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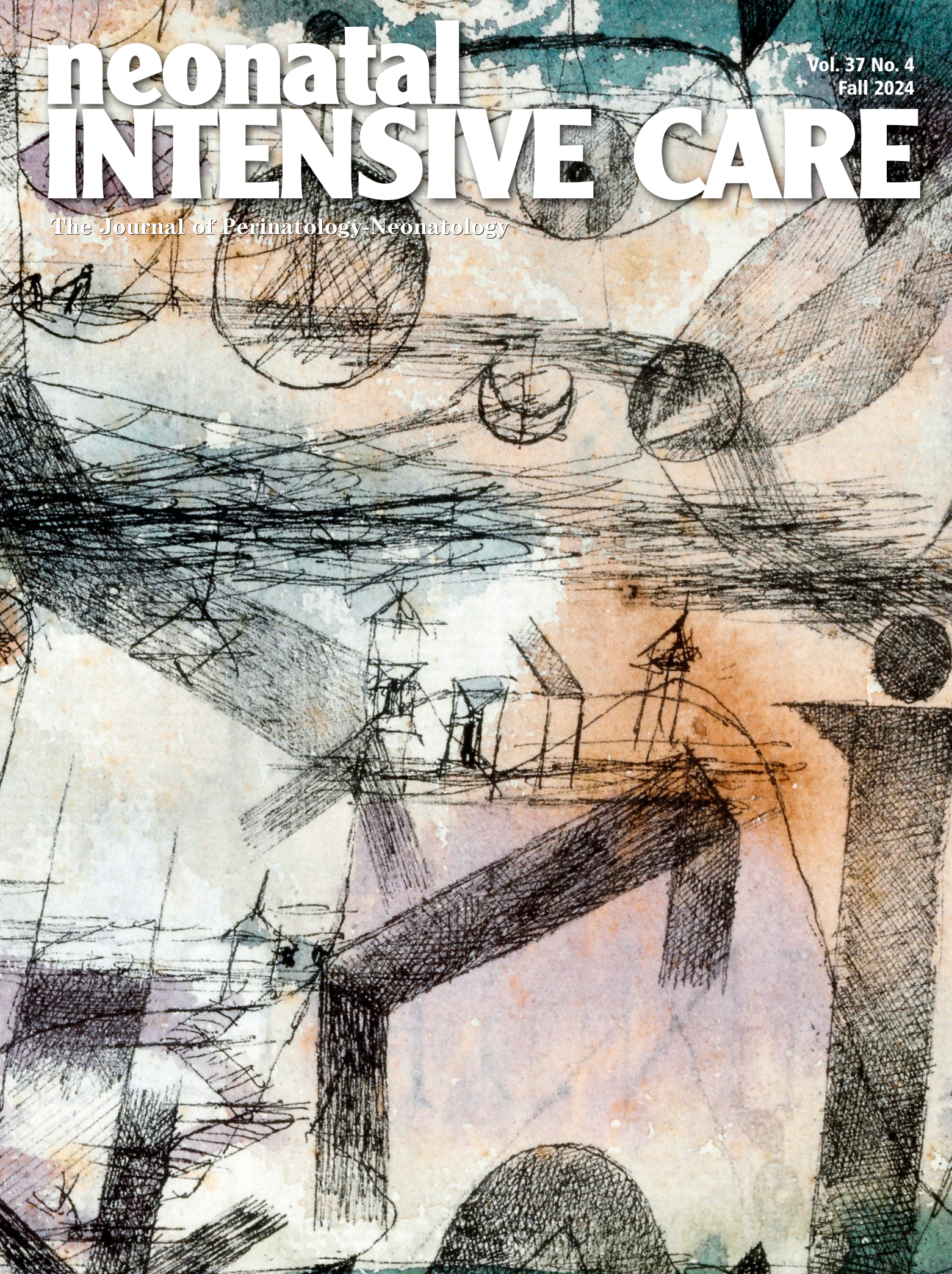
neonatal INTENSIVE CARE

The Journal of Perinatology-Neonatology



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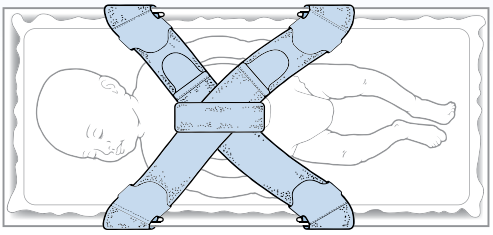

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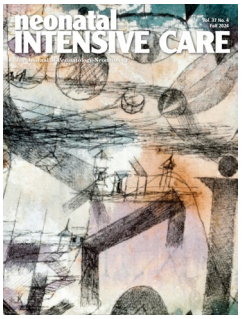

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☐ Fall 2024

Magnesium Sulfate Reduces Cerebral Palsy in Preterm Birth

An international research collaboration conducting a comprehensive review of studies from across the globe has reaffirmed that magnesium sulfate, a medication widely used during pregnancy, significantly reduces the risk of cerebral palsy and death for very preterm babies. The study, recently co-published in *Obstetrics & Gynecology*, was based on six trials involving 5917 women, pregnant with their 6759 babies. It compared the effects of magnesium sulfate with placebo, finding strong evidence for the brain protecting benefits of magnesium sulfate for very preterm infants. One of the lead researchers, Dr Emily Shepherd, a Postdoctoral Research Fellow and NHMRC Emerging Leadership Fellow at SAHMRI, says the results are significant for prematurity research, with magnesium sulfate being one of only two proven prevention strategies for cerebral palsy. "Our review now demonstrates with high certainty, that magnesium sulfate, administered to women at risk of very preterm birth, can reduce the risk of cerebral palsy and death for their children up to two years of age," Dr Shepherd said. All trials included women in preterm labor or with expected or planned preterm birth before 34 completed weeks of their pregnancies. Magnesium sulfate was administered intravenously but various treatment protocols were used across the trials. Importantly, the review showed that medicating with magnesium sulfate doesn't raise the risk of preterm babies or their mothers incurring other short or long-term complications.

Antibiotics in Pregnancy Linked to Increased Risk for Infantile Seborrheic Dermatitis

Maternal in utero exposure to antibiotics was associated with an increased risk for infantile seborrheic dermatitis (SD) regardless of the mother's history of SD, but this association was not as strong for childhood-onset SD. The findings come from a large analysis of data from the United Kingdom that was presented during a late-breaking abstract session at the annual meeting of the Society for Investigative Dermatology. SD is a common skin disease "that shares similarities with atopic dermatitis or atopic eczema as both are prevalent inflammatory skin diseases that can present with a chronic relapsing, remitting course," the study's corresponding author Zelma C. Chiesa Fuxench, MD, MSCE, assistant professor of dermatology at the University of Pennsylvania, Philadelphia, said in an interview. "Like atopic dermatitis, the pathophysiology of seborrheic dermatitis is thought to be complex and involves an interplay between genetics, immune dysregulation, and alterations in lipid composition and the skin microbiome, among others." In a previous study, she and colleagues showed that exposure to antibiotics both in utero and during the first 90 days of life increases the risk for atopic dermatitis (AD) in children, with risk being highest with exposure to penicillin even among children whose mothers did not have a history of AD. For the current study, the researchers drew from a large electronic medical records database in the United Kingdom to perform a prospective cohort analysis of mother-child pairs that used proportional hazards models to examine the association between maternal in uteroantibiotic exposure and SD in the child. The population included 1,023,140 children with linked maternal data who were followed for a mean of 10.2 years, which amounts to more than 10-million-person years of data. At baseline, the mean age of mothers was 28 years, 3% had SD, 14% had AD, and 51% of the children were male. In unadjusted analyses, mothers with SD were more likely to receive an antibiotic during pregnancy than those who did not have SD (odds ratio [OR], 1.42; 95% CI, 1.39-1.46). In addition, maternal in uteroexposure to any

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Cover: In the realm of air (1917) painting in high resolution by Paul Klee. Original from the Kunstmuseum Basel Museum. rawpixel.com

antibiotic was associated with an increased risk for infantile SD (OR, 1.70; 95% CI, 1.65-1.76) but less for childhood-onset SD (OR, 1.26; 95% CI, 1.20-1.32). "This effect changed little after adjustment and was still observed if mothers with SD and their babies were excluded," the authors wrote in their poster abstract. Any penicillin exposure during pregnancy increased the likelihood of a child having SD (OR, 1.54; 95% CI, 1.50-1.59), with the greater risk for infantile SD (OR, 1.70; 95% CI, 1.65-1.76) than for childhood-onset SD (OR, 1.25; 95% CI, 1.18-1.32). "The trimester of the in uteropenicillin exposure did not seem to affect the association with SD," the authors wrote. The risk was also increased with cephalosporin exposure but was less for sulfonamides and not for childhood-onset SD. "We observed that antibiotic exposure in utero was primarily associated with an increased risk of infantile SD regardless of the mother's history of SD, but this association was not as strong for childhood-onset SD," Chiesa Fuxench said. "This would suggest that in utero exposure to antibiotics, particularly penicillin, may have its greatest effect on the colonization of skin microbiota in the newborn period leading to the development of infantile SD. Aside from seeking to improve our understanding of the pathophysiology of SD, our findings also suggest that infantile SD and childhood-onset SD may be separate entities with different risk factors, a hypothesis that needs to be further studied."

Human Milk-Based Fortifiers Cut Mortality Rate by 50% in Preterm Infants, Independent Study Shows

An independent study published in the journal Nutrients found a 50% reduction in mortality among preterm infants fed human milk-based nutritional fortifiers. The meta-analysis assessed short-term outcomes, comparing human milk-based fortifiers (HMBFs) with cow milk-based fortifiers (CMBFs) in premature infants fed a human milk diet of mother's own milk (MOM) or donor human milk (DHM). The analysis comprised data from four clinical studies involving 681 preterm infants born at ≤28 weeks of gestation, with a birth weight of ≤1,500 g. Key findings: Use of a human milk diet with human milk-based fortifiers reduced mortality by 50% compared to a diet with cow milk-based fortifiers ($p = 0.03$); a trend toward reduced bronchopulmonary dysplasia (BPD) with human milk fortifiers that approached statistical significance ($p = 0.05$). "The data associates bovine (cow) milk-based fortifiers with a potentially increased risk of death in preterm infants, which makes a reversal possibly necessary," notes the study, led by Radu Galis, MD, neonatologist at Emergency County Hospital Bihor in Romania. While the authors call for additional research, they concluded: "The most important finding of our analyses was the reduction in mortality across all four clinical studies and data sets." The authors also note, "Bovine (cow) milk products have been introduced into neonatal care without a safety consideration or parental verification." "The analysis underscores that human milk-based fortifiers can save lives for the most vulnerable patients," said Melinda Elliott, MD, FAAP, practicing neonatologist and chief medical officer at Prolacta Bioscience. "Over 20 peer-reviewed studies and abundant real-world data from around the globe demonstrate the clinical benefits of human milk-based fortification for extremely premature infants." This meta-analysis was independent of Prolacta Bioscience, the world's leading hospital provider of 100% human milk-based nutritional products for critically ill and premature infants. Extensive real-world data affirm that adoption of an Exclusive Human Milk Diet (EHMD) enables critical health improvements for premature infants and major cost reductions for hospitals. Analysis of 2019-2022 data from more than 3,000 patients at 60+ US hospitals found EHMD implementation improved health outcomes and reduced costs, generating a 2.6X dollar-for-dollar return on investment. Similarly, a 2023 peer-reviewed report found EHMD implementation resulted in a 3X dollar-for-dollar return on investment from a reduction in comorbidities and shorter lengths of stay among very low birth weight infants.

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Product Line Acquired

Respiralogics announces the Asset Purchase of the Children's Health First Product Line, a Carlsbad, CA company. Respiralogics, a leader in Bubble CPAP and Non-Invasive Respiratory Support of the Newborn, is proud to expand their product portfolio with the StatStrap Neonatal Positioning Strap, Preemie Beenie Poly Lined-Knit Hats and StatStrap Circuit Holder. These quality products fulfill unique niches to help bedside and transport clinicians with ELBW and full-term infants. StatStrap is a single patient-use safety strap set that safely secures and positions newborn infants within an incubator. It easily and securely attaches to the mattress tray of the incubator. StatStrap helps to prevent accidental falls of preterm and term infants receiving care in an incubator. Preemie Beenie is a specially designed Poly-Lined Knit Cap designed for ELBW and Term Infants to aid in their thermoregulation. The snug fit of the soft knit minimizes movement, pressure on the head and color-coded to easily identify the size of the Preemie Beenie StatStrap Circuit Holder assists in keeping tubing's securely attached to the bed clothes for stability and/or the parent during Kangaroo Care. All products are made in the USA, designed for single patient use and Latex Free. Respiralogics specializes in providing innovative respiratory care products to meet the challenging needs of respiratory patients, especially the most

Continued on page 27…

Products That Help Babies Through Tough Early Days

Canadian Hospital Specialties Inc. (CHS) offers a product line that has a strong focus on the NICU, helping clinicians care for the 'tiniest' of patients.

Describe your product(s) and its unique features.
Canadian Hospital Specialties Inc. (CHS) places a strong focus on the NICU, with our specialized products allowing clinicians to protect and care for the tiniest of patients through the following product lines: Natus Nursery Essential products: Minimuffs®; Papoose Boards™; Olympic Circumstraint™; Save the Gonads™; Oraswab™; SurgiLance™; and Neatnick. We also offer the JollyPop pacifier line designed for premature babies. These pacifiers have a unique manufacturing process which combines soft and firm 100% silicone with the low profile and curved shape that babies love. These are comfortable and lightweight, and the low profile design fits all CPAP, nasal cannulas and side lying. CHS also carries the innovative neonatal vascular access line of devices from NeoMedical. The NeoMagic line of vascular access devices include PICC catheters, EPIVs, MSTs, introducers, and other accessories that are designed specifically for neonatal patients.

NeoMagic® Introducer Technologies: The NeoMagic® 30ga MST introducer system has eliminated the need for multiple restarts and multiple introducers in nearly 1200 cases. Allowing for placement of 1.9Fr catheters in preemie and even a micro-preemie of 520grams on the first attempt. This proven technology can nearly eliminate the need to consider using less than optimum sized micro PICC lines (1.2Fr or 1.1Fr).

The NeoMagic® 27ga Sharps Safety Introducer mechanism is a full 65% smaller than the 26ga BD Autoguard. The introducer brings users a profile designed for neonatal patients, not just another adaptation of an Adult product. The very reliable safety feature eliminates any early activation and protects from needle sticks and mucocutaneous blood exposure. Now there is protection that works when needed.

Neo Medical knows that not all Introducers fit all caregiver's needs. That is why the NeoMagic® product-lineup offers two added options to the above innovations: the standard 27ga OTN with many of the features of the Sharps Safety product and a traditional Breakaway Splitting Needle.

NeoMagic® Catheter Technologies: Neo Medical's neonatal PICC and EPIV catheter technology platform provides clinicians with proven solutions that will allow for uninterrupted therapy, preserve the peripheral vasculature, reduce the cost of delivering therapy, and protect the infant from pain associated with multiple PIV restarts.

Peripheral Inserted Central Catheters for the NICU are not a new development most current offerings were developed pre-1999. However, Adult PICC offerings have seen many innovative changes in recent years, why not neonatal PICC Lines?

The NeoMagic® 1.9Fr PICC changes all this. The latest manufacturing techniques, combined with the proven material advantage of silicone and new designs overcome many of the issues involved in the early development of PICC Lines. These advantages have resulted in one of the lowest complication rates of any neonatal PICC in the market.

The NeoMagic® 24ga EPIV is a standard of care changing product that allows for use of up to 29 days. Designed to eliminate the use of PIV's in the neonatal setting and improve the outcomes of many therapies where a PICC line is not necessary.

The NeoMagic® 24ga EPIV reduces the unnecessary complications commonly associate with current neonatal PIV's use. Traditional PIV's have resulted in documented permanent damage to the peripheral veins and complications that have resulted in loss of limbs.

Tell us about the latest advances in the area your product serves.
1.2FR reduced trauma PICC line – Designed for Low and Extreme low birth weight babies. Utilizes a smaller introducer needle thus reducing trauma and making it easier to introduce the PICC line.

Discuss your R&D process, including clinical user input.
We value input from clinicians and focus our efforts on creating specialized products that address the unique challenges of caring for this patient population.

Discuss the educational services you offer for use of your product.
CHS offers many educational services to aid the clinician from webinars and product seminars and demos to in-person support from our trained sales and clinical support team.

What new technology do you see as having the greatest impact on your area of expertise?
In terms of vascular access products, we see a lot of competitive

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

Protecting and caring for the tiniest of patients

CHS provides a comprehensive portfolio of medical device solutions for the NICU

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Save the Gonads™
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NeatNick®
Heel Lancet

Surgilance™
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products using technology from 1997. We use the latest manufacturing techniques, silicone, and engineering designs. There are eight unique features in the NeoMedical PICC; The mini profile luer, The clear extension leg, the unique internal hub design, the flat bottom disc that allows use of both taping or securement device, strain relief and molding that increases strength at hub exit, 3cm marking for tip movement identification, micro-dot printing to limit fibrin attachment to catheter, and available with E-Z Flush stylet for ease of placement. These innovations bring a lot of value and efficiency to all clinical members and staff in the NICU.

ACTUAL SIZE
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Big innovation. Small package.

Contact a representative at 877-566-9466 for more about mini-cylinders

INOmax® (nitric oxide) gas, for inhalation, mini-cylinders

Lightweight mini-cylinders weigh 1.43 lb, contain 4,880™ ppm INOmax, and are filled to approximately 3000 psig.[1,2]

Drug quantity in 4 mini-cylinders equals one 88-size cylinder.[1-3]

INDICATION

INOmax is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.

IMPORTANT SAFETY INFORMATION

- INOmax is **contraindicated** in the treatment of neonates dependent on right-to-left shunting of blood.
- Abrupt discontinuation of INOmax may lead to increasing pulmonary artery pressure and worsening oxygenation.
- Methemoglobinemia and NO_2 levels are dose dependent. Nitric oxide donor compounds may have an additive effect with INOmax on the risk of developing methemoglobinemia. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.
- In patients with pre-existing left ventricular dysfunction, INOmax may increase pulmonary capillary wedge pressure leading to pulmonary edema.
- Monitor for PaO_2, inspired NO_2, and methemoglobin during INOmax administration.
- INOmax must be administered using a calibrated FDA-cleared Nitric Oxide Delivery System.

Please see Brief Summary of Full Prescribing Information on the adjacent page.

References: 1. INOmax EVOLVE™ DS Operation Manual. Madison, WI: Mallinckrodt Pharmaceuticals. **2.** INOmax. Package insert. Mallinckrodt Pharmaceuticals. **3.** INOmax DS_{IR} Plus Operation Manual. Hampton, NJ: INO Therapeutics LLC.

Scan to learn more about mini-cylinders and the device they pair with

Mallinckrodt Pharmaceuticals

INOmax EVOLVE™ DS

INOmax® (nitric oxide) gas

Brief Summary of Prescribing Information

INDICATIONS AND USAGE

INOmax® is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.

CONTRAINDICATIONS

INOmax is contraindicated in neonates dependent on right-to-left shunting of blood.

WARNINGS AND PRECAUTIONS

Rebound Pulmonary Hypertension Syndrome following Abrupt Discontinuation

Wean from INOmax. Abrupt discontinuation of INOmax may lead to worsening oxygenation and increasing pulmonary artery pressure, i.e., Rebound Pulmonary Hypertension Syndrome. Signs and symptoms of Rebound Pulmonary Hypertension Syndrome include hypoxemia, systemic hypotension, bradycardia, and decreased cardiac output. If Rebound Pulmonary Hypertension occurs, reinstate INOmax therapy immediately.

Hypoxemia from Methemoglobinemia

Nitric oxide combines with hemoglobin to form methemoglobin, which does not transport oxygen. Methemoglobin levels increase with the dose of INOmax; it can take 8 hours or more before steady-state methemoglobin levels are attained. Monitor methemoglobin and adjust the dose of INOmax to optimize oxygenation.

If methemoglobin levels do not resolve with decrease in dose or discontinuation of INOmax, additional therapy may be warranted to treat methemoglobinemia.

Airway Injury from Nitrogen Dioxide

Nitrogen dioxide (NO_2) forms in gas mixtures containing NO and O_2. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.

If there is an unexpected change in NO_2 concentration, or if the NO_2 concentration reaches 3 ppm when measured in the breathing circuit, then the delivery system should be assessed in accordance with the Nitric Oxide Delivery System O&M Manual troubleshooting section, and the NO_2 analyzer should be recalibrated. The dose of INOmax and/or FiO_2 should be adjusted as appropriate.

Worsening Heart Failure

Patients with left ventricular dysfunction treated with INOmax may experience pulmonary edema, increased pulmonary capillary wedge pressure, worsening of left ventricular dysfunction, systemic hypotension, bradycardia and cardiac arrest. Discontinue INOmax while providing symptomatic care.

ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse reaction information from the clinical studies does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

Controlled studies have included 325 patients on INOmax doses of 5 to 80 ppm and 251 patients on placebo. Total mortality in the pooled trials was 11% on placebo and 9% on INOmax, a result adequate to exclude INOmax mortality being more than 40% worse than placebo.

In both the NINOS and CINRGI studies, the duration of hospitalization was similar in INOmax and placebo-treated groups.

From all controlled studies, at least 6 months of follow-up is available for 278 patients who received INOmax and 212 patients who received placebo. Among these patients, there was no evidence of an adverse effect of treatment on the need for rehospitalization, special medical services, pulmonary disease, or neurological sequelae.

In the NINOS study, treatment groups were similar with respect to the incidence and severity of intracranial hemorrhage, Grade IV hemorrhage, periventricular leukomalacia, cerebral infarction, seizures requiring anticonvulsant therapy, pulmonary hemorrhage, or gastrointestinal hemorrhage.

In CINRGI, the only adverse reaction (>2% higher incidence on INOmax than on placebo) was hypotension (14% vs. 11%).

Post marketing reports of accidental exposure to nitric oxide for inhalation in hospital staff has been associated with chest discomfort, dizziness, dry throat, dyspnea, and headache.

DRUG INTERACTIONS

Nitric Oxide Donor Agents

Nitric oxide donor agents such as prilocaine, sodium nitroprusside and nitroglycerine may increase the risk of developing methemoglobinemia.

OVERDOSAGE

Overdosage with INOmax is manifest by elevations in methemoglobin and pulmonary toxicities associated with inspired NO_2. Elevated NO_2 may cause acute lung injury. Elevations in methemoglobin reduce the oxygen delivery capacity of the circulation. In clinical studies, NO_2 levels >3 ppm or methemoglobin levels >7% were treated by reducing the dose of, or discontinuing, INOmax.

Methemoglobinemia that does not resolve after reduction or discontinuation of therapy can be treated with intravenous vitamin C, intravenous methylene blue, or blood transfusion, based upon the clinical situation.

Phototherapy as a Drug – a Pharmacological Perspective

Introduction

Early detection of neonatal jaundice and its effective management have led to the use of non-pharmacological therapies such as phototherapy (PT). PT is commonly used to treat neonatal jaundice but there is substantial variation in its application and the measured irradiance.[1]

To improve clinical outcomes, Angelo Lamola, Division of Neonatal and Developmental Medicine, Department of Pediatrics, Stanford University School of Medicine, introduced a pharmacological perspective on the topic of PT and the use of photons as a drug when prescribing it.[2]

M. Jeffrey Maisels, MB, BCh, DSc, Division of Newborn Medicine, Department of Pediatrics, William Beaumont School of Medicine, Beaumont Children's Hospital, further demands that "we should apply the same therapeutic rigor to the use of phototherapy as we do to the use of a pharmacologic agent in the newborn."[3]

A pharmacological example

Imagine a case in which you are caring for your patient Meggie. Meggie is a 35-weeks gestational age (GA) newborn weighing 2,350 g and suffers from a patent ductus arteriosus (PDA).

Due to the symptoms, you strive for a pharmacological closure. Based on clinical evidence, ibuprofen is the drug of your choice and should be administered. Now, a choice needs to be made, whether to administer the 4 ml or 8 ml vial of ibuprofen. However, this depends on the required dosage and not on the volume of the vial.

Let's modify the example so that Meggie is dealing with severe jaundice instead of a PDA, and according to the relevant nomogram, she requires treatment with PT. What kind of PT should be prescribed?

Many factors arise that need to be considered when prescribing PT. Should it be single or double PT therapies? How high should the intensity be: low, middle or high?

What about using older bulb versions or new LEDs? How does the angle or distance influence the workplace set up?

While it is known that the dosage of pharmacological agents is an important factor, the correct dosage of PT has not yet been routinely evaluated.[4] Should the considerations for PT dosage be different than the same considerations for pharmacological agents?

Submitted by Draeger Inc.

Guidelines and clinical evidence

The 2022 released American Academy of Pediatrics (AAP) guidelines give further recommendations on how the dosage of PT can be safest and most efficiently determined.

"Intensive phototherapy requires a narrow spectrum LED blue light with an irradiance of at least 30 µW/cm²/nm at a wavelength approximately 475 nm. Light outside the 460 to 490 nm range provides unnecessary heat and potentially harmful wavelengths."[5,6] In general, shorter wavelengths involve the formation of free radical and reactive oxygen species (ROS) causing oxidative damage.[7]

To measure the PT dosage accurately, a radiometer is used. It calculates the irradiance in µW/cm²/nm, requiring careful attention to ensure the measurement is correct.

But measuring the irradiance with a radiometer over a broader spectrum (e.g. 400-500 nm) can be misleading as the irradiance of >30 µW/cm²/nm might be reached but with light outside of the effective spectrum.

Furthermore, "the general approach is to provide intensive phototherapy to as much of the infant's surface area as possible."[4] But research has shown that 4 out of 6 PT lights

Submitted by Draeger Inc.

PT Checklist

- ☑ Treatment within effective light spectrum (460-490 nm) peaking at 475nm
- ☑ Sufficient irradiance of 30 to 50 µW/cm²/nm
- ☑ Radiometer calibrated to 460-490 nm fAor accurate readings
- ☑ Even and broad distribution of light across the baby's body
- ☑ Eye protection for baby and staff such as:
  - Eye shield
  - Light curtain

tested are not able to cover the surface area of a newborn of 32 weeks and only one can cover the area of a term newborn of 40 weeks of gestational age.[8]

To support Meggie and all other babies needing PT, "Healthcare providers should be aware of spectral irradiance levels and footprint differences between LED-based PT devices.

Therefore, we recommend performing spectral irradiance measurements to enable patient-specific PT, considering PT as a "drug" to be dosed cautiously and appropriately, in analogy to Lamola's pharmacologic view of PT"[3] and in accordance with national guidelines.

Your checklist for safe and effective phototherapy

To properly administer and dose PT, consider the following factors based on industry guidelines and clinical evidence.

- **Light spectrum:** Unconjugated bilirubin absorbs light most strongly in the blue region around 460-490 nm. When thinking of PT in the context of pharmacological agent dosage, the light spectrum is akin to the drug concentration.
- **Irradiance:** Irradiance, or intensity, is inversely proportional to the square of the distance from the source of the light source. When considering irradiance in the terms of drug administration, think of it as the dosage. The smaller the distance, the higher the irradiance, and the greater the distance, the lower the irradiance. The recommended minimal distance is 12in/30cm from baby.
- **Measurement:** To accurately measure the irradiance or "dosage" of PT, utilize a radiometer calibrated to the same spectrum of light (460-490 nm).
- **Distribution:** Illuminating as much skin surface area as possible has been shown to increase the speed of bilirubin clearance in relation to the rate at which bilirubin is produced by the infant so broad distribution is critical.
- **Protection:** Eye protection is needed when administering PT, but rest of the baby's clothing or positioning aids should be minimal or transparent so as not to inhibit surface area coverage.

One baby, one light

Dräger's BiliLux LED phototherapy light system is designed to check the boxes in delivering safe and effective PT, fulfilling the requirements of the AAP guidelines. BiliLux is one of the very few phototherapy lights available to deliver light specifically in the 460 to 490 nm spectrum (think concentration).

Unlike other PT lights with only low and high settings, the BiliLux phototherapy light features five levels of irradiance so clinicians can fine tune the treatment to the individual baby, whether they are in an open or closed care space. For example, if the light must be positioned farther away from the baby, as in closed care, the caregiver can increase the irradiance level to maintain adequate intensity (think dosage).

The BiliLux Radiometer instantly measures the irradiance and helps ensure the correct positioning of the baby under the phototherapy light and the adequate irradiance that the baby receives (30 to 50 µW/cm2/nm).

With regards to PT distribution, the BiliLux phototherapy light features a large surface area to cover full term and premature babies. The irradiance is evenly distributed over the entire mattress to help ensure effective phototherapy.

Conclusion

The application of phototherapy (PT) for the treatment of neonatal jaundice requires a level of precision and consistency comparable to pharmacological interventions. By adhering to industry guidelines and clinical evidence — and employing technology aligned with them — clinicians can optimize PT administration through careful consideration of factors such as light spectrum, irradiance, measurement, distribution, and protection.

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Big Changes for Little Airways: Special Considerations for Speaking Valve Use in Children with Tracheostomies and Mechanical Ventilation

Tiffany Oakes, MS, CCC-SLP

Neonates, infants, and young children who require tracheostomy and mechanical ventilation face many unique challenges. Because of the tracheostomy and mechanical ventilation, they experience changes to pressure and airflow in the upper airway. It also has been long understood that tracheostomies may increase the risk for both expressive and receptive language delays, possibly due to a lack of self-auditory and oral motor feedback.[1] Use of the Passy-Muir® Tracheostomy & Ventilator Swallowing and Speaking Valve (PMV) is an appropriate tool to be used with this population to meet some of those challenges.

In-line use of the PMV restores the airflow needed for phonation and voiced communication. Technically speaking, these patients may not be speaking, but communication occurs with every coo and cry. Use of the Valve may decrease the risk of this delay by improving access to early vocalization, facilitating overall improved language development.[2] These increased vocalizations may also improve patient-caregiver bonding.[3] Even our very small patients have a right to communication. Research also has shown many other benefits related to respiratory function, secretion management, cough, taste, smell, and even postural control and trunk support.[4]

Impact of Restoring Airflow to the Upper Airway

Restoring airflow also restores sensation to the upper airway for increased awareness of secretions and oral stimulation for both nutritive and non-nutritive sucking. With restored positive pressure, the PMV also improves feeding and swallowing in infants, which may allow the patient to develop a more normal suck-swallow-breathe pattern with the returned intraoral and swallowing pressures. A 2021 study by da Cunha de Lima et al. investigated the effects of the PMV on infants who were able to resume breastfeeding. The mothers of these children had reported being afraid of breastfeeding due to choking but that the children did better with the Valve. The authors concluded that with the PMV, the patients were able to feed safely and manage secretions, experienced reduced aspiration, and showed improved coordination of the sucking and breathing pattern.[3]

Tiffany has been a medical SLP in various settings from acute care to home health, treating both the adult and medically complex pediatric populations. Tiffany has experience developing patient care pathways to guide assessment and treatment selection for patients in home health, at both the state and national level. Currently, she is a full-time Clinical Specialist for Passy-Muir and works with multi-media educational development and presents on topics related to tracheostomies and speaking valves regularly.

Closing the respiratory system and restoring normal aerodigestive functions with the PMV may also improve respiratory function, weaning, and decannulation. In a systematic review of the research, which included participants from infants to adults, O' Connor et al. (2019) reported improvements in resting ventilation and lung recruitment during weaning and decreased weaning times with use of the Valve.[4] Investigating the effect of PMV use on respiratory illness and respiratory-related hospital admissions, Li et al. (2021) found that children under two years of age who used the PMV had a statistically significant lower rate of respiratory-related hospitalizations compared to children in the same age group who did not use the PMV. The authors supported early use of the PMV to improve respiratory function and outcomes.[5]

Special Considerations with Mechanical Ventilation

Special considerations for Valve use regarding invasive ventilation and patient selection exist for this population. While practice patterns for this population vary, pressure control ventilation (PCV) is often preferred in neonates and infants, which allows for more careful control of peak inspiratory pressure (PIP) and may help avoid ventilator-induced lung injury.[6] Use of the PMV is compatible with both PCV and volume control ventilation (VCV), which is also commonly used. While each patient needs to be assessed individually and facility policies should be followed, general ventilator parameter suggestions include a set positive end-expiratory pressure (PEEP) of 10 cmH_2O or less and a fraction of inspired oxygen (F_iO_2) of .50 or less.

Prior to cuff deflation and in-line PMV placement, clinicians should also ensure that patients are awake and alert enough to participate in the assessment process and hemodynamically stable. If the patient has a cuffed tracheostomy tube, the cuff must be completely deflated prior to placing a Valve in-line. Patients also should have thin, manageable secretions that are easy to suction and, most importantly, a patent airway.

Determining a patent airway is essential prior to Valve placement, and the preferred methods for assessment include transtracheal pressure (TTP) measurements and noted changes in ventilator readings. Transtracheal pressure measurements read the pressure in the airway with the tracheostomy tube in place. It has been determined as a successful predictor of PMV success, with the general idea being the lower the pressure, the more patent the airway, and the greater success with the Valve.[7] A study by Brooks

Figure 1. Use of the PMV®007 in-line with mechanical ventilation to assist with trunk support and vocalizations.

et al. (2019) investigated predictors for success with using the PMV with medically complex pediatric patients. Along with a transtracheal pressure between 0 and 14 cmH_2O being highly predictive, they also found that the factors associated with PMV success were: higher weight (correlated with age); size of the tracheostomy tube; presence of voicing with PMV application; and a lower respiratory rate, the only ventilator parameter determined to be predictive of success or failure.[7] Other than TTP measurements, airway patency may be determined using the ventilator. With cuff deflation, if the patient is on VCV, clinicians should see a 40%-50% drop in exhaled tidal volume and peak inspiratory pressure (PIP), indicating a sufficient leak through the upper airway. If the patient is receiving PCV, a significant drop in peak inspiratory pressure (PIP) would not be expected but a drop in tidal volume would be.

Factors Affecting Airway Patency

There are several factors that may affect the patient's airway patency. Neonates and infants have very small airways, and even a very small tracheostomy tube may take up quite a bit of space in the tracheal lumen. It is uncommon to downsize a tracheostomy tube in this population, and adequate airflow around the tube may require the child growing and getting a little bigger. However, another consideration is that as these patients grow, they may actually be upsized and receive a larger tracheostomy tube, which can impact airflow and Valve use. This is a special consideration especially if the upsize occurs after they were using the PMV successfully. The patient position and tube position also may impact airflow to the upper airway. Equipment, such as the ventilator circuit, should always be supported so that the extra weight does not change the position of the tube in the patient's airway. Clinicians should also consider the presence and degree of any obstructions in the patient's airway such as growths or tumors, stenosis, edema, tracheomalacia, and anatomical differences. If a patient's airway is not patent or loses patency, then a speaking valve cannot be used. The next step would be evaluating why the airway is not patent and determining if there is any intervention that may help to improve patency and allow speaking valve use.

Environmental and Behavioral Considerations

There are also special considerations for the environment in which the infant is assessed. Time of day can be very important to child behaviors as the assessment should be completed when the child is calm and comfortable. For example, a crying child will show higher TTP measurements that may not be an accurate reading of airway patency. To better establish an environment of trust, family or caregiver involvement may improve patient participation. The patient may also benefit from positive feedback.

Patients should be continuously assessed for changes from their baseline status or for signs of distress or changes in behavior. In an infant, distress may present as increased respiratory rate or increased heart rate. Increased irritability, restlessness, or indications that a patient is fearful should also be noted. Distress may also present as diminished breath sounds, decreased chest movement, increased belly breaths, or stridor. Clinicians should watch for changes to patient color, such as the skin becoming pale or the patient's nail beds becoming blue, as these are physical indications of a change in baseline status. Should these occur, it is best to remove the Valve and observe for the patient to return to baseline. For infants and children, the use of a Valve must sometimes be introduced in short increments of time initially as some react to the change in airflow. Since explanations cannot be provided, with infants and young children, slow introduction of Valve use and play therapy can be quite effective.

Conclusion

While there may be special considerations for this population, assessment for and use of the Passy-Muir Valve should be part of the interdisciplinary conversation. When properly evaluated and determined to be good candidates for Valve use, children with tracheostomies, mechanical ventilation, and complex comorbidities demonstrate excellent tolerance of speaking valves, both with and without mechanical ventilation.[8]

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Arming NICU Clinicians With Etiometry's Risk Index Data for Personalized Care and Better Outcomes

Kathryn Butler, MS, RRT-NPS

How Etiometry Works in the NICU

NICU staff at a major children's hospital made the decision to wean an infant from high-flow oxygen therapy (HFOT) to room air. After the change, concerns were raised about the patient's respiratory status, and it was proposed that the HFOT be restored. However, by leveraging data from the Etiometry platform, the clinical team was able to show that the patient was tolerating the wean and did not require escalation. This avoided prolonging the infant's exposure to high concentrations of oxygen and peripheral equipment, which have been shown to increase the risk of complications.

It's just one more example of how using Etiometry can provide timely clinical data to guide both efficient escalation and safe de-escalation of care — in this case the weaning process.

The NICU: A Unique Environment

Representing about one out of every five ICU beds in the US,[1] the NICU is a unique environment with specialized information needs compared to other ICU settings. These units typically care for the smallest and sickest patients in the hospital and provide comprehensive care 24 hours a day, often with a full range of subspecialties. NICU patients also typically have a much longer stay than other ICU patients, requiring specialized equipment like incubators, ventilators, and small-sized catheters.

Moreover, the NICU is typically the most heterogeneous population in the hospital. Patients require treatment for a mix of medical conditions and surgical repairs. In addition, NICU patients tend to crash and recover much more quickly than patients in adult and even pediatric ICUs.

Most importantly, treatment decisions in the NICU are high-stakes: the room for error is small, and decisions could impact patients for the rest of their lives.

Kathryn Butler is the Director of Clinical Development at Etiometry and has a decade of experience in critical care procedures, training clinicians, and award-winning clinical research. She is responsible for developing, coordinating, and implementing Etiometry's FDA cleared analytics and automated pathways functionality into clinical workflows worldwide. Prior to Etiometry, she worked with hospital leadership to establish clinical practices, policies, and protocols for the opening of Sidra Medicine in Qatar. Ms. Clark's experience spans across pediatric, adult, and cardiac patients at Boston Children's Hospital, Tampa General, and beyond.

The IVCO2 Index and the NICU

Etiometry's risk indices deliver an objective and continuous assessment of the risk of patient deterioration, facilitating both escalation and de-escalation decisions. However, the adjunctive indices do not replace any device monitoring or substitute taking blood samples. The Inadequate Ventilation of Carbon Dioxide (IVCO2) Index™, which calculates the probability of PaCO2 > 50, 60 mmHg, is a novel FDA-cleared algorithm developed by Etiometry to provide insights to monitoring ventilated patients for risk of deterioration, like hypercapnia.

Potential to Improve Outcomes

A pilot study in a NICU setting found that 83% of providers trained in the IVCO2 Index believed it had the potential to improve patient outcomes. Providers reported that the Index:[2]

- Is the most useful setting in the NICU population.
- Helps identify patients needing a blood gas sooner than scheduled, averting deterioration.
- Helps providers better communicate patient states between shifts.
- Provides an effective overview of patient status.
- Helps identify stable patients who are ready to be weaned from the ventilator.
- Provides more reliable information than transcutaneous monitoring.

In addition, 92% of providers trained in IVC02 said they would recommend Etiometry overall to a colleague.

Currently Deployed Pathways

Etiometry's Clinical Pathway Automation capability embeds hospital guidelines to standardize, automate and track clinical workflows to enable timely initiation and consistent adherence to the right guidelines. Etiometry users are currently deploying IVCO2 algorithm data in several automated clinical pathways, including:

- **IVCO2.** The algorithm flags when IVCO2 levels exceed 50, providing early recognition of deterioration and signaling a potential need for attention or escalation.
- **Extubation.** The system collects ventilator data and flags site-specific thresholds for weaning prior to extubation. This potentially reduces the time patients spend on a ventilator, reducing the risk of complications and infections, promoting better lung development, and supporting shorter lengths of stay.

- **Ventilator management.** This pathway uses ventilator data to guide FiO2 titration according to gestational-age-based SpO2 guidelines, ensuring the patient receives appropriate oxygen levels for their gestational age.

Upcoming Research on IVCO2

Etiometry continues to partner with several research projects studying the impact of IVCO2 monitoring in clinical care, including a retrospective paper validating the use of the IVCO2 index.

Other projects are investigating the impact of IVCO2 on hypercapnia, time on mechanical ventilation, and patient outcomes. We are also supporting investigator-led studies looking at IVCO2 and prediction of clinical status, discharge readiness, and ECMO, and more.

Future studies could look at sepsis and FiO2 titration.

A Solution for the NICU

It's clear that the NICU is a high-stakes setting with unique needs, and existing tools and approaches that are commonly used in other settings may not be as effective in this patient population.

When it comes to making treatment decisions like escalation and de-escalation of care, providers need the best possible information at their fingertips. The Etiometry platform can be an ideal solution, with tools specifically suited to the NICU, including the IVCO2 index and more.

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Tradition or Evidence?

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 Caroline Kwong, Nurse Practitioner and Clinical Nurse Specialist at CHOC Hospital in Orange, California.

I know that most people think about neonates and think about using an uncuffed ET tube. I guess the purpose of this presentation is to really just ask ourselves the question, is this because we have evidence, or is this just a tradition, just something we've done forever? It's just something we do, and we don't ask more questions.

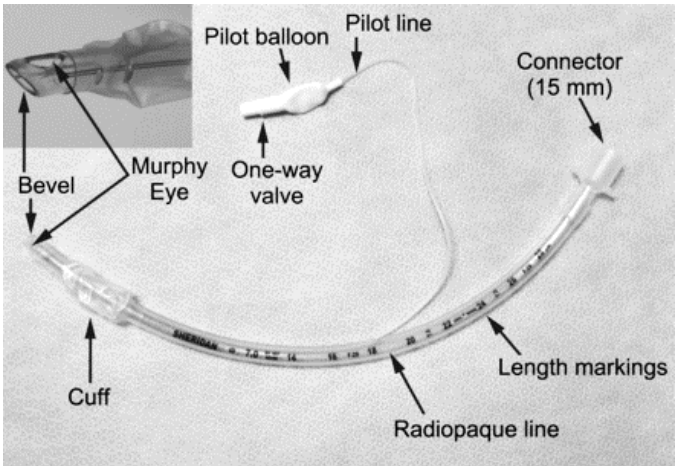
We're going to be talking about ideas rather than telling you exactly what to do. This is just asking a question. Before we start, we need to talk about tradition versus evidence. I will tell you all that. I just got back from a trip to London. Not just London, in the UK. In the UK, everybody drives on the left-hand side of the road. In the car, they're on the right-hand side, but the automobile is on the left-hand side of the road. This is tradition. This is what they've done for forever and ever. Here in the States and other places around the world. I know we drive on the right side of the road, and of course, I mean the right, R-I-G-H-T side of the road, as in the right-hand sided part of the road, but also the correct side of the road. I would say that the people in the UK drive on the wrong side of the road, but is there evidence to support that or this is just a tradition?

This is kind of the idea of how do we separate out what we do because we've always done it and what we do because we know there's good evidence to keep doing it. We could ask ourselves this question about a certain idea that we've been doing for many, many years. We think about tradition as this sort of like the idea of the sacred cow, the sacred golden cow, something that we just don't want to touch because it's so meaningful to us. For whatever reason, we hold on to these traditions, and we are. It's not so easy to let them go. It's something we're comfortable with, something we've been doing for a long, long time.

Had you been born in the Middle Ages, you might be subjected to bloodletting, and that was considered very standard practice, something that they do to treat all kinds of illnesses. But you can ask yourself, is that because they had actual evidence or did it follow a system of beliefs? Now, we do actually do some bloodletting here and there for certain situations, but it's not typical of what we do anymore. More recently, the idea of using bath basins to give baths to our patients, has been disproven or has been proven to lead to infection and hospital acquired infections. There are bacteria that stay in the bath basins. But for years, as a nurse, I remember filling those little bath basins with soap and water and giving my patient a bath, putting the contents of the bath, components, back into the basin and using it the next day and the next day. We don't do that anymore.

Now we use CHG cloth and that's based on evidence. The same thing with feeding tube placement. We are not supposed to auscultate to find proper placement. But believe it or not, people still do that. I think it's just something that they feel comfortable with. It's a tradition. But evidence has shown us that it's not accurate in terms of feeding tube placement. We have to also talk about the anatomy of an ET tube.

By the way, you're going to hear me talk about you're going to hear me say ET tube, tube, endotracheal tube, and all those terms are sort of interchangeable. I'm sure many of you work in places that intubate patients, and I would imagine you're pretty familiar with the interchange of these terms. I've got this picture here, so we'll just review. This is a pretty typical looking endotracheal tube.

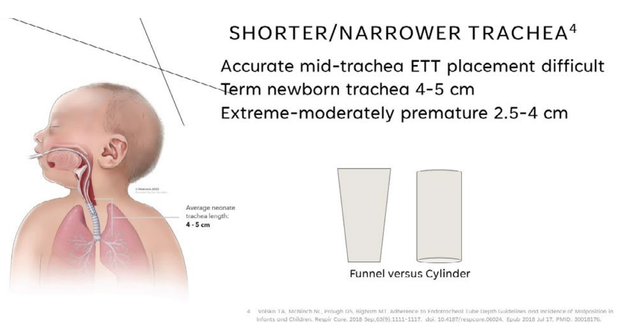


This happens to be a cuffed endotracheal tube. On it or going backwards you can see that, it's curved. It's made of PVC or polyvinyl-chloride, and it's got this curve in here so that it's

Caroline Kwong is a board-certified Nurse Practitioner and Clinical Nurse Specialist with more than 30 years' experience in Pediatric Cardiovascular Critical Care. She has specialty training in congenital heart disease and cares for pediatric patients of all ages, from neonates to young adults, in the Cardiovascular Intensive Care Unit at CHOC Hospital in Orange, California. Her role involves working alongside an expert team of cardiac intensive care physicians, surgeons, and cardiologists to provide complete care for medical and surgical cardiovascular patients and their families. Caroline has a particular interest in education & curriculum design and enjoys teaching advanced care nurses and critical care fellows alike.

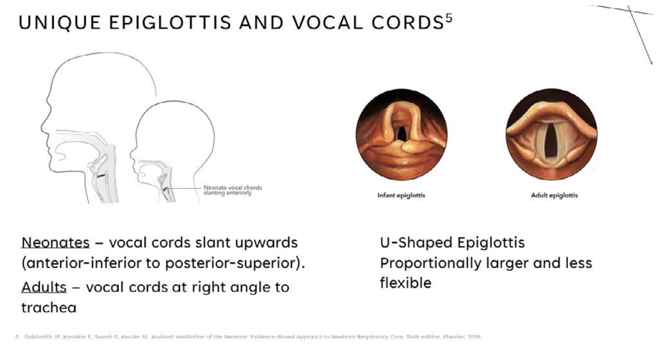
easier to intubate a patient. It's got markings on the outside of the tube that indicate the depth, so you know exactly how far in you've placed the tube. It's got a radiopaque marking so that you can look at an X-ray and say it's in the right place. It's got this kind of slanted tip. Here's a micro, bigger picture of that, of that end of the ET tube. You can see that the tip of the ET tube is slanted, and it's got this extra hole here called a Murphy's eye that allows for extra gasses or gasses to go through if this part of the ET tube is occluded. Then in this case, you can see that there's actually this cuff here. You might be able to see this sort of crumpled up extra plastic that's the cuff of the ET tube. Attached to that is this little plastic tube called the pilot line, and attached to that is this pilot balloon with the one-way valve. This is how you inject air into the cuff. The pilot balloon is made of this flexible, soft plastic so that it acts as a reservoir. If you have an increase in pressure in your airway, this has some flexibility and can extend a little bit, to allow for like a release of pressure so that the ET tube and the cuff don't cause damage to tender, delicate tissue. This one-way valve, once you put air in, it prevents air from escaping.

We've talked about the anatomy of an ET tube. Of course, we have to talk about the anatomy of a neonatal airway. And there are some components, that are a little bit different, some proportions, and parts of the anatomy that are a little bit different than the adult airway. Number one, it's a shorter and narrower trachea. Of course, these are small people. So, a term newborn, has a trachea length of about 4 to 5 cm. But if you happen to be premature, that's going to be smaller.



Traditionally, we understand that a neonate's airway is more funnel shaped than cylindrical. Also, there are some anatomical differences in the vocal cords. In an adult, the vocal cords are more at a right angle to the trachea, whereas in a neonate they slant upwards and backwards. Also, the shape of the epiglottis is a little bit different in a neonate.

You can see here this is kind of U-shaped or some people will say omega shaped. Just looking at these two pictures, you can see that the cords are a little bit, these little bits here and here are the vocal cords. They're a little bit harder to see in the neonate. They're kind of in this little tunnel. The epiglottis is a little bit larger. Makes it harder to see the vocal cords. So why does all this matter?



Why does it matter? The concern is that when you have a shorter trachea, as you do in a neonate, you have less of a target, you have less wiggle room. Imagine your neonate is intubated with a very small endotracheal tube. Your actual target for being intubated is maybe a centimeter, and if your tube moves with the patient's head going either up and down or side to side, you can easily dislodge that tube and either extubate your neonate or cause a bronchial intubation, both of which are bad, right? If you have extubated, you're unable to ventilate the patient.

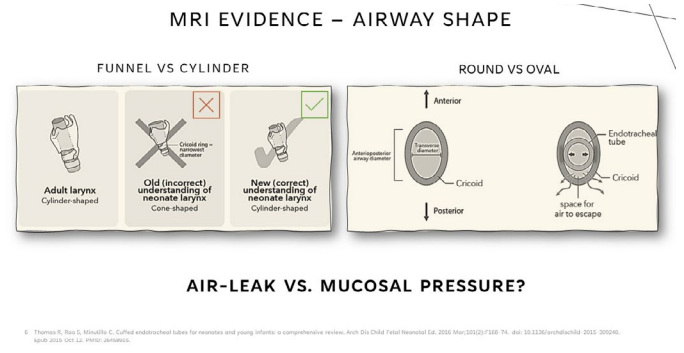
But likewise, if you have a bronchial intubation, you may be over ventilating one lung and under ventilating another lung, which can cause, airway damage. You can cause atelectasis of the under ventilated lung and pressure trauma to the over ventilated lung. Probably won't be ventilating the patient as adequately as if you were intubated properly.

Also, the neonate's epiglottis is made of this very loose, it's called areolar connective tissue. It doesn't have a lot of collagen. So, it's very prone to the formation for edema and inflammation. You end up getting subglottic stenosis and stridor post extubation. Imagine if this neonate is moving, you know, not all neonates will pay attention when you say, please don't move your head, right? They're moving a little bit and you want them to be awake a little bit. But then that movement also causes the tube to move and can cause inflammation.

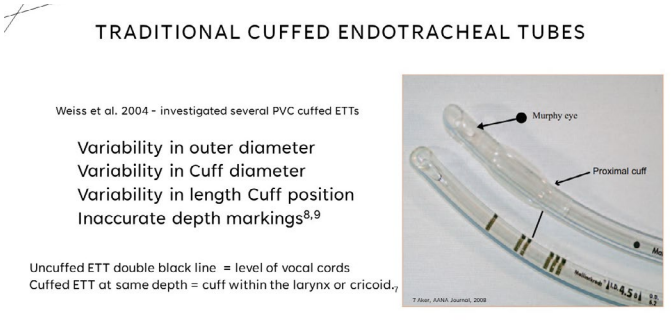
Traditionally, and as we saw in our quick survey, we avoid cuffed ET tubes in patients that are less than 10 years old. Truthfully, that number might be a bit different. There may be some wiggle room, but at least in a neonate, most people use an uncuffed ET tube for the reasons that I mentioned before. You don't want there to be the balloon, the cuff inflated to cause injury to that delicate tissue. But all of this information is based on cadaveric specimens. So dead specimens. The airway shape of an infant and child, based on these, based on these cadaveric specimens, was identified to be funnel shaped and the cricoid cartilage is that narrowest, non-distensible part of the airway that we don't want to cause damage to.

In theory, we place an uncuffed ET tube. We allow for a little bit of an air leak, and we think we're good. We have this snug enough fit, a little bit of an air leak, and we're doing any damage. That's the condition. This is what an uncuffed ET tube looks like. We saw the cuff ET tube. This is a pretty small one. This is 2.5-millimeter tube and look how teeny tiny it is.

This is not unusual to intubate a patient with a 2.5 ET tube. But you can see it looks the same. It's got this curved PVC. It's got the same markings, and it's got that Murphy's eye and the little slant there. These connectors are all the same, whether you're using a cuffed ET tube or an uncuffed ET tube. But there is evidence, this guy, Dr. Thomas, and all his colleagues looked at three studies that looked at MRI evidence and looked at MRI, looked at airway shapes through MRI. Rather than looking at cadaveric specimens, they looked at MRI evidence. They found that actually, the neonate's airway is more cylinder shaped than was previously thought. Instead of being this cone-shaped, funnel shape with the cricoid ring being the narrowest and that subglottic area being the narrowest part, this is more accurate. Also, the airway instead of being round is actually this kind of oval-shaped. If you can imagine an ET tube, even if you have that kind of air leak that we were looking for, you might have an air leak, but you still may be putting pressure on the sides of your airway. That can cause injury and airway inflammation, even if you have an air leak.



Traditionally, cuffed ET tubes were looked at by Dr. Weiss and all his colleagues, and they found that there was a lot of variability actually in ET tubes. Within each manufacturer, there's variability in the outer diameter and in the cuff diameter, how big the cuff inflates, the shape of the cuff, where the cuff is positioned, and the depth markings were inaccurate. For example, if you look at this picture here, this marking here on an uncuffed ET tube shows you where you would be at the level of the cords.



When you pass the ET tube in the airway, you're looking for that marking to be equal with the vocal cords. But if we did that with this tube at the same length, you can see that the cuff would inflate right at the level of the vocal cords The proximal cuff there would perhaps cause injury or could cause injury to the cords. This is also part of the same study. These are some of the tubes that they looked at.

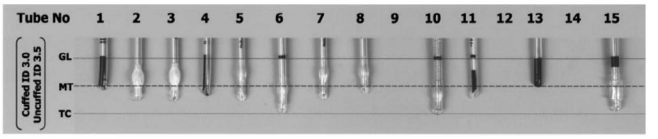


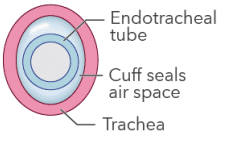
Fig 3 ID 3.0 mm cuffed tracheal tubes and age-related corresponding ID 3.5 mm uncuffed tracheal tubes are shown in 12 available tube brands. Missing CPTT are tracheal tubes not manufactured (Table 1). With the depth marking positioned at the glottic level (GL) or with the upper border of the cuff positioned 1 cm below the vocal cords some of the CPTT become with their tube tip critically low in the trachea (MT=mid-trachea; TC=tracheal carina).

You can see within manufacturers there's a lot of variability in the markings and the shape and attributes of all of these different ET tubes. This is the glottal length, and this is mid-trachea. This is kind of our target, and you can see that there's a lot of variability.

Without making any judgment call or really like thinking, we're trying to persuade ourselves, use a cuffed ET tube or not. Just think for a minute about the advantages of a cuffed ET tube. There's four that I can think of off the top of my head. You're controlling air leak, minimizing gas leak, and that's important if you're in the operating room. Fewer reintubations and the prevention of aspiration. Number one, controlling air leak.

As I said before, we're always looking for that little bit of an air leak when we intubate with an uncuffed ET tube. We want that to happen. It gives us this sense of comfort that we're not putting a tube and that's too tight, and we're going to prevent, some subglottic stenosis or edema stridor when we extubate. But if you use a cuffed ET tube in whatever age, you are going to improve ventilation because you can create a better seal. Which means if you can create a better seal, and you're able to ventilate better, you're going to avoid problems like under ventilation of one lung and over ventilation of the other lung, which causes derecruitment, airway damage.

Here's a little picture so you can see. This is the inner diameter or the endotracheal tube diameter, and around is a cuff.



Properly sized cuffed tube

If you had a cuff that could inflate and remove that air leak, you're going to be able to ventilate better. As I said before, you minimize anesthetic gas leak. This is important because you save money, right? When you are able to save gasses that you use intraoperatively over the long term, you're going to save money.

This study looked at, a conventional uncuffed ET tube and Microcuff ET tube. They actually, did a prospective randomized study. They put these patients into two different groups. Half got conventional and the other half got Microcuffed endotracheal tubes.

Table 1. Comparison of Usage of Oxygen Flow Requirement and Total Volume of Sevoflurane and Isoflurane in Conventional Uncuffed and Microcuff Endotracheal Tubes.

	Microcuff Tracheal Tube	Conventional Uncuffed Tube	*P*
Oxygen	1.57 ± 0.15	1.96 ± 0.17	<.001
Sevoflurane	4.79 ± 1.84	4.58 ± 1.68	.58
Isoflurane	19.2 ± 4.76	29.14 ± 7.06	<.001

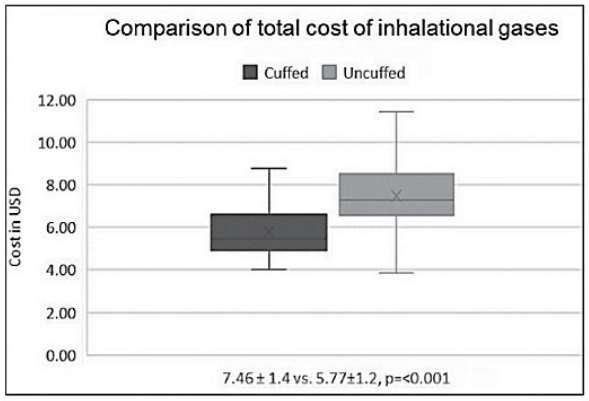


Figure 1. Comparison of total cost of inhalational gases between microcuff and uncuffed conventional endotracheal tubes.

They found that they used less oxygen and less isoflurane, and that's fine. But it also translates into an improved cost. Cuff ET tubes end up costing less in terms of gas requirement. The other, I think pretty impressive thing is that it decreases the amount of aspiration and aspiration and ventilator associated pneumonia is a very big deal in the NICU. These patients are usually not intubated for a short period of time, especially if they're premature.

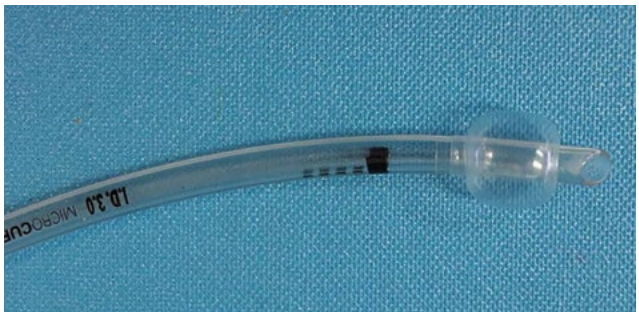
So, if you're preventing through way of a cuff, aspiration of food or secretions or stomach contents, then that's going to decrease the incidence of hospital acquired infections in the way of ventilator associated pneumonia.

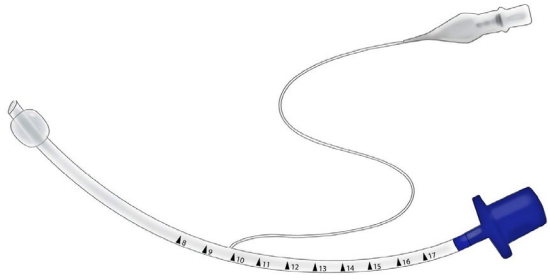
Then, neonates and premature neonates are at a very high risk for chronic lung disease. If you're able to prevent pneumonia or micro aspiration, you're going to help them have healthier lungs in the long term, not just in the short term. Then, there's also a reduced reintubation rate. Sometimes patients come from the emergency room and they may use a cuff tube, send the patient off to the NICU. Then the NICU wants to reintubate with an uncuffed ET tube. Uncuffed ET tubes will move around a little bit more. When you have to reintubate a patient, you run the risk of having hypoxia and derecruitment. You have the trauma of having to reintubate. When you have a reduced reintubation rate that directly relates to length of stay and again, suffering to the patient and harm to the patient, but also money savings.

What if, this is again, suspend your belief for just a second. But what if we had an ET tube that we could safely use in a neonate? We know the problems that can occur with a cuffed ET tube, right? We would never want a cuffed ET tube to damage vocal cords or cause subglottic stenosis. But what if there was an ET tube that had just the right geometry? We could get the benefits of a cuffed ET tube without the risk to the neonate's airway.

Nowadays, there are some companies that are making ET tubes to answer this need. They have shorter cuffs so that you don't have a leak. With better sealing. They don't have this sort of longitudinal fold. When the cuff becomes partially deflated, you can get folds in the ET tube. You still have a chance for micro aspiration to go through, the channels of the cuff. These new ET tubes prevent that from happening. They're lower profile so that when the cuff is completely deflated, it's lower profile as you ease the tube into place. There's no Murphy's eye and you have a hooded tip so that it's not sharp. So, you don't abrade the child's airway when you're intubating.

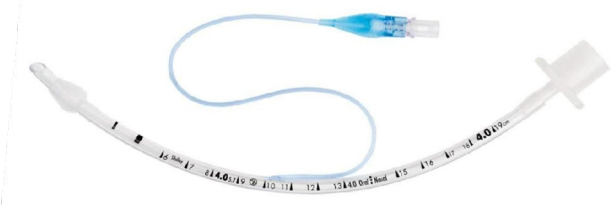
I have a couple of examples here to show you. This one is called a Microcuff ET tube. The cuff itself is made from ultrathin polyurethane, which ends up making a high volume, low pressure cuff.





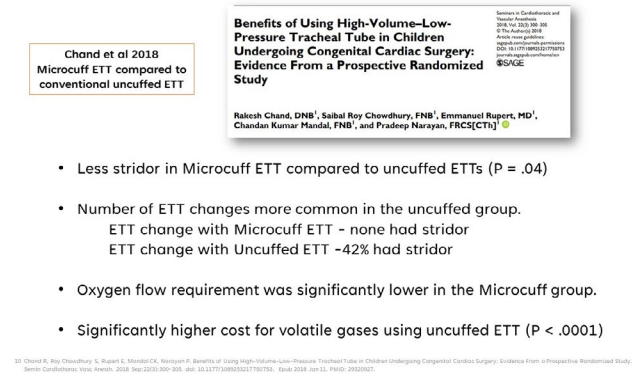
What I mean to say is you can inflate this to a significant volume with low pressure. You don't have the pressure that's pushing on the neonate's airway. There's no Murphy's eye and it has the appropriate intubation marks. It has the same anatomy as the cuffed ET tube we talked about before. This is the pilot line. This is the reservoir and the one-way valve. It has the same connector here.

There's another one made by a different company. It has just a different look. This one has similar markings. There's a little bit more distance you can see between the markings and the cuff. This cuff has a little bit of a different shape. It's got taper guards.



So, it's a little bit wider at this end than it is at this end. These are all things that are helpful and address the very geometry of a neonate's airway.

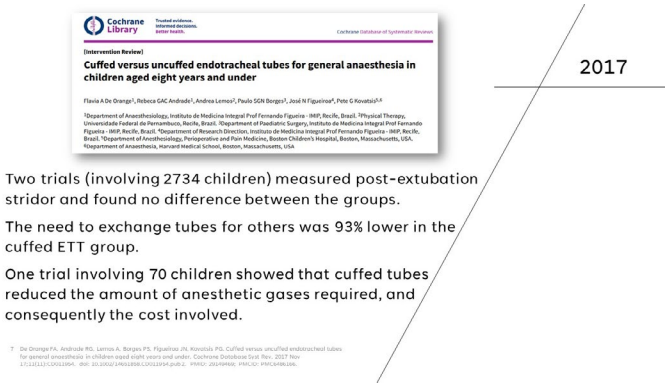
This is a study. This is actually the same study that looked at the prospective.



The two groups that looked at cuffed ET tubes and uncuffed ET tubes where they randomized into two different groups. In addition to finding that they had, less anesthetic gas leak, they found that there was less stridor using this, this brand, this is the Microcuff ET tube compared to an uncuffed ET tube. It was a significant amount. They had more ET tube changes in the uncuffed group.

However, there was no stridor in the cases that they did have to change the tube. There was no stridor when they used the Microcuff ET tube. This is the information that I already shared with you. They had a higher cost for the gasses used, interoperatively.

This is a Cochrane study that also looked at cuffed versus uncuffed tubes in the O.R.



They looked at children eight or under, but that did include, neonates, some neonates. It was a lot of patients. They looked at post-extubation stridor and found that there was no difference between the two groups. Also, there was, a lower need to exchange the ET tube, which is what we found in the other study by Chand. Also, just like Chand, they found that the use of anesthetic gas was reduced compared to uncuffed ET tube, and that, of course, relates to improved cost.

This has all been about, do we rely on our tradition, and we just keep doing an uncuffed ET tube for neonates because we know their airway is a little bit different? Or do we strive to find an ET tube that actually just better suits their anatomy? Recognizing that if we could do that, a cuffed ET tube is actually better because you can ventilate the patient better, more efficiently, more effectively, you have less variability, less gas leak and less aspiration, micro aspiration, which leads to cost savings in terms of length of stay.

In terms of use of anesthetic gas, you have to change the ET tube less often, and a Microcuff at least does not increase stridor. I honestly don't have a dog in the fight. I don't necessarily have an opinion one way or the other right now, but I do think that it's worth asking the question, should we or shouldn't we? This is the idea of medicine, right? Keep pushing the envelope and ask those important questions so we can take better care of this very fragile group.

This presentation was recorded live on March 11th 2024. You can watch this video at https://www.medtronic.com/covidien/en-us/clinical-education/catalog/webinar-wednesdays.html

Can a T-Piece Resuscitator Provide Continuous Positive Airway Pressure (CPAP)?

Captain Steven C LeCroy Sr (Ret) MA, CRT, EMTP

Before answering this question there is a term in cognitive psychology called the "Illusory Truth Effect." The Illusory Truth Effect refers to the tendency for a person to believe something to be true because they have heard the information repeatedly, even if it runs counter to their prior knowledge. A simple Google search provides plenty of papers and opinions that show that CPAP can be provided with a T-piece resuscitator, however none explain how. Everyone knows that if it is on the internet, it must be true, right? What is interesting only one manufacturer of a T-piece resuscitator includes an indication for CPAP in their Directions for Use (DFU). The one exception does not provide the steps, only states that you can. I have had many discussions with clinicians including at least one physician that said they have routinely provided CPAP with a T-piece resuscitator, so it must be true right? The truth is, based on current designs, a T-piece resuscitator is not capable of providing CPAP. Remember it is a resuscitator. I believe the controversy stems from the volume of information readily available on-line about positive pressure therapy. If you search for information on CPAP (with or without a T-piece), it is obvious there is some confusion about the difference between CPAP and PEEP (Positive End Expiratory Pressure) which is often defined as pretty much the same thing.

If a T-piece resuscitator provides (PIP) Peak Inspiratory Pressure to facilitate an inspiratory breath and PEEP to provide expiratory resistance, why can't a T-piece provide CPAP to a spontaneously breathing patient? The simple truth is the only time inspiratory pressure is provided with a T-piece resuscitator is when the user covers the PEEP hole. By covering the PEEP hole oxygen flows towards the patient. When the PEEP hole is not covered most of the gas flow diverts out of the PEEP hole into the environment with little gas flow going to the patient. The minimal gas flow going to the patient is insufficient to meet the patient's inspiratory flow demands. When the inspiratory flow demands are not met, the patient will be starved for air and will over breathe the device reducing inspiratory pressure to zero. So, by definition, if the pressure is not continuous, then it is not Continuous Positive Airway Pressure (CPAP).

What is being provided is PEEP with a minimal amount of free flow oxygen to the patient. A T-piece resuscitator can provide a mix of consistent PEEP delivery and limited PIP when the hole is uncovered. If a patient is effectively spontaneously breathing, PEEP can help prevent atelectasis while the free flow oxygen can assist oxygenation. If the user elects to provide more gas flow during free flow oxygen administration and placing a finger over the PEEP hole, the mask should not be placed in contact with the patient's face. Inadvertently making a seal with the mask and occluding the PEEP hole, could accidentally give a large indefinitely sustained inflation a significant hazard for a newborn or infant. Even though the NRP 6th Edition did recommend placing a finger over the PEEP hole during free flow oxygen the NRP Steering Committee now recommends against this practice "Given the potential to improve safety we recommend leaving your finger off the cap of the T-piece when giving free flow oxygen." The PEEP hole should only be covered during the inhalation phase of manual ventilation. Doing so during blow-by oxygen administration can put the patient at significant risk of injury.

Providing PEEP as a form of ventilatory support can be an effective therapy IF the patient has effective spontaneous ventilation. PEEP is not wrong, it is simply a different therapy but should not be confused with CPAP, the two terms cannot be used interchangeably.

This line of thinking brings up another consideration when it comes to CPAP and neonates. If a T-piece resuscitator is used in an attempt to provide CPAP, could it be an unknown factor contributing to CPAP failure in newborns? According to a paper by Sivanandan published in the Indian Journal of Pediatrics "20-40% of neonates initiated on CPAP might fail and require intubation and mechanical ventilation". If clinicians use an infant T-Piece resuscitator as a CPAP device that cannot maintain inspiratory pressure could this be a contributing factor leading to CPAP therapy failure. Final thought: What if it is the device?

Mr. LeCroy spent more than 30 years with St. Petersburg Fire & Rescue and retired as a Captain Paramedic. Currently he is the Clinical Manager for Mercury Medical. In addition, he has been an adjunct instructor at St. Petersburg College since 1984 and has been certified as a Respiratory Therapist since 1978. He has been retained as an EMS Expert in over 100 cases. Steven has been a national speaker and has published articles in both EMS World and JEMS magazines. He is also the author of the Equipment Technology for Noninvasive Ventilation in the Pre-hospital Setting chapter in the text Noninvasive Mechanical Ventilation: Theory, Equipment, and Clinical Applications published by Springer International Publishing Switzerland.

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vulnerable preterm infants. To benefit clinicians, we have joined with leading specialty respiratory distributors to provide expert local assistance and the training required for successful implementation of our products. Respiralogics' complete line of products is available from Respiralogics and our specialty respiratory care distributors. Respiralogics, Respiralogics Logo, Preemie Beenie are trademarks and StatStrap is a registered trademark of Global Respiratory Solutions, Inc.

Maternal Buprenorphine Affects Fetal Breathing

Measures of fetal breathing movement were lower in fetuses of pregnant patients who received buprenorphine, compared with controls, based on data from 177 individuals. The findings were presented at the annual clinical and scientific meeting of the American College of Obstetricians and Gynecologists by Caroline Bulger, MD, of East Tennessee State University, Johnson City. Pregnant patients with opioid-use disorder in the community surrounding Johnson City receive medication-assisted therapy with buprenorphine during the prenatal period, Dr Bulger and colleagues wrote in their abstract. The current prenatal program for substance use disorder was established in 2016 based on patient requests for assistance in lowering their buprenorphine dosages during pregnancy, said senior author Martin E. Olsen, MD, also of East Tennessee State University, in an interview. "Buprenorphine medication–assisted treatment in pregnancy is associated with long-term effects on childhood development such as smaller neonatal brains, decreased school performance, and low birth weight"; however, data on the fetal effects of buprenorphine are limited, said Dr Olsen. The current study was conducted to evaluate a short-term finding of the fetal effects of buprenorphine, Dr Olsen said. "This study was performed after obstetric sonographers at our institution noted that biophysical profile [BPP] ultrasound assessments of the fetuses of mothers on buprenorphine took longer than for other patients," said Dr Olsen. The researchers conducted a retrospective chart review of 131 patients who received buprenorphine and 46 who were followed for chronic hypertension and served as high-risk controls. Patients were seen at a single institution between July 1, 2016, and June 30, 2020. The researchers hypothesized that BPP of fetuses in patients receiving buprenorphine might be different from controls because of the effects of buprenorphine. Overall, patients who received buprenorphine were more likely to have a fetal breathing score of zero than those who underwent a BPP for hypertension. A significant relationship emerged between buprenorphine dosage and breathing motion assessment; patients on high-dose buprenorphine were more likely than patients on low doses to have values of zero on fetal breathing motion assessment, and a chi-squared test yielded a *P* value of .04269. The takeaway for clinical practice is that clinicians performing BPP ultrasounds on buprenorphine-exposed fetuses can expect that these assessments may take longer on average than assessments of other high-risk patients, said Dr Olsen. "Additional assessment after a low BPP score is still indicated for these fetuses just as in other high-risk pregnancies," he said.

Failed IOL Tied to Poor Outcomes for Mom With Diabetes

Approximately one quarter of mothers with diabetes failed induction of labor, and this failure was associated with a range of adverse outcomes for mothers and infants, based on data from more than 2000 individuals. Uncontrolled diabetes remains a risk factor for cesarean delivery, Ali Alhousseini,
Continued on page 50…

Practical Use of Transcutaneous CO_2 Monitoring in the NICU

Anne M Geistkemper, MSc, RRT, RRT-NPS

Summary
Anne M Geistkemper, MSc, RRT, RRT-NPS discusses the practical applications of transcutaneous CO_2 monitoring in the NICU, its integration into neonatal care practices, and the evolution of this technology's adoption in the Rush University Children's Hospital NICU.

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

Rush University Children's Hospital NICU: An Overview

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

Why Use Transcutaneous CO_2 Monitoring in the NICU?

The NICU admission process is fairly invasive for infants: lights, sounds, sticking for lab tests. So, the less invasive we can be within the NICU, the better. If we can introduce something that minimizes invasiveness, especially in those first 72 hours of a neonate's life, it's a valuable addition to our care regimen. Transcutaneous CO_2 monitoring, because it's noninvasive, is one such addition.

Transcutaneous monitoring provides continuous, real-time measurements of CO_2, allowing us to closely observe changes and trends. This becomes crucial when considering hypercapnia (elevated CO_2 levels) and hypocapnia (low CO_2 levels). Research has demonstrated that both hypercapnia and hypocapnia heighten the likelihood of injury to the brain, including intraventricular hemorrhage (IVH).[1] Because of this risk, we want to make sure that we're closely monitoring CO_2 to maintain levels within a safe range. Transcutaneous monitoring facilitates continuous monitoring of CO_2, providing greater visibility to support its effective management.

Clinical Applications of Transcutaneous Monitoring for Neonates

Reducing Iatrogenic Blood Loss

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

At Rush, we're frequently getting labs, especially in the first 36 to 72 hours of life, as we strive to stabilize neonates and adjust ventilator settings in a timely fashion. If we can reduce the frequency of these blood gases, while also improving the monitoring of ventilation, that's ideal—something that transcutaneous monitoring can help us accomplish by providing continuous visibility into CO_2.

Continuous Monitoring on Mechanical Ventilation

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

Because a neonate's status can constantly change, frequent adjustments are often needed. In these cases, having the option to continuously monitor CO_2 can be extremely beneficial. Instead of depending on scheduled blood gas draws to drive care decisions, continuous transcutaneous monitoring can offer greater visibility for enhanced titration support. The goal is to decrease our use of the ventilator while ensuring proper gas exchange; transcutaneous technology can give us continuous visibility into ventilatory status to help support this goal.

Continuous Monitoring on High-Frequency Oscillatory Ventilation

High-frequency oscillatory ventilation is highly effective in removing CO_2, but consequently, there's the potential for rapid fluctuations. We want to prevent these fluctuations as they can impact an infant's cerebral blood flow, which can put their brain

Anne M Geistkemper is the neonatal-pediatric section manager of respiratory care services at Rush University Medical Center and an instructor in the Department of Cardiopulmonary Sciences at Rush University.

at risk for injury, including IVH.[1] The use of transcutaneous monitoring is helpful because we can closely monitor CO_2 and catch these fluctuations, allowing for proactive management of levels in real time.

Reducing Neonatal Pain

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

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

To minimize pain, we can employ noninvasive methods like transcutaneous CO_2 monitoring. This approach offers continuous CO_2-level visibility, helping to reduce the need for frequent heel sticks. There are also some developmentally appropriate strategies that can help reduce pain and stimuli. This includes swaddling, prone positioning, kangaroo care, or utilizing anesthetic cream or short-acting systemic analgesia for skin-breaking procedures.

Managing Specific Disease Processes

Table 1 outlines recommended CO_2 targets for neonates based on their specific disease process, as well as recommended interventions for neonates experiencing severe hypocapnia or severe hypercapnia. The use of transcutaneous CO_2 monitoring is valuable as we address the unique needs of each patient, providing enhanced titration support to maintain CO_2 levels within the targeted range.

When effectively managing CO_2, observing a reduction in CO_2 levels throughout making adjustments to ventilator settings is important. Transcutaneous monitoring provides instant visualization of the impact of our titrations. We can see the changes happening, and that can help guide effective titrations and drive care.

Special Considerations

Edema

Edema can lead to altered capillary hemodynamics and cause an increase in the blood-skin barrier due to excess fluid. As a result, transcutaneous readings can be inaccurate, making it important to avoid edematous areas when monitoring. Avoiding areas of edema can be challenging, particularly for infants who are fluid-overloaded. In these cases, however, we can still leverage transcutaneous monitoring to track the trend of CO_2 over time rather than using it for precise values.

Premature Skin

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

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

Shunting and Low Perfusion

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

Table 1. Recommended CO_2 targets for neonates based on disease process and recommended titrations of ventilatory settings for severe hypocapnic and severe hypercapnic infants

SEVERE HYPOCAPNIA (30 mmHg)	NORMOCAPNIA (45 mmHg)	PERMISSIVE HYPERCAPNIA (65 mmHg)	SEVERE HYPERCAPNIA
CONSIDER: ↓ Respiratory Rate (RR) ↓ Tidal Volume (VT) ↓ Peak Inspiratory Pressure (PIP) ↓ Amplitude (HFOV) ↑ I:E Ratio (increase inspiratory time)	**Transient Tachypnea of Newborn (TTN)** • Assess & maintain normal ventilation • Follow institutional protocol & best practices **Respiratory Distress Syndrome (RDS)** • Assess & maintain normal ventilation • Follow institutional protocol & best practices **Persistent Pulmonary Hypertension of Newborn (PPHN)** • Routine use of TCM to assess and maintain normal ventilation because hypercapnia and acidosis increase pulmonary vascular resistance (PVR)	**Congenital Diaphragmatic Hernia (CDH)** • Allow permissive hypercapnia (PCO_2 45-65 mmHg) • PCO_2 > 60mmHg is associated with decreased survival[11-13] **Bronchopulmonary Dysplasia (BPD)** • Allow permissive hypercapnia (PCO_2 50-55mmHg) as long as pH remains in normal range • In severe disease, PCO_2 up to 70mmHg may be tolerated[14] **Meconium Aspiration Syndrome (MAS)** • Allow permissive hypercapnia (PCO_2 50-55mmHg) as long as pH remains in normal range	**CONSIDER:** ↑ Respiratory Rate (RR) ↑ Tidal Volume (VT) ↑ Peak Inspiratory Pressure (PIP) ↑ Amplitude (HFOV) ↓ I:E Ratio (decrease inspiratory time)

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

Low perfusion may cause transcutaneous CO_2 values to be falsely high. In this situation, similar to the case of edema, it may be more helpful to utilize the monitor to trend CO_2 in order to observe patterns and track progress during care.

Hypothermia

Hypothermia is something we see often in NICUs, especially with hypoxic-ischemic encephalopathy (HIE) or post-cardiac arrest patients undergoing cooling therapy. HIE, hypovolemia, reduced myocardial contractility, and bradycardia can all lead to decreased cardiac output. Consequently, if the region experiences hypoperfusion, it is important to note that the correlation between the transcutaneous and arterial CO_2 may be poor. In this situation, establishing a correlation between the two values, rather than focusing on the exact values, becomes more clinically valuable. Again, this can be used for tracking the trend in CO_2 throughout care.

AARC Clinical Practice Guidelines

The AARC Clinical Practice Guidelines (shown in part in Figure 1) provides recommendations for the effective use of transcutaneous CO_2 monitoring in clinical care.[7] If you're not fully utilizing your transcutaneous monitors, haven't developed guidelines or implemented it into any protocols, or don't have devices at all, the AARC Clinical Practice Guidelines can guide you. I encourage you to develop a process for your NICU. It can be difficult to get started, but aligning with the AARC guidelines is going to create a standard practice. By adopting this approach, you can foster growth within your team, encouraging increased utilization of the technology. We have a great opportunity especially as respiratory therapists, to help drive care in an efficient, noninvasive manner.

TCM 3.0 SETTING

TCM may be performed by trained personnel in a variety of settings that include, but are not limited to hospitals, extended care facilities, and patient transport. It is utilized in the following specific clinical settings to determine the presence of hypoventilation or respiratory depression:

- **3.1** Mechanical ventilation, including conventional modes of ventilation, high-frequency ventilation, steady state high frequency jet ventilation, and noninvasive ventilation.

TCM 4.0 INDICATIONS

The use of TCM is indicated in patients who either lack arterial access or have the need for continuous monitoring of oxygen and carbon dioxide with minimal blood draws. TCM allows the assessment of:

- **4.1** adequacy of oygenation and/or ventilation
- **4.2** response to diagnostic and therapeutic interventions, as evidenced by $PtcO_2$ and/or $PtcCO_2$ values
  - **4.2.1** Weaning and extubation decisions may be made based on $PtcCO_2$ measurement alone.

Figure 1. 2012 AARC Clinical Practice Guidelines for Transcutaneous Monitoring of Carbon Dioxide and Oxygen[7]

Benefits of Transcutaneous CO_2 Monitoring in the NICU

Transcutaneous CO_2 monitoring offers a noninvasive method to continuously analyze CO_2 levels in all modes of ventilation. With continuous monitoring, we're able to get real-time values for instant visualization of a patient's response to care strategies. This newer technology preserves skin integrity for delicate patients and helps reduce the need for frequent blood draws.

Additional benefits of transcutaneous CO_2 monitoring in the NICU:

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

Tips for Selecting a Monitoring Site

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

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

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

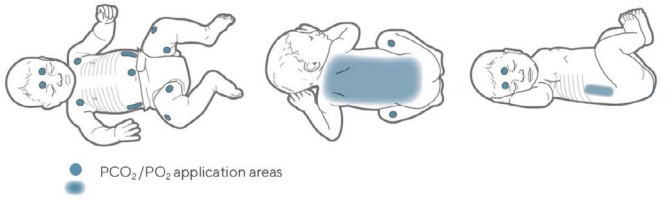

Figure 2. Recommended sensor sites for transcutaneous monitoring include the thorax, the abdomen, the back, the area low on the forehead, the temples, and the inner or anterior aspect of the thigh.

Using Contact Gel: How Transcutaneous Monitoring Use Transformed at Rush

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

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

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

Sample	Site	Seal	Sensor	Status
Record the tcPCO2 value when you draw the sample, not when results are read. Verify proper lab draw technique and operation of blood gas analyzer.	Check for external pressure on the sensor. Check perfusion at measurement site. Sampling site and sensor should be on same side of shunt.	Verify attachment ring is secure on the skin. Use 1-2 drops of contact gel during application. Ensure sensor is clipped into the ring.	Verify correct sensor temperature. Check the quality of the sensor membrane. Check when the sensor was last calibrated.	Shock, sepsis, and edema can impact the local perfusion. Consider the effect of vasoactive medications. Decreased perfusion may cause falsely high tcPCO2.

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

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

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

Integrating Transcutaneous Monitoring Into NICU Protocols

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

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

NICU Conventional Ventilation Protocol

As part of our NICU conventional ventilation protocol, patients who are born at less than 35 weeks get a transcutaneous sensor placed on them for the first 72 hours of life, which allows us to start trending our gases with our $tcPCO_2$. Because there is a high volume of gases and labs being drawn in the first 24 to 36 hours, we're able to lay a good foundation for our correlation. This protocol also gets everybody more comfortable with transcutaneous monitoring in the NICU.

High-Frequency Jet Ventilator Protocol

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

Other Cases to Integrate Transcutaneous CO_2 Monitoring

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

Bronchopulmonary Dysplasia (BPD)

Although gases are not frequently obtained from patients with BPD, their status can change quickly. These patients are often sweaty, which can make finding the proper transcutaneous sensor placement difficult. However, transcutaneous monitoring is a useful tool for this population, providing continuous CO_2 visualization when gas sampling is infrequent.

Noninvasive Ventilation (NIV)

Patients on noninvasive mechanical ventilation are often teetering on the verge of needing an escalation of care, perhaps requiring intubation. Or, they may have just been extubated, and there is uncertainty about their ability to thrive. To be able to have constant CO_2 monitoring in these cases is helpful in guiding our management strategies.

Summary

Transcutaneous monitoring provides clinicians with a noninvasive method to monitor CO_2. This isn't just beneficial for patients in terms of lessening pain; it has the potential to yield benefits for your hospital in terms of cost-effectiveness by supporting the reduction of blood draws. And importantly, as a respiratory therapist, it offers valuable insights into the efficacy of ventilation strategies, which helps guide care.

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

As we continue utilizing transcutaneous CO_2 monitoring, keeping up with current research remains valuable. However, actively engaging with other facilities, who are utilizing devices even more than we are, has also proven significant for our hospital. If you're looking to embrace this technology, or increase its usage, consider reaching out to your colleagues at other hospitals to gain valuable insights on successful implementation. This has played a vital role in our adoption of transcutaneous monitoring in the NICU, and our progress toward utilizing its fullest potential for our patients.

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CLINICAL POCKET GUIDE

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Your comprehensive guide to harnessing the potential of transcutaneous CO_2 monitoring in your NICU.

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- ✓ Reduce iatrogenic blood loss
- ✓ Support continuous monitoring, titration, and weaning of mechanical ventilation support
- ✓ Continuously monitor during high-frequency ventilation

Guidelines for optimal monitoring:

- ✓ Recommendations for sensor application
- ✓ Tailoring monitoring strategies for specific conditions
- ✓ AARC clinical practice guidelines for transcutaneous monitoring

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Proactive Use of Human Milk Cream to Improve Outcomes and Reduce Costs

Amanda Salley, Kim Mack, and Emily Canata

Introduction

It is well-established that very low birth weight (VLBW) infants being cared for in hospital NICUs benefit from a human milk-based diet. In fact, the American Academy of Pediatrics,[1] the Office of the Surgeon General,[2] the World Health Organization,[3] and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition[4] all recommend that premature infants be fed with human milk. Taking that a step further, an exclusive human milk diet (EHMD) that consists of mother's own milk (MOM) or donor milk (DM), with the addition of nutritional fortifiers made from human milk, as needed, has resulted in lower complication[5-11] and mortality rates,[7,12,13] as well as shorter hospital stays,[10] improved feeding tolerance,[14] less time on parenteral nutrition (PN),[7] lower healthcare costs,[10,14-17] and better long-term outcomes[18-20] for this population. Now there is increasing evidence that proactively using human milk cream as part of an EHMD, rather than waiting for suboptimal growth, can further optimize outcomes and reduce costs.

Human milk cream is a source of healthy fat

While human milk is the standard food for VLBW infants in the NICU, it cannot on its own meet their nutritional needs. The VLBW infant population fed with MOM or DM require the addition of supplemental calories, protein, minerals, and fat, which can be met with human milk-based fortifiers and human milk cream.

Amanda Salley is a registered dietitian (RD) with 14 years of experience in the neonatal and pediatric population. Following her internship at Vanderbilt University, she continued her education with a pediatric fellowship at Riley Children's Hospital in Indianapolis, Indiana, and obtained her master's in human nutrition from Alabama University. Amanda currently practices as a neonatal dietitian at Prisma Health Richland Hospital in Columbia, South Carolina.

Kimberly Mack is a perinatal clinical dietitian in a Level III NICU in Hoffman Estates, Illinois. She has been a NICU RD for the past 15 years but considers her true title to be "growth expert." She educates fellow dietitians and students about the NICU, nutrition, and lifestyle. Her work in early/first feeds, early fortification, and growth in and beyond the NICU is her passion.

Emily Canata is a neonatal/pediatric RD with 20 years of experience working in the hospital setting. She currently works as a medical science liaison for Prolacta Bioscience.

Several studies have demonstrated that the nutritional composition of human milk is highly variable[21] and that non-standardized DM obtained from HMBANA milk banks may not contain the labeled macronutrient content,[22] with fat being the most variable nutrient.[23] In addition, loss of fat due to adherence to plastic during tube feeding can be clinically significant.[24,25] Use of human milk cream (Prolact CR, Prolacta Bioscience, Duarte, CA) has been shown to help compensate for losses of fat during storage, mixing, and administration of feeds to VLBW infants in the NICU. Tabata et al measured the fat content of human milk via infrared (IR) analyzer in a simulated feeding system using the Kangaroo ePump and the MedFusion 2010 pump. They compared fat loss in human milk alone, human milk supplemented with human milk fortifier (Prolacta+ H²MF), and human milk supplemented with both H²MF and Prolact CR. With the Kangaroo ePump, the addition of H²MF and Prolact CR increased fat delivery efficiency from 75.0% ± 1.2% to 83.7% ± 1.0% ($P < 0.0001$). With the MedFusion pump, the addition of H²MF increased fat delivery efficiency from 83.2% ± 2.8% to 88.8% ± 0.8% ($P < 0.05$), and the addition of both H²MF and Prolact CR increased fat delivery efficiency to 92.0% ± 0.3% ($P < 0.01$).[26]

The degree of fat loss is influenced by how human milk cream is administered. Hamilton et al infused 45 mL of human milk 3 times through plastic feeding tubing via an infusion pump for 30, 60, 120, 150, and 180 min, using new tubing for each infusion. They compared fat loss of human milk alone (DM or MOM), Prolact RTF26 human milk-based premature infant formula, and MOM fortified with H²MF. Both RTF26 and MOM fortified with H²MF were tested with and without the addition of Prolact CR, with the cream mixed into the feed or infused via a 3 mL syringe before the infusion of fortified milk. Both the fortified and unfortified milk lost fat in the feeding system at 30 min. While fat losses were greater with fortified milk, the amount of fat delivered was higher than for unfortified milk. Administration of Prolact CR before infusions of fortified human milk resulted in the least fat loss.[27]

To increase calories, some NICUs may use medium chain triglyceride (MCT) oil, usually derived from palm kernel or coconut oil. Human milk cream, being made from 100% human milk, has the advantage of containing bioactive factors, such as milk fat globule, milk fat globule membrane, and long-chain polyunsaturated fatty acids,[28] which have additional health benefits for VLBW infants that include superior absorption and metabolism,[29] as well as promotion of gut maturation[30] and reduction in the risk of necrotizing enterocolitis.[31]

In a prospective noninferiority, unmasked study of 78 infants with a birth weight 750-1250 g receiving an EHMD consisting of MOM or DM plus human milk-based fortifier, the infants were randomized to receive Prolact CR if the energy density of the human milk tested <20 kcal/oz (using a near IR human milk analyzer) or to receive no additional supplementation. Those who received Prolact CR had superior weight (14.0 ± 2.5 vs 12.4 ± 3.0 g/kg/d, P = 0.03) and length (1.03 ± 0.33 vs 0.83 ± 0.41 cm/wk, P = 0.02) velocity.[32] A secondary analysis of this cohort revealed that use of Prolact CR was also associated with a decreased postmenstrual age at discharge (39.9 ± 4.8 vs 38.2 ± 2.7 weeks, P = 0.03) and a shorter length of hospital stay (86 ± 39 vs 74 ±22 days, P = 0.05).[33]

An added benefit of human milk cream is that it is concentrated enough to provide needed fat and calories without substantially increasing feeding volumes, which is particularly important for infants on fluid restriction.

Using human milk cream proactively

Salley et al have demonstrated that incorporating proactive use of human milk cream into standardized feeding protocols at the UChicago Medicine AdventHealth Hinsdale, Illinois, NICU can not only improve outcomes among VLBW infants but also reduce costs. She and her team revised their feeding protocol in October 2021, such that Prolact CR at a concentration of 4 mL per 100 mL feed was added to all feeding when PN nutrition and lipids were discontinued (Figure 1). This provided an additional 2 kcal/oz, approximately. Among 36 VLBW infants who received this revised protocol, prospective follow-up revealed a reduced need for Prolact +8 H^{2}MF (43% to 14%), resulting in an average cost savings of USD $2,967.78 per infant. It also resulted in rates of severe malnutrition declining from 3.3% to 2.7% and moderate malnutrition declining from 37% to 8%.[34]

In unpublished data by Kim Mack at Ascension Saint Alexius NICU in Hoffman Estates, Illinois, proactive use of Prolact CR among infants weighing <1250 g helped to keep glycemic levels within range (Figure 2). Previously, it had been a challenge to maintain glucose levels within range when transitioning off PN among infants who were not on full feeds. They found that shortening feeding intervals to every 2 hours and automatically starting Prolact CR when intravenous (IV) lipids are discontinued has helped avoid the need for IV fluids or higher than desired total fluid volumes. With this strategy, they decreased the number of patients needing supplemental IV fluids to maintain glucose levels from 60% to 25% over the previous 18 months.

In 2022, Prolacta Bioscience released an evidence-based feeding protocol to further optimize outcomes of an EHMD among infants ≤1250 g birth weight. This protocol, which was developed in collaboration with independent clinicians, registered dietitians, nurses, and neonatologists, focuses on early fortification and proactive use of Prolact CR tailored to individual infants' needs to optimize outcomes.[35]

Use of human milk cream modular lowers costs

There is evidence that the cost of an EHMD is more than offset by the savings incurred from fewer complications and shorter hospital stays.[10,14-17] Nevertheless, further savings are always welcome in budget-conscious NICUs. Once VLBW infants receive feeds of 160 mL/kg, on average, using human milk fortified with Prolact +6 fortifier or RTF +6 fortifier, they are receiving about 149 kcal/kg and 4.32-4.48 gm/kg protein (precise values vary based on use of preterm vs term milk).[34] At this point, the enteral protein intake recommended by Koletzko et al[36] is being met, so the VLBW infants not meeting growth goals can receive human milk cream, which provides the extra calories needed for growth and is less costly than upgrading to Prolact +8 fortifier. If the human milk cream is introduced earlier (ie, used proactively), then the infants may never experience suboptimal growth. As mentioned, Salley et al calculated average cost savings of USD $2,967.78 per VLBW infant when they switched to a protocol that incorporated proactive use of Prolact CR.[34]

Knake et al compared 2 cohorts of infants born at ≤1250 g who were fed with an EHMD. The first cohort (2010-11) received human milk fortifier while the second cohort (2015-16) received human milk fortifier plus Prolact CR if weight gain was <15 g/kg/day. Growth was similar for both groups, but the mean dose of human milk fortifier was lower in cohort 2, resulting in a cost savings of $2,318 per patient on the cost of human milk products (P < 0.01).[37]

As an EHMD increasingly becomes the standard of care in hospital NICUs due to better outcomes and cost savings, it will be important to optimize its benefits via new evidence-based protocols that incorporate ongoing research and real-world experience. Appropriate use of human milk cream has been shown to further reduce costs and provide the healthiest available source of fat and calories for VLBW infants. In our experience, proactively using this cream, without waiting for VLBW infants to show signs of nutritional deficits, lowered our costs and reduced rates of malnutrition and hypoglycemia.

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	Birthweight	1	2	3	4	5	6	7	8	9	10	11
A	<500gm	1 mL q6h	1 mL q6h	1 mL q6h	1 mL	1.5 mL	2.5 mL	3.5 mL	4.5 mL	5.5 mL	6.5 mL	**
						2 mL	3 mL	4 mL	5 mL	6 mL	7 mL	
B	501–650 gm	1 mL	1 mL	1 mL	2 mL	2.5 mL	3.5 mL	4.5 mL	5.5 mL	6.5 mL	7.5 mL	**
						3 mL	4 mL	5 mL	6 mL	7 mL	8 mL	
C	651–850 gm	2 mL	2 mL	2 mL	3 mL	4 mL	6 mL	8 ml	10 mL	**		
						5 mL	7 mL	9 mL	11 mL			
D	851–1000 gm	2 mL	2 mL	2 mL	4 mL	5.5 ml	8.5 mL	11.5 mL	**			
						7 ml	10 mL	13 mL				
E	1001–1250 gm	3 mL	3 mL	5 mL	7 mL	11 mL	15 mL	19 mL	**			
					9 mL	13 mL	17 mL	21 mL				
F	1251–1500 gm	3 mL	5 mL	7 mL	11 mL	15 mL	19 mL	**Continue advancing BID to goal of 160 mL/kg				
				9 mL	13 mL	17 mL	21 mL					

q#h = every # hours

Use Protocol F if baby is ≤32 weeks but over 1500 grams

Feeds given q3h unless otherwise noted
MOM fortified with Prolact +4 or RTF 24
MOM fortified with Prolact +6 or RTF 26
Fortify with Prolact CR
Included in total fluids

Figure 1. UChicago Medicine AdventHealth Hinsdale NICU Standard Feeding Protocol
Indications: All infants ≤1500 grams and/or 32 0/7 weeks

Day of Protocol	Daily Feeding Advance ml/kg/d	MOM	Insufficient MOM	If No MOM/DM Available	Total Feeding Volume mL/kg/d	Feeding Interval
1	Trophic	1 ml q6h	1 ml q6h MOM/Prolact HM	1 ml q6h Prolact HM	Trophic	q2h
2	Trophic	1 ml q4h	1 ml q4h MOM/Prolact HM	1 ml q4h Prolact HM	Trophic	q2h
3	10–15	MOM	MOM/Prolact HM	Prolact HM	15–20	q2h
4	10–15	MOM	MOM/Prolact HM	Prolact HM	15–20	q2h
5	10–15	MOM	MOM/Prolact HM	Prolact HM	15–20	q2h
6	10–20	MOM	MOM/Prolact HM	Prolact HM	20–40	q2h
7	10–20	MOM/Prolact +6	MOM/Prolact HM Prolact +6	RTF 26	40–60	q2h
8	10–20	MOM/Prolact +6	MOM/Prolact HM Prolact +6	RTF 26	60–80	q2h
9	10–20	MOM/ Prolact +6 with 4 ml CR/100 ml when TPN discontinued	MOM/Prolact HM Prolact +6–4 ml CR/100 ml when TPN discontinued	RTF 26 with 4 ml CR/100 ml	80–100	q2h
10	10–20	MOM/Prolact +6 with 4 ml CR/100 ml when TPN discontinued	MOM/Prolact HM Prolact +6–4 ml CR/100 ml when TPN discontinued	RTF 26 with 4 ml CR/100 ml	100–120	q2h
11	10–20	MOM/Prolact +6 with 4 ml CR/100 ml	MOM/Prolact HM Prolact +6-4 ml CR/100 ml	RTF 26 with 4 ml CR/100 ml	120–140	q2h
12	10–20	MOM/Prolact +6 with 4 ml CR/100 ml	MOM/Prolact HM Prolact +6-4 ml CR/100 ml	RTF 26 with 4 ml CR/100 ml	140–160	q2h

q#h = every # hours

*Prolact CR added for poor growth if not already on CR per guidelines and change to Prolact +8 for poor growth if on CR or with fluid restriction

Figure 2. Ascension Saint Alexius NICU Protocol for Smaller Preterm Infants
Indications: Standard risk factors for gestational age (751-1249 gm/30-34 weeks)

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Thermoregulation of the Neonate

In this feature, Neonatal Intensive Care adapts podcasts delivered by clinicians and healthcare providers about the actual application of specific products and therapies. In this episode of the podcast, Steven Falk, Chief Engineer from GE HealthCare Maternal Infant Care business, shares his expertise on the complex and critical topic of thermoregulation in newborns.

Ben Courchia MD: Hello, everybody. Welcome back to the Incubator Podcast. We are back this time with a Tech Thursday. We are joined by Steve Falk from GE HealthCare. Steve, how are you?

Steve Falk: I'm doing great. Thanks, Ben.

Ben Courchia MD: For people who are not familiar with who you are, I'm just going to go through portions of your bio because your bio is quite extensive. You have over 35 years of product development, technical leadership experience in industry, both in startup environments and in large corporations. You're currently the chief engineer for the maternal infant care strategic business unit at GE Healthcare. You've been with the business for more than 31 years in a variety of roles and responsibilities, including senior engineer, engineering manager, lead program engineer, engineering director, CTO, and so on. You've been integrally involved with all phases of product development, including voice of customer, business development, business model generation, design verification, validation. And you also serve as the patent evaluation board leader. You have led the Giraffe OmniBed, Giraffe and Panda Warmer platform product development efforts, which we are all very much familiar with. So, it's very exciting to talk to you today about thermal regulation in the neonate.

Steve Falk: Thank you.

Ben Courchia MD: It's always very interesting to be able to speak to engineers because as physicians or clinicians, we see things in a certain way, but as an engineer, what are the challenges that present themselves to you as you are trying to solve the problem of thermal regulation of a anewborn?

Steve Falk: Great question. Let me start with how we, as technicians, technologists, think about thermoregulation. It's really an energy balance of a particular control volume or control mass. Let's say this happens to be a premature baby. When we think about that energy balance, we think, 'how does the baby gain heat or gain energy?' They do that by metabolism.

Metabolism, as you know, is when glucose and oxygen come in, and energy, in the form of ATP, is produced. They're losing heat or losing energy in various ways. There's really four major ways to lose heat: conduction, convection, radiation, and evaporation. Conduction is really a solid-to-solid thermal gradient. What that means is if the baby's lying on a mattress, it's going to lose heat or gain heat to the mattress. Convection is where a solid, let's say the baby, in fluid, in air. So, the heating, ventilating, and air conditioning, for instance, in the room, the baby can lose heat. What's interesting about this is it's not only proportional to the temperature differences, but also, it's proportional to the velocity of the air. And most interesting, it's proportional to the surface area of the baby. Conduction is only proportional to the effective contact area. When you think about the baby lying on a mattress, it's not the whole surface area of the baby that's lying on the mattress. It's a smaller area than everybody thinks. With convection, it's proportional to velocity and surface area. With respect to radiation, it is the baby losing heat to the next viewable solid. What does that mean? I'm sitting in a crib and I'm losing heat to the walls, to the ceiling, to any solid that I can radiate to. What's interesting about that is it's proportional to the fourth power of temperature, as well as surface area. And then last is the evaporation, which is water loss. It's based on the humidity or the water concentration difference, as well as surface area. When you think about that, you say, wow, I'm losing heat based on surface area, and my mass as a premature baby is small, my surface area to mass ratio is actually quite large. Mass is kind of directionally proportional to my metabolic energy and surface area is proportional to every which way I can lose heat. So as these premature babies are younger and younger, we think of them, from an engineers perspective, as a surface area to mass ratio and therefore the challenge is how do we keep these babies in a neutral thermal environment where their comfort zone is so that they can grow, they can reduce any kind of caloric expenditure to getting warm, getting cold, and basically

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Mr. Falk has over thirty-five years of product development and technical leadership experience in the industry, both in a start-up environment and a large corporation. He is currently the Chief Engineer for the Maternal Infant Care strategic business unit in GE HealthCare. He has been with this business for more than 31 years in a variety of roles and responsibilities, including Senior Engineer, Engineering Manager, Lead Program Engineer, Engineering Director, CTO, and Chief Engineer. Steve has been integrally involved with all phases of product development, including voice of customer, business development, business model generation, design, verification, validation, and production transfer. He also serves as the Patent Evaluation Board leader. Steve is honored to have led the Giraffe OmniBed and Giraffe/Panda platform product development efforts — a game-changing product solution for the perinatal care setting. If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net

healing, growing, getting better. And the challenge is thermal management.

Ben Courchia MD: I'm very interested in the historical evolution of thermal management of the newborn, and I think it's because it seems like a very simplistic problem, right? It's like, oh, baby gets cold, just wrap them up and keep them warm. And you look through history as how we've been trying to keep babies warm. And the range of ideas is just mind blowing. So obviously we have the late 19th century discovery of the incubator, inspired by incubators for chicks that were identified at the Paris Zoo. I've read reports of parents putting preterm babies in a box with feathers and putting it in the oven to try to keep a baby warm. We have mother skin to skin where we're trying to use another human being as a source of heat.

And so I think that when you're approaching this problem as an engineer and looking at all these attempts and all these iterations, how do you take the best of them and how do you create a solution that makes sense for the clinician at the bedside?

Steve Falk: Also a great question. The one historical incubator you didn't mention that I always like to talk about is the one that was in the World's Fair where the baby is in a small partition above boiling water. And that boiling water, by the way, was heated with propane. So, you can only imagine the fantastic issues that had.

Ben Courchia MD: What? There's a lot of reports of burns in an attempt to try to keep babies warm. Sadly enough.

Steve Falk: Yes, yes, for sure. How we think about everything you just mentioned was the thermal management has to be a pretty tight control that we need to make. There's evidence out there that suggests for premature babies that for every one degree centigrade, basically almost two degrees Fahrenheit, decrease in core temperature, there's a 28% chance more in mortality.

So, we think of this sort of neutral thermal environment, this core temperature we want this baby to be is really plus or minus a half a degree or less in centigrade. It's tight. When we start looking at different ways, as you mentioned, some of these, the feathers in the oven and all this other stuff, it has to be able to be controllable, and we think of the thermal time constant.

And some of the challenges, okay, so we're going to have a heater and a fan and it's going to blow warm air over the baby in some fashion. And we need, because of we're trying to protect the brain and the neuroprotective care, the neurodevelopmental care, we want the sound in that incubator to be low. I can't move air really fast or it's going to be loud. So, I have to move it slow, but I have to have the thermal time constant such that I can react to the baby getting cold or getting warm. There's the need to have that thermal time constant, that responsiveness, to be able to keep the baby within a half-a-degree centigrade and at the same time keeping really low noise. It's those kinds of interesting sort of requirements that almost butt heads against each other. You must find that balance and where that simplistic problem becomes actually quite complicated.

Ben Courchia MD: I think it's exciting to be able to talk to you because if you are, like me, interested in how things work, the idea of the Giraffe OmniBed is something that is really, really, it's something that would pique your curiosity because it seems very straightforward, right? You have a temperature probe that's connected to the baby and an ambient temperature that is regulated based on the baby's temperature. But what's interesting about this is that it is not, these changes in temperature are not immediate, right? So, they're progressive. And like you said, we have an imperative to try to keep the temperature of the baby within a tight range. When you are designing the algorithm that regulates the temperature of an incubator, how do you take all these parameters into account? Mainly how long is like, for example, a baby that has a temperature that's slightly higher than it needs to be, but it's suddenly decreasing. Is that pattern going to reach a point where we're crossing a certain threshold that leads to hypothermia? How quickly do we respond to changes in temperature? And how quickly are these changes in ambient temperature reflected on the baby? And how does that feedback mechanism work? I think I would love to hear more about that.

Steve Falk: For an incubator, there's different algorithms, whether you're an incubator or in a warmer, radiant warmer, and for the Giraffe OmniBed, there's both of those algorithms because the Giraffe OmniBed can be an incubator or a radiant warmer. Let's take an incubator, for example. The old version of incubators would basically turn on and off the heater, and maybe change the fan speed, but turn on and off the heater based on the baby temperature. And what happens is exactly what you said, which is how do you tune that algorithm to a particular baby who may have a slightly more sluggish way of changing temperature just naturally or a faster way depending on their gestational age or just in general their personality, if you will. You end up chasing the temperature and what happens when you do that is that the heater will turn on and off and it will move the air temperature up and down as fast as it can and it generates this volatile kind of environment for the baby, which can lead to some very bad things as you can imagine.

What we do at GE HealthCare or what the Giraffe OmniBed does, is what we call a cascade algorithm. We're not directly changing the heater based on the baby's temperature or the baby's temperature changes. What we're saying is that we're going to control the air temperature in an incubator. What set point that we control that air temperature could change slightly based on how the baby's reacting to it. And it takes the time, thermal time constant, if you will, away and a little less relevant. It is like if you're in your home and you're slightly chilly and you go to your thermostat and you raise it up, let's say, a half a degree or a degree and then you kind of see how that plays out for a certain amount of time. And if that helped, fantastic. If you're still chilly, you knock it up another degree. Think of it as this constant or continual modification of the air temperature to keep the baby temperature where it's at. That sort of sluggishness that we purposely put in there gets a more comfortable control. It allows the baby to change their temperature at whatever rate they need to change their temperature and that we would keep up.

Ben Courchia MD: That's so interesting. As we were talking about these functionalities, I think some people that may be listening in the car may say, yeah, well, I knew how this worked out. I'm not very impressed by that. But I think sometimes what's lost on us is the degree of innovation that happens on a product or on a tool that we've been familiar with for many, many years. And I think as we are synthesizing a lot of the things you said, about the mechanism in which heat can be lost, about the mechanism

in which an incubator functions, can you tell us a little bit about some of these other features that are present in an incubator that are allowing us to deliver the care we deliver on a day to day basis, all the while trying to keep that goal of maintaining normothermia at the forefront? I'm thinking of portholes. I'm thinking of air boost, which I think many people are still not familiar with what air boost is. Can you tell us a little bit about these different features?

Steve Falk: Let's take the Giraffe OmniBed in the closed- bed mode or the incubator version, if you will. What we do with our airflow in an incubator is we have what we call a double wall. Our doors or side panels have an inner wall and an outer wall. It's kind of like a double pane glass in your house. And the airflow goes up that through those walls. And here's a reason for that…a couple of reasons actually. Number one is that the air can be warmer because the baby can't actually feel that air. They can't put their hand over the vent and get hurt in any way so that air can be a little hotter because the baby can't touch that air. And because it comes out of the top of the door. It, at the same time, is warming that inner wall. So, when we talk about our radiant energy, that baby is looking at the next solid. Well, that next solid is the inner wall. So now, the room temperature has less relevance to how the baby's going to either be warm, be cool…it's really in our control. We think about portholes. When we talk about interventions, clinicians are in the portholes, as you know, a lot, and so we've designed the portholes such that they're little tunnels. Those portholes do not in any way break up that inner wall airflow.

If there were, for instance, just portholes there and all we did was open the porthole doors, a lot of that airflow coming through the inner walls would try to escape. And if it tried to escape into the room, it's not going to draw negative pressure in the incubator. There's going to be air that's going to displace it. Well, that air that's going to displace it will be room air. So now I'm going to get cold in my incubator. We have these tunnels, they're gaskets that go around the porthole. What happens is that you open the porthole, and those open portholes are not in any of the forced convection that we are putting into the incubator. The only escape of that warm air is just that natural sort of mixing that happens very slowly and it's not actually very effective. We really don't have any significant temperature drop when you open portholes. That was done very purposefully.

When it comes to the air boost you mentioned, we have the ability to push a button and boost the air. What does that mean? It changes the fan speed such that when I, for instance, open the door of the incubator, you could feel the air coming up because that's the vent that's going to come up. And when you boost that air, it's very similar to when you've gone into a supermarket or some sort of store, you feel this burst of air as you're walking through the entrance. That air can divide warm air and cold air and keep those divided. It's very difficult for that air to cross the air curtain. The faster the air, the better.

Ben Courchia MD: If the flow is fast enough, then it acts as a barrier. Got it.

Steve Falk: Correct. And what we also do is there's a little feature inside of that incubator that when you do that, when the door is open, it kicks the air about four or five degrees inside the incubator, slightly off a vertical. What we're making sure, not only do we have an air boost curtain, but we also have an air curtain that is leaning into the incubator because we don't want to waste that beautiful warm air and put it into the room.

Ben Courchia MD: Yeah, and these are the kinds of things where if you're a provider and we do get, there's always some form of in-service happening in the unit. And I think I'm talking to the doctors and providers here. When people from GE HealthCare come to go over some updates or whatever it is about beds, even if you're a clinician and say, oh, that's for the nurse, that's not for me…go and listen, because that's how I find out. I found out about all these different features, and I was like, holy smokes. I never knew about this. Nobody told me that I should have to press air boost when I'm going into the, into the incubator. That's super helpful. Can you tell us a little bit as we're discussing all these features at the bedside, how does feedback from your users, from the clinical team, how does that play a role in how you iterate on the different products?

Steve Falk: It plays a huge role, Ben. We have a clinical staff in the maternal infant care business, as well as having a tremendous amount of key opinion leaders and clinical partners out in the world. We're constantly going and having those conversations. We see them at conferences, we call them. And that feedback is fantastic. As a matter of fact, in developing the Giraffe OmniBed and that platform, we probably talked to more than a thousand clinicians all around the world as we were developing it and we continued to do that. It wasn't that we scoured the earth and got all this feedback and then just developed this product and launched it. It was continual feedback from focus groups to conferences to road shows to conversations to studies and all throughout the development and even as we were launching the same thing. Even post-release, now it's in the market, we continue to get that feedback so that we can iterate and innovate on what's next and what should we be paying attention to. And we love not only speaking and having these discussions with these clinicians, but we also love learning. They learn and we learn. And at the end of the day, we have a very strong feeling that the diversity in the room is huge, and it brings the best solution possible. We believe wholeheartedly that the clinicians should be part of this design process.

Ben Courchia MD: Something that's interesting in the clinical field is that we feel as providers wrongfully that we are finding best use for tools that we have at the bedside and forget that we are aligned with the team that developed the tool. And I think to that end, a topic that we've discussed a lot on this miniseries has been how there are various aspects of maintaining thermal regulation that are very different from one another.

Most notably in and around the time of birth when we're talking about the concept of golden hour. And so, I am wondering if you could share with the audience a little bit, how has this entity of golden hour and the challenges that it presents influenced or sparked any design or functionality of the tools that is developing to address thermal regulation in a new one.

Steve Falk: The golden hour is an interesting one because there's many different things that are happening within that golden hour evolution even currently from delayed core clamping to all sorts of other things that are going on. We still step it back to the science and the physics. This baby comes out, and was what, 37 and a half, 38C inside of mom? They come out to a 22-degree room wet.

That's incredibly impactful, as you can imagine. Thank goodness we don't remember that experience. We think about the four heat partitions. First, the delivery room temperature. Maybe that should be higher? I know that there's a strong indication that that's the case. Obviously, the radiant warmer brings a tremendous amount to that table, so it's infrared energy radiantly coupling to the baby that's trying to balance all the ways the baby's losing heat.

You know, you hear about very premature babies, some of these extremely low birth weight babies being put in plastic bags. What does a plastic bag do? It, first, reduces the evaporative heat loss tremendously. It reduces a lot of the heat losses, radiantly, convectively. There's no air flow really in the bag. So, the bag, as much as it may seem a little primitive to hear about that, is amazing.

We think about that as we start innovating kind of where we want these microenvironments to go within the golden hour. And thinking about delayed cord clamping. I've had conversations with some of the clinicians about just the delayed cord clamping. When the cord is intact, for instance, for the first, let's say, couple minutes, is the baby gaining heat or losing heat because the cord, you know, the placental blood is still transfusing into the baby.

And the answer is we don't know. And the answer is its controversial and the literature would suggest both ways. It depends on a tremendous number of things from gestational age to perfusion in the cord, to even the heart rate and the blood flow, if you will. And so, we're looking at those kinds of things and how do we get the golden hour to be a smooth thermal sort of transition.

Steve Falk: At the end of the day, the thermals are tremendously important, but airway breathing and circulation is obviously more important, and we don't want to sacrifice one for the other.

Ben Courchia MD: That's great. I mean, as we are getting close to the end of this chat, I'm hearing you speak about all these things, and you can hear a passion behind all these tools and all the development that goes behind it. And you have an impressive resume. I am wondering, you could work in a variety of industries and yet you are here working at GE HealthCare for maternal and newborn health.

What kind of satisfaction does that bring you and what keeps bringing you back to this field day in and day out?

Steve Falk: You know, I get asked that a lot, especially when you're at any place 30-plus years, you get asked a lot. Honestly, it's the babies. It's, you know, you save one life, you save the world, right, so it's the babies. It's the clinicians out there, they're saints, and I just love working with them. It's obviously the team that I work with and in our products, but honestly, it's waking up and saying, you know, how am I putting something, how personally, and our team, how are we making the world better in some way?

And the baby business is such a fantastic business. There's been plenty of opportunities to go elsewhere and I just love it. It's just, it's very personal and it bleeds into your sort of your personal life. And I couldn't think of working anywhere else.

Ben Courchia MD: Yeah, I think it's important for me to ask that question because as clinicians, as frontline healthcare worker, we can sometimes see a company, we can see a logo and think really like a faceless corporation. But I think we should be reminded that behind these tools that we use, there are people that are people that have and that share the same dedication and passion for newborn health. And I think in this day and age to see someone working at a company for over 30 years, it's an outlier. Its people tend to move and seek whatever compensation package is more enticing somewhere else, you know? So, uh, I think, I think it's, it's so refreshing to hear your perspective and, and to hear this dedication, uh, to, to newborn health.

There's a lot of tech and technology is now making the rounds in the news, and it's something that we tend to read about every single day. I am wondering if there are any things coming up on the horizon that you are looking at, and you are just getting super excited about when it comes to the tools that we talked about, when it comes to the care of critically ill newborns.

Steve Falk: Yeah, there's a bunch of technologies out there. I know there is a lot and it sort of goes throughout the whole spectrum. I know you guys have probably seen some of the literature on that's happening at the University of Pennsylvania with the artificial womb, with the lambs?

Ben Courchia MD: Yeah. With the bio bag, I think that is something that had made the rounds in USA Today where they basically put fetal lambs in this, literally looks like a plastic bag full of fluid, but basically creating an artificial womb where they could potentially maintain a fetus for X amount of weeks. And that, I think that was about like a year or two ago, I think, right? Yeah.

Steve Falk: It was, they're still working on it. And I'll tell you, I don't know that I have my opinion of it yet, but is that really the ultimate future? What I love about the fact that they're doing that is that there'll be some amazing technologies we're going to find along the way. And that's what excites me about going, going for the true-blue sky, whether we ever get there or not, whether that's technically going to be acceptable or technically what's going to happen. At the end of the day, with some of these technologies along the way, what are we going to learn about the survival. It's the morbidity and the ability to have a fantastic trajectory of health for these 22, 23, 24 week kids. What we're going to learn from this journey is going to be fantastic and I can't wait.

Ben Courchia MD: That's fun. That's exciting. Steve, thank you. Thank you so much for making the time to be on with us today. I think it was a very enlightening conversation. I think everybody is going to leave this podcast thinking, I never knew that my incubator did all these things. So, I'm sure there's going to be a lot of calls to GE HealthCare to have some rep come and show us around the incubator once again.

And we're very excited about what you guys are going to come up with in the future. I think the dedication you guys have for newborn care and for maternal health is impressive, and I think that's going to translate into more innovative tools. So, thank you for all the work that you do. Thank you.

Steve Falk: Thanks for having me.

Why One Size Feeding System Doesn't Fit All: Implementing Adult Products Into Neonatal Patient Populations

Constance Girgenti, MSN, RN, VA-BC

Introduction

The principle that "one size does not fit all" is particularly relevant in healthcare, especially within the neonatal intensive care unit (NICU). In any one hospital patients can range from as small as 400 grams to 400 pounds, and require medical interventions tailored to their unique needs and size. Adapting adult feeding (AFS) systems for neonatal use exposes this vulnerable patient population to significant risks and adverse events. This paper examines these risks and argues for the necessity of a neonate-specific feeding system (See Chart 1).

Clinical Implications	Neonatal Safety System	Adult Safety System
Specifically designed for the NICU	Yes	No
20+ years of proven safety	Yes	No
Dosing accuracy in the NICU	Yes	No
Cleaning protocol needed	No	Yes
Additional supplies needed for cleaning	No	Yes
Frequent NGT changes	No	Yes
Increase in workflow	No	Yes

Chart 1. Neonatal Feeding System Benefits versus Adult Feeding System

Increased Nursing Workloads and Ineffective Cleaning Protocols

Using an AFS in the NICU significantly increases nursing workloads due to the stringent cleaning protocols required. These protocols are challenging to maintain in a busy NICU. Research indicates that even when adhered to, the feeding tubes often remain contaminated, posing a risk of infection. A recent study demonstrated that bacterial residues on tubes persisted despite cleaning efforts, raising the potential for infections (Lyman et al., 2020). This is particularly alarming in neonatal care, where the vulnerability to diseases such as necrotizing enterocolitis (NEC) is high (Kononova et al., 2022). The correlation between bacterial contamination and the incidence of NEC underscores the urgency of implementing a more accurate feeding system for neonates. The costs associated with cleaning, increased workload, and compromised patient care cannot be overlooked.

Risks of Over and Under Dosing

Dr. Allegaert and Anker emphasize the importance of assessing efficacy and safety to balance the benefits and risks of dose-related adverse events in neonates. These adverse events pose a major challenge, potentially leading to renal, liver, and neurodevelopmental impairment (Allegaert & Anker, 2021). Implementing adult feeding systems in the NICU presents significant risks, particularly concerning dosing accuracy. Despite some manufacturers' claims of no dosing inaccuracies, they have produced low-dose syringes as a solution. Dr. Omara's investigation into the rise of septic workups potentially linked to neonatal overdose reactions highlights the gravity of this issue. Overdoses can cause serious adverse events, with symptoms such as bradycardia and desaturation from medications like morphine or digoxin mimicking sepsis. Misdiagnosis can lead to unnecessary interventions, including nil per os (NPO) status, blood draws, IV insertions, and antibiotic administration, all adding to the stress and trauma experienced by infants (Omara, 2023).

Manufacturer Responses and Regulatory Oversight

Manufacturers have largely dismissed the association between their products and adverse events, yet they have developed low-dose syringes as a solution. The FDA's response highlights potential safety issues with the dose accuracy of ENFit low-dose tip (LDT) syringes, which could lead to overdose if not properly managed. The FDA has requested manufacturers update their labeling and training materials to optimize dose accuracy, emphasizing the need for careful syringe use and proper filling techniques (FDA, 2021). This underscores the need to balance the benefits and risks when using an AFS in the NICU, compared to a safety feeding system specifically designed for this patient population.

Manufacturers Guiding Clinical Practice

Some manufacturers recommend replacing feeding tubes every 3 to 5 days to minimize bacterial growth and eliminate the need for cleaning. This recommendation is outrageous, considering the trauma and stress it imposes on vulnerable neonatal patients. Such a practice is not based on clinical research and primarily benefits the manufacturers by increasing sales (See Chart 2). It is critical to prioritize the well-being of NICU patients, recognizing that they are not simply small adults.

Constance Girgenti, a National Clinical Nurse Educator for VygonUS, is an influential nurse leader renowned for her expertise in NICU care, particularly in advocating for human milk and advancing vascular access. She is a sought-after speaker at conferences worldwide and has authored publications on vascular access. Connie has received prestigious awards, including the AVA 2016 "Impact Award" and the Lasallian Nursing Graduate Award in 2021. She is also a distinguished member of Sigma Global Nursing Excellence.

Frequency of NGT Change	Cost per month (Avg $4.00)	Increase
Every 7 days (4.28 NGTs)	4.28 x $4.00 = $17.12	
Every 5 days (6 NGTs)	6 x $4.00 = $24.00	40.2%
Every 3 days (10 NGTs)	10 x $4.00 = $40.00	133.6%

Chart 2. Cost increase associated with more frequent NGT change recommendation

Implementing a Neonate-Specific Safety Feeding System

To safeguard our patients, we must integrate a neonate-specific safety feeding system in the NICU. Doing so offers numerous benefits:

- **Streamlined Cleaning Protocols:** Reduces the need for extensive cleaning procedures, lowering associated costs and allowing healthcare providers to focus on patient care.
- **Dosing Accuracy and Safety:** Ensures precise and reliable dosing, which is crucial for the delicate physiology of neonatal patients, thereby minimizing the risk of medication errors.
- **Minimized Pain and Trauma:** Reduces the frequency of tube changes, alleviating discomfort and trauma, which is especially important for neonates.

A neonate-specific safety feeding system aligns with the principle of "first, do no harm," prioritizing the unique needs of neonatal patients and enhancing the quality of care they receive.

Conclusion

Using adult safety feeding systems like ENFit in the neonatal patient population poses numerous risks, including increased nursing workloads, ineffective cleaning protocols, dosing inaccuracies, and the recommended frequent NG-tube changes, adding patient stress and discomfort. These risks compromise the health and safety of the patients we care for. Implementing a feeding system specifically designed for neonates, with 20-plus years of safety and efficacy, is essential for safe, accurate, and patient-centric feeding. As healthcare professionals, we must advocate for the safety of our most vulnerable patients.

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Transforming Frontline Healthcare With Family Engagement Technology

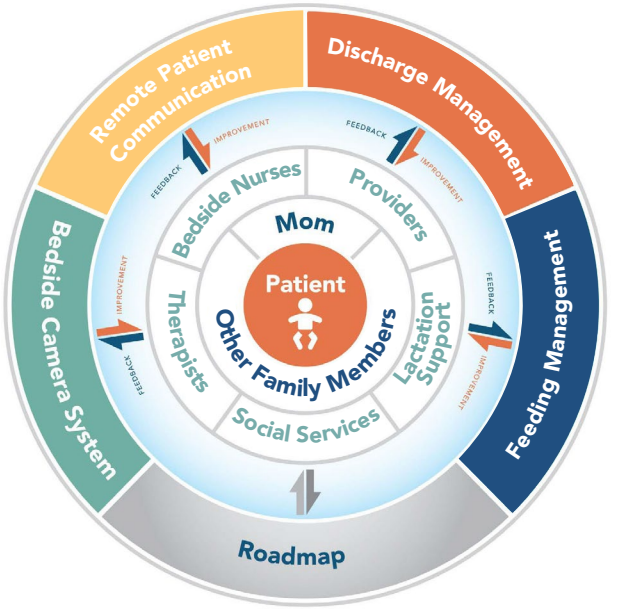
Jaylee Hilliard, MSN, RN, NEA-BC, CPXP and Nicole E Nyberg, MSN, APRN, NNP-BC

The Neonatal Intensive Care Unit (NICU) is a highly specialized area where critically ill newborns and premature babies receive the care they need. In such a setting, nurses face immense challenges, balancing the demanding care routines with the need to communicate effectively with the families of these patients. Emerging and evolving technologies developed for use in the NICU are pivotal in enhancing care and communication. This article will discuss how various technological solutions, from communication and engagement to feeding management and discharge coordination, support NICU nurses, engage families in the care process, and improve patient outcomes.

Enhanced Communication and Family Engagement

NICU cameras and messaging systems support nursing teams by keeping families informed and involved in their baby's care. This type of technology addresses the significant challenge of maintaining family connections when physical presence in the NICU is not possible. Live-streaming video feeds allow parents to view their newborns anytime from anywhere, enhancing emotional bonding and reducing the stress associated with separation.

Bedside cameras with messaging functionality enhance the nursing experience by offering tools that improve communication efficiencies, such as real-time texts, photos, and videos. These features ensure parents receive consistent updates about their child's progress, care plan, and memorable moments. This technology increases parent satisfaction scores for hospitals and streamlines communication, reducing the need for disruptive phone calls. Additionally, the state-of-the-art system provides comprehensive reporting and analytics.



Solutions that Support the Quality of the Nurses' Shift

Overall, NICU cameras with messaging systems are invaluable in supporting nursing teams by improving communication, reducing workload, and enhancing the overall care experience for families and healthcare providers. As technology continues to advance, there are capabilities you'll want to explore with bedside cameras, such as EHR integration to automate camera assignments and support the discharge process, individual family login credentials to improve security, the ability to manage and view multiples with one log-in, a wide range of language translation, and knowledgeable, timely customer support with clinical and IT teams.

Streamlined Feeding Management

The standard of care for bar code scanning and feeding management technology in NICUs and pediatric settings emphasizes safety, accuracy, and efficiency. This approach integrates advanced tools like Milk Scanning & Inventory Management Apps to safeguard against feeding-related errors and optimize nutrition delivery. Here's a breakdown of the core elements you should expect from your solution:

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 Empow-ering 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.

- Prevention of Misadministration: Bar code scanning technology ensures each step of milk and formula management is error-free, significantly reducing the risk of misadministration.
- Accurate Feed Preparation: built-in recipe calculators allow for precise preparation of feeds that may contain both formula and breastmilk, ensuring that infants receive the correct nutrition as prescribed.
- Seamless EHR Integration: The system should integrate smoothly with existing Electronic Health Records (EHR) systems using Biomedical Device Integration (BMDI), facilitating automated data flow and order validation. This integration helps maintain accurate records and supports clinical decision-making.
- Inventory Optimization: The software should provide critical insights into supply levels and expiration dates, helping minimize waste and manage inventory more effectively.
- Adherence to Best Practices: The technology allows you to track mom's own milk, donor milk, and human-milk-derived fortifiers, aligning with best practices in neonatal nutrition.
- Parental Engagement and Education: The software allows parents to receive timely, relevant educational materials and resources electronically, enhancing their understanding of and involvement in their infants' nutritional care.

Real-Time Insights: This solution tracks parents' pumping activities and the volume of milk produced and offers real-time data that can prompt proactive interventions by healthcare providers if issues are detected to improve overall success with the feeding process.

Smooth Transitions from NICU to Home

Navigating the NICU and ensuring effective discharge coordination is crucial for optimizing outcomes and supporting families throughout their NICU stay and transitioning from hospital to home. New technology is emerging that supports this process by offering structured educational content, real-time updates on the baby's condition, and a personalized discharge plan that encompasses the recently developed Interdisciplinary Guidelines and Recommendations for NICU Discharge Preparation and Transition Planning from the National Perinatal Association (NPA). AngelEye Health has partnered with the NPA to distribute these guidelines and has developed tools based on them to support care teams in preparing families for home care. The goal is to streamline the discharge process for care teams while alleviating anxiety about leaving the hospital and maintaining continuity of care for families to reduce the likelihood of readmissions.

Key components that ensure the standard of care in NICU discharge coordination include:

Dynamic Roadmap: Core of Coordinated NICU Care/ The Essence of NICU Coordination

At the heart of AngelEye's solution is the Dynamic Roadmap. This visual guide integrates physiologic milestones and family tasks into a guide from admission through discharge. It empowers parents with a clear understanding of the NICU journey, sets expectations, and promotes better neonatal and familial health outcomes.

Surveys: Tailored Care Through Feedback

Automated, adaptable assessments inform real-time, personalized care adjustments and clinical feedback, ensuring personalized care and education that meets each family's unique needs. This streamlined approach enhances patient outcomes and satisfaction by offering targeted support, social resources, and education, ensuring every family's needs are met.

Education and Resource Delivery/Platform: Streamlining Family Readiness

The solution ensures that families receive essential education and resources tailored to their baby's health journey, readily accessible and seamlessly aligned with their transition to home. This automated delivery system boosts staff efficiency and significantly increases family confidence and discharge readiness, ensuring they feel fully prepared and supported throughout the process.

Flexible Scheduling: Optimizing Clinical Care and Staff Efficiency

This new tool enhances team collaboration and boosts clinical productivity, improving family experiences by enabling precise planning of visits and care activities, such as lactation consultations or breastmilk delivery. This approach ensures that each visit strengthens clinical care and family involvement, optimizing care quality and the family experience.

Secure Messaging: Enhanced NICU Communication

Our secure messaging system empowers families with real-time updates and diverse communication options, such as text, video, and photo, tailored to their preferred language and modality. This fosters a more informed and engaged care experience for families and clinicians, optimizing time and efficiency.

Conclusion

Technology is transforming how care is delivered in the NICU, providing tools that support nurses in their day-to-day tasks, enhance patient care, and improve communication with families. These solutions significantly boost efficiency in the NICU by automating administrative tasks and optimizing care workflows. This increased efficiency allows nurses to dedicate more attention to the direct needs of their patients and less on paperwork.

Solutions from companies like AngelEye Health streamline operations and enhance families' emotional and psychological well-being, making them integral members of the care team. As technology continues to advance, its role in the NICU will undoubtedly grow, further enhancing the capabilities of nurses and improving outcomes for the most vulnerable patients.

Clearing the Air: How to Manage Your Baby's Nasal Congestion

Katie Cabrera

Watching your little one struggle with nasal congestion can be distressing as a parent. Congestion often leads to discomfort and restlessness, affecting both the baby's and the parents' sleep and well-being. Understanding the signs of congestion and knowing how to alleviate it safely can make a significant difference. This article aims to educate parents on identifying early signs of respiratory issues like the common cold or Respiratory Syncytial Virus (RSV) and the safe management of these conditions at home.

Recognizing Signs of Respiratory Distress in Infants

Babies are more susceptible to colds because their immune systems are still developing. Common symptoms include a runny nose, difficulty feeding, irritability, and a distinctive congested sound while breathing. More severe signs, such as those seen with RSV—which often mimics the common cold but can lead to more significant respiratory issues—include wheezing, rapid breathing, and a bluish color around the lips or fingernails. If your baby shows any of these severe symptoms, seeking medical advice is crucial.

The Importance of Mucus Clearance

Effective mucus clearance is vital. A mucus that accumulates in the nose and chest can lead to further complications such as ear infections, throat irritations, and even more severe respiratory conditions like bronchiolitis or pneumonia. Furthermore, a congested baby can have difficulty feeding and sleeping, which can lead to dehydration and weight loss.

Managing Baby Congestion at Home

For day-to-day management of mucus and congestion, here are some parent-friendly tips that can be applied safely at home:

1. **Keep the Air Moist.** Using a cool-mist humidifier in your baby's room helps loosen mucus, allowing for easier breathing. Ensure to clean the humidifier regularly to prevent mold growth.

Figure 1: A. recognizing signs of respiratory distress in infants; B. managing baby congestion at home.

2. **Hydration:** Keeping your baby well-hydrated thins the mucus, making it easier to expel. Breastfeeding or bottle-feeding more frequently can help maintain hydration.
3. **Nasal Saline Drops.** Simple saline drops can moisten nasal passages and help break up thick nasal mucus.
4. **Proper Sleeping Position.** Elevating the head of your baby's crib can help alleviate congestion. This can be done by placing a pillow under the mattress to create a slight angle.

For more info: www.happybreathingsuction.com
email: hello@happybreathingsuction.com

Introducing the Happy Breathing Nasal Aspirator

Here are the features that make it a standout choice for parents:

- **Three Levels of Safe Suction.** The aspirator can be tailored to your baby's needs with adjustable settings, ensuring comfort without irritating their delicate nasal passages.
- **Portable and Cordless Design.** Its compact form makes it easy to use anywhere, whether you're at home or traveling, ensuring you can provide relief for your baby on the go.
- **Ease of Use and Cleaning.** The device is designed for simplicity. Its clear mucus trap allows parents to see the amount and type of mucus being removed, ensuring thorough cleaning and peace of mind.
- **Hygienic.** Constructed from 100% BPA-free materials, the aspirator is safe and easy to sterilize, preventing the risk of contamination.

Parenting is a journey filled with challenges, but with the right

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Katie Cabrera works as a pediatric/neonatal Respiratory Therapist at a children's hospital, and seen countless parents rushing into the emergency room with kids battling RSV, bronchiolitis, pneumonia, and flu. Most of the time, all they needed was suction support to help clear their little one's nasal passages. However, many parents lack the necessary tools or knowledge to perform this vital procedure at home. In 2022, when her 9-month-old baby needed to be hospitalized due to a mucus buildup from RSV, Katie realized just how stressed out these poor parents are, and this is when Happy Breathing was born. Katie hopes to empower parents with a reliable, easy-to-use nasal aspirator.

tools and knowledge, managing common issues like nasal congestion can be less daunting. The Happy Breathing nasal aspirator is an excellent addition to your baby care toolkit, empowering you to manage your child's comfort and health effectively.

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MD, of Corewell Health East, Dearborn, Michigan, and colleagues wrote in a study presented at the annual clinical and scientific meeting of the American College of Obstetricians and Gynecologists. "Identifying and stratifying associated risk factors for failed induction of labor [IOL] may improve counseling and intrapartum care," the researchers wrote in their abstract. The researchers reviewed data from 2172 mothers with diabetes who underwent IOL at a single university medical center between January 2013 and December 2021. They examined a range of maternal characteristics including age, ethnicity, gestational age, medical comorbidities, insulin administration, parity, and health insurance. A total of 567 mothers with diabetes (26.1%) failed IOL and underwent cesarean delivery. Overall, failed IOL was significantly associated with nulliparity (P = .0001), as well as preexisting diabetes compared with gestational diabetes, diabetes control with insulin, maternal essential hypertension, preeclampsia, and polyhydramnios (P = .001 for all). Other factors significantly associated with failed IOL included prenatal diagnosis of fetal growth restriction (P = .008) and placental abnormalities (P = .027).

Human Milk Data Released

Prolacta Bioscience, the world's leading hospital provider of 100% human milk-based nutritional products, announced that data demonstrating the benefits of Prolacta's Exclusive Human Milk Diet (EHMD) for term infants recovering from gastroschisis repair surgery would be presented at the European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) meeting in Milan, Italy, on May 15-18. Gastroschisis is a birth defect in which the intestines, and sometimes other organs, protrude through a hole in the abdominal wall. Infants recovering from gastroschisis repair, especially those with complex disease and comorbidities (e.g., heart or lung disease), require high macronutrient intake for optimal growth.1 Clinicians are increasingly addressing this nutritional need through human milk fortification, which means adding a fortifier to mother's own milk or donor milk to provide additional calories and protein. Until recently, fortification was primarily with cow milk-based fortifiers or formula. These fortifiers have been associated with feeding intolerance and necrotizing enterocolitis (NEC) in preterm infants. The ESPGHAN poster presentation "Human Milk-Based Fortifiers Associated With Improved Growth and Shorter Time to Full Enteral Feeds in Term Infants After Gastroschisis Repair" includes data from a case-control study showing: Term infants who received an EHMD with Prolacta's human milk-based fortifier formulated for term infants achieved full enteral feeds 30 days sooner than infants who received cow milk-based fortifiers or formula (adjusted p = 0.004). The EHMD-fed cohort also experienced higher weight gain velocity (adjusted p = 0.049) and less NEC, with no adverse events reported. "Term infants who require surgery often experience poor growth and significant morbidities when a cow milk-based nutritional fortifier is used," said study lead author Dr Heidi Karpen of the Emory University School of Medicine. "Safe and early postsurgical fortification with an EHMD helps address the specific feeding challenges impacting these infants. It also supports growth and decreases the risk of NEC, which may translate into improved long-term neurodevelopmental outcomes." "This pioneering study for infants with gastroschisis reaffirms the critical importance of optimal nutrition for the growth and health of medically fragile infants," noted Melinda Elliott, MD, FAAP, practicing neonatologist and chief medical

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A New Neonatal BCG Vaccination Pathway in England: A Mixed Methods Evaluation of Its Implementation

Koren Jones, Georgia Chisnall, Tim Crocker-Buque, David Elliman, Jeremy Horwood, Sandra Mounier-Jack, Colin NJ Campbell, Vanessa Saliba and Tracey Chantler

Abstract

Introduction

The introduction of a national evaluation of newborn screening for Severe Combined Immunodeficiency (SCID) in England triggered a change to the selective Bacillus Calmette-Guerin (BCG) vaccination programme delivery pathway, as this live attenuated vaccine is contraindicated in infants with SCID. The neonatal BCG vaccination programme is a targeted programme for infants at increased risk of tuberculosis and used to be offered shortly after birth. Since September 2021 the BCG vaccine is given to eligible infants within 28 days of birth, when the SCID screening outcome is available. We explore the experiences of those implementing the new pathway, and how they made sense of, engaged with, and appraised the change.

Methods

A mixed-methods evaluation was conducted between October 2022 and February 2023. This involved national online surveys with BCG commissioners and providers and qualitative semi-structured interviews with commissioners, providers, and Child Health Information System stakeholders in two urban areas. Survey data was analysed using descriptive statistics and interview data was analysed thematically. The data was triangulated using Normalization Process Theory as a guiding framework.

Results

Survey respondents (n = 65) and qualitative interviewees (n = 16) revealed that making sense of the new pathway was an iterative process. Some expressed a desire for more direction on how to implement the new pathway. The perceived value of the change varied from positive, ambivalent, to concerned. Some felt well-prepared and that improvements to data capture, eligibility screening, and accountably brought by the change were valuable. Others were concerned about the feasibility of the 28-day target, reductions in vaccination coverage, increased resource burden, and the outcome of the SCID evaluation. New collaborations and communities of practice were required to facilitate the change. Three main challenges in implementing the pathway and meeting the 28-day vaccination target were identified: appointment non-attendance; appointment and data systems; and staffing and resourcing. Feedback mechanisms were informal and took place in tandem with implementation.

Conclusion

The new NHS neonatal BCG service specification has created an effective structure for monitoring and managing the BCG vaccination programme, but further work is required to support delivery of the 28-day vaccination target and improve uptake rates.

Introduction

Tuberculosis (TB) is an infectious disease caused by the Mycobacterium tuberculosis complex bacteria and transmitted by the respiratory route.[1] It is a serious infection that primarily affects the lungs but can also affect other organs.[2] TB is the second leading cause of infectious disease mortality globally after COVID-19, despite it being curable and preventable.[2] In 2021, 4,425 people were notified with TB in England and rates remain highest in people born outside of the UK, with social risk factors e.g., homelessness, and from deprived communities.[1] The UK Health Security Agency (UKHSA) and NHS England (NHSE) are committed to meeting the World Health Organisation TB elimination targets through their TB action plan.[3]

The Bacillus Calmette-Guerin (BCG) vaccine was developed in 1921 and remains a vital component of the preventative strategy against TB, alongside intensive treatment and contract tracing. In England, the BCG vaccination programme was introduced in 1953, and was initially offered to 14-year-old adolescents. By the 1960s, the TB burden had shifted to new

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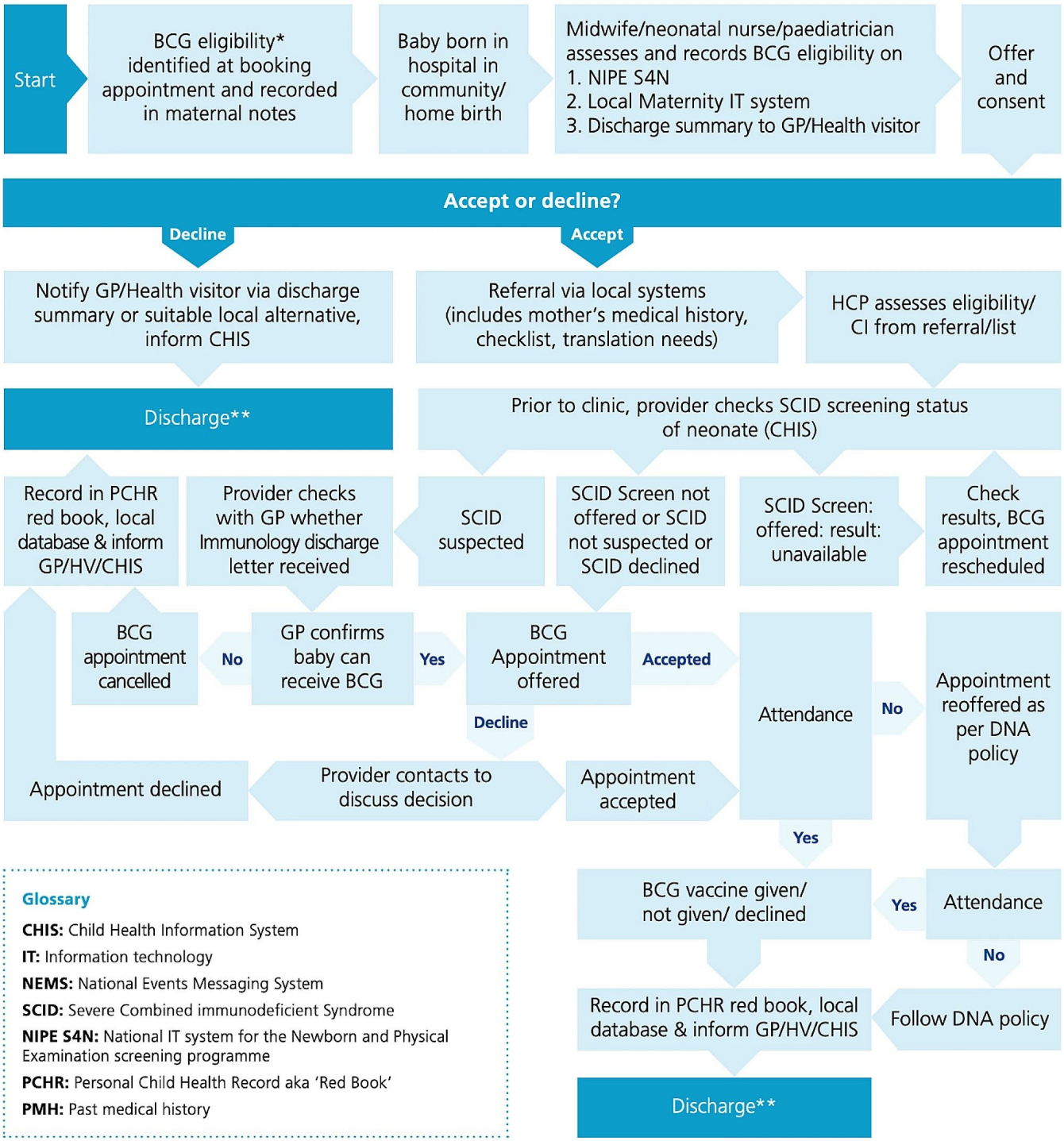
BCG patient flowchart



*BCG eligibility is described in chapter 32 of the Green Book www.gov.uk/government/publications/tuberculosis-the-green-book-chapter-32
**Follow local discharge policies

Figure 1. BCG Patient Flowchart11 Note From UK Health Security Agency (2021).11 Crown copyright 2021. Reprinted with permission

migrants from high-prevalence countries. Recommendations were subsequently made to add a selective neonatal BCG vaccination programme, targeted at individuals based on TB exposure risk. From 2005, the adolescent BCG programme was stopped.[4] The primary component is now the neonatal programme, although BCG is also offered to older children and adults if required.[5] The neonatal BCG immunisation programme aims to protect at-risk infants from the more serious childhood forms of TB[4] and infants eligible for neonatal BCG vaccination include:[6]

BCG neonatal eligibility

- All infants (aged 0 to 12 months) whose parent/s or grandparent/s were born in a country where the annual incidence of TB is 40/100,000 or greater.
- All infants (aged 0 to 12 months) living in areas of England where the annual incidence of TB is 40/100,000 or greater.

In September 2021, the BCG vaccination programme underwent further reform in response to an evaluation of the addition of Severe Combined Immunodeficiency (SCID) to the newborn blood spot test conducted at 5 days of age, as recommended by the UK National Screening Committee (UKNSC).[7] SCID is a rare, inherited condition which results in severely impaired immune system functioning and death within infancy due to infections, if untreated.[8] It is estimated that around 15 to 25 infants are born with SCID each year in the UK, with an incidence rate of around 1 in 40,000.[9] The Joint Committee on Vaccination and Immunisation (JCVI) recognised the dilemma introducing SCID screening had for the timing of BCG vaccination.[7] Because BCG is a live attenuated vaccine, it is contraindicated in infants with SCID due to the elevated risk of serious complications, such as disseminated BCG disease (BCGosis) and death.[10] Hence, the JCVI recommended that BCG vaccination should be moved to 28-days of age, at which point SCID screening results would be available, preventing vaccination of infants with SCID.[6]

This change was implemented in September 2021, and monitoring BCG vaccination uptake among eligible infants at 28 days of age (with a target uptake of 80%) was included as a key aim of England's TB action plan (2021 to 2026).[3] SCID screening was introduced in six evaluation areas (Manchester, Birmingham, Sheffield, Newcastle, London Great Ormond Street Hospital and London Southeast Thames), representing two thirds of infants born in England. To ensure consistency and safety for all infants in England the neonatal BCG vaccination programme was revised nationally, with a holistic shift in delivery of BCG from birth to day 28 (and checking for a SCID screening result) irrespective of whether infants live within SCID evaluation areas.

Table 1 Targeted evaluation participants

Role of participant	Summary of responsibilities
Public Health Commissioners	Public health commissioners fund, plan, agree and monitor services to improve the health and wellbeing of their population e.g., the BCG vaccination programme [16].
Providers	A health care provider is an organisation acting as a direct provider of public health services [17]. Experiences of various BCG vaccination service providers were captured in this study, including NHS trusts, community trusts, maternity services, and specialist TB services.
Child Health Information System (CHIS)	A CHIS is an NHS commissioned service that is responsible for collating data from various organisations for all children aged 0–19 that are either residents or registered with a GP practice in a specified area, into a single Child Health Record [18]. Data is received from various organisations to help with increasing vaccination coverage, supporting the healthy child programme and assisting in the delivery of children's public health services [18].

The decision to move the BCG vaccine offer from birth to day 28 triggered major changes in the commissioning and operational delivery of the NHS neonatal BCG programme. A revised national service specification (S7A) and a new vaccination patient pathway and information resources for health professionals and the public were developed (Figure 1).[11] Prior to the change BCG was commonly delivered in maternity units prior to discharge.[12] BCG is now delivered after a negative SCID result in evaluation areas where the screening is offered or following a SCID screening not offered result in non-evaluation areas, via an outpatient model in the community.[7,12] Concerns were raised that delaying the BCG vaccination could result in more neonatal TB infections and lower BCG vaccine uptake, disproportionately affecting deprived and ethnically diverse populations.[12,13] Pillay et al. (2022) argued that this risk must be limited by effective, sustained, and cohesive working between different NHS sectors. Common barriers to vaccine uptake and strategies to reduce health inequalities were flagged, including language barriers and the need for multilingual, targeted, multi-agency engagement. Other pre-empted challenges included health beliefs regarding proximity to other vaccines in the routine schedule and deferral of vaccination due to mild illness.[13]

The implications of offering both SCID screening and BCG vaccination is an interesting global phenomenon, without a clear consensus. The largest SCID screening programme is in the USA, where the BCG vaccination is not widely used.[14] In countries offering both, the approach has varied significantly. For example, Norway and Taiwan recommend BCG vaccination at six-weeks old and five to eight months old respectively, while Australia and New Zealand have SCID screening and recommend neonatal BCG vaccination without waiting for SCID results.14 The results of the SCID evaluation will determine whether SCID screening will become routinely delivered within England.[13] The UKNSC, together with UKHSA, will consider the impact on the BCG vaccination programme, TB incidence, BCGosis, and the experiences of commissioners and providers. BCG vaccination coverage at 3 months of age increased consistently in England between quarter 1 2022/2023 and quarter 4 2022/2023, (the period where BCG coverage data is available), from 63.4 to 70.4% (+11.0%). Notably, the 80% coverage target has not been met in any quarter, despite coverage being recorded at 3 months instead of 28-days of age.

This evaluation seeks to explore commissioners and providers' experiences of implementing the new pathway, and how they made sense of, engaged with, and appraised the change. This includes the identification of implementation challenges, examples of good practice, and areas for consideration going forward as commissioners and providers strive to increase coverage and meet the 28-day uptake target.

Methods

Evaluation design

This evaluation combined qualitative and quantitative data, in a mixed methods evaluation design to investigate current practice and capture the experience and perspectives of service commissioners and providers (see Table 1). This consisted of qualitative interviews (October 2022-February 2023) in two urban areas where the SCID evaluation was taking place and national questionnaire surveys (November 2022). Initially, the two workstreams were going to produce separate outputs, but once the data was available it was decided that most value could be gleaned from reporting the data in tandem. This enables the evaluation to provide a national overview and rich explanatory accounts.

Survey and qualitative data were analysed separately and subsequently synthesized by applying Normalization Process Theory (NPT) as a guiding framework.[15] NPT is an established theory for exploring the implementation of complex interventions and the integration of new interventions into routine practice. It explores how a change is understood (coherence), how a community of actors coalesce around the change (cognitive participation), put into practice (collective action), and appraised it (reflective monitoring). Strengths and limitations of this evaluation are considered in the discussion.

Qualitative methods

Sampling and recruitment

We selected two urban areas that were part of the SCID screening evaluation for the qualitative component of this study. This means that SCID screening was conducted in these areas and results would be available prior to BCG vaccination. Due to the limited number of people overseeing this change in each area, the interview areas are redacted to uphold the confidentiality of our interview participants. Capturing experience of implementation is critical to understanding what worked well and where modifications relating to aspects of the pathway were required. Site selection was informed by geography, the prevalence of TB in these areas and what types of health organisations (e.g., maternity units, community clinics, CCGs/primary care) were involved in delivering the BCG vaccination programme. Our study sites included commissioners and providers that had to make larger or smaller changes in terms of service delivery to introduce the new BCG pathway.

In each area the study team mapped the provision of BCG vaccination services with the support of commissioners and sent email invites the commissioners and all providers to voluntarily participate in an interview. Potential participants received a study information letter and were given the opportunity to ask questions about the evaluation before deciding to take part. Written informed consent was given by all participants prior to the interviews, which were conducted by LSHTM researchers (TC, TC-B). This workstream was granted ethical approval by the UKHSA Research Support and Governance Office (Ref: NR0328).

Data collection

Interviews followed a topic guide to ensure that interviews covered similar themes, but there was flexibility to ensure participants could talk about things they felt were important. Copies of the topic guides can be found in the additional pdf files supplied [see Additional file 1 and 2]. The interview topic guide was developed using NPT as a guiding theoretical framework. All interviews were conducted virtually (using Microsoft Teams or ZOOM) and were audio recorded; some were transcribed using an automated transcription function (Otter.ai) and some were transcribed by a company that signed a confidentiality agreement. Transcripts were reviewed and cleaned in conjunction with audio recordings. Interview data was collected on encrypted, and password protected audio-devices and computers and stored (in compliance with the 2018 Data Protection Act) in a secure LSHTM data storage folder, that only LSHTM researchers (TC, TC-B, GC) could access via a double authentication process.

Data analysis

Interview transcripts were analysed using the frame-work method, a form of thematic analysis.[19] Frame-work analysis provides a systematic and comprehensive method of drawing conclusions from qualitative data.[20] Framework analysis involves seven core stages:[19] transcription, familiarization, coding, analytical frame-work development, application of the analytical frame-work to the transcripts, charting data into a framework matrix, and interpretation. Codes were built into the analytical framework using NPT theory as a guiding holistic framework (coherence, cognitive participation, collective action, and reflexive monitoring) (GC, TC). While a theoretical framework was used, themes within different components of the framework emerged from the data, hence, the analysis used a blended deductive-inductive approach. The analytical framework was built into NVIVO 12 (a qualitative analysis software produced by Lumivero) and applied to the transcripts (GC, TC) with some segments of text assigned to multiple codes.

Quantitative methods

Sampling and recruitment

The sample for the quantitative component of this study included all NHSE regions (East of England, London, Midlands, North East and Yorkshire, North West, South East, South West), including SCID evaluation and non-SCID evaluation areas. Non-SCID evaluation areas are still required to check for SCID screening results prior to issuing BCG vaccination, even though (unless a family have moved within the baby's first few weeks of life) it may simply be recorded as 'SCID screening not offered'.

This workstream was also granted ethical approval by the UKHSA Research Support and Governance Office (Ref: NR0328). A cover page informed participants of the purpose of the evaluation, that their answers would be confidential, and that the data would be stored in line with the Data Protection Act 2018. No special category data (e.g. race or ethnic origin) was collected in this questionnaire survey. As an online survey, implied consent was deemed appropriate, whereby participants opted into the survey by deciding to complete and submit the form.

Questionnaire design and dissemination

Two online questionnaires were developed to capture experiences of the change and implications for practice nationally (KJ, VS). Copies of the online questionnaires can be found in the additional pdf files supplied [see Additional file 3 and 4]. The questionnaires were designed using SelectSurvey (an online survey software); one for regional BCG commissioners and one for BCG providers and CHIS. Prior to rollout the survey was piloted with Screening and Immunisation colleagues (NHS England). Links to both questionnaires were shared via the NHSE Public Health Commissioning bulletin on the 3rd and 24th

of November 2022. NHSE regional public health commissioning leads or nominated deputies were invited to complete the commissioner questionnaire on behalf of their region and to circulate the provider questionnaire link to all BCG vaccination programme providers in their region. Potential respondents were given 4 weeks to complete the questionnaires.

Data analysis

The questionnaire data were extracted from SelectSurvey on 7th December 2022 for analysis. This data was stored securely in a restricted folder that could only be accessed by UKHSA researchers (KJ, CC, VS) directly involved in the quantitative data analysis. The rating, multiple choice and closed-ended questions were analysed using descriptive statistics. Analysis of the free-text responses was conducted alongside the qualitative data analysis using a form of thematic analysis, as outlined above. Case studies were highlighted, describing examples of good practice.

Results

Evaluation participants

There were 11 commissioner and 54 provider questionnaire survey respondents, with responses to both surveys received from all England NHS regions. Responses were received from providers covering 93/153 local authorities in England, including both SCID and non-SCID evaluation areas. Most providers (96%) had been commissioned to deliver the BCG vaccination programme prior to the change implemented in September 2021. We conducted 11 semi-structured interviews with 16 interview participants from the 2 urban study areas. Interview participants included 8 providers, 5 commissioners and 3 CHIS managers. Data was triangulated across both data sources, the full survey reports for commissioners and providers can be found in Additional files 5 and 6.

Commissioner roles were most often described by participants as 'Screening and Immunisation Manager', other variations included 'Screening and Immunisation Lead' or 'Screening and Immunisation Coordinator'. Providers across the implementation chain were represented, from immunisation nurses through to clinic managers. Provider roles included 'BCG Immunisation Nurse' or 'TB Specialist Nurse' through to 'BCG Immunisation Team Lead', 'BCG Coordinator', and 'Immunisation Service Manager'. CHIS referred to themselves as 'CHIS manager' or 'CHIS project coordinator'.

Coherence (making sense of the change)

Making sense of the new pathway was widely reported as an iterative or reactive process. This sentiment was identified in both the qualitative and quantitative work-streams. In part, this may be attributable to the fact that the BCG pathway was introduced in September 2021 during the COVID-19 pandemic, with 64% of commissioners reporting that this impacted their ability to prepare for the change. Beyond the pandemic, the process was iterative due to trialing different ways of putting the pathway into practice and the emerging scale of the change:

> *…the change to accommodate SCID screening sounds in theory like a very straightforward process, but actually very quickly we understood that it had massive implications right the way through from midwives, screening link midwives, CHIS, the lab, BCG providers, primary care going forward, the patients, the families. It was enormous…(Commissioner)*

> *…a lot of learning on the job, a lot of going back and sitting back, going oh, we haven't thought about that… (Commissioner)*

There was a wide range of experiences when it came to deciding how to implement the new pathway across all participant groups (providers, commissioners, and CHIS), some felt well supported, whilst many expressed the need for more direction on how to implement centralised guidance locally. Survey respondents cited late publication of guidance and a short implementation period as contributing factors.

> *Well, it was relatively quite straightforward, really, which is unusual for us because it's usually lastminute. com with programme changes. (CHIS)*

> *...fraught few months to be honest with you. (CHIS)*

> *And there was a lot of awful lot of stuff that we were looking for guidance for and they were very much saying that's a local decision you need to decide which was really difficult when it was like containing sand at one point it was so difficult. Anyway, we did it so that was fantastic. That was a great outcome. (Commissioner)*

> *…a bit more directional information, but that never came basically. And you just have to get on with it, you know, do what you can do. (Provider)*

Some felt that the diffusion of responsibility to local regions, while well intended, made the pathway implementation challenging. Some reported that more applied guidance and clearer designation of responsibility would have made the implementation process easier and less stressful. This was particularly true given the scale of the change being implemented and its far-reaching impacts across the delivery pathway. Both interview and survey respondents cited that the provision of national BCG training would be welcomed.

From interview data, it could be deduced that people's relationship with the iterative nature of the sense-making process seemed to depend on whether they felt the issue should have been foreseen or whether such occurrences are unavoidable: "*Which was not necessarily something that anybody could have anticipated. And we did try to anticipate most things and I thought it was relatively seamless. I think I can say with some confidence now, but at the time we didn't feel it was just a bit trepidatious… sometimes you don't realize where it's going wrong till it's gone wrong and then you can fix it.*" (Commissioner).

The extent to which people perceived the benefits and importance of the change ranged from positive, ambivalent (or neutral), through to concerned. Those who were positive about the BCG pathway change felt that they knew about the change for a long time: "*We were pre-warned we were expecting it.*" (Provider). Improved data capture, accountability, and more robust eligibility screening for the BCG programme was consistently reported as the primary benefit in both data work-streams, particularly as BCG eligibility and coverage is now captured as part of the national COVER dataset: "*I think there*

being a bigger spotlight on it now probably means that it's more robust in terms of delivery. So maybe we've got more accountability for the babies now…when I first qualified as a midwife, I worked somewhere that we had a universal offer, so we used to catch all our babies on the way out of the wards, but if you missed them, they were gone." (Commissioner).

Some commissioners reported that staff were ambivalent towards the new pathway, and that this posed a challenge in enlisting support for the programme change. Conversely, strong leadership from commissioners and good engagement from providers was cited as a defining feature in successfully implementing the new programme. Those who were concerned about the new pathway consistently discussed one of four things, all of which are supported by both data workstreams. Firstly, the feasibility of the 28-day target (and its rationale):

> *I personally feel the 28 days is not necessarily achievable to level of of 80% which is being asked. I think 3 months or 2 months would be a better target. (Commissioner)*

> *…I understand why obviously it has gone from being delivered pretty much straight after birth, to how can we fit SCID in and still give it as early as possible… although there is a national task and finish group for BCG and one of the other regions asked for a rationale on the 28-day target and we are still waiting for that to come back… (Commissioner)*

Secondly, increased Did Not Attend (DNA) rates. Protecting vulnerable infants through SCID screening was not frequently mentioned as a benefit of the BCG programme change, despite it being the reason for the change. There was concern about the impact of the programme on vaccination coverage and in a minority of interviews there was explicit skepticism over whether the trade-off between SCID screening and increased DNA was a worthwhile trade-off: "*Honestly. Go back, go back to, go back to a universal offer. But in maternity unit. I think you'll pick more babies up."* (Commissioner).

Thirdly, resource pressures. When asked about the impact of the new pathway, many referred to the additional strain placed on staffing and resources. Many felt that this was an unintended consequence which had not been considered during the conceptualisation of the pathway change: "*And I think it is fair to say and I know the national team have commented this also that that the change to accommodate SCID screening sounds in theory like a very straightforward process, but actually very quickly we understood that it had massive implications and change right the way through from midwives, screening link midwives, CHIS, the lab, BCG providers, primary care going forward, the patients, the families. It was enormous…"* (Commissioner).

Fourthly, the changes being driven by the SCID evaluation with no guarantee that the changes would be permanent: "*It's still a pilot. So, if and where obviously a pilot area, but if they come back nationally and say. Actually, if the pilot of SCID not works and you need to go back to a previous model. What happens then*?" (Commissioner). This was particularly poignant for those who were also not part of the SCID pilot.

Cognitive participation (creating a community of practice)

New communities of practice were needed to implement the pathway change. This required new collaborations between vaccination and screening teams due to the newfound interdependence of their programmes. The value of these new working relationships and communication channels were identified by both workstreams. There is no other vaccination programme which is interdependent on another programme (i.e., screening) run by different teams that requires the timely publication and access to dataflows in real time.

Initially, it took some encouragement to enroll people into this new community of practice and articulate the need for them to be involved: *"I think the worst we ever experienced from any of our providers was more kind of a lack of engagement rather than any resistance or reluctance…and probably not quite fully understanding how that would impact them particularly… perhaps providers that we had to spend a little bit more time with to encourage them to be part of that full effort…we probably started those multidisciplinary stakeholder meeting around May and I think we continued them through until about March, April of this year."* (Commissioner).

This new community of practice was credited as a positive outcome of the change, with all actors involved gaining greater understanding and appreciation of the roles played by one another: "*…a positive that came out of this was that stakeholders who previously maybe worked quite in isolation, having everybody together in one place, it does give you appreciation of how important everybody's roles are and particularly CHIS I think that previously the importance of child health holding all information in one place maybe had been underestimated, whereas it became apparent that they were linchpin. Really, that the whole thing would fall apart if it wasn't for CHIS."* (Commissioner).

Collective action (putting the change into practice)

Several challenges and solutions were identified with the implementation and delivery of the new BCG vaccination pathway which are outlined below. Identified challenges and solutions were consistent across the interview and survey workstreams. Commissioners rated the implementation of the change on a five-point scale between 'poor' and 'excellent'. The ratings were good (n = 5, 45%), neutral (n = 3, 27%) and fair (n = 3, 27%), with no commissioners rating the implementation either poor or excellent. All commissioners (100%, n = 11) reported implementation challenges, whilst 73% (n = 7) noted implementation benefits.

Some commissioners reported that the COVID-19 pandemic impacted implementation (45%) and programme delivery (45%) due to staff illness, clinic cancellations and families cancelling BCG vaccination appointments due to illness or COVID-19 anxiety. Commissioners noted that this could have resulted in lower vaccination uptake, delays to vaccination, and the creation or increase of backlogs. Many felt that backlogs associated with the time taken to imbed the new system were posing a challenge in meeting current targets:

> *But for the future, our future planning for neonatal BCG, our ambition is to get 80% uptake or more up four weeks. So, we've got work to do around backlogs and management of clinics. (Commissioner)*

> *…there was a backlog in [site name redacted] of over 450 babies... (Provider)*

There was consensus in the survey and interview responses that meeting the 28-day vaccination target was the primary challenge in delivering the new BCG vaccination pathway. Commissioners were asked to quantify how many BCG vaccinations had been delivered at or before 28-days in the first ten months of the new pathway (01/09/2021–30/06/2022). Low adherence to the target was reported, with 20% (n = 2) reporting < 20%, 30% (n = 3) reporting between 20% and 39%, and 50% (n = 5) reporting between 40% and 59%, whilst one commissioner did not provide a response. Three key challenges in implementing the new pathway and meeting the 28-day target were identified which are outlined below.

Vaccination uptake

DNA rates posed a significant challenge in meeting the 28-day target for most providers. The appointment DNA rates reported by providers varied, with 48% reporting DNA rates of less than 20%, whilst 52% reported DNA rates between 20% and 59%. Many felt that this challenge had been "*underestimated*" (Commissioner) and that this was inherently (but not exclusively) associated with moving from a bedside to a community-based model of delivery: "*…it's easier with a captive audience, isn't it? If they're already in hospital you give them the vaccine and then they go home, but it's trying to get them to come back again at a later date…"* (CHIS).

Many were unclear about the reasons for DNAs and how to best address meeting the 28-day target. When asked how DNA rates could be improved responses included "*not sure*" (provider) and "*no idea*" (Provider). Many referred hesitantly to parental decision-making and cultural norms but acknowledged that active refusal was "*…few and far between*" (Provider). There was a shared understanding that there is "*still work to be done between [CHIS] and providers to understand why the figures don't look better."* (CHIS).

Others drew on their individual experiences of delivering the BCG programme to share potential reasons for DNA's. Challenges such as English literacy and demographic related health inequalities were reported in both data workstreams, although they acknowledged that these affect all vaccine programmes and not just BCG. Approximately half of provider survey respondents who gave details on their provision of additional information (52%, n = 16) reported that beyond the translation of centrally provided flyers no bespoke language support was offered. 74% Providers felt that improved vaccine education and literacy around the BCG programme was needed, particularly considering the programme change: "*Well actually, did they not inform you we actually have to wait for your SCID results. Oh, SCID results. What's that? And we have to have that conversation."* (Provider).

Providers who were interviewed reported that parents were often concerned by the proximity of the BCG vaccination to the 8-week vaccination schedule and were surprised that the vaccine used to be given at birth. When given the choice parents may defer vaccination until a child is a bit older: "*…we do try to explain that it was given on the day of birth before in the maternity wards, which parents are always shocked by, but if they've got a choice in the matter, which indeed they do, then they would rather wait.*" (Provider). Similarly, survey respondents suggested that parents may want more time to consider the vaccination.

Clinic accessibility was another challenge reported in the interviews and survey responses that may be contributing to DNA rates. At the time of survey completion (November 2022), 44% of providers (n = 24) reported that they had not completed an accessibility assessment. Daytime clinics were the most common, with 76% of providers (n = 41) offering daytime only clinics, with no weekend or evening clinic provision. Travel distance was also highlighted, with 57% of providers (n = 31) reporting a maximum travel distance of at least 10 miles, which was particularly challenging for families reliant on public transport.

There were several examples of good practice from both workstreams to overcome this challenge, including ensuring that BCG vaccination clinic timings were convenient for families, heat mapping where families live to select clinic locations, and offering parents flexibility in their choice of clinic location and appointment timings. Other examples of good practice included: phoning parents and ensuring allocated appointments were acceptable, rescheduling unsuitable appointments prior to DNA occurring, and sending text reminders in the primary language of the recipient. One CHIS provider expressed interest in alerting GPs to unvaccinated infants who could be signposted back to the BCG service.

Appointments and data systems

Developing appointment and data systems to meet the 28-day target was challenging. Implementing the new BCG vaccination pathway required additional eligibility screening and referral processes, involving multiple stakeholders, which took time to embed. Setting up data systems between CHIS and providers was initially challenging with delays in receiving results or BCG eligibility not being completed on the computer system (S4N). Some providers noted that systems had been developed to overcome this: "*I say it was difficult trying to get the SCID result in setup, but we've conquered that now.*" (Provider). Survey respondents felt there was a need to improve recording of BCG eligibility recording on S4N, suggestions included making it a mandatory field or revising the national template to make it easier to complete.

Some providers reported that when SCID results had not been shared by CHIS providers they were able to use alternative data systems to access the results directly, although this caused additional administrative burden. Both workstreams identified that the data systems struggle to monitor infants who have moved in/out of area, and this is an ongoing area which is being addressed: "*I still think we've got some work to do around the movement in pathway.*" (CHIS). One example of good practice was GPs and health visitors acting as a failsafe for infants who were not referred for BCG or those who had three DNAs and had been discharged. The survey workstream also suggested that the new pathway had promoted better knowledge regarding the programme and BCG eligibility, but that there were still issues with eligible infants not being referred or inappropriate referrals.

The small window available to book in and vaccinate infants between the availability of the SCID result and the 28-day target was considered challenging by some providers: "*…to try and meet that 28-day but currently it's really difficult because if we have to wait for the SCID result, that's 21-days. It doesn't give*

us enough time to book an appointment well in advance…" (Provider).

Although, survey data reported that most providers (74%) were booking the vaccination appointment at referral, ahead of the SCID result becoming available. Providers who used this appointment booking system reported that it was a suitable approach, and that "*nine times out of ten*" (Provider) the results would be available ahead of the scheduled appointment.

Staffing and resourcing

Staffing and resourcing were another challenge in meeting the 28-day target. Many felt this was an unintended consequence not fully considered during conceptualization of the pathway change. This was widely attributed to the changes to appointment and data systems, which resulted in a sizable administration burden including searching and screening SCID results, appointment booking, reminders, recall and data input: "*…making sure the letters and the paperwork and are getting done every week. And as I say, whereas I didn't have to do that before…It's a lot more work involved now than what it was.*" (Provider). The additional administrative burden often fell on BCG vaccinators, and many services were already short staffed: "*You're the band 6. All you should be doing is vaccinating the baby. And you think that doesn't work with that, you know, because there's a lot of work involved in it."(Provider).* However, this experience varied between providers, exemplified by the number of BCG vaccine appointment reminders; 22% sent no reminders, whilst 33% sent one reminder, 30% sent two reminders, and 15% sent three or more reminders.

Consequently, many programmes have built capacity across several roles (e.g., administrative staff, coordinators, and vaccinators) to deliver the new pathway. Those who have been able to expand capacity cited how this was fundamental in delivering the pathway. Expanding the capacity for BCG vaccinators is particularly challenging given the shortage of qualified staff and the additional training requirements needed to deliver BCG: "*…to get a BCG nurse trained and up to speed and have to deliver this program you're looking at three months minimum. It's just so difficult to find trained nurses to deliver this program and to the level it needs to be delivered at.*" (Commissioner).

Beyond staffing, other resource constraints included securing an appropriate clinic location and funding: "*Yeah, and funding. I think trying to deliver a BCG program on potentially £15.00 for an urgent service is not even close to the bar really, and there needs to be some specific amount of funding to deliver these programs.*" (Commissioner). Examples of good practice included the introduction of a new contract in one region which facilitated 'blocked' rather than 'per item' payment and building sustainable implementation pathways using a combination of staff groups.

Reflective monitoring

From the start, the implementation of the new BCG pathway was an integrative and reflexive process as reported within the coherence building section. Consequently, the process of reflexive monitoring was very much embedded within, and acting in tandem to, the sense-making and implementation process whereby several refinements were made early on (e.g., how SCID results were accessed, when BCG vaccination appointments were being booked). These appraisal and feedback mechanisms were widely informal taking the form of candid conversations and team meetings among the devised communities of practice. None of the commissioners who undertook the survey reported conducting evaluations of the case studies they presented.

> *Consulting with every stakeholder at that point so that they could raise what progress they've made, what challenges they've got and that we could try and work our way through it… (Commissioner)*

We were meeting with everybody who was involved in this. So, the lab and CHIS and maternity and you know, BCG providers really regularly and trying to just keep up to date with making sure that everybody receives the information as it as it was coming through… (Commissioner)

Discussion

This study explored commissioners, CHIS, and providers' experiences of implementing the recent change to the BCG vaccination pathway. Through using NPT, we were able to explore how staff made sense of the change, formed a community of practice, delivered the operational work needed to implement the new pathway (with a focus on implementation challenges and examples of good practice), and understood the appraisal work going into reconfiguring implementation. Here we re-visit the central findings and compare them with the potential challenges and opportunities raised within opinion pieces published ahead of the change. Where appropriate, we also situate our findings within wider literature. At the end of the discussion, we present key areas of consideration for policy stemming from the findings of this study.

Contextually, it is important to note that this change was implemented during the COVID-19 pandemic (September 2021) which impacted commissioners' ability to prepare for and implement the change alongside ongoing service delivery. This was predominantly due to staff and patient illness, COVID-19 anxiety, and appointment cancellations, all of which have been reported as wider barriers to healthcare delivery during the COVID-19 pandemic.[21] The challenge of implementing a complex programme change at a time of constrained resource had implications for BCG vaccination uptake and timeliness of vaccination, a phenomenon which has been reflected in other childhood vaccination programmes globally.[22] BCG vaccination backlogs created while the new program was implemented (whether this be due to COVID-19 disruption or time taken to bed in the new system) continue to drain staff resources and skew performance ratings, despite significant improvements in the implementation of the new pathway. It is difficult to fairly assess the performance of the BCG vaccination service until these backlogs have been cleared and resources are fully allocated to providing a prospective service. While it is important to acknowledge the contextual challenges posed by the COVID-19 pandemic and service backlogs this does not diminish the wider challenges identified with the implementation of the new pathway, or the opportunity posed for programme learning and adaption going forward.

This evaluation identified three core challenges in meeting the 28-day target: DNA rates; data and appointment systems; and staffing and resourcing. DNA was consistently reported as one of the most significant challenges in meeting the 28-day target and was a concern raised within several publications ahead of the programme change.[12,13] Academic and NHS Trust

colleagues voiced a need to proactively cater for general barriers to vaccination such as language barriers and advocated for the use of tailored, multi-agency interventions.[13] They also noted the risk of negative health beliefs regarding the proximity of BCG vaccination to other vaccines given as part of the routine programme at 8-weeks of age.

Despite these concerns, commissioners and providers within this study voiced that the challenge of DNA had been "underestimated," and the loss of a captive audience was having implications on vaccination uptake. There was a shared understanding that more work was needed to better understand and respond to poor vaccine uptake, although many felt active vaccine refusal was unlikely to be the primary reason; reflecting the findings of several studies which have found refusal of childhood vaccinations to be uncommon within the UK.[23-26] Instead, there is growing need to better understand DNA as a separate phenomenon to vaccine refusal.[23]

Pillay et al.'s concern regarding health education and the need to address the proximity of other routine vaccinations[13] was also a finding of this study, however further communication regarding SCID, and the recent programme change were recommended. Study participants shared the view of Pillay et al. that English literacy and other health inequalities were likely barriers.[13] Given this, it is concerning that at the point of data collection most providers offered limited appointment times, clinic locations, and limited additional language support. Furthermore, 44% of providers reported that they had not yet completed their accessibility assessment. We recommend that all providers complete outstanding accessibility assessments and implement additional, tailored provision where necessary. Due to the selective nature of BCG, the impact of this pathway change disproportionately falls on those from deprived and ethnically diverse populations.[12] Hence, it is particularly important that service accessibility is addressed. Vaccine service-related provision (i.e., number of reminder letters, appointment availability, provision of educational material, etc.) varies considerably within the routine vaccine programme.[23] It is essential that service delivery differences do not result in geographical variation in the quality or quantity of the intervention. Targeted action and interventions aimed at improving vaccine uptake have been limited within the wider routine immunisation schedule.[23] We share Crocker-Buque et al.'s recommendation that additional support is needed to implement strategies to reduce inequalities.[23]

This is not to say that there were not a number of providers going to great lengths to improve DNA rates through offering appropriate clinic times, locations, parent communication, re-booking, and reminder systems. Furthermore, these findings need to be heavily considered in conjunction with the challenge posed by staffing and resourcing. Some commissioners extended team capacity by contracting additional vaccinators and administrative staff to facilitate delivery of the new pathway. However, this was not universally available due to limited funding and availability of BCG trained immunisers or appropriate vaccination clinic venues. Without the option of expanding team capacity absorbing the sizable administration burden (e.g., appointment booking, reminders, recall) associated with the new pathway was challenging and sometimes fell on the BGC vaccinators themselves.

Pillay et al. cited concerns about additional NHS workload, focused on laboratory processes.[13] Our findings go beyond this to identify the additional staffing and resourcing requirements to deliver the programme effectively. Ongoing monitoring and evaluation of this challenge is required, with adaptations made accordingly. While administration burden associated with the BCG vaccine has increased, this is common across other vaccination programmes. Crocker-Buque et al. found that almost two-thirds (59.7%) of time associated with delivery of the routine immunisation programme was spent on administrative tasks with significant variation on where this burden was felt dependent on the model of delivery; some models placing greater strain on clinical (as opposed to non-clinical) staff.[23]

Understanding and implementing new appointments and data systems was initially challenging; some issues have since been resolved while others are ongoing. Notably, some providers (26%) were waiting for SCID results prior to scheduling BCG appointments, which introduces unnecessary delays.[27] Additionally, most providers were still struggling with identification and fail-safe provision for infants moving in or out of the area. The survey finding regarding eligible infants not being referred and inappropriate referrals warrants further investigation.

Making sense of the new pathway and putting the specification into practice was challenging, some felt that there could have been stronger provision of centralised guidance on how to implement the change while still devolving power and autonomy to local stakeholders. This was associated with variations in how the programme change was implemented. Variation in the implementation of vaccination programmes because of iterative, local interpretation and tailoring is a finding shared with another process evaluation conducted by Crocker-Buque et al.[23] Management factors, such as leadership, performance management, and stress are all known to affect programme effectiveness.[28]

Innovative and varied solutions were developed in response to challenges, and consequently some challenges identified following the programme change were reported to have been resolved. Information sharing and localized, self-driven standardization was essential, although the mechanisms for this were often informally driven. The importance of collaboration and effective cross-system working was highlighted ahead of the change,[13] and this was reflected in our findings with the formation of new communities of practice. This is particularly interesting here, due to the new interdependence between the vaccination and screening programme teams. Enrolling people into the new communities of practice required encouragement by articulating how the incoming change was relevant to them. Fostering these communities of practice and sharing learning could enable challenges to be overcome on a larger scale and contribute to the effective development of the programme going forward. The tension between providing centralised procedures and local autonomy has been observed in the literature before; comparing localised models of delivery to enable comparison and adoption of efficient pathways has been one suggestion.[23]

Participant's sentiment towards iterative programme implementation learning centered on whether they perceived this as part of putting a change into practice or a lack of foresight and appropriate planning. Those who felt positively

about the new pathway reported the value of improved data capture and accountability. Comparatively, those who were concerned about the change commented on the feasibility of the 28-day target, increased DNA rates, resource pressures, and the lack of certainty that the change would be permanent. Notably, the protection of vulnerable infants through SCID screening was not frequently mentioned as a benefit, despite this being the reason for the change. Ambivalence was also challenging, as commissioners needed providers engagement to implement the change. The use of NPT to capture the contextual workplace culture towards the proposed BCG pathway change takes a first step in this under researched area.[23]

It is common that programme implementation becomes less strategic and more sporadic over time.[23] Further cross-system collaboration is needed to improve the implementation of the new BCG pathway in line with the findings of this evaluation and ensure ongoing strategic oversight, particularly in relation to quality improvement cycles and addressing inequalities in BCG coverage.

To summarise, as indicated by the findings of this study, key areas of consideration for policy and practice are as follows

1. The need to address DNA rates with tailored interventions;
2. the shortfall in staffing and resources needed to absorb the increased administrative burden;
3. the adoption of streamlined appointment systems (i.e., booking appointments preemptively in advance of SCID results);
4. the need for improved failsafe strategies to identify infants who were eligible for BCG but have not received vaccination (particularly for infants moving in/out of area);
5. the reticence/ambivalence of some staff towards the change;
    a. by responding to the four concerns identified (the feasibility/rationale of the 28-day target; DNA rates; resourcing; and service change permanence);
    b. by leveraging/celebrating the value of the new pathway for BCG delivery (improved data capture, accountability, and eligibility identification) but also strengthening the narrative around the duty of care to protect infants with SCID.

Strengths and limitations

A strength of this study was the mixed methods approach, where the survey data provided an overview, and the qualitative data provided an in-depth examination of how the change was implemented and experienced. While we acknowledge that the synergy between the survey and qualitative data may have been better were this conceptualised as a mixed methods study from the offset, using NPT as a framework was an appropriate approach to triangulating the data from these two workstreams.

We would also like to acknowledge the interpretive nature of NPT, which is defined as a flexible and dynamic framework, providing areas of inspiration while allowing scope for concepts to emerge from the data.[29] As a result, certain domains of the theory are more strongly represented than others keeping true to the original data while using the theory to stimulate analytical insights. It is posited by the creators that findings may not fit neatly within the parameters of the theory, as is the case with any framework; in this analysis due to the iterative nature of coherence building, it was difficult to distinguish and separately report reflexive monitoring as in reality these factors were operating in tandem. This does not represent a weakness of the analysis, but an empirical finding in its own right.

Several limitations were identified. The surveys and interviews were conducted approximately one year after the change, and therefore captured views and experiences of the programme at a particular snapshot in time. There were not enough interviews to compare responses across commissioners, providers and CHIS', but it is a strength that views from these stakeholder groups were captured. The provider and commissioner surveys focused on distinct aspects of the change, so responses cannot be compared between these groups.

It should be noted that where potential reasons for DNA are explored in this manuscript, this is based on the interpretations and beliefs of healthcare workers rather than directly from parents themselves. Further work is planned to capture parent perspectives, understand inequalities in BCG vaccination coverage, and investigate the impact of the change on TB and BCGosis cases. Similarly, while many participants expressed a need for greater guidance on implementation and 26% were using sub-optimal booking systems, we are unable to deduce whether this was due to an absence of guidance or gaps in communication and knowledge brokering. Nonetheless, our findings illustrate the need to either produce further guidance or improve the dissemination of preexisting resources.

Conclusion

The new BCG pathway has created an effective structure for monitoring and managing the BCG vaccination programme, but further work is required to support delivery of the 28-day target and improve uptake rates. The discussion provides insights for policy and practice, which could address challenging implications of the new pathway and ongoing tensions between national guidance versus local autonomy. Any ongoing risk of delaying

BCG vaccination for SCID screening could be heavily mitigated by optimizing the implementation of the programme change. These findings are relevant to England and other countries which currently (or may go onto) deliver a BCG vaccination programme alongside SCID screening.

This study contributes to our growing understanding of the implementation of vaccination programmes within England. Efforts should be made to celebrate reform and promote a tolerant attitude towards service development. This requires a compromise between commissioners and service providers. A willingness from commissioners to proactively explore unintended implications of programme changes and provide appropriate guidance, alongside a willingness from providers to work iteratively within their locality where challenges could not be foreseen. When implementing new national vaccination pathways, stakeholder collaboration is essential for addressing challenges, harnessing benefits and sharing learning.

Author contributions

Conceptualization: all authors (CC, DE, GC, JH, KJ, SMJ, TCB, TC, VS). Methodology: GC, KJ, TC, VS. Data curation: GC, KJ, TC, TCB. Formal analysis: GC, KJ, TC. Writing - original draft: GC, KJ, TC. Writing - review & editing: all authors (CC, DE, GC, JH, KJ, SMJ, TCB, TC, VS).

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Data availability
The datasets generated and/or analysed during the current study are not publicly available due to their containing information that could compromise the privacy of research participants but are available from the corresponding author on reasonable request.

Declarations
Ethics approval and consent to participate
Ethics approval was granted by the UKHSA Research Support and Governance Office (Ref: NR0328). Participants in both the interview and online survey workstream were informed of the purpose of the evaluation, their right to confidentiality, and that any data would be appropriately handled. Written consent was obtained for the interview workstream, while implied consent was deemed appropriate for the online survey vis-à-vis the completion and submission of the online form. A data protection impact assessment was completed with the support of the LSHTM data protection office and agreed by LSHTM and UKHSA researchers to ensure that this evaluation adhered to the 2018 Data Protection Act.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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Incidental Finding of Thyroglossal Duct Cyst in a Neonate During Endotracheal Intubation: A Case Report

Emanuele Trovalusci, Carlo Pizzolon, Silvia Tesser, Stefano Doratiotto, Dalia Gobbi and Paola Midrio

Abstract

Background

Thyroglossal Duct Cyst (TDC) is a common lesion of the midline neck, originating from an incomplete involution of the thyroglossal duct. It is typically observed in pre-scholar patients and surgery is the treatment of choice to prevent infections. Here reported a case of incidental diagnosis in a newborn patient.

Case presentation

A 3-week-old male baby was admitted to our hospital for weight loss and projectile vomits after breastfeeding. After a diagnosis of hypertrophic pyloric stenosis, the baby underwent pyloromyotomy. During the endotracheal tube placement, the anesthetist noticed the presence of a midline neck mass. The suspect of TDC was confirmed by an intraoperative ultrasound, so, despite the age of the patient, we proceeded with the excision of the lesion according to Sistrunk's procedure to avoid future complications and anesthesia.

Conclusions

Even if TDC is a common lesion of pediatric patients, anecdotical neonatal cases were described in the literature, all of them symptomatic. An accurate physical examination and ultrasound are essential diagnostic tools to distinguish TDC from other middle neck lesions, particularly ectopic thyroidal tissue. Sistrunk's procedure is the most effective surgical approach. When diagnosis is made in a newborn, we suggest postponing surgery, unless the baby requires general anesthesia for other surgical procedures, such as in our case.

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Background

Thyroglossal Duct Cyst (TDC) is the most common congenital lesion of the midline neck, affecting about 7% of the population. It is the result of an incomplete involution of the thyroglossal duct and, therefore, it can be found anywhere along the thyroid's path of migration, from the foramen caecum to the sternal region.[1]

TDC typically appears as an asymptomatic and circumscribed mass in the hyoid bone region filled with mucinous fluid, smooth and non-tender at the physical examination. Due to the continuity with the tongue, the cyst can get infected by oral bacteria. It may evolve into an abscess and eventually to intermittent drainage through a fistula opening on the skin or in the throat.[2]

TDC is usually diagnosed in preschool-aged children, but it can be observed also in adult life, with a slight predominance for male patients.[3] A few cases of TDC in patients under 1 year of age are described in the literature, but there are no cases of accidental findings reported in newborns. Our experience with an incidental finding of TDC in a 3-week-old patient is hereby described.

Case Presentation

This was a male baby born at 40 weeks of gestational age by caesarian section after a failed labor induction, weighing 3450 g. Fetal ultrasonography (US) revealed left renal pelvis dilatation and borderline cerebral ventriculomegaly, but the baby was completely asymptomatic and discharged after birth. An US performed two weeks later confirmed the diagnosis of left hydronephrosis (IV grade), and dilatation of cerebral ventricles at the upper limit of normal ranges.

At 21 days of life the patient was taken to the emergency room for recurrent projectile vomits after each breastfeed and weight loss. US examination confirmed the suspect of hypertrophic pyloric stenosis, and the baby was admitted to the surgical ward and taken to the operating room the next day.

During orotracheal intubation, the anesthetist perceived the presence of solid swelling on the midline of the neck (Figure 1).

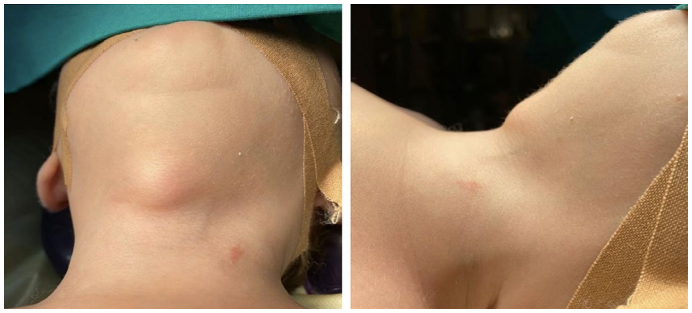

Figure 1. Pre-operative picture of the thyroglossal duct cyst after endotracheal intubation.

An ultrasound was then performed in the operating room and revealed a 2 × 2 cm cyst filled with anechoic fluid and delimited by thin walls; the thyroid was normal. Despite the patient's age, the finding was compatible with a TDC, and the decision was to proceed with the cyst removal, after the pyloromyotomy, to prevent future episodes of inflection and to avoid another surgical session. After an anesthesiologist and surgical team discussion, an open pyloromyotomy was performed with a small supraumbilical incision according to Bianchi. The procedure was completed without issues and the abdominal wall closed in layer with absorbable sutures.

Upon the parents' agreement, the cyst was removed according to Sistrunk's procedure (Figure 2). Considering the age of the patient, a 2.5X optical magnification was used to perform the anatomical dissection of the thyroglossal duct and cyst, plus the middle portion of the hyoid bone dissection, to avoid any damage of the respiratory tract, vessels, and nerves. An abundant presence of colloid material was observed during the cyst isolation, reinforcing the diagnostic suspect.

The postoperative course was regular. Analgesia was obtained with 15 mg/kg of paracetamol three times per day and a progression feed started the day after with 15 ml of formula milk *per os*. The child reached the full feeds on the same day, and no episodes of vomiting were documented. The baby was discharged on the 3rd post-operative day.

Histopathologic examination of the cyst confirmed the diagnosis of TDC. A genetic consult was also requested considering the presence of multiple anomalies, but the family refused to perform further analysis.

Discussion and Conclusions

TDC should always be considered when evaluating a midline neck mass in a pediatric patient. The usual presentation consists of an asymptomatic mass which can sometimes be detected by parents. The cyst can also become evident after infections, appearing as a swollen and painful mass. If not treated, the infection can lead to spontaneous rupture and evolve into a draining sinus. This occurrence is more frequently associated with an upper respiratory infection.[2]

In our case, the features and position of the lesion resembled an asymptomatic TDC, even if the age of the patient was atypical. Different studies disagree on the mean age of presentation for TDC. In fact, TDC has a bimodal age distribution, with a peak in the first and the fifth decade of life, being frequently observed in prescholar age children.[4] Anecdotic cases of TDC diagnosed in infancy have been reported in the literature, and the earliest presentation was observed in a 3-month-old baby.[5]

Many differential diagnoses should be considered when a midline neck lesion is observed in a pediatric patient, in particular dermoid cysts, pilomatrixomas, branchial cleft remnants, lymphadenopathy, and ectopic thyroid.[2] A careful physical examination, asking the patient to extend the neck and swallow or protrude the tongue, could be helpful to distinguish TDC from other lesions of the neck.[6] Indeed, TDC usually moves accordingly to the tongue due to its attachment to the hyoid bone. This explains why the anesthetist was able to identify the cyst in our patient during the endotracheal tube placement.

To confirm our suspicion and exclude thyroid anomalies, an US was performed at the operating table. TDC usually appears as a thin-walled and well-circumscribed anechoic/hypoechoic cystic lesion, strictly associated with the hyoid bone.[7] Sometimes cysts could be filled with debris secreted by the epithelial cells, especially after episodes of infection or inflammation.[8] US imaging is also mandatory to exclude the presence of median ectopic thyroidal tissue in or near the thyroglossal duct. If this is the case, thyroid hormones should be dosed before surgery, because in 75% of cases, the ectopic thyroid is the only functional tissue.[8] Second-level imaging exams, such as CT, MRI, and thyroid scan, could be helpful in inconclusive cases.

US revealed that the midline lesion of this patient had the typical characteristic of a TDC and the thyroid was normal. For this reason and the concomitant general anesthesia, we decided to proceed with TDC excision after pyloromyotomy. Surgical management is the best therapy in the case of TDC and it should be performed early to avoid infections or malignant degeneration (about 1% of cases).[4] Sistrunk's procedure represents the gold standard treatment because it has the best outcome in terms of recurrence and complications.[9] It consists of the excision of the cyst together with the central portion of the hyoid bone and the thyroglossal duct tract connected to the base of the tongue. A wide core of surrounding tissues should be excised to remove all the remnants that could cause recurrence.[10,11]

Our patient presented a series of pathological conditions, such as high-grade hydronephrosis, borderline ventriculomegaly, hypertrophic pyloric stenosis, and TDC, and a genetic consultation was requested. No specific syndromes were identified, and the CGH-array exam was suggested but was refused by the parents.

In conclusion, even if extremely rare, the diagnosis of TDC should be considered when a midline neck lesion is observed in

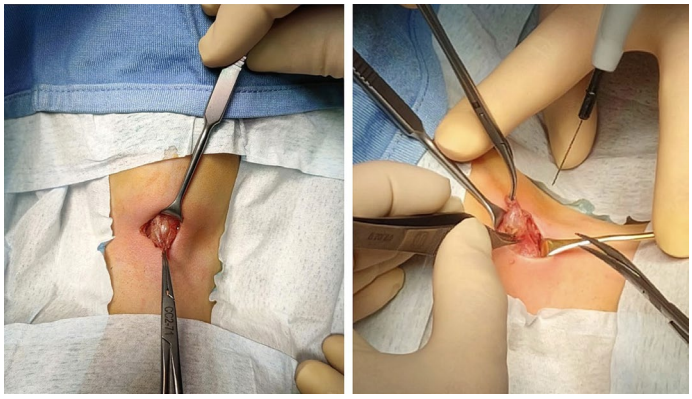

Figure 2. Thyroglossal duct cyst isolation during Sistrunk's procedure.

a newborn baby. In our opinion, the excision of the cyst should be performed to avoid infections and malignant degeneration; however, we also recommend evaluating the risks and benefits of the procedure in babies < 6 months, considering the impact of general anesthesia neurodevelopment of these patients, but also the availability of proper neonatal surgery facilities to guarantee an uneventful surgical and postoperative outcome in such small patients.

Supplementary Information
The online version contains supplementary material available at https://doi.org/10.1186/s12887-024-04742-x.

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Author contributions
Conceptualization, P.M., E.T. and D.G.; investigation, S.D.; writing — original draft preparation, C.P. and E.T.; writing — review and editing, E.T. and P.M.; supervision, P.M. All authors have read and agreed to the published version of the manuscript.

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Data availability
The authors confirm that the data supporting the findings of this study are available within the article.

Ethics approval and consent to participate
All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Competing interests
The authors declare no competing interests.

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officer for Prolacta. "It is well-established in the medical community and in hospitals across the country that Prolacta's EHMD is beneficial for extremely low birth weight premature infants. This data demonstrates that the benefits extend to term infants who require surgery for gastroschisis repair."

Ontario IVF Program Linked to Drop in Multifetal Pregnancies

In Ontario, Canada, the publicly funded fertility program mandated an elective single-embryo transfer (eSET) policy in 2015 for in vitro fertilization (IVF), and this mandate was associated with a decrease in multifetal pregnancy rates, according to a new study. Multifetal pregnancy rates decreased from 29.4% to 7.1% after IVF and from 12.9% to 9.1% after ovulation induction or intrauterine insemination (OI/IUI). "The Ontario publicly funded fertility program was implemented to provide equitable access to fertility treatment. Another goal is to decrease multifetal pregnancy rates after IVF by promoting the transfer of a single embryo at a time," lead author Maria Velez, MD, PhD, associate professor of obstetrics and gynecology and chair of reproductive endocrinology and infertility at Queen's University in Kingston, Ontario, Canada, said. "Multifetal pregnancy can be associated with maternal health complications and preterm birth and in some cases with associated long-term consequences," she said. "While most of the epidemiological surveillance about the outcomes of fertility treatments worldwide is focused on IVF, we also wanted to study the impact of IUI on multifetal pregnancy. We are fortunate to have access to such data in Ontario through ICES." Velez and colleagues conducted a population-based, retrospective cohort study of Ontario administrative health data to analyze all births and fetal reductions from April 2006 through March 2021, looking at differences between unassisted conception, IVF, and OI/IUI. They compared the time before eSET was promoted (2006-2011) with the time after the 2015 mandate (2016-2021), calculating adjusted relative risks (ARRs), population attributable fractions (PAFs), and absolute rate differences.

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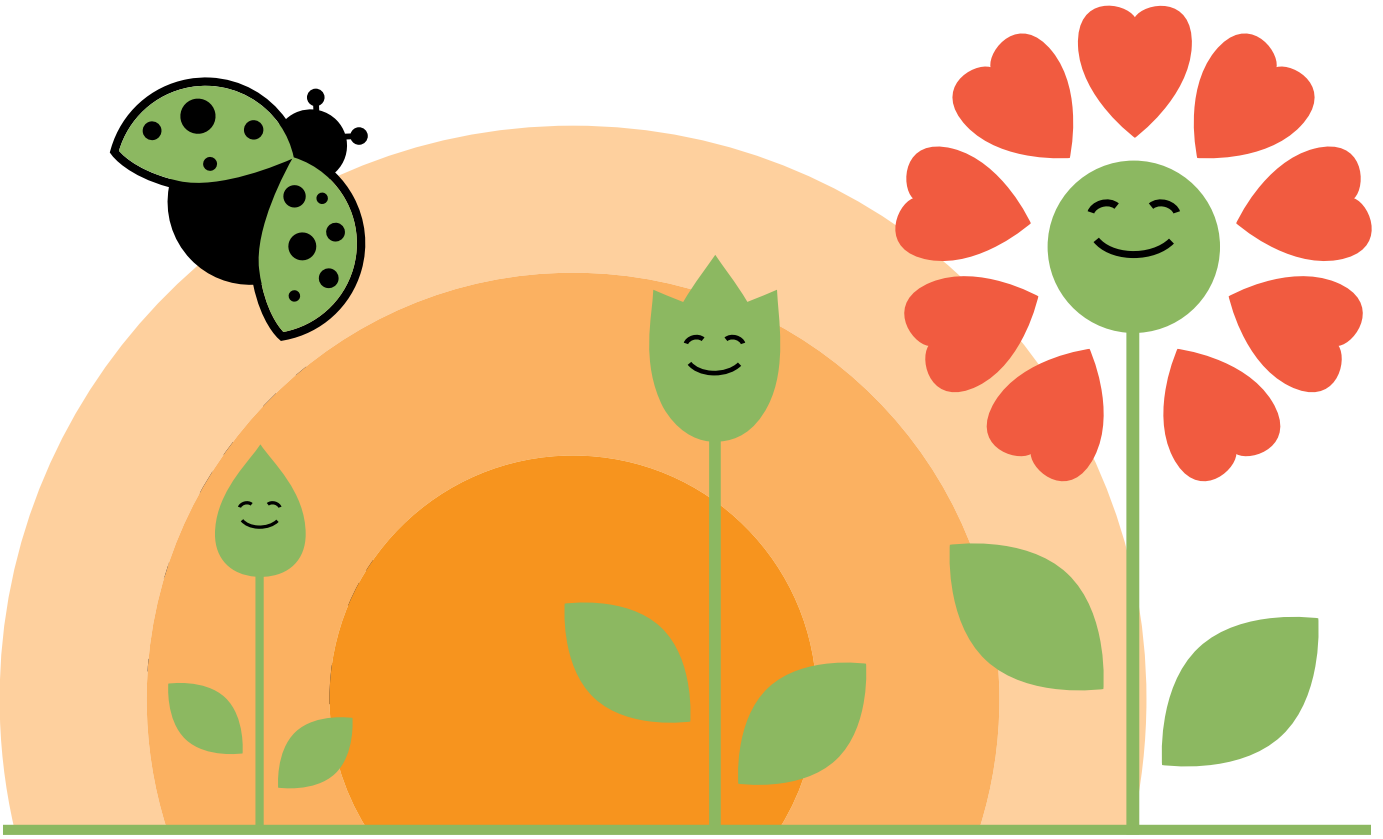

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