrated. Despite this design limitation, patients in the EHMD arm had an adjusted absolute 14.5% reduced morbidity and mortality index, which approached statistical significance, at $p < 0.07$, and may represent a meaningful clinical effect.[2]

Statistical Implications

Recently, results became available for the prospective NFORTE trial comparing HMBF (Prolacta, Duarte, CA, USA) with a standard CMBF commonly used in Sweden involving 228 infants born between 22 weeks 0 days and 27 weeks 6 days GA who were fed MOM or DM with individualized targeted fortification. All centers in this multicenter study fortified milk based on measured protein content of breast milk (target of 4.0-4.5 gm/kg/day with a gradual decrease in protein intake with approaching term equivalent age). The primary outcome identified was the composite of NEC, sepsis, and mortality.[8]

No statistically significant differences between the two groups were reported for primary or secondary outcomes (in unadjusted analyses). However, it appears that the study was underpowered for some measures, making it difficult to interpret the findings. An *a priori* interim analysis was performed to evaluate the adequacy of the sample size (a predetermined upper limit of 322 was set during sample size calculations based on incidence of 47.7% for the primary outcome). However, the actual incidence in the control group was much lower (34.5%); a smaller difference between control and target intervention incidence means it would take more subjects to show a true difference. To reach statistical significance of any difference, a total sample size of about 1,600 infants would have been required, yet the study sample size remained at 222. Finding no difference does not necessarily mean that no difference exists; it means that one cannot say based on these results.[8]

Closer review of the data suggests that a larger sample size likely would have identified potential benefits of the HMBF. Mortality was decreased by 47% in the HMBF arm (7 in HMBF group vs. 13 in CMBF), which is an interesting trend and potentially clinically important even though not statistically significant in this underpowered study. After adjusting for GA, the HMBF group had a statistically significant decreased risk of developing bronchopulmonary dysplasia (BPD) at 36 weeks GA ($P = 0.049$).[8]

Protocol Implications

Like the O'Connor study, fortification in the Jensen trial did not start until infants reached at least 100 mL/kg/day of feeding volume and differed between the two treatment groups. Fortification started at a significantly higher feeding volume in the CMBF group ($P = 0.001$), than in the HMBF group. In the CMBF arm, 25% of the study subjects were not fortified until reaching at least 114 mL/kg/day. This could be interpreted as a sign that providers were reluctant to start CMBF sooner, given that the two treatment groups were not blinded. Initiating fortification at this volume of feeding may now be considered late fortification and may not be generalizable. Based on 15 years of real-world clinical data, an EHMD feeding pathway for Prolacta HMBF was introduced in 2022 and indicates that to achieve the best short- and long-term outcomes with an EHMD, fortification should begin as soon as possible, ideally in the first few days of life.[3,4,9-15]

As is almost inevitable in clinical trials, the Jensen trial suffered some protocol deviations that could have significant impact on conclusions. For instance, survival for at least 3 days of life was an inclusion criterion in the study, yet one infant in the HMBF arm died at 2 days of life. In trials with outcome measures that may be underpowered, one such instance can greatly affect statistical significance. The study was analyzed as intent-to-treat, as is standard for reporting such outcomes. It warrants discussion that three patients in the HMBF group and seven in the CMBF group never received fortification and would be useful to see additional analyses comparing outcomes exclusive of these subjects.

Study Population Implications

The Jensen trial authors conclude that routine fortification for infants born at less than 28 weeks GA using HMBF is not supported by their findings. It should be recognized that this conclusion is for the primary outcome measure (the composite of NEC, sepsis, and mortality), that there were power limitations for the outcome measures of interest, and that other interesting outcomes may not have been evaluated. For example, the trial does not address whether HMBF may be beneficial among select high-risk infants, such as those born small for gestational age, weighing <1,250 g, with significant fetal acidosis, hypoxia or ischemia, requiring cardiopulmonary resuscitation, or when used as rescue for infants who develop complications, or fail to thrive on standard manufacturer recommended feeds. These are the typical situations in which an HMBF strategy is currently being used in NICUs.

Non-RCT Evidence on EHMD

As even RCTs have limitations that impact how to best interpret and implement the findings, it is important to look to other evidence. There are numerous non-RCT studies of the effects of an EHMD of varying strength of evidence. Delaney-Manthe et al implemented an EHMD for all infants born weighing 1,250 g or less in 2016 with the goal of improving feeding tolerance and reducing complications (specifically NEC and PN days). Infants who received an EHMD maintained desirable weight trends, had statistically significantly fewer late-onset sepsis evaluations ($P = 0.0027$) and less BPD ($P = 0.018$) than historical controls. There was a statistically nonsignificant trend toward less surgical NEC (57% of total NEC cases vs. 14.3%), though possibly clinically and fiscally significant.[12]

Non-Evidence-Based Implications

One potential downside of HMBF and an EHMD is concern that HMBF displaces MOM, resulting in the infant missing out on important bioactive factors only available in MOM. While use of HMBF with high caloric density can greatly displace MOM,[16] high caloric density HMBF is used sporadically and for short time periods in specific clinical instances. Typically, an infant fed with 100% MOM who receives Prolact+6 HMBF will have 30% of MOM displaced by the fortifier (30 mL fortifier to 70 mL MOM). In comparison, an infant fed with 100% MOM who receives a commercially available liquid CMBF will have approximately 17% of MOM displaced by the fortifier (5 mL of fortifier to 25 mL MOM). These calculations assume on-label use of Prolacta fortifiers and 2 commercially available liquid CMBF (Abbott, Reckitt/Mead Johnson). It should be noted that, when increasing calories, off-label mixing strategies for both HMBF and CMBF have been used and result in increased MOM displacement. Additionally, most preterm infants in the NICU require DM at some point due to insufficient MOM,[17] and DM, which has reduced bioactive properties compared to MOM,[18] would be displaced preferentially before displacing MOM. In many cases, there is minimal, if any, displacement of MOM. When it does occur, MOM is not discarded or wasted, but saved for use later, thus extending the availability of MOM to the infant, which is also associated with better outcomes.

While only fresh MOM would seem ideal for all infants, the reality is that nearly all preterm infants require fortifiers to reach nutritional targets. Both HMBF and CMBF result in some displacement of MOM or DM. While the volume of displacement may be less for CMBF, the substance added lacks protective bioactive properties. HMBF ensures that 100% of the protein fed to the infant is human-derived and also more than replenishes displaced bioactive components. Philip et al analyzed the biochemical and immunochemical properties of fresh and frozen MOM as well as pasteurized banked DM that were supplemented with either HMBF or CMBF. They demonstrated that DM has less lactoferrin and α-lactalbumin than MOM, but HMBF (not CMBF) not only reinstates both but also has higher antioxidant activity. They concluded that "freshly expressed MOM fortified with HMDF and given early, enterally, and exclusively appears to be an optimal nutritional choice for extremely premature infants."[18]

Another concern with using an EHMD has been growth. This, too, is closely related to following recommended feeding guidelines. Those institutions that follow optimal feeding protocols report good growth.[3,4,19] Those that delay fortification with HMBFs have more difficulty. As with feeding tolerance and infant morbidity, the feeding protocol and appropriate use of the HMBF is critically important to see the best outcomes.

Finally, an EHMD is not a trivial cost for NICUs, which has led to concerns about return on investment. An analysis of 2019-2022 data from more than 3,000 premature infants treated at more than 60 US hospitals found EHMD implementation improved health outcomes and reduced costs, generating a 2.6-fold dollar-for-dollar return on investment.[20] In addition, a 2023 peer-reviewed report found EHMD implementation resulted in annual cost savings of $500,000 to $3.4 million per hospital from a reduction in comorbidities and shorter lengths of stay among very low birth weight infants.[21]

Balancing Evidence With Our Clinical Insights

As clinicians, it is our duty to fully consider all sources of data — RCTs, observational studies, and real-world data — for their utility and limitations. We must also keep in mind the continual evolution of these data. Because of the time and resources necessary to carry out larger scale RCTs, they may reflect clinical knowledge of the past, and can be confined in what they report because of the need for narrowly defined endpoints and protocols. This isn't to say we should ignore RCT data, only to understand both their distinct advantages and limitations and thus what can be concluded. We should then integrate RCT conclusions with other data, possibly of lesser study design control but still with potential utility, to develop best practices for our patients.

While research regarding the utility of EHMD in preterm neonates has produced useful results for defining the potential risks and benefits of human milk fortification, there are limitations in the data and what can be interpreted from that data. A large enough RCT to tease out true head-to-head superior fortifier is unlikely to happen in the United States, due to lack of funding and ethical constraints as EHMD has become standard care in so many NICUs that randomizing patients to CMBF would be unacceptable to providers and families. In every study published evaluating EHMD, at least one beneficial effect of HMBF and EHMD has been shown. With all the evidence available, one *can* conclude that infants fed EHMD have at least as good outcomes as those fed CMBF, possibly better, certainly not worse. Some will interpret this as CMBF is doing a good enough job. We must ask ourselves, with *all* the information available now, is "good enough" good enough for the lives depending on us?

References

1 Chandrasekharan P, Kozielski R, Kumar VH, et al. Early use of inhaled nitric oxide in preterm infants: is there a rationale for selective approach?. *Am J Perinatol.* 2017;34(5):428-440. doi:10.1055/s-0036-1592346

2 O'Connor DL, Kiss A, Tomlinson C, et al. Nutrient enrichment of human milk with human and bovine milk-based fortifiers for infants born weighing <1250 g: a randomized clinical trial [published correction appears in *Am J Clin Nutr*. 2019 Aug 1;110(2):529] [published correction appears in *Am J Clin Nutr*. 2020 May 1;111(5):1112]. *Am J Clin Nutr*. 2018;108(1):108-116. doi:10.1093/ajcn/nqy067

3 Hair AB, Hawthorne KM, Chetta KE, Abrams SA. Human milk feeding supports adequate growth in infants ≤ 1250 grams birth weight. *BMC Res Notes*. 2013;6:459. Published 2013 Nov 13. doi:10.1186/1756-0500-6-459

4 Huston R, Lee M, Rider E, et al. Early fortification of enteral feedings for infants <1250 grams birth weight receiving a human milk diet including human milk based fortifier. *J Neonatal Perinatal Med*. 2020;13(2):215-221. doi:10.3233/NPM-190300

5 Wyble L, Ferry J, Vaughan E, Lee M. Earlier, more rapid feeding of exclusive human milk diet leads to lower incidence of bronchopulmonary dysplasia (BPD). Presented at: 3rd Congress of joint Neonatal Societies; Maastricht, Netherlands. September 17-21, 2019.

6 Salas AA, Gunawan E, Nguyen K, et al. Early human milk fortification in infants born extremely preterm: a randomized trial. *Pediatrics*. 2023;152(3):e2023061603. doi:10.1542/peds.2023-061603

7 Blanco CL, Hair A, Justice LB, Roddy D, Bonagurio K,

Williams PK, Machado D, Marino BS, Chi A, Takao C, Gordon EE, Ashrafi A, Cacho N, Pruetz JD, Costello JM, Cooper DS, & Cardiac Neonate Nutrition Study Group. A randomized trial of an *exclusive human milk diet in neonates with single ventricle physiology. J Pediatr*. 2022;256: 105–112. doi. org/10.1016/j.jpeds.2022.11.043

8 Jensen GB, et al. Effect of human milk-based fortification in extremely preterm infants fed exclusively with breast milk: a randomised controlled trial. eClinicalMedicine, Volume 0, Issue 0, 102375

9 Sullivan S, Schanler RJ, Kim JH, et al. An exclusively human milk-based diet is associated with a lower rate of necrotizing enterocolitis than a diet of human milk and bovine milk-based products. *J Pediatr*. 2010;156(4):562-7.e1. doi:10.1016/j.jpeds.2009.10.040

10 Hair AB, Peluso AM, Hawthorne KM, et al. Beyond necrotizing enterocolitis prevention: improving outcomes with an exclusive human milk-based diet [published correction appears in *Breastfeed Med*. 2017 Dec;12 (10):663]. *Breastfeed Med*. 2016;11(2):70-74. doi:10.1089/bfm.2015.0134

11 Visuthranukul C, Abrams SA, Hawthorne KM, Hagan JL, Hair AB. Premature small for gestational age infants fed an exclusive human milk-based diet achieve catch-up growth without metabolic consequences at 2 years of age. *Arch Dis Child Fetal Neonatal Ed*. 2019 May;104(3):F242-F247. doi: 10.1136/archdischild-2017-314547. Epub 2018 Nov 13. PMID: 30425116; PMCID: PMC6764250.

12 Delaney Manthe E, Perks PH, Swanson JR. Team-based implementation of an exclusive human milk diet. *Adv Neonatal Care*. 2019;19(6):460-467. doi:10.1097/ANC.0000000000000676

13 Hair AB, Lee ML. The effectiveness of an exclusive human milk diet in premature infants <750g birthweight. Presented at jENS September 2021.

14 Bergner EM, Shypailo R, Visuthranukul C, et al. Growth, body composition, and neurodevelopmental outcomes at 2 years among preterm infants fed an exclusive human milk diet in the neonatal intensive care unit: a pilot study. *Breastfeed Med*. 2020. 15(5):304-311. doi:10.1089/bfm.2019.0210

15 Rahman A, Kase J, Murray Y, et al. Neurodevelopmental outcome of extremely low birth weight infants fed an exclusive human milk diet is not affected by growth velocity. *Breastfeed Med*. 2020;15(6):362-369. doi:10.1089/bfm.2019.0214

16 Perrin MT. Donor human milk and fortifier use in United States Level 2, 3, and 4 neonatal care hospitals. *J Pediatr Gastroenterol Nutr*. 2018 Apr;66(4):664-669. doi: 10.1097/MPG.0000000000001790. PMID: 29045350

17 Carroll K, Herrmann KR. The cost of using donor human milk in the NICU to achieve exclusively human milk feeding through 32 weeks postmenstrual age. *Breastfeed Med.* 2013 Jun;8(3):286-90. doi: 10.1089/bfm.2012.0068. Epub 2013 Jan 16. PMID: 23323965; PMCID: PMC3663453.

18 Philip RK, Romeih E, Bailie E, Daly M, McGourty KD, Grabrucker AM, Dunne CP, Walker G. Exclusive human milk diet for extremely premature infants: a novel fortification strategy that enhances the bioactive properties of fresh, frozen, and pasteurized milk specimens. *Breastfeed Med*. 2023 Apr;18(4):279-290. doi: 10.1089/bfm.2022.0254. PMID: 37071630; PMCID: PMC10124176.

19 Huston RK, Markell AM, McCulley EA, Gardiner SK, Sweeney SL. Improving growth for infants ≤1250 grams receiving an exclusive human milk diet. *Nutr Clin Pract*. 2018;33(5):671-678. doi:10.1002/ncp.10054

20 Data on file; hospital-provided outcomes analysis from 2019 to 2022.

21 Swanson JR, Becker A, Fox J, et al. Implementing an exclusive human milk diet for preterm infants: real-world experience in diverse NICUs. *BMC Pediatr*. 2023;23(1). doi. org/10.1186/s12887-023-04047-5

The Effect of the Swaddling Method on Stress Levels in Newborns Administered Nasal CPAP

Zehra Akkoca, Betul Yavuz, Ayşe Koçak Sezgin and Yaşar Bildirici

Abstract

Background. This study aims to investigate the effects of the swaddling method on the stress levels in newborns receiving nasal continuous positive airway pressure (nCPAP).

Methods. The study was conducted between 1 June 2022 and 1 October 2022 with 40 newborns who underwent nCPAP in the second-level Neonatal Intensive Care Unit (NICU) of a city hospital in the Central Anatolia Region of Turkey. Data were collected using a descriptive form, including the characteristics of newborns, a patient follow-up chart, and the Newborn Stress Scale (NSS). The descriptive form, the patient follow-up chart, and the NSS were completed by the researcher 30 min after the nCPAP was started and the first saliva sample was taken. The patient follow-up chart and NSS were completed 30 min after applying the swaddling method and the second saliva sample was collected. The data were analyzed using IBM SPSS Statistics 25.0 package software and presented with number, percentage, mean, standard deviation, min-max, and t-test.

Results. The study found that the mean score of the NSS after the intervention (3.52 ± 2.57) was lower than that before the intervention (10.02 ± 2.05) ($p < 0.05$). The mean saliva cortisol levels of the newborns after the intervention (4.99 ± 1.89) were lower than before the intervention (5.51 ± 1.65) ($p < 0.05$). The mean heart (135.50 ± 14.15) and respiratory rates (68.07 ± 10.16) of the newborns after the intervention were lower than those before the intervention (140.82 ± 18.11; 72.95 ± 9.06, respectively) ($p < 0.05$). There was no difference between the mean oxygen saturation of newborns before and after the intervention ($p > 0.05$).

Conclusions. The study showed that the swaddling method played a role in reducing the stress levels in newborns who underwent nCPAP. It is recommended that randomized controlled trials examining the effect of swaddling on the stress levels of newborns who underwent nCPAP be conducted.

Background

Nasal continuous positive air pressure (nCPAP), one of the noninvasive mechanical ventilation methods, is used in patients with spontaneous breathing and when free oxygen therapy is not sufficient.[1] Thus, nCPAP improves impaired gas exchange by providing a continuous flow of positive pressure to prevent alveolar collapse.[2] nCPAP is the treatment of choice for bronchopulmonary dysplasia (BPD), respiratory distress syndrome (RDS), meconium aspiration syndrome (MAS), pulmonary hypertension, pneumonia, as well as transient tachypnea of newborn (TTN).[1]

Nasal cannulas used during nCPAP administration to newborns may irritate their nasal mucosa and nasal septum;[3] nasal masks may compress the nasal root and nasal circumference,[4] and excessive pressure may cause gas accumulation in the abdomen and stomach.[5] In addition to the respiratory stress, nCPAP application may cause newborns to experience stress due to its undesirable effect (nasal travma).[6] In the literature, it is recommended to use pharmacological and non-pharmacological methods (oral sucrose/glucose, breast milk, pacifier, kangaroo care, flexion posture, swaddling, reducing environmental stimuli) to reduce the pain and stress levels experienced by newborns in interventions applied to newborns in neonatal intensive care units (NICU).[7-9] When premature babies are wrappeded, they show improved neuromuscular development, less physiological distress, better motor organization, and greater self-regulation ability.[10] Swaddling is a nonpharmacological method that can be used frequently in NICUs because it reduces the stress caused by simple, safe, moderate, and low interventional pain.[8,11] Swaddled term and preterm infants wake up less and experience less physiological distress and stress.[12] In the literature, studies using the Premature Infant Pain Profile (PIPP)[11,13-15] and Neonatal Infant Pain Scale (NIPS)[16-19] to evaluate pain have reported

Zehra Akkoca is with Neonatal Intensive Care Unit, Eskisehir City Hospital, Neonatal Nurse, Eskisehir, Turkey.
Betul Yavuzis with Faculty of Health Sciences, Department of Pediatric Nursing, Kütahya Health Sciences University, Kutahya, Turkey.
Ayşe Koçak Sezginis with Faculty of Medicine, Basic Medical Science, Medical Biochemistry Department Kutahya, Kütahya Health Sciences University, Kutahya, Turkey.
Yaşar Bildirici s with Department of Pediatrics Eskisehir, University of Health Sciences, Eskisehir City Hospital, Eskisehir, Turkey.

that swaddling reduces pain and therefore stress. However, no investigation has examined the effect of the swaddling method on the stress levels of newborns undergoing nCPAP. Based on the literature review, it was thought that the swaddling method during nCPAP application may have a positive effect on reducing the stress levels of newborns and this application can be easily applied by nurses providing care in NICUs.

To date, no investigation has examined the effect of the swaddling method on the stress level of newborns undergoing nCPAP.

Study hypotheses

H_1 Swaddling of newborns receiving nCPAP has an effect on the stress score.

H_2 Swaddling of newborns receiving nCPAP has an effect on saliva cortisol levels.

Methods

Design and sample

This study was designed in a single group, pretest-posttest experimental type. The study was conducted in the second-level NICU of a city hospital in the Central Anatolia Region of Turkey between 1 June 2022 and 1 October 2022. The study included 42 newborns who underwent nCPAP in the NICU. Of the patients, two were excluded from the sample group because they developed sepsis, and the study was completed with 40 newborns (Figure 1).

The inclusion criteria were as follows: (1) Newborns with a gestational age of 35 weeks or more; (2) a birth weight of 2,000 g or more (there is no consensus on when the cortisol circadian rhythm is established or whether it depends on gestational age or postnatal age[20]); (3) had a diagnosis of TTN; (4) been decided to administer nCPAP; (5) whose parents agreed to participate in the study.

The exclusion criteria were as follows: (1) Newborns whose mothers took cortisol-containing drugs in the antenatal period, used addictive substances in the antenatal period; (2) newborns with chorioamniotic and metabolic disease (adrenal insufficiency, etc.) (3) newborns whose amniotic fluid was stained with meconium, who were intubated, (4) whose APGAR score was < 6, (5) who were administered analgesic or anesthetic drugs for sedation, who were administered cortisol-containing drugs, (6) whose saliva sample could not be obtained or was contaminated with blood, (7) who had signs of nasal injury during nCPAP, (8) who had congenital defects that prevent the swaddling method, (9) who were administered resuscitation, (10) who were asphyctic at birth, who had non-respiratory causes,[21,22] (11) neonatal sepsis, or hypocalcemia were not included in the study.

Variables of the study The independent variable of the study was the swaddling method; the dependent variables were the stress score of the newborn and the saliva cortisol levels.

Data collection

Newborn descriptive form This form was prepared by the researchers in line with the literature on the subject. The form includes information about the newborn's age, height, head circumference, birth weight, birth week, mode of delivery, APGAR score, gender, nasal cannula and nasal mask use in nCPAP application, invasive intervention applied, and mother's age.[23]

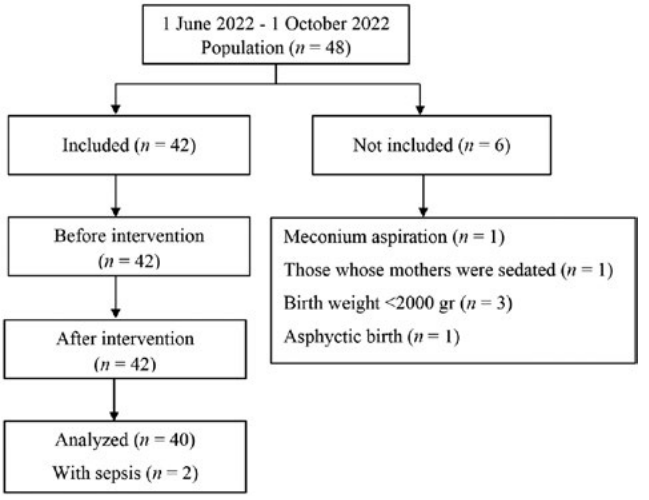

Figure 1. Flowchart of the study

Inclusion and exclusion Criteria Form This form includes inclusion and exclusion criteria in order to determine the sample.

Patient follow-up table This table includes vital signs (heart rate, oxygen saturation, respiratory rate) and cortisol level at the time the saliva sample was taken.

Newborn Stress Scale (NSS): The NSS was developed by Ceylan and Bolışık (2017) to assess the level of stress in premature infants. Opinion about the use of the scale in term infants was obtained from one of the scale developers, Assoc. Prof. Dr. Sibel Serap Ceylan, via e-mail. In this three-point Likert-type scale, items are grouped into eight subgroups: facial expression, body color, respiration, activity level, comfort, muscle tone, extremities, and posture. In scoring, each subgroup is evaluated between 0 and 2 points. A minimum score of 0 and a maximum score of 16 points are obtained from the scale. A high score on the scale shows increased stress levels in the baby. Cronbach's alpha coefficient was reported to be between 0.65 and 0.81.[24]

Intervention

Applications made by the researcher during the data collection process; (1) swaddling of newborns, (2) assessing stress levels, (3) collecting saliva samples, (4) recording vital signs.

nCPAP Application Method nCPAP application was performed using a Hamilton c1 neo device. Air leakage, circuit, and oxygen sensor control tests were performed before the application. Before the baby was connected to the ventilator, an interface (nasal tube 50, 70, 100 mm) and a binasal cannula or nasal mask (S, M, L) in sizes suitable for the baby's weight were selected at the end of the ventilator set and connected to each other and worn on the newborn's head. A sponge was placed in the area where the hat [appropriate size for the head circumference (17-22, 22-25, and 25-29 cm)] meets the nasal tube to reduce the risk of compression on the baby's head, and the circuit connection was established. An orogastric catheter was inserted into the newborn to prevent gastric distension, and gastric decompression was provided by leaving the tip of the catheter open.

Table 1 The Newborns' Descriptive Characteristics

Variables	Mean ± *SD*	Min	Max
Week	36.90 ± 1.50	35	41
Mother's age	29.07 ± 5.23	17	41
Age (hour)	2.10 ± 1.48	1	5
APGAR score (min 1)	8.30 ± 0.96	6	9
APGAR score (min 5)	9.40 ± 0.90	7	10
Birth weight (gr)	2,829.12 ± 522.88	2,000	4,410
Birth height (cm)	48.17 ± 2.09	43.00	53.00
Head circumference (cm)	33.25 ± 1.42	30.00	35.00
	n	**%**	
Gender			
Female	14	35	
Male	26	65	
Delivery type			
Vaginal	20	50	
Caesarean	20	50	
nCPAP application method			
Nasal cannula	13	32.5	
Nasal mask	27	67.5	

Swaddling Method The newborn was placed in the supine position on a fabric blanket, naked except for a diaper; the upper edge of the fabric blanket was aligned with the newborn's shoulder, the newborn's arms were placed in the flexion-adduction position, and the horizontal ends of the fabric blanket were folded in the opposite direction to cover the upper trunk.[25] The baby's head was allowed to move freely. The upper torso was completely wrapped with the fabric blanket. Then newborns were wrapped with the fabric blanket legs in flexion and abduction a suitable space was left at the bottom of the fabric blanket for the comfort of the newborn's feet, and it was ensured that it was not too tight.[17,18] This whole swaddling process was completed in approximately one minute. A heat probe was placed in the axillary region before swaddling and for preventing hyperthermia the body temperature of the newborns was kept between 36.6 and 37.5ºC.[19,26] In the NICU, the incubator temperature is kept at 33.3 ± 1.0°C in 1,500–2,500-gram babies and 32.8 ± 1.5°C in 2,500-gram and above babies. Cotton, a soft textured fabric that does not irritate the skin of the newborn, was used for swaddling. The fabric blanket was square, 1800 cm^2 (90 × 90 cm), and 75 g.

Collection of Saliva samples In newborns, cortisol production fluctuates during sleep-wake cycles. In particular, cortisol levels decrease while the infant sleeps.[27,28] Stressors, including painful stimuli, cause cortisol to rise. Cortisol levels peak approximately 20-30 min after an infant is exposed to an acute stressor. In preterm infants, the daily rhythm of cortisol production does not occur until at least one month of age.[22,29,30] Cortisol is secreted in a pulsatile way in a circadian rhythm in term infants from one month.[22] Therefore, saliva samples were collected in the study without regard to the morning-evening cycle.

It has been reported in the literature that saliva samples can be stored at -20 degrees for a maximum of 28 days[31] and at -80 degrees for one year.[32] Saliva samples collected in the study were stored at -20 degrees for approximately 14 days and at -80 degrees for approximately 4 months. Additionally, the study team included a researcher who had previously studied salivary cortisol levels.

Saliva samples of the newborns were collected using the SalivaBio Children's Swab, which was specially prepared for this procedure. Saliva samples were collected at least 30 min after the completion of oral feeding of the infants in order to prevent the saliva sample from being mixed with milk.[33] In this process, after removing the cotton roll from the tube, it was held at one end and placed under the newborn's tongue or in the corners of the mouth (2.5 cm) where saliva could accumulate. The cotton was allowed to become saturated with saliva for approximately 2 min. The cotton roll was held at the dry end and the wet part was placed back into the tube and the cap of the tube was closed. A barcode with the newborn's name was affixed on the tube containing the saliva sample. The saliva sample was centrifuged at 1500 g for 15 min within 30 min after saliva collection.[34] The main purpose of centrifugation is to precipitate the saliva samples in the absorbent swab. All samples were stored at -80°C until the number of samples (n = 40) was completed.[35,36]

Pre-intervention

The newborn was placed in a supine position to better observe their chest movements and respiratory pattern. In order to ensure the patency of the airway of the newborn, who was connected to nCPAP, the newborn's neck was supported with the help of rollers and placed in a slight extension position. At the 30th minute, when nCPAP, which is a stressful application, was started, the NSS was filled out by the researcher, and the first saliva sample was taken after vital signs were taken and recorded in the patient follow-up Tables.[3,21,37]

Post-intervention

Before the intervention, the newborn was monitored in the supine position connected to nCPAP and the slight extension position of the neck was maintained to ensure airway patency. After the first saliva sample was taken, the newborn was swaddled. In the swaddling procedure, the whole body of the newborn, who was laid on a fabric blanket with their legs in flexion and abduction position, was loosely swaddled. After 30 min of swaddling, the NSS was filled out by the researcher, vital signs were taken and the second saliva sample was taken from the newborn after being recorded in the patient follow-up Tables.[3,21,34,37]

Table 2 Distribution of NSS Score and the Mean Saliva Cortisol Levels

Variables	Before intervention (nCPAP min 30)			After intervention (nCPAP min 60)			*t*-test/ *p-value*
	Mean ± *SD*	Min	Max	Mean ± *SD*	Min	Max	
NSS score	10.02 ± 2.05	6	14	3.52 ± 2.57	0	9	13.569/ ***p* < 0.001**
Saliva cortisol level (ng/Ml)	5.51 ± 1.65	1.22	7.41	4.99 ± 1.89	0.74	7.45	2.614/ **0.013**

Table 3 Distribution of Vital Signs of Newborns

Variables	Before intervention (nCPAP min 30)			After intervention (nCPAP min 60)			*t*-test/ *p-value*
	Mean ± *SD*	Min	Max	Mean ± *SD*	Min	Max	
Heart Rate (min)	140.82 ± 18.11	96	175	135.50 ± 14.15	100	173	2.38/ **0.022**
Oxygen Saturation	98.05 ± 3.35	85	100	98.62 ± 1.82	92	100	-1.06/ 0.292
Respiratory rate (min)	72.95 ± 9.06	56	92	68.07 ± 10.16	54	95	4.74/ ***p* < 0.001**

ELISA Study All samples tested in a blinded manner. Saliva-specific Enzyme-Linked ImmunoSorbent Assay (ELISA) was used for the study. The ELISA kit (DRG International, USA) was purchased commercially. User instructions were followed for kit contents. Standard and sample wells were measured in a spectrophotometer (ThermoScientific, USA) at 450 nm wavelength. Total concentration was calculated from the absorbance values for the standard and samples and cortisol levels were given as µg/dL.

Data analysis

Sample size

In the study, the minimum sample size was calculated as 30 as a result of repeated measures analysis of variance with 80% power and alpha = 0.05 using the G Power 3.0.10 program in the known population (annual number of newborns in the said hospital).[38] In the post hoc analysis based on pre-intervention and post-intervention NSS score averages, in the study was calculated as the effect size of 0.83 and 100% power (p < 0.001). In the post hoc analysis based on pre-intervention and post-intervention salivary cortisol levels average, in the study was calculated as the effect size 0.15 and 72% power (p = 0.013).

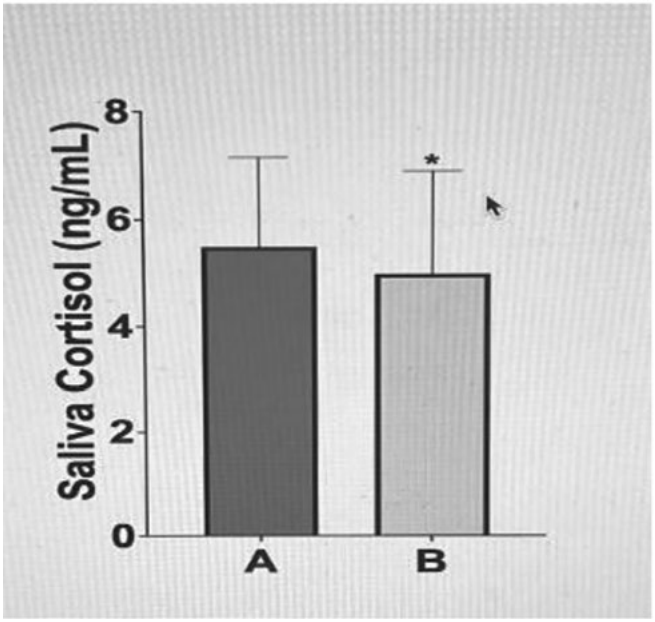

Figure 2 Pre and post-intervention saliva cortisol levels

Statistical analysis

IBM SPSS Statistics 25.0 (IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) package program was used for data analysis and numerical data were presented as mean, standard deviation, and minimum-maximum. In statistical analyses, the Shapiro-Wilk test was used to test whether the data fit the normal distribution. In the comparison of means in the dependent groups, a *t*-test was used because the data were normally distributed. The threshold level of statistical significance was $p < 0.05$.[39]

Results

The mean gestational age of the newborns was 36.93 ± 1.50 (min. 35, max. 41) weeks and the mean maternal age was 29.07 ± 5.23 (min.17, max. 41) years. The mean age of the newborns was 2.10 ± 1.48 (min.1, max.5) hours, and the mean 1st- and 5th-minute APGAR scores were 8.30 ± 0.96 (min. 6, max. 9) 9.40 ± 0.90 (min.7, max. 10), respectively (Table 1).

The mean birth weight of the newborns was 2,829.12 ± 522.88 (min. 2,000, max. 4,410) g, birth height was 48.17 ± 2.09 (min.43, max.53) cm, and birth head circumference was 33.25 ± 1.42 (min. 30, max. 35) cm. In the study, 65% of the newborns were male and 50% were born vaginally. Nasal cannula was used in 32.50% of the newborns and the nasal mask was used in 67.50%. (Table 1).

A statistically significant difference was found between the mean NSS scores of the newborns before and after the intervention ($p < 0.001$). In addition, there was a statistically significant difference between the mean saliva cortisol levels of the newborns before and after the intervention ($p < 0.05$; Figure 2; Table 2).

A statistically significant difference was found between the mean heart rate of the newborns before and after the intervention ($p < 0.05$). The difference between the mean oxygen saturation of the newborns before and after the intervention was not statistically significant ($p = 0.292$). Additionally, there was a statistically

significant difference between the mean respiratory rate of the newborns before and after the intervention ($p < 0.001$; Table 3).

Discussion

In this part of the study examining the effect of swaddling method on stress levels in newborns receiving nCPAP, NSS scores, salivary cortisol levels and vital signs before and after the intervention were discussed.

The study found that the mean NSS score of the newborns at the 30th minute after the swaddling method was applied was lower than the 30th minute before the intervention ($p < 0.05$). Apaydin Cirik and Efe (2020) reported that the combined method of swaddling + breast milk significantly reduced the premature infant pain profile (PIPP) score of preterm newborns during orogastric catheter insertion compared to other groups (whom routine care, swaddling, facilitated tucking, expressed breast milk, facilitated tucking + expressed breast milk were applied), and the pain score of newborns whom swaddling method was applied was lower than the routine care group ($p < 0.001$).[11] A previous study found that newborns who underwent the swaddling method during heel prick blood collection had a lower mean NIPS score during the procedure than newborns who were placed supine on the procedure able.[16] Another study reported that three different methods (swaddling, swaddling + holding, and swaddling + holding + breastfeeding) played a role in reducing the pain felt during the heel prick procedure and that the mean NIPS score was lower in newborns who underwent the swaddling method compared to the control group (supine position).[17] Another study found that two different methods (swaddling and holding) were effective in reducing the pain felt during the heel prick procedure in newborns, and the mean NIPS score was lower in newborns who underwent the swaddling method compared to the control group (supine position) ($p < 0.05$).[18] In the study conducted by Ho et al. (2016), the mean PIPP score of preterm infants who underwent the swaddling method during the heel prick procedure was lower than the control group who were given the supine position.[15] According to the results of this study, the swaddling method applied during invasive interventions (Orogastric (OG) insertion, heel prick, etc.) applied to newborns plays a role in reducing the pain level of newborns and also the stress level they experience. To date, no investigation has examined the effect of the swaddling method on the stress level of newborns undergoing nCPAP. It is thought that the swaddling method is instrumental in reducing the stress experienced by newborns undergoing nCPAP due to respiratory distress.

In the present study, the saliva cortisol levels in the 30th minute of the swaddling method during nCPAP applied to newborns were lower than that in the first 30 min during which no intervention was applied ($p < 0.05$). No study examining the effect of the swaddling method on saliva cortisol levels in newborns receiving nCPAP was found in the literature; it is thought that the swaddling method also plays a role in reducing the stress experienced by newborns diagnosed with TTN and receiving nCPAP due to respiratory distress.

This study found that the mean scores of heart rate and respiratory rates in the 30th minute of the swaddling method during nCPAP applied to newborns were lower than those in the 30th minute before the intervention without any intervention ($p < 0.05$). Ho et al. (2016) reported that the heart rate of newborns to whom the swaddling method was applied during the heel prick procedure was higher than that of the control group, and it was lower than the control group immediately after the heel prick procedure.[15] It was reported in the study of Apaydin Cirik and Efe (2020) that the mean heart rate during the OG insertion procedure was lower in the swaddling group compared to the routine care group and other groups (swaddling + expressed breast milk, facilitated tucking, expressed breast milk, and facilitated tucking + expressed breast milk).[11] In the study of Huang et al. (2004), there was no difference between the heart rates of premature newborns who were swaddled during the heel prick procedure and those who were given the fetal position; however, the premature babies who were swaddled returned to the initial heart rate in a shorter time.[14] The results of the studies which reported that the swaddling method was effective in decreasing respiratory and heart rate, an indicator of the stress experienced by newborns due to pain,[11,14,15] are consistent with the results of this present study. In this study, it is thought that swaddling played a role in decreasing the respiratory rate and heart rate of newborns during nCPAP, which were high in the 30th minute before the intervention.

Limitations of the study

The limitations of the study were that it was not a randomized-controlled study, newborns under 35 weeks of age were not included, and only infants with TTN were included in the study.

The time of hospitalization of the newborns included in the sample group to the clinic was variable; therefore, the study data were collected at different times of the day, which was the difficulty experienced in the study. Accordingly, the samples were collected by the researcher to ensure that the data were collected according to the same standards. Since the samples were collected at different times of the day, the data were also collected outside of working hours. In addition, these samples were temporarily stored at -20°C in the Blood Bank laboratory of the city hospital, where the research was conducted to prevent the deterioration of the samples. Every two weeks, the samples were transferred to Kütahya Health Science University, Central research laboratory, where the analyses would be performed, for storage at -80°C in accordance with the cold chain conditions.

Since the research was a master's thesis, there was a time constraint. Therefore, gestational age could not be held constant. Since the baby was receiving treatment in the neonatal intensive care unit, the mother's stress level could not be measured because it was not possible for the mother and baby to be together. Since the days and hours worked by the nurses in the neonatal intensive care unit, where the research was conducted, were not fixed, a second observer could not be included in the study.

Conclusions

Based on the results of this study, the swaddling method plays a role in the reduction of the NSS score and saliva cortisol levels. In this context, H1 and H2 hypotheses were accepted. It was concluded that the swaddling method applied to newborns decreased heart rate and respiratory rate, but it had no effect on oxygen saturation. In conclusion, randomized controlled trials, including long-term follow-ups of the effect of swaddling on relieving stress and pain in newborns on nCPAP in NICUs, should be conducted. The swaddling method should be used to reduce the stress level of newborns during nCPAP, and this method should be included in the care protocols to be established for nCPAP application.

Abbreviations

nCPAP	Nasal Continuous Positive Airway Pressure
TTN	Transient Tachypnea of newborn
BPD	Bronchopulmonary Dysplasia
RDS	Respiratory Distress Syndrome
MAS	Meconium Aspiration Syndrome
NICU	Neonatal Intensive Care Units
NSS	Newborn Stress Scale
PIPP	Premature Infant Pain Profile
OG	Orogastric

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Author contributions

ZA was involved in the project conception, the collection of data, the interpretation of analyzed data, and the drafting of the manuscript for this study. BY conceived this study, developed the study design, interpreted and analyzed the study data, and wrote the manuscript. AK conceived this study, developed the study design, the did ELISA study of samples collected in the laboratory, interpreted and analyzed the study data, and wrote the manuscript. YB interpreted and analyzed the study data and wrote the manuscript. All authors contributed to the Scientific Research Project application. All authors have seen and approved the final, submitted version of this manuscript.

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Data Availability

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was approved by the from Non-Interventional Ethics Committee of the Kütahya Health Sciences University (approval number is 2022/04-23) date 06 April 2022 and was performed in compliance with the Declaration of Helsinki and its later amendment. The study began after obtaining the approval of the Neonatal Intensive Care Unit Supervisor of the Hospital, Hospital Management, and Provincial Health Directorate. Written informed consent was obtained from the parents of the newborns included in the study. This study was registered at ClinicalTrials.gov as the registration number NCT05657977 (20/12/2022).

References

1 Yücesoy E, Duman N. Prematürede Solunum Problemleri ve Yönetimi [Respiratory problems and management in Prematurity]. Klinik Tıp Pediatri Dergisi. 2017;9(4):17–32.

2 Conlon P. Overview of Oxigen and Carbon Dioxide Exchange. In: Hockenberry MJ, Wilson D, editors. Wong's Nursing Care of Infant and Children. 10th Edition. Canada. Elsevier Mosby; 2015. p. 1148.

3 Osman M, Elsharkawy A, Abdel-Hady H. Assessment of pain during application of nasal-continuous positive airway pressure and heated, humidified high-flow nasal cannulae in preterm infants. J Perinatol. 2015;35(4):263–7. https://doi.org/10.1038/jp.2014.206.

4 Yong SC, Chen SJ, Boo NY. Incidence of nasal trauma associated with nasal prong versus nasal mask during continuous positive airway pressure treatment in very low birthweight infants: a randomised control study. Arch Dis Child Fetal Neonatal Ed. 2005;90(6):F480–3. https://doi.org/10.1136/ adc.2004.069351.

5 Priyadarshi A, Rogerson S, Hinder M, Tracy M. Neonatologist performed point-of-care bowel ultrasound: is the time right? Australas J Ultrasound Med. 2018;22(1):15–25. https://doi.org/10.1002/ajum.12114.

6 Abd El Aziz El Sayed Abd El, Aziz R, Mohsen M, Fathy Attia MM, A. Effect of non-invasive respiratory support care bundle on Preterm infants' nasal Injury and Pain Response. Egypt J Health Care. 2022;13(1):1954–70. https://doi.org/10.21608/ejhc.2022.249681.

7 Pillai Riddell RR, Racine NM, Turcotte K, Uman LS, Horton RE, Din Osmun L, Ahola Kohut S, Hillgrove Stuart J, Stevens B, Gerwitz-Stern A. Non-pharmacological management of infant and young child procedural pain. Cochrane Database Syst Rev. 2011;(10):CD006275. https://doi.org/10.1002/14651858. CD006275.pub2. Update in: Cochrane Database Syst Rev. 2015;12:CD006275.

8 COFAN and SOAAPM (Committee on Fetus And Newborn And Section on Anesthesiology and Pain Medicine). Prevention and management of procedural pain in the neonate: an update. Pediatrics. 2016;137(2):e20154271. https://doi.org/10.1542/peds.2015-4271.

9 Yigit Ş, Ecevit A, Köroğlu ÖA. Yenidoğan Döneminde Ağrı ve Tedavisi Rehberi [Pain and its treatment guide in the newborn period 2021 update.], Türk Neonatoloji Derneği [Turkish Neonatal Society], 2021.

10 van Sleuwen BE, Engelberts AC, Boere-Boonekamp MM, Kuis W, Schulpen TW, L'Hoir MP. Swaddling: a systematic review. Pediatrics. 2007;120(4):e1097–106. https://doi.org/10.1542/peds.2006-2083.

11 Apaydin Cirik V, Efe E. The effect of expressed breast milk, swaddling and facilitated tucking methods in reducing the pain caused by orogastric tube insertion in preterm infants: a randomized controlled trial. Int J Nurs Stud. 2020;104:103532. https://doi.org/10.1016/j.ijnurstu.2020.103532.

12 Blom MA, Van Sleuwen BE, de Vries H, Engelberts AC, L'hoir MP. Health care interventions for excessive crying in infants: regularity with and without swaddling. J Child Health Care. 2009;13(2):161–76. https://doi. org/10.1177/1367493509102476.

13 Deshpande VR, Jamadar RK. Effectiveness of swaddling on pain in neonates during chest physiotherapy: a Randomized Control Trial. JMSCR. 2016;4(11):14096–102. https://doi.org/10.18535/jmscr/v4i11.93.

14 Huang CM, Tung WS, Kuo LL, Chang YJ. Comparison of pain responses of premature infants to the heelstick between containment and swaddling. J Nurs Res. 2004;12(1):31–40. https://doi.org/10.1097/01.jnr.0000387486.78685. c5.

15 Ho LP, Ho SS, Leung DY, So WK, Chan CW. A feasibility and efficacy randomised controlled trial of swaddling for controlling procedural pain in preterm infants. J Clin Nurs.

2016;25(3–4):472–82. https://doi.org/10.1111/ jocn.13075.
16 Erkut Z, Yıldız S. The Effect of swaddling on pain, vital signs, and crying duration during heel lance in newborns. Pain Manag Nurs. 2017;18(5):328–36. https://doi.org/10.1016/j.pmn.2017.05.007.
17 Yılmaz D, İnal S. Effects of three different methods used during heel lance procedures on pain level in term neonates. Jpn J Nurs Sci. 2020;17(4):e12338. https://doi.org/10.1111/jjns.12338.
18 İnal S, Aydin Yilmaz D, Erdim L. The effectiveness of swaddling and maternal holding applied during heel blood collection on pain level of healthy term newborns; randomized controlled trial. Early Child Development and Care. 2022;192(13):2066–77. https://doi.org/10.1080/03004430.2021.1979536.
19 Shu SH, Lee YL, Hayter M, Wang RH. Efficacy of swaddling and heel warming on pain response to heel stick in neonates: a randomised control trial. J Clin Nurs. 2014;23(21–22):3107–14. https://doi.org/10.1111/jocn.12549.
20 Kidd S, Midgley P, Nicol M, Smith J, McIntosh N. Lack of adult-type salivary cortisol circadian rhythm in hospitalized preterm infants. Horm Res. 2005;64(1):20–7. https://doi.org/10.1159/000087324.
21 Badiee Z, Asghari M, Mohammadizadeh M. The calming effect of maternal breast milk odor on premature infants. Pediatr Neonatol. 2013;54(5):322–5. https://doi.org/10.1016/j.pedneo.2013.04.004.
22 Ivars K, Nelson N, Theodorsson A, Theodorsson E, Ström JO, Mörelius E. Development of salivary cortisol circadian rhythm in preterm infants. PLoS ONE. 2017;10(8):e0182685. https://doi.org/10.1371/journal.pone.0182685.
23 Lee SH, Choi CW, Oh YK, Kim BI. Atypical acute respiratory disorder in late preterm and term newborn infants. J Matern Fetal Neonatal Med. 2016;29(9):1430–4. https://doi.org/10.3109/14767058.2015.1050663.
24 Ceylan SS, Bolışık B. Yenidoğan Stres Ölçeği'nin psikometrik özelliklerinin incelenmesi [Examining psychometric properties of newborn stress scale] ACU Sağlık Bilimleri Derg 2017;(2):97–103.
25 Richardson HL, Walker AM, Horne RS. Minimizing the risks of sudden infant death syndrome: to swaddle or not to swaddle? J Pediatr. 2009;155(4):475–81. https://doi.org/10.1016/j.jpeds.2009.03.043.
26 İmamoğlu EY. Yenidoğanda ateş ve hipotermiye yaklaşım [Fever and hypothermia in newborn]. Klinik Tıp Pediatri Dergisi 2018;10(4).
27 Tryphonopoulos PD, Letourneau N, Azar R. Approaches to salivary cortisol collection and analysis in infants. Biol Res Nurs. 2014;16(4):398–408. https:// doi.org/10.1177/1099800413507128.
28 Stoye DQ, Boardman JP, Osmond C, Sullivan G, Lamb G, Black GS, Homer NZM, Nelson N, Theodorsson E, Mörelius E, Reynolds RM. Saliva cortisol diurnal variation and stress responses in term and preterm infants. Arch Dis Child Fetal Neonatal Ed. 2022;107(5):558–64. https://doi.org/10.1136/archdischild-2021-321593.
29 White-Traut RC, Schwertz D, McFarlin B, Kogan J. Salivary cortisol and behavioral state responses of healthy newborn infants to tactile-only and multisensory interventions. J Obstet Gynecol Neonatal Nurs. 2009;38(1):22–34. https:// doi.org/10.1111/j.1552-6909.2008.00307.x.
30 Ramsay D, Lewis M. Reactivity and regulation in cortisol and behavioral responses to stress. Child Dev. 2003;74(2):456–64. https://doi. org/10.1111/1467-8624.7402009.
31 Toone RJ, Peacock OJ, Smith AA, Thompson D, Drawer S, Cook C, Stokes KA. Measurement of steroid hormones in saliva: effects of sample storage condition. Scand J Clin Lab Invest. 2013;73(8):615–21. https://doi.org/10.3109/00365513.2013.835862.
32 Garde AH, Hansen AM. Long-term stability of salivary cortisol. Scand J Clin Lab Invest. 2005;65(5):433–6. https://doi.org/10.1080/00365510510025773.
33 El-Farrash RA, Shinkar DM, Ragab DA, Salem RM, Saad WE, Farag AS, Salama DH, Sakr MF. Longer duration of kangaroo care improves neurobehavioral performance and feeding in preterm infants: a randomized controlled trial. Pediatr Res. 2020;87(4):683–8. https://doi.org/10.1038/s41390-019-0558-6.
34 Srinath BK, Shah J, Kumar P, Shah PS. Kangaroo care by fathers and mothers: comparison of physiological and stress responses in preterm infants. J Perinatol. 2016;36(5):401–4. https://doi.org/10.1038/jp.2015.196.
35 Pourkaviani S, Zhang X, Spear EA, D'Agostino M, Satty RE, Liu SH, Stroustrup
A. Clinical validation of the neonatal ınfant stressor scale with preterm infant salivary cortisol. Pediatr Res. 2020;87(7):1237–43. https://doi.org/10.1038/ s41390-019-0713-0.
36 Filippa M, Monaci MG, Spagnuolo C, Serravalle P, Daniele R, Grandjean D. Maternal speech decreases pain scores and increases oxytocin levels in preterm infants during painful procedures. Sci Rep. 2021;11(1):17301. https:// doi.org/10.1038/s41598-021-96840-4.
37 Kleberg A, Warren I, Norman E, Mörelius E, Berg AC, Mat-Ali E, Holm K, Fielder A, Nelson N, Hellström-Westas L. Lower stress responses after Newborn Individualized Developmental Care and Assessment Program care during eye screening examinations for retinopathy of prematurity: a randomized study. Pediatrics. 2008;121(5):e1267–78. https://doi.org/10.1542/peds.2006-2510.
38 Nahcivan N. Nicel Araştırma Tasarımı [Quantitative Research Design]. In: Erdoğan S, Nahcivan N, Esin M. editors. Hemşirelikte Araştırma-Süreç, Uygulama ve Kritik [Research in Nursing-Process, Application and Critical]. 3. Baskı., İstanbul: Nobel Tıp Kitapevi; 2018. p. 87–129.
39 Büyüköztürk Ş. Sosyal Bilimler için Veri Analizi El kitabı [Handbook of data analysis for social sciences] – İstatistik, araştırma deseni SPSS uygulamaları ve yorum [Statistics, research design SPSS applications and interpretation]. 8 Baskı, Ankara. Pegem Akademi Yayıncılık; 2014.

The Benefits of Using NAVA-PAP in Premature Neonates With Apnea of Prematurity

Chris Campbell

Effectively managing apnea of prematurity can be a challenge for clinicians especially when treating the smallest of these patients. When less invasive therapeutic options fail to provide adequate support, intubation and mechanical ventilation is their only option. Avoiding intubation in these patients is challenging.

According to a recent study out of two US hospitals, these neonates "clinically deteriorate because continuous positive airway pressure (CPAP) provides inadequate support during apnea."

And so the study authors conducted a prospective, two-center, observational study of preterm neonates using neurally adjusted ventilatory assist (NAVA) which, according to the authors, "provides proportional ventilator support from the electrical activity of the diaphragm. When the NAVA level is 0 cmH_2O/mcV (NAVA-PAP), patients receive CPAP when breathing and backup ventilation when apneic. This study evaluates NAVA-PAP and time spent in backup ventilation."

The study ended up concluding that the neonates suppported with NAVA-PAP exhibited fewer CSEs PAP and spent little time on backup ventilation.

The study authors, Alison Protain, Kimberly Firestone, Saima Hussain and Daniel Lubarsky, looked at preterm patients admitted to the NICUs of ProMedica Ebeid Children's Hospital and Akron Children's Hospital during the period between August 2019 and February 2020.

In all, 28 patients were studied and the gestational age was 25 ± 1.8 weeks and a study age of 28 ± 23 days. "The number of CSEs was 4 ± 4.39/24 h. The patients were on NAVA-PAP for approximately 90%/min, switched to backup mode 2.5 ± 1.1 times/min, and spent 10.6 ± 7.2% in backup," the authors wrote.

The study said that premature neonates are "vulnerable" to the impacts of AOP, with consequences including bradycardia and desaturation[1] — something dangerous for such "fragile" patients.

"Caffeine citrate and continuous positive airway pressure (CPAP) are commonly used therapeutic modalities that demonstrate significant benefits,[2-4]" the authors wrote in their study, entitled Evaluation of NAVA-PAP in premature neonates with apnea of prematurity: minimal backup ventilation and clinically significant events. "Unfortunately, increasing respiratory support may be required for the smallest and most fragile premature neonates. Non-invasive respiratory strategies have shown promise, with synchronization of nasal ventilation showing further improvement for respiratory stability,[5] although intubation and mechanical ventilation may be needed for severe apnea.[2,3,6]

The Benefits of NAVA-PAP

NAVA-PAP, according to the study authors, is a sort of next line of defence for such tiny patients struggling to breathe.

"Neurally adjusted ventilatory assist (NAVA) provides support in synchrony with the respiratory efforts of a patient based on the detected electrical activity of the diaphragm (Edi)," the authors wrote. "It is delivered with the Servo-I/U/N ventilator (Getinge, Germany) using NAVA software. The NAVA level is a proportionality factor that converts the Edi signal into a pressure above the positive end-expiratory pressure (PEEP) supporting each spontaneous breath. If no Edi signal is detected for a predetermined amount of time (apnea time), the ventilator switches into pressure control ventilation until the patient breathes spontaneously again, which provides a minimum rate."[7]

Data was downloaded after 24 hours and the CSEs were documented. There was also a paired t-test used to analyze the data. In all, more than 40,000 data points were collected from the 28 patients.

In the discussion part of the study, the authors said a priority is reducing the need for intubation through the application of non-invasive ventilation strategies.[8]

The authors said CPAP is still the "gold standard" but there are some preterm neonates who will "require increased respiratory support.[6,9,10]

"Non-invasive respiratory support subsequently evolved with options such as nasal intermittent positive pressure ventilation (NIPPV) to augment lung inflation and respiratory muscle unloading.[11] The flow-triggered synchronized mode of NIPPV was also found to have beneficial effects on reducing apnea and desaturations compared with CPAP and NIPPV,"[12] the authors wrote.

NAVA stands out for its benefits, the authors said.

Chris Campbell is the Senior Editor of Neonatal Intensive Care.

"NAVA, a novel mode of ventilation, changed the paradigm by providing synchronized ventilation in which the patient controls both timing and degree of ventilatory assistance. Several studies have demonstrated decreased PIPs, oxygen requirement, and apnea in preterm neonates receiving NAVA ventilation compared with those receiving traditional synchronized intermittent mechanical ventilation (SIMV) and pressure control ventilation."[13-16]

"NAVA-PAP is the only non-invasive mode that delivers CPAP while breathing and backup ventilation when the patient is apneic," the authors added. "Utilizing NAVA-PAP as a strategy in neonates with AOP while on CPAP was recently studied and demonstrated significant benefits in reducing CSEs.[1] This approach offers the advantage of reducing CSEs while minimizing exposure to non-invasive ventilation."

The study concluded by saying that the data show a dramatic reduction in the time spent on backup ventilation.

"Compared with CPAP, some data suggest that NIV NAVA in neonates may reduce the need for intubation, facilitate early extubation, and decrease extubation failures.[17-19] NIV NAVA has also been shown to decrease the number of CSEs compared with non-synchronous, non-invasive ventilation,[20]" the authors wrote. "NAVA-PAP is the only non-invasive mode that delivers CPAP while breathing and backup ventilation when the patient is apneic."

References

1 Firestone KS, Al Horany B, Belden L, Stein HM. Nasal continuous positive airway pressure versus non-invasive NAVA in preterm neonates with apnea of prematurity: a pilot study with a novel approach. *J Perinatol.* (2020) 40:1211–5. doi: 10.1038/s41372-020-0661-x

2 Eichenwald E, Newborn CoFa. Apnea of prematurity. *Pediatrics*. (2016) 137(1):1097–105. doi: 10.1542/peds.2015-3757

3 Sammour I, Karnati S. Non-invasive respiratory support of the premature neonate: from physics to bench to practice. *Front Pediatr*. (2020) 8:214–8. doi: 10.3389/fped.2020.00214

4 Moschino L, Zivanovic S, Hartley C, Trevisanuto D, Baraldi E, Roehr CC. Caffeine in preterm infants: where are we in 2020? *ERJ Open Res*. (2020) 6. doi: 10.1183/23120541.00330-2019

5 Moretti C, Gizzi C, Montecchia F, Barbara C, Midulla F, Sanchez-Luna M, et al. Synchronized nasal intermittent positive pressure ventilation of the newborn: technical issues and clinical results. *Neonatology*. (2016) 109(4):359–65. doi: 10.1159/000444898

6 Hussain WA, Marks JD. Approaches to noninvasive respiratory support in preterm infants: from CPAP to NAVA. *NeoReviews*. (2019) 20(4):e213–21. doi: 10.1542/neo.20-4-e213

7 Sinderby C, Beck J. Neurally adjusted ventilatory assist. In: Tobin MJ, editor. *Principles and practice of mechanical ventilation*. 3rd ed. McGraw Hill/Medical (2012). p. 351–75

8 Sweet D, Carnielli V, Greisen G, Hallman M, O'zek E, te Pas A, et al. European consensus guidelines on the management of respiratory distress syndrome—2019 update. *Neonatology*. (2019) 115(4):432–50. doi: 10.1159/000499361

9 Dargaville PA, Gerber A, Johansson S, De Paoli A, Kamlin OF, Orsini F, et al. Incidence and outcome of CPAP failure in preterm infants. *Pediatrics*. (2016) 138(1):e20153985. doi: 10.1542/peds.2015-3985

10 Morley C, Davis P, Doyle L, Brion L, Hascoet J, Carlin J. Nasal CPAP or intubation at birth for very preterm infants. *N Engl J Med*. (2008) 358(7):700–8. doi: 10.1056/NEJMoa072788

11 Kiciman NM, Andréasson B, Bernstein G, Mannino FL, Rich W, Henderson C, et al. Thoracoabdominal motion in newborns during ventilation delivered by endotracheal tube or nasal prongs. *Pediatr Pulm*. (1998) 25(3):175–81. doi: 10.1002/(SICI)1099-0496(199803)25:3%3C175::AID-PPUL7%3E3.0.CO;2-L

12 Gizzi C, Montecchia F, Panetta V, Castellano C, Mariani C, Campelli M, et al. Is synchronised NIPPV more effective than NIPPV and NCPAP in treating apnoea of prematurity (AOP)? A randomised cross-over trial. *Arch Dis Child Fetal Neonatal Ed*. (2015) 100:F17–23. doi: 10.1136/archdischild-2013-305892

13 Stein HM, Howard D. Neurally adjusted ventilatory assist (NAVA) in neonates less than 1,500 grams: a retrospective analysis. *J Pediatr*. (2012) 160(5):786–9. doi: 10.1016/j.jpeds.2011.10.014

14 Mally P, Beck J, Sinderby C, Caprio M, Bailey S. Neural breathing pattern and patient–ventilator interaction during neurally adjusted ventilatory assist and conventional ventilation in newborns. *Pediatr Crit Care Med*. (2018) 19(1):48–55. doi: 10.1097/PCC.0000000000001385

15 Shetty S, Hunt K, Peabody J, Ali K, Greenough A. Crossover study of assist control ventilation and neurally adjusted ventilatory assist. *Eu J Pediatr*. (2017) 176:509–13. doi: 10.1007/s00431-017-2866-3

16 Protain AP, Firestone KS, McNinch N, Stein H. Evaluating peak inspiratory pressures and tidal volume in premature neonates on NAVA ventilation. *Eur J Pediatr*. (2021) 180(1):167–75. doi: 10.1007/s00431-020-03728-y

17 Yagui AC, Meneses J, Z'olio BA, Brito GM, Justino da Silva R, Rebello CM. Nasal continuous positive airway pressure (NCPAP) or noninvasive neurally adjusted ventilatory assist (NIV-NAVA) for preterm infants with respiratory distress after birth: a randomized controlled trial. *Pediatr Pulmonol*. (2019) 54(11):1704–11. doi: 10.1002/ppul.24466

18 Lee BK, Shin S, Jung Y, Kim E, Kim H. Comparison of NIV-NAVA and NCPAP in facilitating extubation for very preterm infants. *BMC Pediatr*. (2019) 19:1683–4. doi: 10.1186/s12887-019-1683-4

19 Makker K, Cortez J, Jho K, Shah S, Nandula P, Lowrie D, et al. Comparison of extubation success using noninvasive positive pressure ventilation (NIPPV) versus noninvasive neurally adjusted ventilatory assist (NI-NAVA). *J Perinatol*. (2020) 40(8):1202–10. doi: 10.1038/s41372-019-0578-4

20 Tabacaru CR, Moores RR, Khoury J, Rozycki HJ. NAVA—synchronized compared to nonsynchronized noninvasive ventilation for apnea, bradycardia, and desaturation events in VLBW infants. *Pediatr Pulmonol*. (2019) 54(11):1742–6. doi: 10.1002/ppul.24464

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Nellcor Pulse Oximetry Performance in Neonates

Clark R Baker, BS and Scott McGonigle, MEng

Background

Pulse oximetry first became standard of care in the operating room in 1986, when the American Society of Anesthesiologists released its Standards for Basic

Anesthetic Monitoring.[1] Since then, its use has expanded dramatically to include the PACU, critical care units, NICU, ED, and medical and surgical care units. Today, pulse oximetry is considered a standard of care in these areas and is often relied upon to ensure patient safety.[1] Since the introduction of the Nellcor Bedside SpO_2 Patient Monitoring System PM100N, the Nellcor pulse oximetry brand has been a market leader and maintained trust by offering reliable, accurate measurements.

The principle of pulse oximetry (SpO_2) is to noninvasively measure blood oxygenation by estimating the fraction of effective hemoglobin bound to oxygen in pulsing arterial blood (e.g. functional saturation). This parameter primarily reflects oxygen transfer from the lungs to tissues via the blood and provides an early indication of oxygenation issues. Nellcor pulse oximetry is quantitative, accurate, continuous, and convenient.[2]

The purpose of this paper is to review key evidence examining Nellcor pulse oximetry use in neonates in Labor and Delivery and the NICU. Key technical features include SpO_2 accuracy versus blood draw (SaO_2), time to first post (TTFP), pulse rate accuracy, and alarm management.

Pulse Oximetry in Labor and Delivery Units

In labor and delivery units, pulse oximetry is used to achieve oxygenation targets during the time-critical neonatal transition. Nellcor pulse oximetry with OxiMax technology provides adhesive and nonadhesive sensors that can be applied to neonatal feet, hands, and great toes, depending on patient needs (Figure 1). Nellcor pulse oximetry with Oximax technology is designed with high-efficiency LEDs that enhance the Nellcor sensor's ability to acquire a pulsatile signal, even when challenged with thicker or darkly pigmented skin or weak pulses.[a] Size permitting, fingers and toes have larger pulses and denser microvasculature than feet and hands and have been observed to provide better accuracy when $SaO_2 < 90\%$ in patients under two years old.[3]

Clark R Baker and Scott McGonigle are with the Research and Development, Patient Monitoring, Medtronic.

Several studies have examined the performance of pulse oximeters in term or near-term newborns following delivery, as discussed further below. These studies have examined time to post a stable reading (critical for determining whether a resuscitation protocol is necessary), comparison of HR accuracy to reference standards, and utility screening for CCHD.

In a 2021 single-center prospective study independent of manufacturers, sixty newborns (55 with ECG, mean age 4 minutes) delivered by C-Section were monitored by Nellcor and Masimo pulse oximeters.[3] The Nellcor pulse oximetry monitor achieved stable readings (e.g. consistent for at least three beats and consistent with clinical appearance and ECG if available) with the following results:

	Nellcor	Masimo
Stable 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%)

*Masimo's performance generated multiple letters to the editor noting that this study had not used their latest newborn specialty sensor and signal processing options.

Another single-center randomized cross-over study using a Nellcor pulse oximeter with OxiMax technology found that the fastest method to stable SpO_2 is to apply the sensor to the patient first, and then connect it to the monitor.[4] In 40 stable NICU patients, this method yielded SpO_2 accompanied by accurate pulse rate ($HR_{PO} = HR_{ECG} \pm 3$ BPM) after a mean of 22 seconds.[4] This method is preferable for all patients and areas of care, as it ensures that the first sensor data the monitor encounters consists of "clean pulses", rather than ongoing sensor manipulation. This compares favorably to a 25 second time for accurate pulse rate acquisition using Masimo technology, in a parallel randomized cross-over study conducted by the same research group, at the University of Melbourne.[5]

Even newborns who appear to be developing appropriately are screened for CCHD within the first few days of life. In the United States, mandatory universal pulse oximetry screening was associated with a 33.4% decline in CCHD deaths.[6] The utility of Nellcor pulse oximetry with OxiMax technology in CCHD screening is corroborated in studies from tens of thousands of patients.[7-12] In fact, Nellcor pulse oximetry

Figure 1. Examples of nonadhesive and adhesive sensors for monitoring SpO2 in neonates.

with OxiMax technology was the first to obtain FDA 510(k) clearance (K123581) for a motion-tolerant pulse oximeter that is also compliant with ISO 80601-2-61:2011. In one prospective, observational study, 6,329 babies in a post-natal ward were screened post-ductally with a Nellcor pulse oximeter with Oximax technology (age 6-72 hours).[7] Of these, 14 had screening SpO_2 < 95%. All 14 were unwell, diagnosed with CCHD, CHD, respiratory illness, or sepsis. One additional baby with normal SpO_2 was later diagnosed with transposition of the great arteries. In this study, Nellcor pulse oximetry screening yielded sensitivity and specificity of 93.3% and 100% respectively.[7] These results, consistent with those demonstrated in significant patient sample sizes, demonstrate that Nellcor pulse oximetry can help clinicians screen for CCHD.[7-12]

Pulse Oximetry in the NICU

For the most delicate and challenging newborns, pulse oximetry monitoring can stretch from the moments of neonatal transition to weeks or months of continuous monitoring in the NICU. Nellcor pulse oximetry is designed to monitor even the tiniest patients. In one clinical study, nine Extremely Low Birth Weight (≤1000 g) infants were monitored with three brands of pulse oximetry, with probes switched between feet every four hours.[13] In 27 hours of data collection, Nellcor and Masimo pulse oximetry monitors each "dropped out" (stopped posting while the sensor was applied) only once, while the Phillips monitor dropped out four times, indicating the relative ability for the Nellcor pulse oximetry monitor to adequately obtain a proper signal, even in such undeveloped patients. For best results in monitoring of such small patients, the authors concluded that "clinical practice, such as the place and positioning of the probe" is key to monitoring performance in these most challenging patients.

SpO_2 accuracy in this population is challenging to demonstrate. Nellcor pulse oximetry sensors are calibrated and approved "under controlled conditions" based on controlled hypoxia studies in adult volunteers, with sensors applied to fingers, as it would be unethical to deliberately subject newborns to hypoxia. The translucent foot of a newborn is physio-optically different from an adult finger. However, direct confirmation of SpO_2 accuracy versus SaO_2 in NICU patients is possible from observational clinical studies. Based on an internal, restrospective analysis, accuracy in 27 NICU patients monitored with Nellcor pulse oximetry with Oximax technology is consistent with ±3 sensor accuracy specification for this population, with results as follows:[14]

	All Events	Excluding Motion Artifact
Total Blood Draws	85	82
Bias, SpO_2 vs SaO_2	0.40	0.57

Mean SaO_2 = 93.72 Range: 86.40 – 99.30

Beyond SpO_2 accuracy, pulse oximeters also provide pulse rate (heart rate). Clinicians have long viewed agreement between oximeter pulse rate and ECG as reassuring in the interpretation of SpO_2.[15,16] Nellcor pulse oximetry signal processing is based on an unchanging physiologic tenet: The patient's true arterial oxygen saturation is associated with the patient's underlying cardiac-induced pulsatile signals. In one prospective, single center study involving 29 NICU patients, pulse rate accuracy versus ECG was 3.93 and 5.07 BPM for Nellcor pulse oximetry with Oximax technology and Masimo SET.[17] The authors chose to exclude one subject as an outlier due to Masimo pulse rate errors beyond 3δ. They found that SpO_2 RMSD (root mean square deviation) between oximeters was 1.41 when both pulse rates were within 5 BPM of ECG. During periods when the Masimo pulse rate diverged by ≥40 BPM from ECG, SpO_2 RMSD between oximeters was 3.81, emphasizing that inaccurate pulse rate often implies questionable SpO_2. Taken together, this suggests that the Nellcor pulse oximeter measures pulse rate more accurately in NICU patients, compared to the Masimo SET module. This is consistent with the results identified in Khoury et al.[3]

Alarm Management in the NICU

Neonates may face risks due to hyperoxia as well as hypoxia. FiO_2 management based on a target range for Nellcor pulse oximetry with Oximax technology has been demonstrated to safely reduce FiO_2 requirements and evidence of oxidative stress.[18-21]

High and low SpO_2 alarm management is integral to help ensure that clinicians are alerted to important changes in patient condition, while avoiding alarm fatigue. A 50 patient NICU study found that 75% of threshold- defined oxygen desaturations lasted ≤10 seconds, and approximately 10% of threshold-defined desaturations were associated with clinical interventions.[22] Although a time-based delay would eliminate some of these alarms, it would provide suboptimal notification of longer and steeper desaturations that do warrant immediate intervention.[22] Nellcor pulse oximetry provides an alarm management algorithm: Nellcor SatSeconds alarm management. It is engineerd to suppress alarms that

are too shallow or transient (or in combination) to result in interventions.

Nellcor SatSeconds accounts for these short-duration and typically shallow desaturations to reduce alarm frequency while still alerting clinicians to long-duration desaturation events. After comparing Nellcor pulse oximeter alarms with and without Nellcor SatSeconds in 29 NICU patients, 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."[23] Nellcor SatSeconds applies similar processing to reduce nuisance alarms.[23]

Conclusion

Multiple clinical studies support the use of Nellcor pulse oximetry for newborn screening and NICU monitoring in the most delicate patients.[2,13, 17, 20, 21] It is quantitative, accurate, continuous, and convenient.[2,17]

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.

References

1 American Society of Anesthesiologists. Committee of Origin: Standards and Practice Parameters. Standards for Basic Anesthetic Monitoring. Approved ASA House of Delegates on October 21, 1986, last amended October 20, 2010.

2 Khoury R, Klinger G, Shir Y, Osovsky M, Bromiker R. Monitoring oxygen saturation and heart rate during neonatal transition. comparison between two different pulse oximeters and electrocardiography. J Perinatol. 2021;41(4):885-890.

3 Sedaghat-Yazdi F, Torres A, Jr., Fortuna R, Geiss DM. Pulse oximeter accuracy and precision affected by sensor location in cyanotic children. *Pediatr Crit Care Med.* 2008;9(4):393-397.

4 Saraswat A, Simionato L, Dawson JA, et al. Determining the best method of Nellcor pulse oximeter sensor application in neonates. *Acta Paediatr.* 2012;101(5):484-487.

5 O'Donnell CP, Kamlin CO, Davis PG, Morley CJ. Obtaining pulse oximetry data in neonates: a randomised crossover study of sensor application techniques. *Arch Dis Child Fetal Neonatal Ed.* 2005;90(1):F84-85.

6 Abouk R, Grosse SD, Ailes EC, Oster ME. Association of US State Implementation of Newborn Screening Policies for Critical Congenital Heart Disease With Early Infant Cardiac Deaths. *JAMA*. 2017;318(21):2111-2118.

7 Oakley JL, Soni NB, Wilson D, Sen S. Effectiveness of pulse-oximetry in addition to routine neonatal examination in detection of congenital heart disease in asymptomatic newborns. *J Matern Fetal Neonatal Med.* 2015;28(14):1736-1739.

8 Mathur NB, Gupta A, Kurien S. Pulse Oximetry Screening to Detect Cyanotic Congenital Heart Disease in Sick Neonates in a Neonatal Intensive Care Unit. *Indian Pediatr.* 2015;52(9):769-772.

9 Özalkaya E, Akdağ A, Şen I, Cömert E, Melek Yaren H. Early screening for critical congenital heart defects in asymptomatic newborns in Bursa province. *J Matern Fetal Neonatal Med.* 2016;29(7):1105-1107.

10 Narayen IC, Blom NA, van Geloven N, et al. Accuracy of Pulse Oximetry Screening for Critical Congenital Heart Defects after Home Birth and Early Postnatal Discharge. *J Pediatr.* 2018;197:29-35.e21.

11 Arlettaz R, Bauschatz AS, Mönkhoff M, Essers B, Bauersfeld U. The contribution of pulse oximetry to the early detection of congenital heart disease in newborns. *Eur J Pediatr.* 2006;165(2):94-98.

12 Van Niekerk AM, Cullis RM, Linley LL, Zühlke L. Feasibility of Pulse Oximetry Pre-discharge Screening Implementation for detecting Critical Congenital heart Lesions in newborns in a secondary level maternity hospital in the Western Cape, South Africa: The 'POPSICLe' study. *S Afr Med J.* 2016;106(8):817-821.

13 van der Eijk AC, Horsch S, Eilers PH, Dankelman J, Smit BJ. "New-generation" pulse oximeters in extremely low-birth-weight infants: how do they perform in clinical practice? *J Perinat Neonatal Nurs.* 2012;26(2):172-180.

14 Unpublished NICU blood draw data collected by Nellcor.

15 De Pauw C, Poelaert J, Rolly G, Colardyn F. Clinical evaluation of pulse oximetry monitors on critically ill patients. *Acta Anaesthesiol Belg.* 1990;41(1):33-9.

16 Murphy MC, Jenkinson A, Coveney J, McCarthy LK, O Donnell CPF. Randomised study of heart rate measurement in preterm newborns with ECG plus pulse oximetry versus oximetry alone. Arch Dis Child Fetal Neonatal Ed. 2021 Jul;106(4):438-441.

17 Batchelder K, Sethi R, Pinto Y. Pulse Rate Performance of Two Pulse Oximeters in the NICU. *Internal Medtronic Study.* 2015; 15-PM-0038.

18 Stola A, Schulman J, Perlman J. Initiating delivery room stabilization/ resuscitation in very low birth weight (VLBW) infants with an FiO2 less than 100% is feasible. *J Perinatol.* 2009;29(8):548-552.

19 Ezaki S, Suzuki K, Kurishima C, et al. Resuscitation of preterm infants with reduced oxygen results in less oxidative stress than resuscitation with 100% oxygen. *J Clin Biochem Nutr.* 2009;44(1):111-118.

20 Rook D, Schierbeek H, Vento M, et al. Resuscitation of Preterm Infants with Different Inspired Oxygen Fractions. *The Journal of Pediatrics.* 2014;164(6):1322-1326.

21 Kaufman DA, Zanelli SA, Gurka MJ, Davis M, Richards CP, Walsh BK. Time outside targeted oxygen saturation range and retinopathy of prematurity. *Early Hum Dev.* 2014;90 Suppl 2:S35-40.

22 Stefanescu BM, O'Shea TM, Haury F, Carlo WA, Slaughter JC. Improved Filtering of Pulse Oximeter Monitoring Alarms in the Neonatal ICU: Bedside Significance. *Respir Care.* 2016;61(1):85-89.

23 Brostowicz HM, Rais-Bahrami K. Oxygen saturation monitoring in the neonatal intensive care unit (NICU): Evaluation of a new alarm management. *J Neonatal Perinatal Med.* 2010;3:201-205.

Advancing NICU Environments through AngelEye Health's Family Engagement Platform: Addressing Nurse Turnover and Burnout

Jaylee Hilliard, MSN, RN, NEA-BC, CPXP and Nicole Nyberg, MSN, APRN, NNP-BC

Introduction

This paper explores the critical issues of nurse turnover and burnout within Neonatal Intensive Care Units (NICUs) and evaluates the transformative role of technology in addressing these challenges, focusing on the application of AngelEye Health's Family Engagement Platform.

Despite significant growth in healthcare fields, nurses remain a critical and large group of healthcare professionals.[1] The COVID-19 pandemic exposed hidden issues like high dissatisfaction, burnout, and moral distress among nurses. Studies indicate that nurses suffer from higher burnout rates than other healthcare workers.[2]

Nurse Turnover and Burnout in NICUs

Many nurses have exhibited moderate to high burnout over the past decade.[3] This burnout and moral distress contribute to high turnover rates and a global nurse shortage.[4] These factors form a vicious cycle where fewer nurses lead to unsafe ratios, worsening burnout, and additional turnover. The remaining nurses face increased workloads, causing significant emotional and physical strain. Shortages of neonatal nurses, though less studied, mirror these trends in other specialties, with the intense nature of neonatal care adding unique challenges.[5] This observation has been seen in both bedside nurse roles, as well as leadership roles.

Challenges in NICU Environments

An analysis of NICU challenges reveals factors like workload, emotional exhaustion, and inadequate support systems. Technological advances in neonatal care have expanded treatment capabilities for critically ill infants, but they also raise moral and ethical concerns among families and clinicians. Differences in care opinions often lead to moral distress among neonatal clinicians, who face dilemmas in balancing clinical decisions with family wishes, affecting infants' perceived quality of life.[6-7]

NICU nurses dealing with critically ill infants often face traumatic experiences and high burnout levels due to the intense nature of their work and exposure to frequent infant deaths.[8] This trauma, combined with ethical complexities and the stress of understaffing, leads to physical and moral exhaustion among NICU staff.

Furthermore, neonatal nurses are crucial in supporting parents during stressful experiences in NICUs. Factors contributing to parental stress include the NICU's technological environment and the altered/limited parental role. Parental distress, if unaddressed, can negatively impact their bonding with the infant, affecting the child's long-term development and the parent's mental health.[9-13]

Impact on Patient Care and Outcomes

High nurse turnover and burnout significantly impact patient care in NICUs, with a direct correlation between staff well-being and care quality. Post-COVID 19, the nursing shortage has escalated into a global healthcare crisis. Nurses in understaffed units, frustrated by their inability to deliver quality care, often leave for other positions or exit the profession.[5] This turnover leads to moral distress, affecting patient care and nurse retention.[6]

The widespread effects of this crisis compromise patient care and team dynamics. Neonatal nurses facing burnout often become disengaged and less compassionate, adversely impacting patient outcomes, including more extended hospital stays and increased pain.[6,14] Additionally, the shortage increases medical errors, unplanned extubations, and infections.[5,15-16]

The financial implications of nurse turnover are substantial. According to the 2023 NSI National Health Care Retention & RN Staffing Report, the average cost of turnover for a bedside RN is $52,350, leading to average annual losses of $6.6-$10.5 million per hospital. Each percentage change in nurse turnover can cost or save an average hospital an additional $380,600 annually.[17] Replacing or avoiding the use of 20 travel nurses with permanent staff can save a hospital about $3,140,000 yearly.[17]

Jaylee Hilliard is the Senior Director of Clinical Strategy at AngelEye Health, revolutionizing patient and family support through advanced technology. With extensive experience in nursing leadership and NICU parenting, Jaylee drives product innovation, supports healthcare leaders, and empowers hospitals to achieve the quadruple aim.
Nicole Nyberg is a Neonatal Nurse Practitioner with Cone Health, CEO and Founder of Empowering NICU Parents, and the host of the Empowering NICU Parents' Podcast. After her son's NICU experience, she is devoted to supporting, educating, and empowering NICU parents and clinicians with a particular focus on the positive effects parental engagement and family-integrated care have on the infant's long-term trajectory and the family's overall well-being.

Family-Centered Models in NICUs

Family-centered care models in NICUs mitigate parental trauma and enhance parent-infant attachment, improving overall outcomes. Fundamental principles include dignity, respect, effective communication, and partnership.[18] Healthcare providers can tailor interventions to improve parental well-being and family outcomes by addressing specific parental stressors.

Parents prioritize enhanced communication and honest information from staff to reduce stress.[9] Clear and accessible communication is crucial in meeting these needs. However, parental dissatisfaction in NICUs often stems from unmet needs due to inadequate nurse-parent communication.[19-20] NICU nurses play a vital role in fostering parent-infant bonding and trust through consistent communication and rapport-building.[21-23]

Nurse burnout and high nurse-to-patient ratios hinder the provision of optimal, individualized parental support. Nurses value family-centered principles but face challenges in engaging effectively with parents due to their workload.[19,24-25] Technological resources support nurses in enhancing parent-infant attachment and communication, fostering trust, and reducing parental distress.

The Role of AngelEye Health's Family Engagement Platform in NICUs

This overview examines the impact of technology in healthcare, particularly its role in enhancing patient and family engagement in NICUs. AngelEye Health's family engagement solutions are developed to integrate parents effectively into the care team, improving family experience, patient outcomes, and care delivery efficiency.

AngelEye offers a suite of family engagement solutions, including bedside cameras for live-streaming and secure messaging, facilitating parent-child bonding and team integration. The MilkTracker system improves feeding management, enhancing patient safety and staff efficiency while enriching the family experience with access to lactation support and inventory of milk in the hospital. Additionally, the EmpowerPathway delivers automated, journey-based education from birth to six months post-discharge, providing timely and relevant information supporting the families' transition from NICU to home.

AngelEye Health prioritizes family-centered care, focusing on consistent communication to strengthen the patient-provider relationship. These tools, developed with feedback from clinicians and parents, support staff in delivering safe, efficient, and precise care, alleviating mental and emotional burdens.

NICU staff using AngelEye's solutions report enhanced parental experience and improved workflow efficiency. The system streamlines parent updates, reducing communication-related complaints and facilitating regular parent-staff interaction. This approach optimizes time management and minimizes workflow interruptions for nurses.

Research demonstrates the positive impact of these technologies in NICUs. A 2023 Australian study showed that implementing a camera system was well-received by parents and staff, reducing parental stress and enhancing parent-infant bonding.[26] A UK study found that asynchronous video messaging significantly improved parental experience, promoting emotional closeness and supportive family-staff relationships.[27]

> "[Messaging] makes it easy and fun to send updates to parents. Parents don't always have to call in to get a quick update, decreasing interruptions in nurse workflow."
>
> — NICU Nurse

In summary, AngelEye Health's Family Engagement Platform is pivotal in tackling nurse turnover and burnout in NICUs. This technology markedly improves staff well-being and workflow efficiency by enhancing communication, fostering family involvement, and easing administrative tasks. For optimal patient and family outcomes, clinicians require support with resources that bolster patient engagement and connection. Embracing these innovative technological solutions is essential in creating a supportive NICU environment addressing staff workload, emotional distress, and burnout challenges.

References

1 Haddad, L. Annamaraju, P., & Toney-Butler, T. (2023). Nursing Shortage. Stat Pearls. Retrieved from: https://www.ncbi.nlm.nih.gov/books/NBK493175/

2 Rotenstein, L., Brown, R., Sinsky, C., & Linzer, M. (2023). The Association of Work Overload with Burnout and Intent to Leave the Job Across the Healthcare Workforce During COVID-19. *Journal of General Internal Medicine*, 38(8): 1920–1927.

3 Meng-Wei, G., Fei-Hong, H., Yi-Jie, J., Tang, W., Wan-Qing, Z., & Hong-Lin, C. (2023). Global prevalence of nursing burnout syndrome and temporal trends for the last 10 years: A meta-analysis of 94 studies covering over 30 countries. *Journal of Clinical Nursing*, 32(17-18), 5836-5854.

4 Woo, T., Roger, H., Tang, A., & Tam, W. (2020). Global prevalence of burnout symptoms among nurses: A systematic review and meta-analysis. *Journal of Psychiatric Research*, 123, 9-20.

5 Bagwell, G., Cesario, S., Fraser, D., Kenner, C., & Walker, K. (2023). Breaking the Cycle of Nursing Chaos: The Need to Address the Nursing Shortage. *Neonatal Network*, 1;42(6):316-319. doi: 10.1891/NN-2023-0053.

6 Mills, M. & Cortezzo, D. (2020). Moral distress in the Neonatal Intensive Care Unit: What it is, why it happens, and how we can address it. (2020). *Frontiers in Pediatrics*. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7511509/pdf/fped-08-00581.pdf

7 Ravaldi, C., Mosconi, L., Mannetti, L., Checconi, M., Bonaiuti, R., Ricca, V., Mosca, F., & Vannacci, A. (2023). Post-traumatic stress symptoms and burnout in healthcare professionals working in neonatal intensive care units: Results from the STRONG study. *Frontiers in Psychiatry*, 3(14). doi: 10.3389/fpsyt.2023.1050236

8 Butcher, I., Morrison, R., Balogun, O., Duncan, H., St Louis, K., Webb, S., & Shaw, R. (2023). Burnout and coping strategies in pediatric and neonatal intensive care staff. *Clinical Practice in Pediatric Psychology.* Advance online publication. https://doi.org/10.1037/cpp0000474

9 Govindaswany, P., Laing, S., Waters, D., Walker, K., Spence, K., & Badawi, N. (2019). Needs and stressors of parents of term and near-term infants in the NICU: A systematic review with best practice guidelines. *Early Human Development*,

139. doi: 10.1016/j.earlhumdev.2019.104839
10 Sabnis, A., Fojo, S., Nayak, S., Lopez, E., Tarn, D., & Zeltzer, L. (2019). Reducing parental trauma and stress in neonatal intensive care: Systematic review and meta-analysis of hospital interventions. *Journal of Perinatology*, 39(3), 375-386.
11 Hoffman, C., Dunn, D.M., & Njoroge, W.F.M. (2017). Impact of postpartum mental illness upon infant development. *Curr Psychiatry Rep*, 19(12), 100.
12 Garthus-Niegel, S., Ayers, S., Martini, J., von Soest, T., & Eberhard-Gran, M. (2017). The impact of postpartum post-traumatic stress disorder symptoms on child development: A population-based, 2-year follow-up study. *Psychol Med*, 47(1), 161–170.
13 Huhtala, M., Korja, R., Lehtonen, L., Haataja, L., Lapinleimu, H., & Rautava, P. (2014). Associations between parental psychological well-being and socio-emotional development in 5-year-old preterm children. *Early Hum Dev*, 90(3), 119–124.
14 Thorne, S., Konikoff, L., Brown, H., & Albersheim, S. (2018). Navigating the dangerous terrain of moral distress: Understanding response patterns in the NICU. *Qualitative Health Research*, 28(5), 683-701.
15 Le Blanc, G., Jabbour, E., Patel, S., et al. (2022). Organizational risk factors and clinical impacts of unplanned extubation in the neonatal intensive care unit. *Journal of Pediatrics*, 249, 14-21.
16 Rogowski, J.A., Staiger, D., Patrick, T., Horbar, J., Kenny, M., & Lake, E.T. (2013). Nurse staffing and NICU infection rates. *JAMA Pediatrics*, 167(5), 444-450.
17 NSI Nursing Solutions. (2023). 2023 NSI National Health Care Retention & RN Staffing Report. Retrieved from https://www.nsinursingsolutions.com/Documents/Library/NSI_National_Health_Care_Retention_Report.pdf
18 Reid, S., Bredemeyer, S., & Chirella, M. (2021). The evolution of neonatal family centred care. *Journal of Neonatal Nursing*, 27(5), 327-333.
19 Sidek, S., Marup, S., & Zolkefli, Y. (2021). Nurses' view of the nature of the support given to parents in the neonatal intensive care unit. *Belitung Nursing Journal*, 7(6), 522-528.
20 Lake, E., Smith, J., Staiger, D., Shoenauer, K., & Rogowski, J. (2020). Measuring parent satisfaction with care in Neonatal Intensive Care Units: The EMPATHIC-NICU-USA Questionnaire. *Frontiers in Pediatrics*.
21 Foe, G., Hellmann, J., & Greenberg, R. (2018). Parental moral distress and moral schism in the neonatal ICU. *Journal Bioethical Inquiry*, 3, 319-325.
22 Sankar, V., Batra, P., Saroha, M., & Sadiza, J. (2017). Parental satisfaction in the traditional system of neonatal intensive care unit services in a public sector hospital in North India. *South African Journal of Child Health*, 11(1). doi. org/10.7196/sajch.2017.v11i1.1253
23 Cano-Gominez, E. & Sanchez, Luna, M. (2015). Providing parents with individualised support in a neonatal intensive care unit reduced stress, anxiety and depression. *Controlled Clinical Trial*, 104(7):e300-5.
24 Shirazi, Z., Sharif, F., Rakhshan, M., Pishva, N., Jahanpour, F. (2015). The obstacles against nurse-family communication in family-centered care in neonatal intensive care unit: A qualitative study. *Journal of Caring Sciences*, 4(3), 207-216.
25 Milrashari, J., Brown, Khoshnavay, F., Salaberry, J., Khanmohamad, T., & Khoshkhou, F. (2020). The challenges of implementing family-centered care in NICU from the perspectives of physicians and nurses. *Journal of Pediatric Nursing*, Jan-Feb:50, e91-e98. https://doi.org/10.1016/j.pedn.2019.06.013
26 Legge, A., Middleton, J., Reid, S., & Gordon, A. Implementation of a web camera system in an Australian neonatal intensive care unit: A pre- and post evaluation of the parent and staff experience. JMIR Pediatrics and Parenting, 22(6). doi: 10.2196/47552
27 Kirolos, S., Sutcliffe, L., Giatsi Clausen, M., et al. (2021). Asynchronous video messaging promotes family involvement and mitigates separation in neonatal care. *Archives of Disease in Childhood - Fetal and Neonatal Edition*, 106, 172-177. Retrieved from https://fn.bmj.com/content/106/2/172

Reduced Trauma for Micro-Preemies: The Discontinuation of Peel-Away Sheaths

Machele Duvall, RN, BSN

Micro-preemies, those born before 26 weeks that often weigh between 700-800 grams, are still in the exceedingly early stage of development. Because of this, they are incredibly fragile and are at risk for multiple health complications which require vascular access. Products used today, such as peel-away/tear-away sheaths, are still overly invasive and often create added issues. Rumors of pending innovation in this arena have circulated throughout the neonatal medical community for months; hopefully 2024 will be the year when the quality of vascular access care for this most vulnerable population is finally advanced.

Frontline doctors and nurses are the warriors that stand between life and death for these tiny little humans, and they are *painfully* aware of the fragility of all body systems. These neonatal experts weigh out death versus survivability versus disability with each interventional effort. Myriad complications arise for micro-preemies including immature digestion, hemodynamic compromise, fetal shunts, poor myocardial contraction, intraventricular hemorrhage, respiratory distress, infections, and extremely fragile skin and vasculature; it is utterly amazing that any of them survive with so many issues. Vascular access is a mandatory hallmark for effective treatment, but at what cost?

These tiny babies, and the brave medical professionals that stand up daily to fight for their survival, desperately need less-invasive devices for vascular access. Micro-preemie skin is so very delicate, that the avoidance of touch is crucial; unfortunately, peel-away sheaths certainly do not minimize this concern. When a vascular access procedure is initiated, most professionals will tell you that they are holding their breath every time and hoping that the procedure will go smoothly with minimal damage. It may be successful with a single first attempt, but multiple issues occur. Insertion of a peel-away/tear-away device creates a larger opening into the skin, and the internal vasculature, to accommodate the larger size of the device because it has a sheath. The sheath then requires added room to be torn outward and then pulled away risking severe damage to the vessel. The larger diameter of a peel-away sheath, accompanied by the pressure placed on the exterior skin to tear it away, can result in skin tearing and vascular damage. Additionally, the device may be defective resulting in an unevenly torn or partially removed sheath; tissue damage ensues from the required manipulation to complete the access. This may compromise treatment due to infection, leakage, and vascular collapse, not to mention *the pain that increases trauma* for the patient.

For now, peel-away/tear-away devices are the only viable tools available for vascular access in this patient population, but rumors of a new device are rapidly being discussed throughout the neonatal community. Neo Medical, Inc. has been an industry leader for years and has now developed a ground-breaking new device; it is a Reduced Trauma 1.2Fr catheter system for micro-preemies with an integrated introducer that **does not have a peel-away/tear-away sheath!** The innovative device is barium sulfate-loaded, thermosensitive polyurethane (in-body softening) that allows for prolonged vascular access. According to the creator of the patent-pending device at Neo Medical, it is slated for release in early summer of 2024 if not sooner.

Hopefully, more medical innovators and manufacturers will continue to perfect vascular access for our most vulnerable population to reduce trauma and medical complications. Survivability cannot be improved without innovative technology from the finest minds in the industry combined with the outstanding skills and courage of the medical staff who use it.

References

1 Gupta S., Donn S.M. (2020). Assessment of Neonatal Perfusion. *Semin Fetal Neonatal Medicine*, 25, 101144.
2 Natalucci G. (2022). Extremely Preterm Birth and Its Consequences: The ELGAN Study. *Neuropediatrics*, 53, 80.

Machele Duvall is an RN, BSN and has worked in multiple medical specialties such as Pediatric Emergency, Orthopedics, and Post-Surgical Cardiac Care. She is also a Clinical Consultant for Medical Device manufacturers to help them understand the clinical applications of their products.

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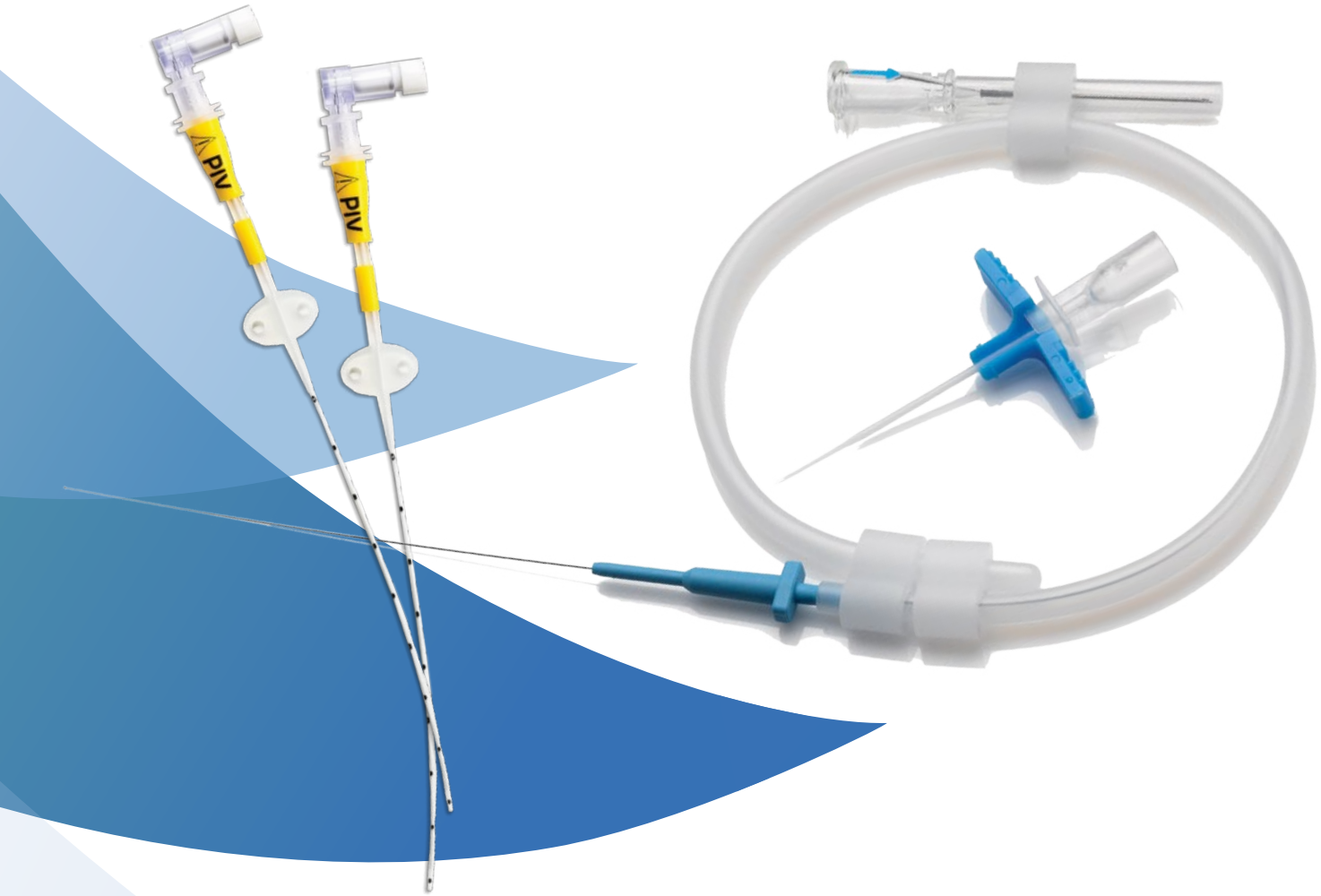

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Key Considerations for Pediatric Care Following Tracheostomy

Kristin A King, PhD, CCC-SLP

Understanding the potential impact of tracheostomy tubes on development in the pediatric patient may influence interventions and treatment plans. Tracheostomies, a medical intervention to assist with respiratory support, may present challenges that extend beyond the immediate respiratory system. Potential disruptions to development may occur with fine and gross motor movements, causing delays in reaching developmental milestones in areas such as mobility, feeding, and speech and language. A review of the underlying mechanisms, and strategies for early intervention, assists with addressing these challenges.

Introduction

Tracheostomy, a medical procedure involving the creation of an artificial airway through the neck, is sometimes necessary for infants with respiratory issues. While it is a life-saving intervention, the potential consequences of a tracheostomy on the overall development of infants may be substantial. Tracheostomy is often performed in infants with severe respiratory distress, chronic lung disease, or congenital anomalies affecting the airway. Understanding the underlying reasons for this procedure is essential for evaluating its potential impact on various aspects of infant development. It affects factors such as airway resistance, humidification, and filtration, which also may have repercussions on the developing respiratory and cardiovascular systems.

Impact of Tracheostomy on Developmental Milestones

The development of mobility in infants is not solely about physical movement; it is intricately linked to cognitive and socio-emotional development.[1] The ability to explore the environment independently enhances spatial awareness, stimulates curiosity, and fosters a sense of autonomy. Furthermore, mobility plays a vital role in social interactions, allowing infants to engage with caregivers, peers, and their surroundings. It also allows the infant to engage more with food exploration, developing self-feeding, and even speech and language.

With 25 years of experience in medical, academic, and industry settings, Dr King brings a unique perspective of medical speech pathology. Her research, publications, and teachings focus on traumatic brain injury, swallowing disorders, and critical care (tracheostomy and mechanical ventilation) for both pediatric and adult patient populations. She has been an invited speaker both domestically and internationally and has published in peer-reviewed journals. Currently, Dr King is the Vice President of Clinical Education and Research for Passy-Muir, Inc.

Communication and cognitive development are enhanced through the interactions that a child has with both their environment and the people around them. If mobility is limited, then the ability to interact with the environment and people may be restricted. The need for early intervention, specialized care and therapies, and ameliorating potential delays are crucial factors to consider when assessing the overall developmental trajectory.

Motor Development

Infants with tracheostomies may face challenges in achieving motor milestones due to the presence of the tracheostomy tube and associated caregiving requirements. Mobility development in infants is a remarkable process that unfolds in a sequence of interconnected milestones. From reflexes and tummy time to crawling, standing, and walking, each stage contributes to the overall growth and maturation of the infant. Understanding these milestones provides caregivers and healthcare professionals with valuable insights into the child's development and allows for targeted interventions if necessary. As infants progress through these stages, they not only gain physical abilities but also lay the foundation for future skills development, such as self-feeding; learning, including cognitive development; and exploration, assisting with independence.[2] The development of mobility in infants is an intricate process that unfolds during the early stages of life. From the moment of birth, infants embark on a journey of motor development that encompasses a series of milestones, gradually building the foundation for independent movement. Considering the key stages in the development of mobility in infants and the significance of each milestone informs the healthcare professional and caregiver for treatment planning.

Reflexes and Early Movements. In the first few months of life, infants rely on reflexes and involuntary movements as a means of interaction with their environment. Primitive reflexes, such as the grasp reflex and the Moro reflex, provide the initial building blocks for more sophisticated movements. Simple actions, like turning the head or grasping objects, emerge as infants become more attuned to their surroundings.

Tummy Time and Crawling. Around 3 to 6 months of age, infants begin to gain more control over their neck and upper body muscles, enabling them to lift their heads during tummy time. This strengthens the muscles needed for crawling, a significant milestone in mobility development. Crawling not

Figure 1. Early intervention with a PMV®007 (Aqua color™) Valve being used in-line with mechanical ventilation in the ICU.

only fosters spatial awareness but also enhances bilateral coordination and builds core strength, laying the groundwork for future motor skills.

Sitting and Exploring. As infants approach the 6 to 9-month mark, they start to sit independently. This newfound ability expands their exploratory capabilities, allowing them to interact with objects and people in a more upright position. Sitting is a pivotal skill that paves the way for further independence and facilitates the development of fine motor skills. By gaining an upright or sitting position, the infant now has their hands free for hand-to-mouth exploration of their environment but more importantly for self-feeding.

Pulling to Stand and Cruising. Between 9 and 12 months, infants demonstrate increased strength and coordination in their lower limbs, leading to the ability to pull themselves to a standing position. Once standing, they often begin to cruise along furniture, holding on for support. This marks a crucial step towards independent walking, as infants refine their balance and weight-bearing skills.

First Steps and Toddler Mobility. Around the age of 12 to 18 months, many infants take their first tentative steps, marking the transition from crawling to walking. Initially unsteady, these early steps gradually evolve into more confident and purposeful strides. As infants gain proficiency in walking, they enter the realm of toddlerhood, where mobility becomes a tool for exploration and play.

Speech Development

The development of speech in infants begins shortly after birth and unfolds rapidly during the first few years of life. Initially, infants communicate through cries, coos, and babbling, laying the foundation for language acquisition. Around 6 months, they start to produce consonant-vowel combinations, experimenting with the sounds of their native language.[2] This developmental milestone coincides with the ability to sit upright, hand-to-mouth exploration, and self-feeding. Engaging the mouth in oral stimulation assists with articulatory development.

By 9 to 12 months, infants typically produce their first recognizable words, marking the onset of expressive language. This stage is characterized by a rapid expansion of vocabulary and a growing ability to imitate sounds and gestures. Infants also engage in joint attention, responding to facial expressions and gestures during social interactions.

As they approach the age of 18 months, toddlers enter the "vocabulary explosion" phase, rapidly acquiring new words and beginning to form simple sentences. The development of speech is closely intertwined with cognitive and social-emotional growth, as infants learn to convey needs, share experiences, and form connections with caregivers. This early linguistic foundation lays the groundwork for more complex language skills, setting the stage for a lifetime of communication and expression.

Potential Challenges Following Tracheostomy

A tracheostomy may disrupt the coordination between respiratory and motor functions. With changes and difficulties in coordinating breathing with activities such as reaching, grasping, and crawling, infants may have reduced pressures in the body that impact movement, trunk support, and postural control.[3] These changes may impact their overall motor coordination and the ability to engage in age-appropriate physical play. If an infant's range of motion, especially in the neck and upper body, is limited then this may impede the natural movements required for activities like turning the head, reaching, and exploring the environment. Tummy time, a crucial activity for strengthening neck and upper body muscles, may also be compromised after tracheostomy. Since infants typically begin to explore weight-bearing activities around the age of 6 to 9 months, pulling themselves to a standing position and eventually cruising along furniture, a tracheostomy in earlier months may impose challenges to these activities due to the open system. Another fundamental milestone is crawling which contributes to the development of bilateral coordination and spatial awareness. A tracheostomy may hinder the natural progression of crawling and other movements as postural control and trunk stability may be impaired secondary to diminished pressures.

When considering speech-language development, speech disruption may occur due to the impacts of a tracheostomy tube. Some disruptions to consider are the changes in airflow - since a tracheostomy changes the direction of airflow from the mouth and nose to in and out the tracheostomy tube at the neck, bypassing the vocal folds. This modification impacts natural airflow typically used during speech production as there is no airflow through the vocal folds, affecting vocal fold vibration and resonance. This alteration in airflow dynamics may contribute to changes in speech, production, quality, and intelligibility. Since speech production relies on precise coordination between respiratory, laryngeal, and articulatory mechanisms, a tracheostomy tube can disrupt this coordination, leading to difficulties in breath control and vocal expression. Pediatric patients with tracheostomies may experience challenges in vocabulary acquisition and expressive language development. If speech and language are impacted, consideration must also be given as to how this may influence social interaction, psycho-social development, and communication.

Importance of Early Intervention

Recognizing the potential disruptions in motor and speech-language development, early intervention becomes crucial for infants who have undergone tracheostomy. Physical therapy, occupational therapy, speech-language pathology, child life therapy, and respiratory therapy, among others, all provide developmental interventions to address specific challenges, promote motor skills, and support the attainment of developmental milestones.

Figure 2. Sitting upright with good trunk support and postural control while using a PMV®007 (Aqua color™) Valve.

One key intervention is the use of a speaking valve. Placement of a no-leak speaking valve on a tracheostomy tube closes the system and redirects airflow through the upper airway. This closed system and redirected airflow facilitate speech and aid in the management of respiratory function. Using a speaking valve also restores pressures necessary for motor development. In the context of infants and toddlers, really all ages, a one-way, no-leak speaking valve offers a means to promote positive pressure ventilation and improve airflow, ultimately contributing to enhanced respiratory outcomes; restored speech; improved functions, such as cough, smell, taste, and swallowing; and improved pressures.[4]

When considering speech-language development, a scoping review of the literature by Zabih et al. (2016) identified eight studies reporting verbal communication with speaking valve use.[5] More recently, studies have reported improvements in phonation with speaking valve use.[6] Even in prelingual infants and children with neurologic deficits, having the ability to cry and vocalize may significantly improve patient safety and quality of life, for both the patient and caregivers. Quality of life may also be impacted by the Improvement in cough and constipation, which may be restored or improved secondary to the ability to generate subglottic pressure and perform Valsalva.[7]

Caregiver Education and Support

Ensuring caregivers are well-informed and adequately trained to support gross and fine motor skills and speech and language development in pediatric patients with tracheostomies is crucial. Providing a supportive environment, engaging in targeted activities, and collaborating with healthcare professionals are essential components to ensuring the overall well-being and development of the infant.

Conclusion

Tracheostomy tubes can have a significant impact on achieving the developmental milestones of pediatric patients. Recognizing these challenges and implementing targeted interventions, including the use of speaking valves and early intervention programs, is essential for promoting optimal outcomes in this population. Tracheostomies in infants, while necessary for respiratory support, introduce challenges to motor and speech-language development that should not be overlooked. Awareness of potential disruptions in these milestones, coupled with early intervention strategies, can contribute to optimizing the developmental outcomes for infants who have undergone tracheostomy. It is essential for healthcare professionals and caregivers to work collaboratively, tailoring interventions to address the unique needs of each infant and supporting their journey toward achieving developmental milestones despite the challenges posed by a tracheostomy. While a tracheostomy is not the sole factor impacting the achievement of these milestones, it certainly complicates an already complex patient population, regardless of the primary diagnosis.

References

1 Iverson, J. M. (2010). Developing language in a developing body: the relationship between motor development and language development. *Journal of Child Language*, *37*(2), 229 - 261.

2 NIDCD. (2020). Speech and language developmental milestones. Retrieved from https://www.nidcd.nih.gov/health/speech-and-language

3 Massery, M. (2014). Expert interview: The role of the Passy-Muir valve in physical therapy. *Talk Muir* (3 Feb. 2014), 2-4.

4 O'Connor, L. R., Morris, N. R., & Paratz, J. (2019). Physiological and clinical outcomes associated with use of one-way speaking valves on tracheostomised patients: A systematic review. *Heart Lung*, *48*(4), 356-364. https://doi.org/10.1016/j.hrtlng.2018.11.006

5 Zabih, W., Holler, T., Syed, F., Russell, L., Allegro, J., & Amin, R. (2017). The use of speaking valves in children with tracheostomy tubes. *Respiratory Care*, *62*(12) 1594-1601 https://doi.org/10.4187/respcare.0559931

6 Buswell, C., Powell, J., & Powell, S. (2017). Paediatric tracheostomy speaking valves: Our experience of forty-two children with an adapted Passy-Muir® speaking valve. *Clinical Otolaryngology*, *42*(04) 941-944. https://doi.org/10.1111/coa.12776

7 Simons, J.P., Mehta, D., & Mandell, D.L. (2010). Assessment of constipation in children with tracheostomy. *Archives of Otorhinolaryngology-Head Neck Surgery*, *136* (01) 27-32. https://doi.org/10.1001/archoto.2009.207

Staying on Top of Respiratory Technology and Techniques in the NICU

Ongoing Clinical Education and Training Key to High Quality Care and Healthy Patient Outcomes

Winnie Sywulak, BS, RRT-NPS and Anduin Anderle, RN

As medical technology continues to advance, offering innovations in both diagnostics and therapeutics, it is more important than ever to ensure clinicians have the training they need to use equipment effectively and safely—and in a world of clinical staffing shortages, efficiently.

Two areas where technology is rapidly evolving to meet patient needs is in respiratory care and the neonatal intensive care unit (NICU). The COVID-19 pandemic has demonstrated the importance of effective and safe ventilation. When it comes to babies born prematurely, respiratory support and NICU care converge as NICU teams work to help preemies' immature lungs develop outside of the womb.

In this article, we look at how clinical education and training is critical to high-quality outcomes in respiratory care and the NICU environment.

Keeping Pace with Healthcare Innovation

In 2021, the US Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) approved or authorized 103 novel (new) medical devices. Overall, the CDRH oversees 236,000 regulated devices from 25,000 device manufacturers.[1]

With each new technology that enters a hospital comes the need for staff education and training. Patient safety is at risk when clinical staff do not understand how to properly use a device. But keeping up with education in a rapidly changing world is not easy, as the authors of a recent article published in *The Online Journal of Issues in Nursing* state:

> "Advancing the mission of nursing education for a future that we cannot yet fully conceive is a daunting task, but leading and promoting change is not discretionary. Today, awash in accelerated knowledge creation and sweeping innovation, professionals in the healthcare and higher education find themselves facing isomer-like challenges to provide value, positive outcomes, access, and affordability for their consumers—or become obsolete."[1]

Memorial Hermann Health System in Houston experienced "an instance of actual patient harm due to staff unfamiliarity with a medical device," which prompted the health system to "design a 'fail-safe' process to analyze and scale training for use of medical devices, with a risk assessment tool predicting the potential severity and frequency of harm to patients."[1]

Under the fail-safe process, educational rigor, tracking, and accountability management are scaled to the level of device risk. Its objective is to "ensure the competence of clinical staff in the operation of all approved new and updated medical devices." Based on its success, the process became an approved procedure and practice standard at Memorial Hermann Health System.[1]

Research has shown how proactive, ongoing education and training is key to patient care and safety. Case in point: a urology unit in a large acute NHS hospital introduced a new training program, including a "time out" training day "that covered medical device and mandatory training, alongside evidence to support nurses' revalidation and a forum for peer support." Following program implementation, medical device training competency among urology staff increased from 65% to 97% across all staff groups, including nurses and healthcare assistants.[2]

Challenges to care delivery in the NICU

NICU teams are tasked with caring for the smallest, most fragile patients with under-developed bodies, including lungs unprepared to breathe on their own. Neonatal respiratory distress syndrome (RDS) is the leading cause of death in

Winnie Sywulak, BS, RRT-NPS, is the Senior Marketing Manager for Dräger's Respiratory Care Solutions in North America. Anduin Anderle, RN, is the Marketing Manager for Dräger's Neonatal Care & Thermoregulation Solutions in North America.

premature infants.[2] While tremendous strides have been made in neonatal respiratory care over the decades, NICU teams still struggle with supporting pre-term babies' fragile lungs to prevent long-term health consequences.[3]

Respiratory equipment manufacturers continue to advance in ventilation technologies and treatments aimed at improving both short and long-term outcomes for premature infants. But the complexity of some advancements may overcome the benefits for clinicians using them at the bedside.

"Understanding the complexities of care given to any neonate requiring mechanical ventilation is essential to deliver safe and effective care," states the author of Understanding Neonatal Ventilation: Strategies for Decision Making in the NICU. "The range of modes and parameters in ventilation practice can pose a challenge for both the novice nurse and for those more experienced who require an update of knowledge."[3]

Healthcare organizations striving for value-based care must ensure their clinical teams are leveraging devices, including ventilators, effectively and safely to improve outcomes and reduce complications. Neonatal ventilators featuring smart applications and monitoring tools can help clinicians facilitate decisions, but only in conjunction with adequate instruction and support.

Supporting NICU teams through technology, education and training

There are many considerations when pursuing improved mechanical ventilation education and training among NICU staff members, including respiratory therapists (RT) and nurses (RN).

When a new mechanical ventilator is introduced to the NICU, the manufacturer will provide initial in-servicing and training on device usage. Equally important is the availability of ongoing education to reinforce best practices and train users on new techniques.

In a world of healthcare staffing shortages, where caregivers must do more with less, it is critical to make continuing education opportunities convenient and accessible. This is particularly true of the respiratory therapy field, where growing demand for RTs has drastically outpaced the number of current RTs, and myriad factors will exacerbate the shortage in the years to come (e.g., decreased RT program enrollment, 92,000+ RTs retiring by 2030, etc.).[3]

One option for NICUs is to encourage their RT team members to take part in online Continuing Respiratory Care Education (CRCE) courses that promote effective and safe use of neonatal mechanical ventilation. Through its "A Breath Ahead" platform, Dräger offers free online courses accessible 24/7 where RTs can earn CRCE hours to further develop their skills and meet licensing requirements. In 2021, the platform had more than 72,000 complimentary CRCE-accredited course completions by respiratory professionals.[3]

Neonatal respiratory care CRCE course topics on A Breath Ahead include the following related to mechanical ventilation, among many others:

- Use of Airway Pressure Release Ventilation (APRV) in pediatrics and neonatology
- The theory, clinical application, and operating principle of Mandatory Minute Ventilation (MMV) in neonates
- Caring for severe bronchopulmonary dysplasia (BPD) patients
- Volume-Targeted Ventilation in neonatal care

"CME (continuing medical education) is crucial to the prosperity of health care providers — it allows a practitioner to learn and discover viable ways to improve on the patient care they deliver and effectively manage a career in the ever-changing landscape of the medical industry," says the American Association of Continuing Medical Education.[3]

Conclusion

Technological advancements in healthcare delivery broaden the reach of what clinicians can achieve when caring for patients. Looking at mechanical ventilation, it is incredible to see how far oxygen delivery has come since Heinrich Dräger patented the very first ventilator, the "Pulmotor," in 1907. Today, NICU teams provide a level of precision in respiratory support that was unimaginable 100 years ago, enabling extremely low birth weight (ELBW) and extremely-low-gestational-age neonates (ELGAN) to survive and thrive.

With advancement comes responsibility — of ventilator manufacturers to educate and train NICU clinicians on effective and safe use of their devices — and for NICU clinicians to continue to refine their knowledge and skills based on the latest research and literature.

Fortunately, there are many continuing education opportunities available to NICU teams, including RTs, from in-person conferences and events to webinars and presentations.

Healthcare leaders should encourage their NICU clinicians to pursue these opportunities for individual professional development, but most importantly, to minimize the risk for errors and provide patients with the highest quality care available.

References

1 Center for Devices and Radiological Health (CDRH), 2021 Annual Report, https://www.fda.gov/media/155793/download

2 Kavanagh, J.M., Sharpnack, P.A., (January 31, 2021) "Crisis in Competency: A Defining Moment in Nursing Education" OJIN: The Online Journal of Issues in Nursing Vol. 26, No. 1, Manuscript 2, DOI: 10.3912/OJIN.Vol26No01Man02, https://doi.org/10.3912/OJIN.Vol26No01Man02

3 Hercules P, Shabot MM, Ryan T, Ratcliff S. Optimizing Fail-Safe Use of Complex Medical Devices. AACN Adv Crit Care. 2019 Spring;30(1):25-39. doi: 10.4037/aacnacc2019400. PMID: 30842071.

4 Hercules P, Shabot MM, Ryan T, Ratcliff S. Optimizing Fail-Safe Use of Complex Medical Devices. AACN Adv Crit Care. 2019 Spring;30(1):25-39. doi: 10.4037/aacnacc2019400. PMID: 30842071.

5 Shields R, Latter K. Improving the uptake of medical device training to promote patient safety. Nurs Stand. 2019 Aug 31;35(1):31-34. doi: 10.7748/ns.2019.e11219. Epub 2019 May 30. PMID: 31736285.

6 Dyer J. Neonatal Respiratory Distress Syndrome: Tackling A Worldwide Problem. P T. 2019 Jan;44(1):12-14. PMID: 30675087; PMCID: PMC6336202.

7 Davidson L, Berkelhamer S. Bronchopulmonary Dysplasia: Chronic Lung Disease of Infancy and Long-Term Pulmonary Outcomes, J Clin Med. 2017 Jan; 6(1):4. https://www.ncbi.

nlm.nih.gov/pmc/articles/PMC5294957/
8 Petty J. Understanding neonatal ventilation: strategies for decision making in the NICU. Neonatal Netw. 2013 Jul-Aug;32(4):246-61. doi: 10.1891/0730-0832.32.4.246. Erratum in: Neonatal Netw. 2013 Nov-Dec;32(6):415. PMID: 23835544. http://www.academyofneonatalnursing.org/Ventilation/UnderstandNeoVent.pdf
9 Why We Need More RTs – and How to Help, https://www.morerts.com/growing-need/
10 2022 Global Neonatal Devices & Neonatal Care Industry report, Frost & Sullivan, https://www.draeger.com/Library/Content/Draeger-Award-Write-Up-2022.pdf
11 What is CME, American Association of Continuing Medical Education, https://aacmet.org/cme/what-is-cme/

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streaming video, the Stork Vitals bundle replaces the camera with a health hub, which connects the Stork vital signs sensor/boot to the Stork app, while still allowing parents to hear and speak to their baby. Stork also monitors the temperature of the baby's room. Dr Ryan S. Bode, a national leader in pediatric hospital medicine and pediatric quality and safety, commented, "I have cared for hospitalized children for over 20 years. In addition, my passion and research interests have focused on quality improvement and patient safety in delivering high value pediatric care and ensuring optimal patient outcomes. Masimo SET® pulse oximetry technology is unmatched in its ability to measure accurately even when children move or have low perfusion. Any caregiver, parent, or clinician looking to monitor key vitals in young babies should ensure they have accurate, reliable technology, like SET® pulse oximetry." Dr Mitchell R. Goldstein, Professor of Pediatrics at Loma Linda University, said, "I had the privilege of having access to one of the earliest Masimo SET pulse oximeters. A young baby, Joshua, came to our unit at extremis, and we attempted all life-saving measures to get his pulse on a non-Masimo device. With no success, we then tried the Masimo monitor and were able to get readings of his vitals, a signal that we should continue to provide care. Joshua survived and was eventually sent home with his parents, and our unit has relied on Masimo SET ever since. It is the only pulse oximeter I'm aware of that has provided the ability from the beginning to measure through challenging conditions and with darker skin colors, as was the case with Joshua. I am glad to see this life-saving technology being expanded to the home." For non-medical use, Masimo Stork bundles are available for direct consumer purchase at MasimoStork.com and on shelves at major and specialty US retailers. To access Masimo Stork's FDA-cleared features, parents can discuss Stork with their child's primary care physician or, in a soon-to-be-released update, online with a physician via the Masimo Stork App. For prescription use, Masimo Stork is 510(k) cleared for the following intended use: Masimo Stork is a wearable device intended for the monitoring of multiple physiological parameters. Masimo Stork is intended to be used in home environments. Masimo Stork is indicated for the spot-checking and continuous monitoring of SpO_2 and PR in infants and neonates during no motion, motion, and low perfusion conditions. Masimo Stork is also indicated for continuous skin temperature measurements of infants and neonates.

Human Milk-Based Nutrition Touches the Lives of 100,000 Premature and Critically Ill Infants

Prolacta Bioscience, the world's leading hospital provider of 100% human milk-based nutritional products for critically ill, premature infants, proudly commemorates Prematurity Awareness Month 2023 by announcing a significant milestone: more than 100,000 preterm and critically ill infants' lives have been touched by Prolacta's Exclusive Human Milk Diet (EHMD) in hospitals worldwide. "Prematurity Awareness Month is an important time to raise awareness about the challenges and triumphs faced by premature and critically ill infants, as well as their families," said Melinda Elliott, MD, chief medical officer of Prolacta and a practicing neonatologist. "We're proud that for more than two decades, Prolacta's 100% human milk-based nutritional products have supported hospitals on the forefront of progressive care to help so many fragile infants in need." Back in 2013, Delvin and Brandi Peeks from Virginia experienced an emotional NICU journey after the birth of their daughter, Leah Michelle, who was born at 23 weeks weighing just 1 lb 8 oz. Leah Michelle experienced intolerance to the cow milk-based fortifier she initially received and subsequently developed necrotizing enterocolitis (NEC), the most common and serious intestinal disease among premature infants and one of the leading causes of preterm mortality. The Peeks advocated for Leah Michelle to be on an EHMD and asked the hospital to fortify Brandi's breast milk with a Prolacta fortifier. Today, Leah Michelle is a thriving 9-year-old who is considered everyone's best friend at school and enjoys playing the clarinet, acting, and singing. She's also on a competitive swim team and won her first race this past summer. Available since 2006, Prolacta's human milk-based fortifiers have transformed the standard of care in hospitals worldwide by offering a proven alternative to cow milk-based fortifiers. All types of hospitals have seen the benefits of an EHMD to treat the critically ill, premature infants in their care, including those supporting underserved populations. Recognizing that the preterm birth rate is highest among people of color and that prematurity is the leading cause of death among Black infants,5 hospitals are working to bridge healthcare disparities by making Prolacta's EHMD more accessible to disadvantaged families. One example is Los Angeles General Medical Center (formerly LAC+USC Medical Center), among the largest public hospitals in the US. This safety-net hospital implemented Prolacta's EHMD and witnessed less NEC, less bronchopulmonary dysplasia (BPD), less cases of severe retinopathy of prematurity (ROP), and shorter lengths of stay among its premature infants while achieving net savings of $2.7 million over a two-year period. "We have shown substantial reductions in mortality and long-term morbidity that benefits infants especially at high risk, including those born to mothers of substantial social risk, lower socioeconomic status, and lack of access to prenatal care," said Dr Rangasamy Ramanathan, professor of pediatrics and division chief of the Division of Neonatal Medicine at Los Angeles General Medical Center. The clinical benefits and cost savings of an EHMD are reinforced by a recent peer-reviewed report that showed Prolacta's human milk-based fortifiers reduced comorbidities among preterm infants while saving hospitals up to $3.4 million annually.

Pregnancy in Rheumatic Disease Quadruples Risk of Cardiovascular Events

Pregnant individuals with autoimmune rheumatic diseases (ARDs) are at least four times more likely to experience an acute cardiovascular event (CVE) than are pregnant individuals without these conditions, according to new research presented at the American College of Rheumatology (ACR) 2023 Annual Meeting. Pregnant individuals with primary antiphospholipid syndrome (APS) had a 15-fold increase in CVE risk. Patients who experienced CVEs were also more likely to experience preterm birth and other adverse pregnancy outcomes (APOs). Rashmi Dhital, MD, a rheumatology fellow at the University of California, San Diego, and colleagues examined the medical records of pregnant individuals in California who had delivered singleton live-born infants from 2005 to 2020. Using data from the Study of Outcomes in Mothers and Infants (SOMI) database, an administrative population-based birth cohort in California, they identified more than 7 million individuals, 19,340 with ARDs and 7758 with APS. They then analyzed how many patients experienced an acute CVE during pregnancy and up to 6 weeks after giving birth. CVEs occurred in 2.0% of patients with ARDs, 6.9% of individuals with APS, and 0.4% of women without these conditions. CVE risk was four times higher in the ARDs group (adjusted relative risk [aRR], 4.1; 95% CI, 3.7 - 4.5) and nearly 15 times higher in the APS group (aRR, 14.7; 95% CI,

13.5 - 16.0) than in the comparison group. Patients with systemic lupus erythematosus (SLE) had a sixfold higher risk of CVE, which was further exacerbated by concomitant APS (18-fold higher risk) or lupus nephritis (15-fold higher risk). Dhital also classified CVEs as either venous thromboembolism (VTE) and non-VTE events. Pregnant patients with APS had a high risk for VTE-only CVE (40-fold greater) and a 3.7-fold higher risk of non-VTE events, compared with pregnant patients without these conditions. Patients with SLE along with lupus nephritis had a 20-fold increased risk of VTE-only CVE and an 11-fold higher risk of non-VTE CVE. Although the study grouped rheumatic diseases together, "lupus is generally driving these results," Sharon Kolasinski, MD, of the University of Pennsylvania in Philadelphia noted. She moderated the plenary session where the research was presented. "If you take out lupus, then what is the risk? That would be an interesting question." Between 25% to 30% of all CVEs occurred in the postpartum period, highlighting the importance of close monitoring of cardiovascular risks and events in women with ARDs or APS both during pregnancy and postpartum, Dhital noted. Recognizing these risks "can sometimes be challenging due to a lower suspicion of CVE in younger patients, and also symptoms overlap with normal pregnancy," Dhital said during her plenary presentation. Working with other clinical teams could help physicians detect these risks in patients, she noted.

Early-Onset MASLD Risk Higher in Low-Birth-Weight Babies

Babies with low birth weight or those who are small for gestational age (SGA) have a sixfold increased relative risk for progressive liver disease at an early age, a nationwide Swedish study finds. The study aimed to associate birth anthropometrics (birth weight, gestational age, and birth weight for gestational age) with MASLD (metabolic dysfunction-associated steatotic liver disease, formerly known as NAFLD) and progressive liver disease in children and young people. The Swedish nationwide ESPRESSO longitudinal cohort database (medical registries) was linked to the Swedish Medical Birth Register (maternal, birth, and infant factors). In all, 165 biopsy-proven MASLD in people aged < 25 years matched to 717 controls in the general population were identified and analyzed.

COVID Shot While Pregnant Limits Severe Cases in Infants Says CDC

Getting a COVID-19 vaccine during pregnancy significantly reduces the chance that a baby will be hospitalized for COVID-19, new data shows. The study from the CDC found that vaccines were 54% effective at protecting infants from COVID-19 hospitalization in the first 3 months of life, and 35% effective at protecting babies from ages 3 months through 5 months old. Infants can be vaccinated against COVID-19 starting at 6 months old. Infants who were hospitalized with COVID-19 whose mothers were unvaccinated were more likely to need help breathing, compared to infants whose mothers had been vaccinated. For the study, researchers analyzed data for 716 babies hospitalized between March 2022 and May 2023. Among the babies in the study, 377 were hospitalized with COVID-19. Mothers were considered vaccinated if they'd had at least two COVID vaccines, one of which was given during pregnancy. All other mothers of babies in the study were unvaccinated. Vaccinated mothers pass antibodies against COVID-19 through the placenta to the fetus. The authors noted that a limitation of the study was that prior infection of mothers was not analyzed, including among unvaccinated mothers. They also said it is possible that "infection-induced antibodies could provide some protection against infant COVID-19-related hospitalization." "Maternal vaccination during pregnancy provides some protection against COVID-19-related hospitalizations among infants, particularly those aged less than 3 months," the authors wrote. "Expectant mothers should remain current with COVID-19 vaccination to protect themselves and their infants from hospitalization and severe outcomes associated with COVID-19."

'No Measurable Change' in Global Preterm Birth Rates

Across the world, preterm birth is one of the main risk factors for neonatal mortality among children younger than 5 years. Yet according to a new study, the international community has made few strides over the past decade when it comes to reducing the rates of preterm births and recording the related routine data.

"There has been no measurable change in preterm birth rates over the past decade at global level," according to the authors. "Despite increasing facility birth rates and substantial focus on routine health data systems, there remain many missed opportunities to improve preterm birth data." The study, published in *The Lancet*, was funded by the Children's Investment Fund Foundation through grants awarded to the London School of Hygiene and Tropical Medicine, the United Nations Children's Fund, and the World Health Organization (WHO). Building on the WHO's last update on the topic, which was published in 2015, the researchers conducted an analysis that included 679 data points (222 million births) from January 1, 2010, to December 31, 2020, from 103 countries and areas. They pointed out that global data on preterm births must be systematically updated so that suitable public policies can be designed and implemented. Preterm birth rates were estimated by using a hierarchical Bayesian framework that accounted for data quality differences. As the results show, preterm birth is not just a concern in low- and middle-income countries. Indeed, rates of 10% or higher occur in high-income countries, such as Greece and the United States. The situation, however, is worse in places with fewer resources. Around 65% of preterm births in 2020 occurred in sub-Saharan Africa and southern Asia. The highest preterm birth rates were in Bangladesh (16.2%), Malawi (14.5%), and Pakistan (14.4%), whereas the lowest were in Serbia (3.8%), the Republic of Moldova (4%), and Kazakhstan (4.7%). Although Brazil's rate, 11.1%, is above the overall average, its average annual rate of reduction between 2010 and 2020 was 0.7%. Among those who have commented on the study is Anshu Banerjee, MD, PhD, director of the WHO Department of Maternal, Newborn, Child and Adolescent Health and Aging. He called for the adoption of strong and decisive measures to turn the situation around. "These numbers show an urgent need for serious investment in services available to support [preterm babies] and their families, as well as a greater focus on prevention — in particular, ensuring access to quality healthcare before and during every pregnancy." "Countries need to prioritize programmatic investments to prevent preterm birth and to ensure evidence-based quality care when preterm birth occurs," wrote the study authors. "Investments in improving data quality are crucial so that preterm birth data can be improved and used for action and accountability processes."

A Dozen Genes Found Dangerous in Pregnancy

Approximately 1 in 40 women are carriers of single gene disorders that could manifest as pregnancy complications, based on data from more than 90,000 individuals. Single gene

disorders remain a leading cause of morbidity and mortality in newborns and children, but carrier screening for such disorders was limited until recent advances in DNA sequencing, wrote Vivienne Souter, MD, of Natera in Austin, Tex., and colleagues. Identifying single gene disorders in carrier screening also includes the discovery of genetic variants that could affect the carrier parent during pregnancy, they said. In a study published in Obstetrics and Gynecology, the researchers reviewed data from 91,637 female patients who underwent testing via a 274-gene carrier screening panel. The median age of the participants was 32.8 years, and approximately half were pregnant at the time of the testing. Based on previously published reports, the researchers identified 12 genes with potential for carrier manifestations during pregnancy; of these, 9 had manifestations whether or not the fetus was affected by the genetic condition (ABCB11, COL4A3, COL4A4, COL4A5, DMD, F9, F11, GLA, and OTC) and 3 had manifestations only if the fetus was affected by the condition (CPT1A, CYP19A1, and HADHA). Overall, 66% of the tests were positive for at least one of the 274 genes; the frequency of potentially pathogenic variants for the 12 genes that could manifest as complications during pregnancy ranged from 1 in 117 individuals for the F11 gene to 1 in 8,331 for the OTC gene. A total of 2.3% of the participant tests were associated a pathogenic or likely pathogenic variant in at least 1 of the 12 genes, which accounted for 3.5% of all positive samples, and 2.0% were identified as carriers for 1 of the 9 genes that could affect women during pregnancy regardless of fetal genetic status. "People of Ashkenazi Jewish heritage were over-represented in the carrier group, representing 6.0% of carriers but only 1.9% of the entire study cohort," the researchers noted. Manifestations related to the 12 genes included cardiomyopathy, hemorrhage, gestational hypertensive disorders, cholestasis of pregnancy, acute fatty liver, hyperammonemic crisis, and maternal virilization. "The reported incidence of pregnancy complications in carriers ranged from 10% to 62% depending on the gene involved, but information was limited for most of the conditions," and published literature identified management recommendations for 11 of the 12 genes, the researchers wrote. The findings were limited by several factors including the use of cases received by the laboratory, which might have yielded more women with above-average risk because of family history, the researchers noted. Other limitations included a lack of data on further evaluation or counseling after the screening, and the lack of separation of the results according to the specific variant, they said. Also, the study population was limited to those who had access to carrier screening, and may not be generalizable to the population at large.

Ultrasonic Irradiation and Fetal Damage: Researcher Explores Possible Link

In her compelling book, *The Dark Side of Prenatal Ultrasound*, researcher and birth advocate Jeanice Barcelo offers "a ground-breaking analysis of the documented facts concerning the dangers of prenatal ultrasound." She states, "Despite the medical establishment repeating the mantra that ultrasound is 'just sound waves' and therefore 'perfectly safe' during pregnancy, in truth, ultrasound is based on non-ionizing radiation, and many thousands of studies have confirmed that this type of radiation is harmful, especially for children and developing babies in the womb." In her book, Barcelo includes nearly 300 pages of sourced material and more than 1,800 citations to back up her findings that ultrasound is causing harm to developing babies. Barcelo asserts that ultrasound "should be banned from obstetrics immediately." "What I found out through my research is that ultrasound IS radiation," she said, "and I can very clearly state to you that the Food and Drug Administration has known for many, many decades about the harm this technology is causing." Among the risks Barcelo cites that can be attributed to ultrasound exposure in utero are: radiation-induced genetic mutations that can negatively affect future generations; damaging reproductive effects that can lead to fertility issues and sterility later in life; radiation-induced brain damage and/or neurodevelopmental delays that can contribute to autism; and many childhood diseases. "Our children have never, ever been this diseased and this sick," Barcelo said. "One in six children in the United States is neurodevelopmentally disabled — one in six children! One in 30 children is autistic. And when did autism start? In the 1970s, when they started using ultrasound, mainstreaming it into obstetrical care." Barcelo's goal is to encourage parents and those who want to become parents to fully understand the facts — and the potential risks — of ultrasound technology, fetal heartrate monitors and other devices that make use of non-ionizing radiation."The book contains life-altering information that could save the lives of many children," Barcelo added. "It is time to take a stand to protect the children."

Death Rate Rises in Babies

For the first time in two decades, the infant mortality rate in the United States is up, rising 3 percent between 2021 and 2022. The data comes from a new provisional report by the Centers for Disease Control and Prevention's National Center for Health Statistics, which says that last year, 20,538 babies across the US died before reaching their first birthday. The number is a worrisome indicator about the state of maternal health care in one of the most developed countries in the world. "In a country as well-resourced as the US, with as much medical technology and so on, we shouldn't have babies dying in the first year of life," Arjumand Siddiqi, a University of Toronto professor who studies population health, told the *Wall Street Journal*. "That should be super rare, and it's not." The report found that there were 5.6 infant deaths per 1,000 live births, up from 5.44 in 2021. While that degree of growth seems small, Danielle Ely, the lead researcher on the report, told the Associated Press that it's the "first statistically significant jump" since the 2001-2002 data period.

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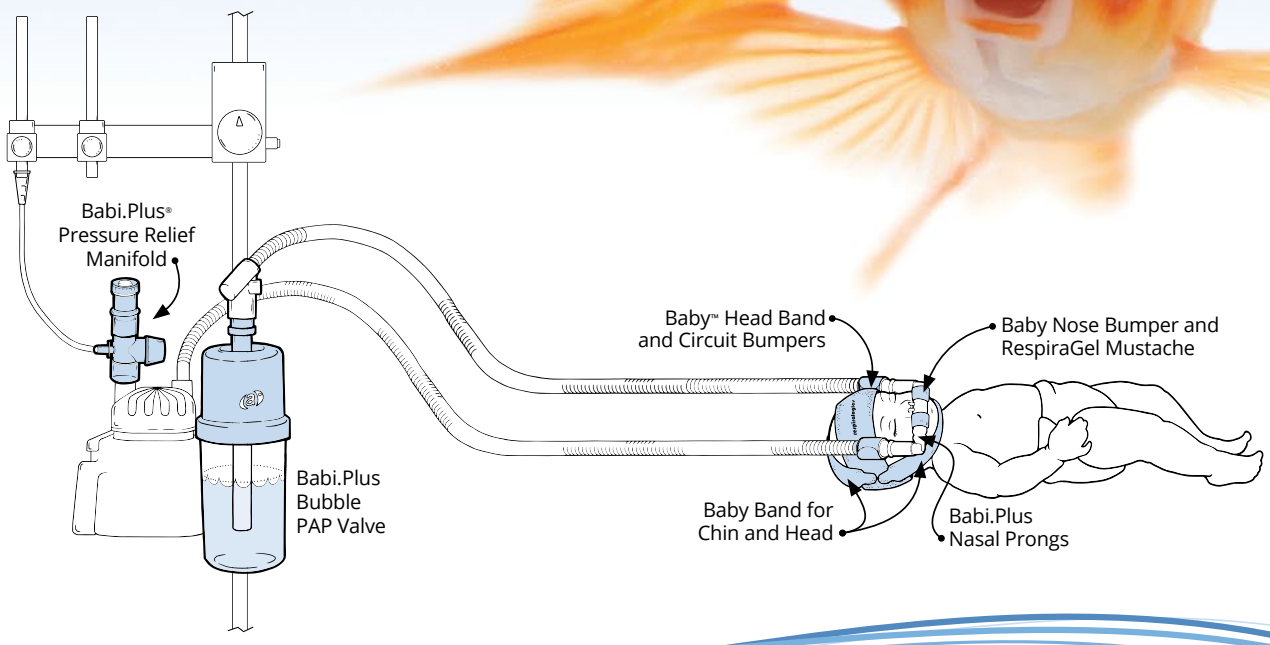

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