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neonatal INTENSIVE CARE

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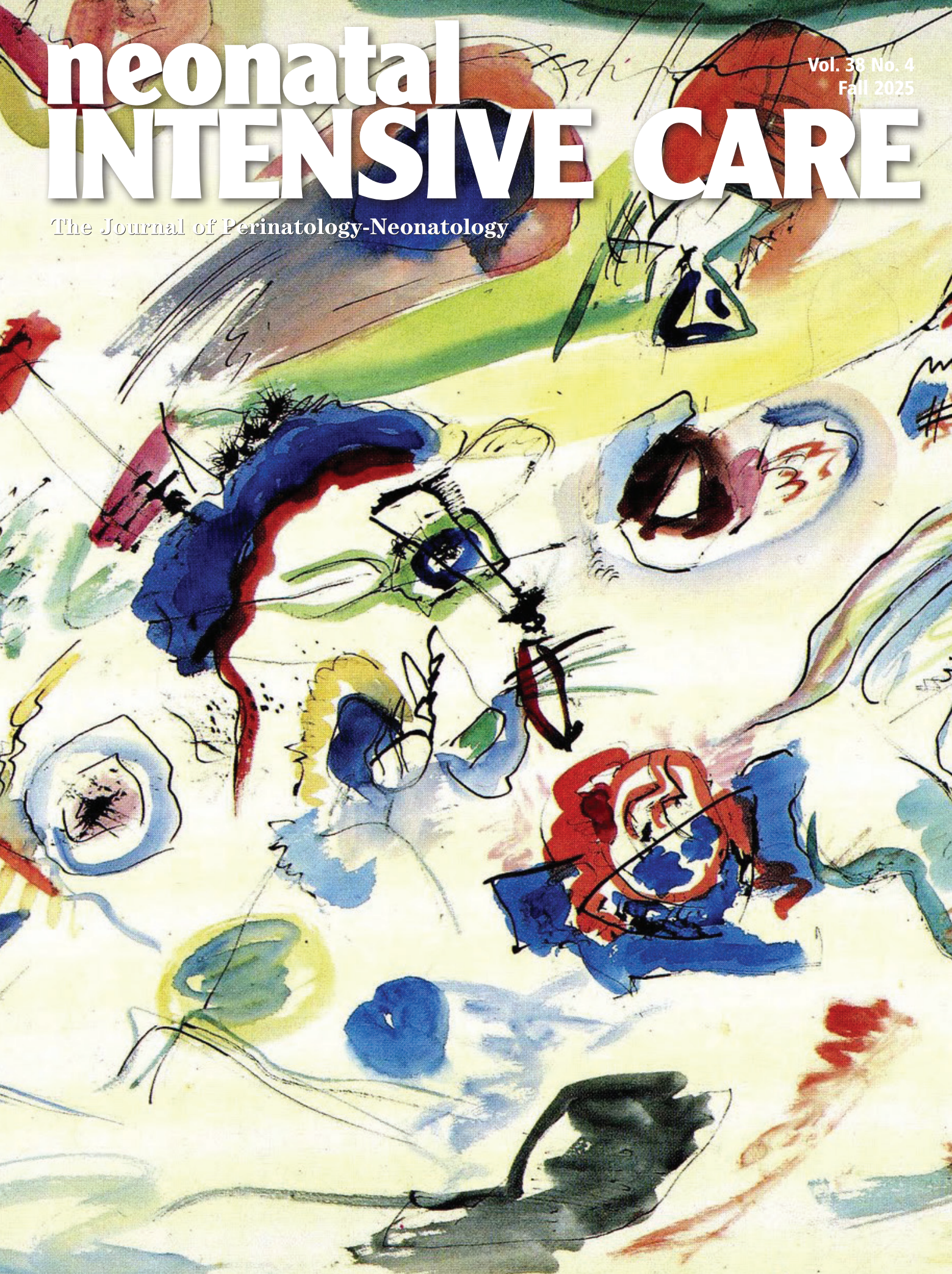

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INDICATION

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.

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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.

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News

☐ Fall 2025

Severe Neonatal Illness Predicts Mortality Into Adolescence

Severe neonatal morbidity (SNM) significantly increased the risk for death from infancy through late adolescence, particularly for neurologic conditions. Female infants and those born term with SNM faced higher relative mortality risks. Researchers conducted a population-based cohort study using data from the Swedish Medical Birth Register to assess the association between SNM and all-cause and cause-specific mortality from infancy to adolescence. This study included 2,098,752 live-born singleton infants born between 2002 and 2021, of whom 49,225 (2.4%) were diagnosed with SNM (defined as respiratory infections or neurologic or procedural complications within 27 days of birth). Mortality was classified on the basis of age as infancy (28 days to 11 months), early childhood (1-4 years), later childhood (5-9 years), and adolescence (≥ 10 years). Primary outcomes were all-cause and cause-specific mortality from 28 days to a follow-up duration of 21.2 years. The mortality rate was 1.81 vs 0.13 per 1000 person-years among children with SNM vs those without SNM (adjusted hazard ratio [aHR], 5.92; 95% CI, 5.27-6.64). Neurologic morbidity had the strongest association (aHR, 17.67; 95% CI, 15.08-20.71). Female children with SNM had a higher risk for mortality than male children (aHR, 7.28 vs 4.97; *P* for interaction < .001), with the association between SNM and neurologic morbidity notably stronger among female children. Among children aged 1 year or older, SNM was strongly associated with deaths from neurologic diseases (aHR, 18.64; 95% CI, 12.51-27.79), circulatory diseases (aHR, 5.41; 95% CI, 2.67-10.94), and metabolic disorders (aHR, 3.56; 95% CI, 1.70-7.44). Among children with SNM, those born preterm had higher absolute mortality rates than those born term (2.76 vs 1.30 per 1000 person-years); however, infants born term showed a stronger relative risk than those born preterm (aHR, 7.16 vs 3.51). "Efforts to further prevent severe neonatal morbidity, ensure early identification, and provide long-term follow-up care may help reduce mortality and inform discussions with families regarding prognosis and follow-up needs," the authors wrote. This study was led by Hillary Graham, MS, Clinical Epidemiology Division, Department of Medicine Solna, Karolinska Institutet, Stockholm, Sweden. It was published online on June 10, 2025, in *JAMA Pediatrics*.

US Neonatal Mortality Rate: Unveiling the Perinatal Causes

The neonatal mortality rate in the US decreased from 1999 to 2022, with deaths from interstitial emphysema and related conditions showing the steepest decline, yet mortality from slow fetal growth and malnutrition rose by nearly 2% annually. A retrospective study was conducted to examine neonatal mortality rates from 1999 to 2022 using data sourced from CDC Wide-Ranging Online Data for Epidemiologic Research, with diagnostic codes used to identify the cause of death related to perinatal complications. The top 10 causes of neonatal death were identified based on cumulative frequency over the study period. Mortality rates were stratified by sex, delivery method, birthplace, and age at death. From 1999 to 2022, 283,696 neonatal deaths were reported owing to perinatal complications, with male neonates accounting for 56.2% of deaths. The top 10 causes accounted for 79.8% of the deaths. Disorders related to short gestation and low birth weight were the leading cause of neonatal deaths, with a crude rate of 102.10 per 100,000 live births. They were followed by deaths in newborns due to maternal complications of pregnancy and issues related to the placenta, cord, and membranes. Mortality from interstitial emphysema and related conditions showed a steep decline, followed by respiratory distress from the perinatal period, with annual average percent changes of -5.40% (95% CI, -6.20% to -4.64%) and -3.63% (95% CI, -4.45 to -3.00), respectively. Mortality from slow fetal growth and fetal malnutrition increased by

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Cover: Untitled First Abstract Watercolor, 1910. Wassily Kandinsky (1866–1944). The image is public domain.

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Editorial Advisory Board

1.91% annually (95% CI, 0.46%-3.82%), whereas mortality due to maternal complications and bacterial sepsis in newborns remained stable. US neonatal mortality has generally decreased, likely due to medical advancements, improved prenatal care, and neonatal intensive care interventions." the authors wrote. "Vaginal deliveries were associated with nearly three times the neonatal mortality rate of cesarean deliveries, potentially due to complications, such as birth trauma and prolonged labor." This study was led by Muzamil Khan, MD, of the George Washington University School of Medicine and Health Sciences in Washington, DC. It was published online on June 23, 2025, in *JAMA Pediatrics*.

Preterm Birth Risk and Second-Trimester Medical Termination

Medical termination of pregnancy (mTOP) in the second trimester was considered safe and not significantly associated with the risk for future spontaneous preterm birth (sPTB). Researchers conducted a single-centre cohort study to investigate the association between mTOP in the second trimester and the risk for subsequent sPTB in 1438 individuals who underwent an mTOP with mifepristone and/or misoprostol between 2008 and 2023. The mean maternal age at the time of mTOP was 32.5 years; by December 2024, 1033 participants had a known subsequent pregnancy, and 405 did not. Interpregnancy intervals were categorised as 0-3, 3-6, 6-12, 12-24, and more than 24 months; the gestational age at mTOP was 12^{+0}-16^{+0}, 16^{+0}-19^{+6}, and more than 20 weeks. The primary outcome was the rate of sPTB before 37 weeks in subsequent pregnancies, whereas secondary outcomes included rates of preterm births before 28, 32, and 37 weeks; miscarriage; repeated terminations; and variations in birth weight. The incidence rate of subsequent sPTB before 37 weeks was 4.7% among singleton pregnancies and 16.7% among multiple pregnancies. Participants with a short interpregnancy interval (< 3 months) had a higher incidence rate of sPTB than those with an interval of 12-24 months (6.8% vs 3.2%; adjusted odds ratio [aOR], 2.2; $P = .2$). The incidence rate of sPTB was 5.9% and 2.6% for mTOP conducted at gestational ages of more than 20 weeks and less than 15 weeks, respectively (aOR, 2.2; $P = .07$). The rate of subsequent sPTB before 37 weeks after excluding participants with prior sPTB before 37 weeks was 4.1% among singletons and 17.4% among multiples; when cases with prior curettage were excluded, the rate was 4.5% among singletons and 20.0% among multiples. A higher gestational age at mTOP was significantly positively associated with subsequent sPTB before 37 weeks (β coefficient, 0.56; coefficient of determination, 0.31; $P = .04$). "Second-trimester medical termination of pregnancy can be considered safe with regards to subsequent spontaneous preterm birth risk. As recommended following preterm and term birth, patient counseling should include the importance of allowing time for cervical remodeling to mitigate preterm birth risks, especially for those with a medical termination of pregnancy at higher gestational ages," the authors wrote. This study was led by Annabelle L. van Gils, MD, Amsterdam UMC - location University of Amsterdam, Department of Obstetrics and Gynecology, Meibergdreef, Amsterdam, the Netherlands. It was published online on May 19, 2025, in *American Journal of Obstetrics and Gynecology*.

Antibiotic Exposure in Premature Infants May Impair Lung Function

Neonates born preterm with very low birth weight (VLBW) exposed to multiple perinatal antibiotics were at an increased risk for impaired lung function and asthma episodes at early school age, according to a new study. This population-based,

multicentre cohort analysis included 3820 neonates born preterm with VLBW (< 1500 g; median gestational age, 28.4 weeks; 49.0% girls) from 58 German Neonatal Network centres between 2009 and 2017. Researchers stratified participants into the following three groups on the basis of the antibiotic risk score (ARS): Low-risk group (ARS I; 9.4%) that received only surgical antimicrobial prophylaxis, intermediate-risk group (ARS II; 42.7%) that received prophylaxis plus postnatal antibiotics, and high-risk group (ARS III; 47.9%) that received additional antenatal maternal treatment. The analysis focused on 3109 participants born by caesarean delivery. The primary endpoint was the forced expiratory volume in 1 second (FEV1) z score at the ages of 5-7 years; secondary outcomes included the forced vital capacity (FVC) z score and the number of childhood asthma episodes. About 90.6% of VLBW participants born by caesarean delivery received postnatal antibiotics for suspected or confirmed sepsis, and 47.9% had additional antenatal antibiotic exposure. Higher ARS levels were significantly associated with lower FEV1 z scores at early school age ($P < .001$). An increased exposure to antibiotics (ARS III vs II) was correlated with impaired FVC z scores ($P = .02$) and an increased risk for early childhood asthma episodes (odds ratio, 1.91; $P = .001$). "Early identification of high-risk individuals allows for targeted parental counseling and structured prevention strategies. Evidence-based programs and prevention bundles are needed to support respiratory health and optimize long-term outcomes in the vulnerable group of preterm individuals," the authors wrote. This study was led by Ingmar Fortmann, MD, University Hospital of Schleswig-Holstein, Campus Lübeck, Lübeck, Germany. It was published online on May 12, 2025, in *JAMA Network Open*.

Infection Risk High in Very Low Birth Weight Hospitalized Infants

Late-onset invasive *Staphylococcus aureus* infections affected a substantial proportion of infants hospitalized in neonatal intensive care units (NICUs), with infants with very low birth weight (VLBW; < 1500 g) experiencing a much higher incidence than those with a birth weight ≥ 1500 g. VLBW babies accounted for more than three fourths of infections and the majority of attributable deaths. Researchers conducted a retrospective cohort study to determine the incidence of invasive *S aureus* infections among 468,201 infants (55.6% boys; median gestational age, 36 weeks) admitted to NICUs across the United States between 2016 and 2021. The primary outcome was late-onset invasive *S aureus* infection, defined as a positive culture result for *S aureus* from an abscess, blood, cerebrospinal fluid, peritoneum, or pleural fluid, collected at least 4 days after birth. Mortality attributed to *S aureus* infection was defined as the absolute difference in deaths occurring within 7 days of an invasive *S aureus* infection and deaths among matched infants without an *S aureus* infection. Among infants with invasive infections, 80.9% were born at 32 weeks of gestation or earlier, 76.5% had VLBW, and 87.5% required central line placement during their NICU stay. Infants with VLBW experienced nearly a 20-fold higher incidence of *S aureus* infection rates than infants with a birth weight ≥ 1500 g (227.1; 95% CI, 215.3-239.4 vs 10.1; 95% CI, 9.1-11.1 per 10,000 infants). Among infants with *S aureus* infections, all-cause mortality during NICU admission was substantially higher in infected infants than those without an infection (12.1% vs 1.0%), with VLBW infants accounting for 90.4% of deaths. The absolute difference in 7-day all-cause mortality between infants with *S aureus* infection occurring between postnatal days 4 and 28 and matched infants without infection was 5.3% (95% CI, 3.8-6.8). "Late-onset invasive *S aureus* is an important contributor to disease burden in hospitalized infants, especially among infants with VLBW," the study authors wrote. "The lack of change in the incidence mediated by enhanced infection prevention measures suggests the need for novel strategies to further reduce the incidence and burden of *S aureus* infections," the study authors wrote in the related editorial.

NICU Admissions Higher in Pregestational Diabetes

Neonatal intensive care unit (NICU) admission rates were significantly higher among infants born to mothers with pregestational diabetes than among those born to mothers with gestational diabetes (GD). This Irish study compared risks for NICU admission across maternal diabetes subtypes (type 1 diabetes [T1D], type 2 diabetes [T2D], and GD) to refine counselling and neonatal care. Researchers conducted a retrospective analysis of 25,238 births (January 2018 to December 2020) and identified 3905 neonates born ≥ 34 weeks to mothers with diabetes, including those with T1D (n = 67), T2D (n = 60), and GD (n = 3712). Data on gestational age, birth weight, mode of delivery, and maternal age were extracted from the registry. NICU admission details (indications, hypoglycaemia, and respiratory support) and maternal characteristics (body mass index [BMI] > 30 and preeclampsia) were obtained via electronic records. The analysis was performed using quasi-Poisson regression for assessing NICU admission risk ratios (RRs), analysis of variance for comparing gestational age/birth weight, and chi-square tests for comparing categorical variables. The primary outcome was the NICU admission rate; secondary outcomes included respiratory distress, severe hypoglycaemia, and maternal discharge timing. Neonates born to mothers with

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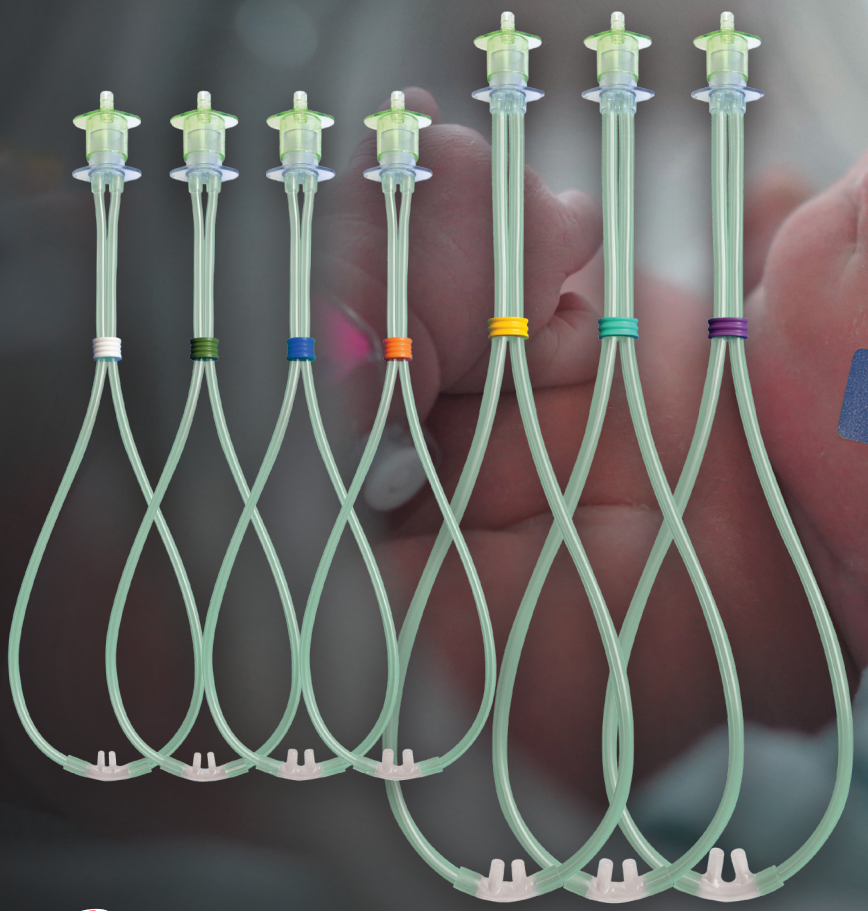

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T1D and T2D had a admission rate of 41.8% (RR, 3.32) and 31.1% (RR, 3.89), respectively, with both significantly higher than that in those born to mothers with GD (12.5%; RR, 0.133; $P \leq .001$); the hospital baseline admission rate was 11.5%. Neonates of mothers with T1D were born earlier (mean, 37 + 1 weeks) than those of mothers with T2D (mean, 38 + 1 weeks; $P = .0019$) and GD (mean, 39 weeks; $P \leq .001$). Moreover, they showed significantly higher birth weight centiles than those of mothers with T2D and GD at 25th (T1D vs T2D, $P = .0042$; T1D vs GD, $P \leq .001$), median ($P \leq .0001$ for both), and 75th centiles (T1D vs T2D, $P \leq .0001$; T1D vs GD, $P = .0009$). Respiratory distress dominated T1D admissions (36.7%), while hypoglycaemia was primary in T2D (73.7%). Mothers with pregestational diabetes were more frequently discharged before their infants (T1D, 42.9%; T2D, 31.5%) than those with GD (21.2%). "It is important to counsel mothers on risks and expectations for the newborn period," the authors of the study wrote. "The aim of our study is to describe how the type of maternal diabetes impacts admission to NICU and to provide up-to-date, local data to support healthcare professionals when counselling patients with diabetes in pregnancy," they added. This study was led by Dearbhla Hillick, Rotunda Hospital, Dublin, Ireland. It was published online on May 22, 2025, in the *European Journal of Pediatrics*.

Study Finds Etiometry's Risk Analytics Algorithms Help Predict Extubation Failure

A newly published multicenter study has found that Etiometry's FDA-cleared physiologic risk analytics—IDO2 and IVCO2—can help predict extubation failure (EF) in neonates recovering from congenital cardiac surgery. The retrospective cohort study, led by Dr. Daniel Hames of Boston Children's Hospital and colleagues and featured in *Pediatric Critical Care Medicine*, analyzed 736 neonates across eight international pediatric cardiac intensive care units (ICUs). The research found that elevated IDO2 and IVCO2 values in the hours before extubation were associated with a significant increase in odds of EF. The IDO2 and IVCO2 indices, delivered via the Etiometry Platform, provide near real-time, continuous assessment of a patient's risk for inadequate oxygen delivery or ventilation. These metrics are FDA-cleared for use in patients from birth through 12 years of age and are designed to support more informed clinical decision-making in intensive care. Extubation failure—defined as the need for reintubation within 48 hours—has demonstrated association with increased odds of cardiac arrest, longer ICU stays, and mortality. It also contributes to prolonged mechanical ventilation, which has been widely linked in previous studies to ventilator-associated complications such as pneumonia, increased sedative exposure, and other hospital-acquired conditions. The study demonstrates that incorporating continuous physiologic monitoring and risk analytics alongside traditional clinical assessment may improve clinicians' ability to identify high-risk patients and time extubation more precisely. "The novelty of this work is that it lays the foundation for hospitals to harness high-fidelity data sets to better understand how vital signs, care practices, decision-making, and outcomes are interrelated," said Dr Daniel Hames of the Division of Cardiovascular Critical Care at Boston Children's Hospital and Assistant Professor of Pediatrics at Harvard Medical School. "It's a step toward enabling ICUs to continuously and automatically evaluate their clinical practices—like extubation protocols—and refine them based on real-world data to ultimately improve care." Study highlights include: The study incorporated high-fidelity data merged from 8 participating centers, with 13.9% of neonates experienced extubation failure. Neonates with single ventricle anatomy and those requiring preoperative respiratory support had significantly greater odds of EF. Elevated DO2 (≥25) or IVCO2 (≥50) in the two hours prior to extubation were independently associated with increased odds of EF (OR 1.77 [95% CI, 1.01–3.12]). Adding IDO2/IVCO2 to clinical models improved predictive performance, with a Net Reclassification Index (NRI) of 45%. Kaplan-Meier analysis showed that neonates with lower IDO2 and IVCO2 had significantly higher likelihood of remaining successfully extubated.

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Study Looks at Benefits of Clinical Intelligence Platform on Care for Neonates

In this feature, Neonatal Intensive Care interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Shane Cooke, President and CEO of Etiometry.

What were the findings from the recent study conducted at Children's National Hospital?
Preterm infants are at risk of Retinopathy of Prematurity (ROP) and Bronchopulmonary Dysplasia (BPD) due to prolonged mechanical ventilation and oxygen supplementation during their Neonatal Intensive Care Unit (NICU) stay. To minimize risks, staff maintain oxygen saturation from 90% to 95% to avoid hypoxia and hyperoxia. The study at Children's National Hospital in Washington, DC, was conducted to examine the role of Etiometry's clinical intelligence platform in assessing neonatal oxygen therapy compliance, while also identifying potential areas for improvement. Etiometry is a data management software that collects, analyzes, visualizes and archives pulse oximetry data. Clinicians can use this data for assessment of day-to-day compliance with set parameters.

Researchers confirmed well-documented findings that time spent in hypoxemia (low oxygen levels) increases the odds of developing Bronchopulmonary Dysplasia (BPD), a chronic lung disease that can lead to long-term respiratory issues, while time in hyperoxemia (excess oxygen) is linked to a higher risk of Retinopathy of Prematurity (ROP), a serious eye disorder that can result in lifelong vision impairment or even permanent blindness. These conditions pose significant risks to fragile premature babies, making precise oxygen management critical.

The study found that intervention for hypoxic events occurred more frequently than hyperoxic events. It also found that ventilation mode and oxygen therapy can now directly be captured by the Etiometry Platform, allowing the development of hospital-configured pathways that flag the degree of non-compliance to decrease FiO2 use. Interventions can then be developed to improve compliance for quality improvement.

Can you share what the parameters for this study were?
The study's objective was to determine compliance with oxygen saturation parameters (time in range) for neonates with ROP and BPD compared to controls to use as baseline data for quality improvement.

Data from 879 unique patients over 50 months were analyzed. Total compliance rate for all groups was 34.8%, with 7.2% intervenable hypoxic and 36.9% intervenable hyperoxic. Intervenable events increased with lower gestational age (GA) ($p<0.001$). In the low compliance group, neonates < 28 weeks GA had 1.83 odds, and 28-<34 weeks GA had 1.91 odds of developing ROP compared to the high compliance group. No statistically significant difference was seen in the 34-<37 weeks GA. Similarly, the low compliance group in <28 weeks had twice the odds and 28-<34 weeks GA had 4.74 odds of developing BPD compared to the high compliance group.

Oxygen saturation data for neonates <37 weeks GA at birth was automatically uploaded from the bedside monitor to the Etiometry Platform every 5 seconds. Mode and duration of oxygen therapy, ROP and BPD diagnoses were extracted from the medical record. Patients were divided into three groups (<28, 28-<34, and 34-<37 weeks GA). Children's National researchers calculated time in range and FiO2 adjustments resulting in five compliance states (Figure 1). The researchers calculated total compliance time and divided groups into high and low compliance groups (above and below median). Neonates with ROP and/or BPD were compared to controls using multivariate analysis. Relationships between GA and intervenable events were analyzed using Spearman's rank correlation coefficient.

Please share an overview of the Etiometry Platform.
Etiometry is the only FDA-cleared AI-based clinical intelligence platform that uses AI-enabled analytics to support clinician decision-making by organizing patient data and visualizing trends. It provides insights to help clinicians recognize changes in patient condition earlier, informing timely care decisions.

Shane Cooke joined Etiometry in 2019 as President & CEO, bringing over 20 years of experience in the medical device and pharmaceutical market spaces in a variety of sales, marketing, strategy and portfolio management roles. Before joining Etiometry, Shane spent 5+ years as Chief Strategy Officer of Cheetah Medical, which was acquired by Baxter International in 2019. Prior to Cheetah, Shane spent 11 years with Covidien in the patient care, vascular therapies and corporate sectors, with positions such as: corporate strategy, market and competitive intelligence, leading the market development center of excellence and leading strategy efforts for Japan, Europe, Australia and Canada. Shane holds a BA in psychology from the University of Rochester, as well as an MBA from Suffolk University. If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

The Etiometry Platform offers a solution that both standardizes and individualizes care, thereby reducing variability and supporting clinicians in both the escalation and de-escalation of care in the ICU setting. It contains advanced AI analytics and algorithms that are embedded in clinical workflows through the Platform to empower increased care quality, associated with reduced length of stays by 36%, decreases ICU readmissions by up to 41% and reduces ventilation time by up to 30%, which has been associated with operational efficiencies and improved outcomes in multi-center studies.*

What actionable, specific opportunities were found? How did Etiometry's Platform aid in identifying these opportunities?
The study found that intervention for hypoxic events occurred more frequently than hyperoxic events. It also found that ventilation mode and oxygen therapy can now directly be captured by Etiometry, supporting the development of hospital-configured pathways that flag the degree of non-compliance to decrease FiO2 use. Interventions can then be developed to improve compliance for quality improvement.

What is the significance of this study? Why is it important?
While the association of hyperoxia and hypoxia with ROP and BPD is well known, this is the first study to measure real-world compliance on such a large dataset. The findings highlight and quantify the significant opportunity for sophisticated tools to improve practices and continue to improve patient outcomes. And at the end of the day, this study demonstrates the importance of better care given the significant risks ROP and PBD pose to premature babies, the hospital's most fragile patients.

How does Etiometry's platform help clinicians adhere to protocols?
By leveraging near real-time data and analytics, the Etiometry Platform helps clinicians make more informed decisions at critical moments.

The use of advanced AI analytics and algorithms that are embedded in clinical workflows through the Platform help standardize and individualize care, which reduces variability. The Platform also uses real-time pathways to alert clinicians when oxygen saturation is out of compliance, and to what degree.

In addition to these efforts, we also recently received additional FDA clearance on our IVCO2 Index for neonatal care in detecting inadequate ventilation of carbon dioxide. We also have ongoing projects around temperature management and ventilation liberation all focused on supporting clinicians' ability to adhere to important protocols in high-acuity environments where patients' conditions are changing rapidly.

What role does the continuous feedback of data gathered play in helping to optimize oxygen therapy management and support targeted interventions?
With the Etiometry Platform, ventilation mode and oxygen therapy are streamed directly into the system, enabling the development of near real-time pathways that flag clinicians to degrees of non-compliance. This continuous feedback helps optimize oxygen therapy management and support targeted interventions to improve compliance, hopefully reducing ROP and BPD in these fragile babies.

In addition to this study, Etiometry recently received FDA clearance for its IVCO2 Index algorithm and has ongoing projects around temperature management and ventilation liberation. You've mentioned that these are all part of strengthening your overall company commitment to advancing neonatal health. Can you talk about these efforts you have underway?
As I touched on earlier, we recently received expanded FDA clearance on our IVCO2 Index for neonatal care—it can now be used to care for newborns in the neonatal ICU who weigh under two kilograms—in detecting inadequate ventilation of carbon dioxide. The IVCO2 and IDO2 indices, delivered via the Etiometry Platform, provide near real-time, continuous assessment of a patient's risk for inadequate oxygen delivery or ventilation to support more informed clinical decision-making in intensive care.

A newly published multicenter study has found that Etiometry's IDO2 and IVCO2 indices were associated with increased odds of extubation failure (EF) in the published observational study, supporting clinician awareness.*

This is extremely important because as your readers know, extubation failure has a demonstrated association with increased odds of cardiac arrest, longer ICU stays, and mortality. It also contributes to prolonged mechanical ventilation, which has been widely linked in previous studies to ventilator-associated complications such as pneumonia, increased sedative exposure, and other hospital-acquired conditions.

The retrospective cohort study, led by Dr Daniel Hames of Boston Children's Hospital and colleagues that was featured in *Pediatric Critical Care Medicine*, analyzed 736 neonates across eight international pediatric cardiac ICUs. The research found that elevated IDO2 and IVCO2 values in the hours before extubation were associated with a significant increase in odds of EF. The study demonstrates that incorporating continuous physiologic monitoring and risk analytics alongside traditional assessments and hospital-defined criteria may improve clinicians' ability to identify high-risk patients and time extubation more precisely.

We understand that Etiometry also recently conducted a survey of hospital staff that received training on the Etiometry Platform. What were the key findings observed from that?
The key findings supported positive feedback we have heard many times anecdotally, including:

- 100% of neonatologists would recommend it to a neonatology colleague.
- 100% of users find the Etiometry Platform useful for mechanically ventilated NICU patients.
- 80% trust the IVCO2 Index to provide a meaningful assessment of the risk for PaCO2 >60 mmHg or 50 mmHg for mechanically ventilated patients.
- 83% believe the IVCO2 Index has the potential to support practices associated with improved patient outcomes.

What are some recommendations for additional follow up or ongoing research needed after this?
Ongoing research is essential to not only evaluate the long-

term effectiveness of interventions but also to uncover new opportunities for care optimization. Future initiatives should focus on measuring the sustained impact of changes at both the unit and hospital-wide level—particularly in areas such as clinical outcomes, resource utilization, and protocol adherence.

Etiometry's robust Quality Improvement (QI) application is a powerful enabler of both clinical research and operational excellence. By continuously capturing and storing high-fidelity physiologic and clinical data from a wide range of sources—including EHRs, bedside monitors, and ventilators, the QI App makes information readily available to clinicians and researchers. To date, the Etiometry QI App has supported more than 150 quality improvement initiatives and research projects across leading hospitals and academic centers.

*These results are observational; the Etiometry Platform is intended to aid decision-making, not to improve outcomes independently.

Why Neonatal Patients Experience High Rates of IV Leakage

In this feature, Neonatal Intensive Care interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Roland van Rens.

Can you explain why neonatal patients experience such dramatically high rates of IV leakage compared to other patient populations, and what makes the 80% infiltration rate in NICUs so concerning?

Neonatal patients have uniquely fragile and small-caliber veins, and even the smallest available catheters—such as a 26-gauge—may occupy a disproportionately large percentage of the vessel diameter. This high catheter-to-vein ratio significantly increases the risk of infiltration, extravasation, and other vascular access-related complications. The risk is even greater in extremely preterm infants, whose vessels are not only smaller but also more fragile and reactive.

Insertion of short peripheral IVs (SPCs) can cause mechanical trauma and chemical irritation to the endothelium, leading to early failure or local tissue reactions. While central venous catheters may be preferred for long-term therapy, peripheral catheters remain far more commonly used due to ease of placement—making them the leading source of complications in neonatal vascular access.

Furthermore, the volume and osmolality of infusates—especially when hyperosmolar or irritating drugs are administered—contribute to tissue injury when infiltration occurs. In neonates, even small volumes of extravasated fluid can cause serious damage to the skin and subcutaneous tissue, potentially leading to necrosis, infections, and severe pain.

Although infiltration rates vary across studies, published evidence suggests that peripheral IV failure rates—including infiltration—can exceed 50%, with some studies reporting rates up to 80% in high-risk neonatal populations. This makes early detection and prevention a critical aspect of neonatal care.

What makes traditional methods of detecting IV infiltration and extravasation inadequate in the NICU setting, particularly given the urgency of care these infants require?

It often comes down to the human factor. Clinicians in the NICU are under constant pressure, managing critically ill patients and frequently working long shifts. Even the most experienced staff—including vascular access specialists—are limited by the subjectivity of manual assessment.

In neonates, early signs of infiltration or extravasation can be subtle or hard to detect. Swelling may be minimal or difficult to visualize, especially under phototherapy or in fragile skin. The infants cannot verbalize pain or discomfort, so we rely heavily on visual and tactile cues that can be missed or misinterpreted.

That's where we need something objective—technology that alerts us when a problem might be developing. Then, we can apply our clinical tools—Touch, Look, and Compare (TLC)—with greater focus. We are good clinicians, but in this case, the human touch alone isn't always enough. Objective, real-time monitoring can fill this gap and enhance safety without replacing human judgment.

How does the proprietary sensor technology using near-infrared and visible light work to detect IV leakage in real time, and what advantages does this offer over visual inspection methods?

The ivWatch sensor uses near-infrared and visible light to detect early signs of fluid leakage into subcutaneous tissue. It continuously monitors the IV insertion site and identifies subtle changes in tissue characteristics—such as fluid accumulation—by analyzing shifts in light absorption and reflection. These changes often occur before any visible or palpable signs appear.

The system scans the site five times per second, resulting in about 18,000 assessments per hour. In contrast, manual inspection of IV sites is typically conducted once per hour or even less frequently, depending on staffing and protocols. While the Infusion Nurses Society (INS) recommends routine and frequent assessments, these are still bound by human limitations and can disrupt neonates' rest and neurodevelopment if performed too often or intrusively.

Matheus ('Roland') van Rens has over twenty years of clinical experience in neonatal nursing and holds a MA in Advanced Nursing Practice (Ma ANP), awarded in 2005 from Erasmus University in the Netherlands. He has worked as an advanced neonatal nurse practitioner, performing complex vascular access procedures in this patient group, developed and delivered multi-professional education activities and carried out clinical research in Europe and more recently in the Middle East. Most recently he served as the Clinical Director of Nursing for the newborn intensive care unit (NICU) at Women's Wellness and Research Center, Qatar. His research engages with issues around improving neonatal care, most notably around the broad topic of vascular access, a topic on which he has been the primary investigator for several studies. With his international research collaborators and co-authors, he has presented at international conferences and published several referred journal articles concerning neonatal vascular access, infusion therapy and related technology.

In practice, to avoid disturbing a sleeping infant, clinicians may perform partial assessments—looking and touching, but not comparing with the opposite limb—thereby reducing the accuracy of the TLC (Touch, Look, Compare) approach. The sensor addresses this by providing a real-time, objective alert when tissue changes suggest infiltration or extravasation, prompting timely and focused clinician evaluation.

The sensor technology is easy to use; the key is to trust that the technology is working. Clinicians are generally taught that seeing is believing, so unless they observe an injury that has already occurred, they may be hesitant to change their practice. Implementing new clinical workflows can be daunting, particularly when it challenges ingrained habits. That's why education, training, and building trust in the effectiveness of the device are critical for successful adoption. Once staff understand how the sensor works and witness its performance, skepticism tends to disappear quickly.

Given that neonatal patients often require vesicant medications like antibiotics, respiratory stimulants, and vasopressors, how does real-time detection technology help mitigate the tissue damage risks these life-saving drugs can cause?

In our recent study, we observed that when extravasation or infiltration is detected early, the severity of tissue injury is significantly reduced. This is especially relevant if neonates receive vesicant or irritant medications such as antibiotics, dopamine, or caffeine citrate, where even small volumes can cause considerable harm if leakage into the surrounding tissue occurs.

This is where the value of real-time detection becomes most evident. When used alongside the Touch, Look, Compare (TLC) method and supported by an infant intravenous infiltration grading scale, the technology enables earlier identification of complications—often before visible signs or skin changes occur. In our cohort, the use of this grading approach in combination with early alerts from the sensor system was associated with a meaningful reduction in the proportion of high-grade extravasation injuries.

Instead of presenting with a severe complication, most events were graded as minor, requiring no interventions. The earlier an infiltration is identified and the smaller its extent, the less likely it is to result in long-term damage to the skin, subcutaneous tissue, or underlying structures.

Can you walk us through a typical scenario where this detection technology would alert NICU staff to an IV infiltration, and how quickly can interventions be implemented?

It's hard to imagine a scenario where this technology wouldn't be beneficial. In the NICU, every peripheral IV should be monitored continuously—regardless of the patient's gestational age, clinical condition, or the type of fluid being infused. The risk of infiltration or extravasation is always present, and in neonates, the margin for error is extremely small.

In one case, I published a case study on a patient who developed severe necrosis when a 5% glucose solution extravasated—something you would not typically expect to cause harm. The sensor would have detected the early tissue changes, triggered an alert, and allowed staff to stop the infusion and intervene within minutes—before the injury progressed.

Reducing extravasations and infiltrations in all NICU patients is critical. And while hospitals have to invest in technology, the long-term cost of not implementing it is likely to be far higher.

What specific outcomes have you observed in NICUs that have implemented this sensor technology in terms of patient safety, tissue preservation, and overall care quality?

Trust the technology to see what we cannot see as humans with subjectivity. I typically find that any time technology is implemented that changes workflow or clinical practice, there may be some initial skepticism.

In my NICU and another NICU in the Netherlands, where the sensor technology was being trialed, any doubt was gone within a day or two once nursing staff realized how well the product detected infiltrations and extravasations and reduced their injury severity. Infiltrations and extravasations are inevitable, but we as clinicians have an obligation to our patients to leverage technology once available to us to help improve patient outcomes. Having a specific device for a specific target - in this case, peripheral vascular access - just makes sense.

How does the fragile nature of neonatal skin and tissue make early detection of IV complications even more critical than in adult patients?

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

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

The impact on parents and caregivers is also substantial. When they come to visit and see a new vascular access device in another hand or foot, they start wondering what's happening and become alarmed. It's a stressful situation, and the sensor technology can help reduce that stress when they know their baby is being continuously monitored for complications.

What global variations have you seen in NICU practices regarding IV monitoring, and how is this technology being adopted internationally?

The US is fortunate to have a relatively high number of vascular access specialists, which is not as common in many parts of Europe or the Middle East. The varying levels of sophistication within hospital systems both in the US and worldwide means there's often a lack of reporting because there's no system in place to grade peripheral IV injuries that is adopted universally. Even when there is a sophisticated system with strong protocols in place, it's not always properly documented. But data collection matters, not just for the severe complications like Grade 3s and 4s, but for the full spectrum. Because at the end of the day, they're all injuries. Whether it's a Grade 1 or 4, they can still lead to added procedures, delayed therapies, and increased workload…the list goes on.

Unfortunately, the cost of vascular monitoring plays a role in adoption and is often the first question, even before what the benefits are to the patient. We need to shift that mindset. We should start with what's best for the patient, and then work out how to support that with the right tools. Proven technology deserves a place in our care models, regardless of geography.

Beyond immediate patient safety, what are the longer-term benefits for neonatal patients when IV complications are detected and addressed more quickly?
Once you lose usable vasculature in a neonate's hand or foot due to severe infiltration or extravasation, the chances of successfully placing future IVs in that area drop significantly. These infants may become Difficult Intravenous Access patients—DIVAs—and that's a situation we want to avoid at all costs. Preserving veins early on not only improves care in the neonatal period, but also reduces the risk of access challenges later in life. A vein that becomes unusable in infancy can remain damaged well into adolescence or adulthood, making that person a DIVA for life.

Extravasation injuries can also evolve over time. What starts as a small blister can quickly develop into necrotic tissue—sometimes within hours, sometimes days after the infusion. As scar tissue builds up, it can cause long-term complications like restricted mobility or reduced motor function. I've spoken with young adults who report that the scars from their neonatal IV injuries are sometimes mistaken for self-harm.

And the consequences aren't just physical. The psychological toll is real. I've interviewed 25–30 adults who were born preterm, and more than 80% told me they still experience anxiety when approached with a needle. Some have visible scarring, some have limited function in their hands or feet, and in the most severe cases, a limb was lost.

Looking ahead, how do you see vascular access monitoring technology evolving to further improve outcomes for this most vulnerable patient population?
Vascular access technology should be top of mind for clinicians because it directly impacts the quality and safety of care. IV access is the lifeline for nearly every neonatal patient, yet we often treat its monitoring as secondary. That has to change.

While this technology is still considered novel and does require up-front investment, the return on investment—both clinically and financially—is clear from the data we've seen. Preventing complications, preserving veins, and reducing the need for escalation of care all translate into better outcomes and lower costs over time.

Looking ahead, I believe vascular access monitoring will become a standard component of neonatal care. Every patient deserves access to this level of protection. It's not just a technological upgrade—it's an ethical obligation.

Exploring Neonatal Tracheostomy: Diagnoses and Clinical Insights

Megan Quinn, MSN, CPNP-PC

Introduction

Tracheotomy is a medical procedure that has been performed on adults, children, and neonates for hundreds of years. In the neonatal population, there are multiple diagnoses that can cause the need for tracheostomy placement. Currently, tracheostomies in neonatal intensive care unit (NICU) patients are often placed when prolonged ventilation is needed, to facilitate ventilator weaning, and/or to bypass upper airway obstruction.[1] Understanding the common diagnoses requiring tracheostomy in the neonatal population can help improve understanding of neonatal tracheostomy and the care required.

Advances in Medical Technology and Survival Rates

Prior to the invention of influenza and diphtheria vaccines, younger patients often required tracheostomies for these acute bacterial and viral infections,[1] however with the invention of vaccines, these indications have decreased. In recent years, there has been an increase in tracheostomies placed for cardiopulmonary indications.[2] Overall, there has been significant improvement in medical technology and greater survival of premature infants. Despite improvements, tracheostomy will continue to be a mainstay in neonatal care[1] as an overall greater survival rate of premature infants will mean that the need for prolonged respiratory support in the NICU will increase. Additionally, the number of infants with associated upper airway anomalies is likely to increase, and these anomalies often require tracheostomy placement to manage the complex airway.[4]

Criteria for Tracheostomy in Neonates

In the smallest patients, there is no agreed upon pathway for when to place a tracheostomy during an infant's medical course. Many infants who undergo tracheotomy have already experienced long intubation periods as well as extubation attempts[1] however there is no set number of attempts required for tracheostomy. Additionally, there is no minimal weight requirement for placing a tracheostomy in a NICU patient,[2] but the size of neonatal airway must be able to accommodate the smallest available tracheostomy tube.[2]

Airway Obstruction & Upper Airway Anomalies

There are multiple diagnoses resulting in airway obstruction in the neonatal population. Many of the diagnoses necessitate the need for a tracheostomy tube to bypass the obstruction, which can occur throughout the neonatal airway.

Subglottic Stenosis

Subglottic stenosis is a common upper airway anomaly requiring tracheostomy in the neonatal population.[4] For a typical neonate, the subglottis is the narrowest part of their airway. Any additional narrowing in this region can make it difficult for NICU patients to support their airway.[5] Often, subglottic stenosis presents as biphasic stridor and respiratory distress.[5] Subglottic stenosis can either be congenital or acquired and is officially diagnosed when the cricoid diameter is noted to be less than 3.5mm.[5] Congenital subglottic stenosis can be seen with various genetic disorders, including Trisomy 21, CHARGE syndrome (Coloboma, heart anomalies, atresia of the choanae, restriction of growth and development, genital or urinary abnormalities, and ear abnormalities), and 22q11 deletion syndrome.[5] Congenital subglottic stenosis is much less common (5%) than acquired subglottic stenosis.[5] Acquired subglottic stenosis can happen after prolonged or traumatic intubation.[5] Both congenital and acquired subglottic stenosis can require tracheostomy to overcome the narrowing in the airway.

Pierre Robin Sequence

Pierre Robin sequence is a congenital defect that consists of a triad of symptoms: micrognathia, glossoptosis, and upper airway obstruction.[6] The upper airway obstruction that accompanies this diagnosis can require tracheostomy. When upper airway obstruction is noted in a patient with Pierre Robin sequence, other interventions will be trialed for airway management prior to tracheotomy, such as mandibular distraction osteogenesis.[6] However, tracheostomy is utilized frequently for the most complex patients with Pierre Robin sequence.[6] In addition to the airway concerns, this sequence can be associated with other issues, such as GI reflux and feeding issues, contributing to the medical complexity of the patient.[6]

Tracheomalacia

Tracheomalacia is a dynamic airway disorder characterized by cartilage in the airway that is not strong enough to remain appropriately patent throughout inhalation and exhalation.[1] This diagnosis is seen frequently in the neonatal population and can require tracheostomy placement to overcome this area of weakness.[1] As tracheomalacia can occur throughout the trachea, severe malacia could require a distally longer tracheostomy tube to bypass the weak areas in the lower trachea.[1]

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Vocal Cord Paralysis

Vocal cord paralysis accounts for 10% of congenital laryngeal lesions and is the second most common cause of neonatal stridor.[7] The paralysis could be so severe that the infant is unable to protect their airway, in this case their airway must be stabilized immediately, and the patient could require a tracheostomy.[7] Vocal cord paralysis can be congenital or acquired.[7] Congenital causes of vocal cord paralysis can be a sequalae from central nervous system (CNS) disease, peripheral neuropathies, idiopathic causes, and neurologically based (most commonly from Chiari malformation).[7] Vocal cord paralysis can be acquired from neoplastic disease, trauma, or inflammatory disorders that affect the vagus nerve.[7] Both congenital and acquired causes could require a tracheostomy tube to facilitate a safe airway.

Mechanical Ventilation

Tracheostomy could be required to facilitate prolonged mechanical ventilation in neonates. While there is no universally agreed-upon pathway for deciding to place a tracheostomy after using an endotracheal tube, placing a tracheostomy provides long-term stability of the airway.[10] This stability helps to ensure safer handling of the neonate as well as facilitate safe discharge from the hospital. Additionally, there are situations where prolonged weaning from mechanical ventilation is required. In this case, tracheostomy provides similar benefits: a stable airway and safer ability to participate in daily care and rehabilitation.

Bronchopulmonary Dysplasia (BPD)

Bronchopulmonary dysplasia (BPD) is a common diagnosis for patients in the NICU. BPD is a lung condition resulting in abnormal lung development often necessitating tracheostomy and mechanical ventilation.[4] Advanced technology has allowed for increased survival rate of premature infants with severe BPD, when previously this population did not survive.[8] Improved survival rate has increased the need for long-term mechanical ventilation in the BPD population.[8] BPD is now the most common indication for tracheostomy for infants less than 1-year old.[8] Tracheostomy is commonly indicated in this population of patients to provide a safe method for maintaining ventilation, facilitating discharge from the hospital.[8] It has been found that tracheostomy in patients with severe BPD may improve both neurodevelopmental and respiratory outcomes, short term and long term.[8]

Neurological Impairment

Neurological impairment can result in the need for tracheostomy tube in the neonatal population, largely to facilitate long term or prolonged weaning from mechanical ventilation.[4] Neuromuscular diseases such as muscular dystrophy, myotonic dystrophy, and chest wall disorders requiring ventilation could lead to tracheostomy placement in a neonate with one of these conditions.[9] Complete cervical cord lesions and spinal cord injury are associated with the highest degree of respiratory dysfunction, often leading to tracheotomy. These conditions were previously not survivable; however, tracheostomies now enable long-term support for neonates with neurological impairments.

Selecting the Optimal Tracheostomy Tube for Neonates

There are numerous reasons for neonatal tracheostomy, and it is imperative that the tracheostomy tubes are designed for these delicate airways. The Tracoe Silcosoft tracheostomy tube is specially designed for neonates, featuring a soft, flexible material

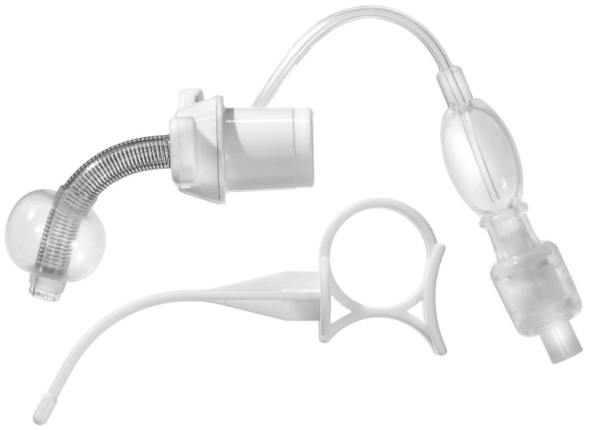

Figure 1. Silcosoft Neo/Pediatric Tracheostomy tube with H2O Cuff.

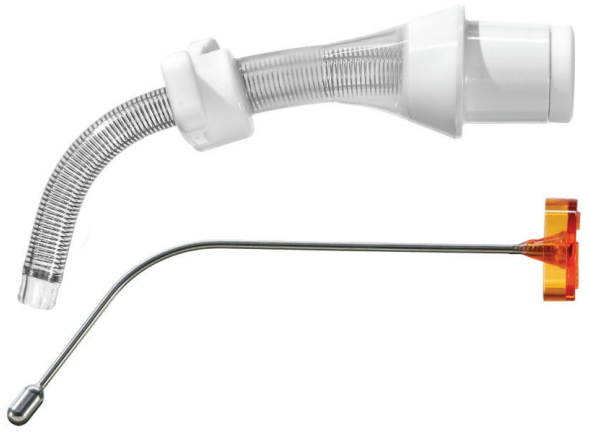

Figure 2. Silcosoft Neo/Pediatric Tracheostomy tube with proximal length, cuffless.

that can also maintain its shape in the fragile neonatal airway. Tracoe Silsocoft tracheostomy tubes can come both cuffed and cuffless, which can help meet a variety of patients' needs. Additionally, these tracheostomy tubes have various distal length options, both shorter and longer than the standard size. This could be extremely beneficial in a condition like tracheomalacia, where a longer length tube is needed to bypass areas of malacia. These tubes must also be able to fit comfortably in the small neonatal airway. Silcosoft Neo tracheostomy tube line comes in sizes that fit the neonatal airway, with the smallest size being 2.5 mm. Selecting the appropriate tracheostomy tube for neonatal patients is imperative to provide the largest diameter for airflow while not causing harm to the airway. Tracoe Silcosoft Neo tracheostomy tubes are a great option for neonatal patients who require tracheostomy tubes.

Conclusion

Infants in the neonatal intensive care unit who undergo tracheostomy placement often have multiple medical comorbidities. Overall, tracheostomies are performed more frequently in children with chronic conditions, such as congenital heart and lung disease as well as neurological impairment.[1] One article noted that 43% of children who underwent tracheostomy had three or more chronic conditions.[3] These chronic conditions could require additional medical care, 29% of infants who had a tracheostomy had additional medical technology (outside of tracheostomy supplies) to aid

in their care.[3] Recognizing that tracheostomy is one of several comorbidities impacting neonatal patients can enhance the quality of care provided.

Over the last 30 years, the prevalence of long-term ventilation has risen dramatically.[9] The neonatal intensive care unit will continue to see patients requiring tracheostomy for airway protection, long term mechanical ventilation, and/or helping to wean from mechanical ventilation. While there are a multitude of diagnoses that could require a neonate to have a tracheostomy tube, there are some that are more common within the NICU population. Understanding these diagnoses can help broaden the understanding of why tracheostomy tubes are needed in critically ill infants and improve the overall management and outcomes for these vulnerable patients.

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The Physical and Emotional Toll of Stillbirth and Current Treatment Protocols

Rachel Dynkin, Shmuel D Silverstein, edited by ChatGPT

Introduction

Stillbirth—the loss of a fetus after 20 completed weeks of gestation but before birth[1]— is a devastating and complex public health issue with profound emotional, medical, and social consequences. Globally, an estimated 13.9 stillbirths occur per 1,000 total births, amounting to approximately 2.0 million stillbirths annually.[3] In the United States, approximately 1 in 175 births result in stillbirth.[8] Women who have experienced first-trimester losses, early or late stillbirths, or intrapartum deaths face an increased risk of recurrent stillbirth. These risks highlight the need for thorough monitoring and specialized care in subsequent pregnancies to improve outcomes.[4] Additionally, congenital abnormalities, which affect roughly 3% of pregnancies, account for 20% of perinatal deaths.[5] Despite advancements in maternal-fetal medicine, early detection of congenital issues can prolong parental grief.

Following perinatal loss, most women conceive again, with pregnancy rates reaching up to 80% within the first 18 months.[4] However, these subsequent pregnancies can be exceptionally stressful, as parents continue to grieve while also facing the fear of another loss. The lack of clarity surrounding the initial stillbirth often leaves them uncertain about preventive measures. Moreover, many healthcare providers are ill-equipped to address the psychological impact of stillbirth, further complicating emotional recovery. Research indicates that while depressive symptoms may gradually decrease, only about 5% of parents achieve long-term healthy adjustment after stillbirth.[5]

A multi-pronged approach is needed, including universal guidelines to ensure standardized, high-quality care for all families, regardless of race or socioeconomic status; equitable access to bereavement services; efforts to eliminate healthcare disparities that create barriers to care. By prioritizing compassionate emotional support, implementing standardized protocols, and addressing systemic inequities, we can work toward reducing the devastating impact of stillbirth and improving the well-being of grieving families.[7]

Risks/causes of stillbirth

Stillbirth is a complex issue influenced by biological, behavioral, and systemic factors. Congenital abnormalities account for approximately 20% of perinatal deaths, while maternal conditions like hypertension, diabetes, and preeclampsia, along with infections such as CMV, further increase the risk.[3,5,6] Other maternal factors such as obesity, advanced age, smoking, and substance abuse further elevate risk of stillbirth.[3,6] Placental complications and umbilical cord issues—responsible for about 10% of stillbirths—and fetal growth restrictions are also major contributors.[3] However, many cases remain unexplained, underscoring the need for continued research.[7]

Predicting and preventing stillbirth remains challenging. Traditional risk factors like maternal age and BMI have limited predictive value. At the same time, advanced screening methods like Doppler studies and sonograms may detect fetal growth concerns but have uncertain effectiveness in improving outcomes.[3] Biomarkers such as PAPP-A and PlGF show promise but lack sufficient predictive reliability for clinical use.[3] While fetal movement monitoring is commonly used, its predictive value remains unclear, often leading to preterm births, inductions, or cesarean deliveries without significantly reducing stillbirth rates.[3]

Self-blame among parents

Traumatic grief following stillbirth can manifest through a range of emotional, physiological, social, and psychological symptoms, including disruptions in appetite and sleep, deep yearning, social withdrawal, and overwhelming feelings of guilt and shame.[1] Parents often report intense emotions such as anger, rage, and a sense of inadequacy, along with a profound loss of purpose.[1] Despite its devastating impact, stillbirth has long been marginalized, often referred to as the "invisible death."[1] This neglect is partly due to its unjustified association with pregnancy loss and abortion.[1] Researchers have highlighted how stillbirth is systematically disregarded as a public health concern by governments, healthcare systems, reproductive rights opponents and activists, and even medical professionals.[1]

A global study by Frøen et al. found that healthcare providers in non-Western countries frequently misattribute the cause of stillbirth.[1] Between 29-43% linked the fetal death to the mother's past sins, lifestyle choices, diet, etc., while another 20-46% perceived the loss as a personal failure, blaming the mother entirely for the tragedy.[1] Research by DeFrain et al. revealed that nearly all mothers of stillborn infants experience profound self-blame, both in terms of behavior and character.[1] Nearly 30% of bereaved mothers in the study seriously contemplated suicide following their baby's death, 13% turned to substance use as a coping mechanism, and 62% wished they could "go to sleep and wake up after the pain was gone."[1] Despite these

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alarming statistics, few quantitative studies have examined the relationship between self-blame and psychological outcomes following stillbirth.[1]

Weinberg observed that dual blame—holding both oneself and others accountable—is more prevalent after traumatic or unnatural deaths. Individuals who did not engage in self-blame demonstrated better coping mechanisms than those who did.[1] Both internalized (self-directed) and externalized (other-directed) blame have been identified as risk factors for poor bereavement adjustment.[1]

Even when no specific cause or preventable factor can be identified, many mothers internalize guilt, feeling they could have somehow prevented the loss. This sense of personal responsibility is exacerbated by societal pressures that place the primary responsibility for a healthy pregnancy on the mother.[7] As one study noted, "There is a perceived failure, which may result in an ambiguous relationship with their bodies."[6] The ambiguous nature of many stillbirths further intensifies self-blame, as bereaved mothers frequently scrutinize their actions during pregnancy, questioning whether they could have done something differently—even when they meticulously followed all medical advices.[6] This uncertainty can lead to a profound sense of personal failure and a distorted perception of their role as a mother.[1] Identifying a clear cause of death can provide a sense of closure and facilitate grieving, but such explanations are often unavailable, leaving mothers with unresolved guilt.[3]

Impact on Families

A stillbirth represents not only the death of an unborn child but also the loss of a future relationship with a family member who, though never physically integrated into family life, holds a significant psychological presence within the family system.[5] When a death occurs without clear, tangible markers that facilitate psychological closure, it is considered ambiguously bounded, meaning it lacks the definitive structure needed for adaptive coping [5]. The unexpected and unclear nature of such a loss can thrust parents into crisis as they struggle to redefine their parental roles while grappling with the reality of the death.[1]

Mothers frequently experience intrusive thoughts, while fathers often feel helpless yet compelled to assume the role of protector while grappling with their own grief and emotional vulnerability. As one study noted, "Fathers felt overlooked during the pregnancy after the loss. They had to stay strong on the outside, but inside they felt stressed and vulnerable."[6] While grief may bring some couples closer, it often leads to marital strain.[6] Siblings, too, experience sadness, confusion, and isolation, mourning not only the loss of their brother or sister but also the emotional changes in their parents. Including siblings in farewell rituals, such as allowing them to touch or hold their stillborn sibling, can help them process their grief.[6] Children born after a stillbirth may also face challenges, sometimes being viewed as a "replacement child" or experiencing "vulnerable child" syndrome.[6]

The economic burden of stillbirth can further exacerbate family stress. Funeral costs, returning to work before emotional readiness, and increased healthcare utilization create significant financial hardship.[6,7] Partners, in particular, often face social stigma and inadequate emotional support, further straining their relationships.[7] The economic burden of stillbirth is substantial, with estimated annual costs in the United States reaching $1.6 billion.[6] These costs include medical care, funerals, and the long-term financial strain on grieving families.

Discussions surrounding autopsies require sensitivity and should be led by trained professionals. While an autopsy may not always provide definitive answers, it can offer some families a sense of closure.[7] Addressing the multifaceted effects of stillbirth requires a holistic approach that includes comprehensive emotional, social, and financial support systems to help families navigate their grief and rebuild their lives.

Society's response

Society's response to stillbirth is often marked by silence, stigma, and a lack of public awareness, leaving bereaved families feeling isolated and unsupported. Stillbirth rates vary even among nations with similar resources, suggesting that "we can do better" in implementing effective prevention measures.[3] Despite this, stillbirth remains unacknowledged in many societies, disrupting social connections as parents feel they "no longer fit in with other families."[6] Cultural norms further shape grief, either suppressing or supporting mourning. For instance, women in Oromia, Ethiopia are pressured to restrain their sorrow, while other communities encourage open expressions of grief.[6]

Beyond social stigma, stillbirth can trigger profound existential and spiritual struggles, with parents questioning, "Why did my baby die?" or viewing the loss as divine punishment.[6] The lack of public awareness and societal support creates barriers to healing, as stillbirth remains a taboo subject.

Disenfranchised grief—grief that is not socially recognized or supported—often affects bereaved parents.[5] Societal norms dictate "who, when, where, how, how long, and for whom people should grieve,"[5] leaving parents feeling their loss is minimized. The pressure to find a reason for stillbirth further intensifies distress. One mother said, "But there has to be a reason. There doesn't have to be, but most people think there's got to be a reason for things to happen."[6] Studies show that validation from healthcare professionals, family, and society significantly reduces the likelihood of complicated grief, whereas the absence of validation increases both the severity and duration of grief.[5] Breaking the silence around stillbirth is crucial to fostering a more compassionate and informed society. Public awareness campaigns, improved data collection, and proven care strategies can help reduce stigma and ensure better support for affected families.[3]

Solutions that already exist and what can be done better

More than 80 classification systems have been developed to determine the causes of stillbirth, with significant variation in the level of information and testing required across these systems.[3] The Initial Causes of Fetal Death (INCODE) system, developed by the National Institute of Child Health and Human Development's Stillbirth Collaborative Research Network (SCRN),[3] is commonly used in the United States.

To improve care for women who have experienced stillbirth, Rainbow Stillbirth Clinics were introduced by Dr. Alex Heazell in the UK in 2013. These clinics focus on providing specialized care by incorporating additional testing to detect early indicators of fetal growth restriction and placental dysfunction.[2] Multidisciplinary teams at these clinics receive specialized training to address both the medical and emotional needs of affected families.[2] Individualized care plans include pre-

conception evaluations, a review of past medical history, and personalized management strategies for the current pregnancy.[2] Mount Sinai Medical Center in New York City was among the first OB/GYN departments in the United States to establish such a clinic.[2]

Medical Interventions (Medications, Imaging, Testing)

While significant progress has been made in preventing stillbirth, continued advancements are essential. Standardized care bundles have improved outcomes by addressing fetal growth restriction (FGR), monitoring decreased fetal movement, and enhancing prenatal care. Public health efforts, such as smoking cessation resources and improved nutrition, also play a role in reducing risk of stillbirth[3]. Perinatal audits have been particularly effective in identifying gaps in care—The Netherlands saw a 6.8% decline in stillbirth rates between 2000 and 2015 through audits and public health initiatives, compared to just 0.4% in the U.S. during the same period.[3]

Low-dose aspirin has shown promise in reducing complications linked to stillbirth, especially in women with antiphospholipid syndrome, though further research is needed.[3] Enhanced fetal surveillance, including frequent ultrasounds and amniotic fluid monitoring, allows for earlier detection of complications, while timely labor induction has been associated with reduced stillbirth risk, though it must be carefully weighed against potential risks.[3]

Artificial intelligence (AI) advancements offer exciting possibilities for improving risk prediction by analyzing biomarkers, genetic data, and imaging to help optimize delivery timing.[3] Programs like Rainbow Clinics demonstrate the value of comprehensive medical and emotional support while expanding access to specialized maternity care with trained professionals that can further improve outcomes.[7]

Post-mortem evaluations, including genetic and placental assessments, sometimes provide grieving families with crucial answers. The Subsequent Pregnancy Program at Sunnybrook Health Sciences Centre in Toronto serves as a model for comprehensive monitoring, offering antiphospholipid syndrome testing, first-trimester PAPP-A measurement, and second-trimester uterine artery Doppler studies to ensure ongoing assessment of placental function.[4]

Psychological care and the Dual Process Model

The dual-process model (DPM) is an optimal approach to grief counseling for parents navigating perinatal loss. The DPM suggests that healthy grieving requires natural shifting between focusing on the loss itself (loss-oriented coping) and dealing with other stressors that arise as a result of the loss (restoration-oriented coping), in order to support the overall coping process.[5] Counselors should recognize that grief is not a temporary phase but a transformative process that shapes a person's identity.[5] A recovery-oriented model that frames grief as a return to a pre-loss state is often inadequate.[5] Instead, the restoration-oriented approach in the dual-process model addresses bereavement's internal and external consequences.[5] For example, internal stressors include negative self-perception, such as struggling with identity after loss, while external stressors include social isolation or perceived lack of support. Restoration-oriented coping helps individuals develop autonomy and transitional coping skills, discouraging denial or avoidance of grief.[5]

Engaging with painful emotions fosters reconciliation, whereas avoidance often leads to prolonged distress.[1] Kurtz emphasizes the need to acknowledge and transform shame into a constructive force.[1] Middelton-Moz described shame as a "master of disguise" that can trigger a harmful pattern of repeated shaming.[1] Recognizing the presence of shame within the therapeutic context is a crucial first step in the healing process.[1]

Mindfulness-based therapies can be particularly effective in addressing shame, promoting acceptance, attunement, and trust in the therapeutic process.[1] This approach deviates from the medicalized model of grief, acknowledging that negative emotions are a natural part of the healing process. Creative reconciliatory strategies—such as writing a letter to the deceased baby, engaging in volunteer work, or performing rituals—can help parents reframe self-blame, guilt, and shame, fostering self-compassion, meaning-making, and emotional well-being.[1]

Support groups and counseling services provide grieving parents with a sense of community, helping to reduce isolation and post-traumatic stress.[6] Meaningful rituals, such as creating memory boxes or participating in remembrance ceremonies, offer comfort and a way to honor their baby.[7] Many parents also find healing through activism, awareness campaigns and fundraising efforts to transform grief into advocacy.[6]

To improve psychological care, bereavement counseling should begin at diagnosis and continue throughout the postnatal period. Equally important is training healthcare providers to offer sensitive, empathetic support while ensuring continuity of care with familiar midwives and obstetricians.[7] Incorporating feedback from parents can further refine care protocols, making families feel heard, validated, and supported.

A holistic approach that acknowledges both medical and emotional needs is essential. Giving parents clear medical explanations and the ability to choose their mode of delivery (vaginal or cesarean) can help restore a sense of control during an otherwise overwhelming experience.[7] Ultimately, the emotional toll of stillbirth often outweighs the medical challenges. Families find reassurance in frequent prenatal visits, ultrasounds, and hearing their baby's heartbeat, which can help ease anxiety in subsequent pregnancies. As one study notes, "The emotional support of families during a pregnancy after stillbirth is arguably more critical than their medical care."[3] Structured bereavement protocols, like those in Rainbow Clinics, ensure families receive compassionate, continuous care from diagnosis through postnatal follow-up.[7]

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Little Airways, Big Impact: Considerations for Speaking Valve Use in Pediatrics

Gabriela Ortiz, RCP

Speaking Valve placement—such as the Passy Muir® Tracheostomy & Ventilator Swallowing and Speaking Valve (PMV)—must be thoughtfully tailored in pediatric patients. While the goals align with adult care (e.g., improved communication, secretion management, and swallowing), the approach in children, especially neonates, must account for physiological and developmental differences at every stage.

Communication: When Words Are Limited

Adults often understand instructions, express needs, and report discomfort. Pediatric patients, especially neonates and toddlers, communicate through physiological and behavioral cues. Educating staff and caregivers as to what cues to watch for is essential for best care. Education regarding trials and how a trial with a speaking valve may proceed is important, including how to closely monitor for indications of distress, as an infant or young child may not be able to provide direct feedback.

Clinical Tip
Nonverbal Cues of Distress in Pediatrics:

- Nasal flaring
- Furrowed brow
- Grimacing
- Head bobbing, turning, or neck/back arching
- Fidgety or restless movement
- Vital sign changes
- Desaturations

Positioning: Considering Pediatric Anatomy

In adults, neutral alignment is typically straightforward and easily achieved in most patients. In pediatrics, however, alignment is not the only consideration as their proportionally larger heads and small chins, also affect airway openness. Proper support (e.g., towel roll under shoulders, pillows) is critical for maintaining airway patency during Valve trials. Having an interdisciplinary approach and including physical therapy and occupational therapy to assist with proper positioning can impact the success of therapeutic interventions.

Gabriela Ortiz has been in the field of respiratory care since 2006. She has worked in various roles, both clinically and professionally, where she gained extensive knowledge about mechanical ventilation as it relates to use within acute and subacute care hospitals. She combines this with her clinical experiences to provide support to others through education and clinical publi-cations. She is currently a prn clinical consultant with Passy-Muir, Inc.

Comfort Equals Cooperation

Pediatric success with Valve placement hinges on comfort and trust. Developmentally appropriate toys, caregiver presence, and calm tone can make or break a trial. Often, distraction with a toy or music can help promote a successful trial. Just as a young child may not be able to indicate distress, they also may not understand what a clinician is doing with them. They react to change, and sometimes that is a negative reaction. Finding a way to increase comfort may equal improved cooperation.

Clinical Tip
Tips to Maximize Comfort

- Use familiar voices (parent or caregiver)
- Offer a pacifier or soft toy
- Use familiar toys or music
- Avoid overstimulation
- Time the trial for after suctioning or feeding

Airway Patency & Transtracheal Pressure: Navigating Tiny Airways

What is TTP? Transtracheal pressure (TTP) is the pressure measured within the trachea at the end of exhalation. TTP is an objective method for assessing upper airway patency. This technique involves measuring the pressure within the trachea, below the tracheostomy tube, at the end of exhalation, once airflow is redirected through the upper airway. The Johnson

study (2021) reports tracheostomy tube manometry can objectively identify within minutes which patients can use speaking valves, which need downsizing, and for which patients capping and decannulation should be considered.[1]

Why It Matters in Pediatrics. Pediatric airways are smaller and more reactive, meaning that even minor swelling or the presence of secretions may lead to a significant increase in airway resistance. In these cases, airway compromise may not be immediately visible through observation alone. TTP provides an objective method to assess upper airway patency, helping to identify obstructions that could otherwise go undetected. Research has indicated that a TTP reading of greater than 10 cm H_2O may indicate the need to delay or further evaluate the airway.[2]

Clinical Tip
Understanding Transtracheal Pressure

- General evidence-based guideline range: < 10 cm H_2O for speaking Valve tolerance.
- Pediatric readings may fluctuate more, requiring multiple measurements across different times of day due to secretions, edema, or tracheomalacia.

PMV Use with Mechanical Ventilation

Ventilator Adjustments: Pediatric-Specific Priorities.

Moody et al. (2018) reported that tracheostomies are routinely performed in children requiring long-term mechanical ventilation.[3] While lifesaving, the presence of a tracheostomy tube, especially in infants, can negatively impact language development and swallowing. The use of a Passy Muir Valve helps mitigate these effects by restoring expiratory airflow through the vocal cords, enabling phonation and supporting improved swallowing function.

When used in-line with mechanical ventilation, the PMV redirects exhaled flow away from the ventilator, which can affect how the ventilator reads certain ventilator parameters. The respiratory therapist would closely monitor a patient's respiratory function and status while using a speaking valve in-line. During use, it is recommended to reduce the set PEEP (positive end-expiratory pressure) to avoid complications such as auto-triggering of breaths and to ensure effective Valve function; however, in pediatrics, it is recommended that PEEP is adjusted down by no more than half.

Monitoring During Valve Trials

In infants, even subtle changes in ventilator readings, such as a drop in exhaled tidal volume (Vte) or alterations in pressure waveforms, may indicate changes in airway patency. These small shifts may reflect increasing airway resistance, obstruction, or improving patency, and may guide clinical decisions about PMV tolerance or the need for further assessment. Ongoing interdisciplinary communication is critical to ensure safety and effectiveness throughout speaking Valve trials and continued Valve use.

Suggested Criteria for Pediatric PMV Trials

Pediatric patients being considered for PMV use should generally demonstrate:

- $FiO_2 \leq 50\%$
- PEEP ≤ 10 cmH_2O
- Peak Inspiratory Pressure (PIP) within normal limits for age/size

Clinical Tip
Monitor for Vent Changes:

- **Visible Vte Drop:** Should expect to see a noticeable drop in exhaled tidal volume (Vte) (40-50%) following cuff deflation. Continue to monitor closely, especially in neonates and infants, while using a speaking Valve.
- **PEEP:** PEEP should never be turned off in pediatrics. It is essential for preserving functional residual capacity (FRC) and preventing alveolar collapse in pediatric lungs. PEEP may be adjusted down (by no more than half) to avoid auto-triggering of respiratory breaths.
- **Alarms Stay Active:** Always keep ventilator alarms on, only adjust to avoid false-positive alarms. Pediatric patients may decompensate rapidly, and early detection is critical. Patient safety first is critical.
- **Leak Compensation:** Make ventilator changes gradually. Small, incremental increases in tidal volume should be closely monitored to avoid overdistension, especially in smaller or more fragile lungs.

Earlier Mobility: Improved Breathing Mechanics

Our bodies naturally operate as a closed system, relying on pressure gradients to support breathing, stability, and function. This system is essential not just for moving air but for performing nearly any task that requires core strength (e.g., sitting up, standing), postural stability (e.g., crawling, walking), or effective respiratory mechanics.

When a tracheostomy is placed, a "hole" has been poked into a closed system, converting it into an open system and releasing pressure. This has significant consequences in that patients can no longer easily build the internal pressures needed for basic physiologic functions.

One of the most critical pressures lost is physiological PEEP. PEEP is the pressure that remains in the lungs at the end of exhalation. PEEP also helps keep the lungs stented open and prevents alveolar collapse. Under normal conditions, physiologic PEEP is generated through the upper airway, which creates natural resistance to expiratory flow due to the narrowed airway and engagement of the vocal folds. However, when a tracheostomy tube is placed, the exhaled air now bypasses the upper airway and exits directly through the tracheostomy tube. As a result, natural resistance, and thus physiologic PEEP, is lost.

A PMV helps re-establish a closed system, restoring more normal pressure gradients and improving multiple physiological functions by closing the system on exhalation. A patient still breathes in through the tracheostomy tube, but exhalation is redirected up and out through the upper airway.

A study by Sutt et al. (2017) demonstrated that speaking valve use both with and without mechanical ventilation led to increased end-expiratory lung volume (EELV) and improved lung recruitment. Improved respiratory mechanics support earlier mobilization and may improve participation in rehabilitation efforts, particularly in pediatric patients where developmental progress is closely tied to mobility and interaction.

Troubleshooting: Pediatric-Specific Challenges

When evaluating PMV tolerance and use in pediatric patients, several common challenges must be considered:

- **Tracheostomy Tube Considerations.** Downsizing is not usually an option in neonates and infants, as the current

tracheostomy tube is typically already the smallest available internal diameter for their airway. Often tracheostomy tubes are actually upsized due to growth and development. Further, a reduction in size may increase airway resistance and compromise airflow during inhalation. Additionally, it is not uncommon for pediatric patients to have cuffed tracheostomy tubes, adding another layer of complexity when assessing tolerance. The cuff must be fully deflated during speaking Valve use.

- **Secretions.** Airway obstruction from mucus plugging may be a challenge in pediatric patients. Given their small airway diameter and limited physiologic reserve, they are particularly vulnerable to rapid desaturation when blockages occur. To support safe and effective PMV use, regular suctioning and adequate humidification are critical for maintaining airway patency and promoting Valve tolerance.
- **Assessing for Obstruction.** Signs of upper airway obstruction may include stridor, increased work of breathing, or changes in vocal quality. When these signs are present, further assessment, such as an instrumental, transtracheal pressure manometry, or an ENT consult, may help identify the location and severity of the obstruction. Early identification assists with improved interventions and proper planning for potential Valve use.

Clinical Tip

When to Pause a Valve Trial:

- Oxygen desaturation
- Apnea or bradycardia
- Agitation or cyanosis
- Inability to exhale (tight chest, no vocalization)

Clinical Takeaway

Speaking Valve placement in pediatric patients, particularly neonates, is a delicate yet highly impactful intervention. It enables vocalizations, crying, verbal communication, improved secretion management, and significantly improved quality of life. Success depends on a thoughtful, individualized approach that accounts for the unique anatomical and developmental needs of children. Above all, clinicians must prioritize airway safety, patient comfort, and interdisciplinary collaboration throughout the process.

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Building Trust in New Technology: One NICU's Experience With TCOM

A Q&A with the NICU Team at Woman's Hospital

The NICU team at Woman's Hospital in Baton Rouge, Louisiana, reintroduced transcutaneous CO_2 monitoring ($TcPCO_2$) as part of a broader harm-reduction initiative and reduced blood gases performed in their NICU by 50%. In this conversation, NICU team members Mark Schorr, RRT, and Meagan Dexter, RNC-NICN, reflect on the challenges, breakthroughs, and process changes that helped make the technology effective and sustainable. This interview has been lightly edited for clarity, grammar and length. Ellipses (…) and brackets [ ] indicate minor editorial changes made for clarity or to reflect the structure of the conversation. The clinicians interviewed were not compensated by Sentec and do not have a financial relationship with the company.

Why CO_2 and Why Continuous?

Sentec Education Team (SET): Why is CO_2 such a critical parameter in neonatal care, and what makes continuous monitoring particularly important for extremely premature infants?

Mark Schorr, RRT: Most of the premature babies' problems are respiratory in nature. Their lungs are not developed enough, so they all need support. And we'd struggled for long periods of time with trying to prevent lung problems. We'd had O_2 saturation monitoring for decades, and hadn't had the ability to measure CO_2 other than drawing a blood gas, which is pretty invasive, and a point-in-time measurement. The ability to monitor CO_2 and see the impact of the changes we make with the ventilator guides us as we try to deliver the safest ventilation strategy possible to help prevent lung damage.

Meagan Dexter, RNC-NICN: The main focus from the nursing perspective is to not have as many pokes and blood draws for our babies. Regardless of whether or not the infant has a line in, you're still making hemodynamic changes by drawing blood from that baby. If you draw too fast, the vessels in those [premature] babies' brains are extremely fragile, and any drawing of blood from those infants can shift blood volume in these fragile vessels and cause damage. So this was a way for us to minimize those things, and to see how the baby was reacting to the changes that were being made.

Mark Schorr, RRT: I've been in this business for over 30 years, and I didn't realize the effects we can have on the neonatal brain. When we have to draw so many blood gases, we're changing the wiring of the baby's brain. Over the course of time that a baby is in our unit, by reducing the pokes and sticks, that means less negative wiring of the baby's brain. I think we really learned that just in the last 10 years.

The Quality Improvement Initiative

The successful initiative undertaken by the team at Woman's Hospital is outlined in detail in their white paper "Reducing Pain in the NICU: A Quality Improvement Initiative" which is featured in the 2025 Summer issue of Neonatal Intensive Care.

The paper outlines the broader clinical context and data behind their unit's effort to reduce invasive procedures and improve outcomes for extremely low birth weight infants.

The initiative by the the NICU team at Woman's Hospital allowed them to:

- Reduce blood gas draws by over 50% in extremely premature infants
- Build clinical trust in $tcPCO_2$ monitoring across RT and nursing teams
- Standardize CO_2 monitoring protocols to limit noxious stimuli
- Empower staff to use real-time, noninvasive CO_2 data for clinical decision-making

Read the paper here: nicmag.ca

Why the First Attempt at Adoption Failed

SET: Previously your team tried adopting transcutaneous CO_2 monitoring, and it didn't pan out. What do you think was the difference the second time around? Did you make specific changes in your approach?

Mark Schorr, RRT: I remember that when we first installed transcutaneous monitoring, we were taught to use saline [instead of contact gel, where the sensor makes contact with the patient's skin], and that did not allow us to get accurate measurements. So people thought, "*This is not going to work. I don't believe these measurements*." So we were provided the wrong education, but also no one in our unit had experience with transcutaneous. But they had tons of experience with blood gas. Everybody—especially RTs—had a lifetime of experience with drawing blood gases, but nobody had an idea of how they could depend on transcutaneous monitoring. They didn't understand how the technology worked. It took a lot of education to get them to understand that transcutaneous CO_2 measurements

were reliable. So, it took education, time, and a whole lot of data, as we mentioned in our webinar and paper, to make them understand that this really works.

Starting Fresh, With the Right Strategy

SET: Were the two of you the ones who were the first to say, "Hey, let's try it again?"

Mark Schorr, RRT: The NICU director brought it up. We had done a lot of work on improvement in our unit on all kinds of different things, and we had moved to a more volume-targeted ventilation strategy. The director wanted to have continuous CO_2 monitoring along with this initiative to change ventilator strategy. I said, "*Okay, if we're going to do this, then we have to do it a different way [this time].*" We're going to have to do it in a way using all the things that I had learned from my experience with quality improvement over the last 10 years. That's the only way I know. And it worked out.

SET: So the NICU director introduced it as you were changing focus to a new ventilation strategy, as an improvement initiative, and when you launched it, you wanted to focus on good education: how to use the monitor, and get accurate readings?

"We have found that face-to-face education is the most important. It allows for people to voice their concerns, ask questions, and think of things that maybe we didn't think of initially."

Mark Schorr, RRT: And the timing was right. Our RTs—all of our staff—had been developing a mentality of less harm. We developed a mental state: less harm is better for the babies. So it was an easier sell to the staff, I guess, because everybody wants the best for the babies, right?

SET: That makes sense. There's already a culture shift happening.

Mark Schorr, RRT: Yeah, I believe so. Definitely.

Training and Education at Scale

SET: As leaders on your staff, how many people—RTs and nurses—are we talking about trying to get educated when you started this protocol?

Meagan Dexter, RNC-NICN: We have almost 300 nurses.

Mark Schorr, RRT: We have about 50 RTs.

SET: So how do you ensure, once you've created the initiative and are rolling it out, that 350 people stick to it?

Mark Schorr, RRT: Well, we collected and presented a lot of data.

Meagan Dexter, RNC-NICN: And from the nursing perspective, we had some champions—just a few people who would check on other nurses caring for small babies and say, "*We're trying to do this process. We need you to stick to it.*" If they saw the protocol not being followed, they'd ask, "*What happened? Why did we deviate from the plan*?" If our people aren't following what we need to do, how do we change that?

Mark Schorr, RRT: And the quality improvement team met regularly. We were meeting at least every two weeks, and then maybe monthly for probably two years. We were constantly talking about it, and we were constantly monitoring the data and identifying what was going on.

Meagan Dexter, RNC-NICN: If you don't stay on top of it… you can put out computer-assisted in-services, you can send out emails, but we have found that face-to-face education is the most important. It allows for people to voice their concerns, ask questions, and think of things that maybe we didn't think of initially. And then we go back and talk about it as a group and say, "*This came up. How do we handle this and tweak it as we're going?*"

Protocol Development and Process Tuning

SET: Were there any specifically difficult or hard decisions that had to be made when you were forming those first protocols or processes for adopting transcutaneous monitoring?

Mark Schorr, RRT: Well, in the very beginning, our protocol was for every baby less than 30 weeks. And that made it hard to identify whether the process was working because if you're getting a lot of high acuity babies, you're going to be doing lots of blood gases. So for this second attempt, we revamped the protocol and separated the babies by gestational ages because you can't have the same protocol for a 22-weeker as you have for a 28-weeker. They're not the same babies.

Measuring Impact

SET: When do you think you realized the new protocol and new adoption process were working?

Mark Schorr, RRT: To be honest with you, we realized it was working pretty early in the process. Probably in the first few months we started to realize this was going to work. I had a feeling it was going to work because I understood the value of transcutaneous monitoring. I think it was the first few months that I saw that the process was reducing blood gases tremendously.

"For me as a respiratory therapist, the future is TCOM. The future is CO_2."

The hardest thing was getting people to follow the protocol. It wasn't that if they followed the protocol it wouldn't work—it's just, people are nervous. The easiest thing to do is to draw a blood gas. If the baby's status was changing and they didn't fully trust the transcutaneous value, they would fall back on what they knew, which was to draw a blood gas. I mean, it's hard to rely on a technology that you're a little unsure of. Maybe it's easier just to draw an arterial blood gas.

Meagan Dexter, RNC-NICN: I knew that it was working, but I did not know how well it was working until Mark started showing the rest of the group the numbers. 50% reduction. I knew we weren't performing as many gases—I just didn't realize we had cut that number in half. Walking around, I could see we were relying on the TCOM a significant amount more than what we had previously been. So I knew there was a difference, but I was thinking 25%, 30%. I didn't realize it was a 50% reduction.

SET: Did you have a target for percent reduction in blood gases performed?

Meagan Dexter, RNC-NICN: I want to say it was 10%.

Mark Schorr, RRT: We targeted a 10% reduction; we didn't want to overpromise. We did very well, I guess.

Can This Be Replicated in Other NICUs?

SET: Do you think the strategy you used to incorporate transcutaneous monitoring is replicable in other NICUs?

Meagan Dexter, RNC-NICN: Yes. Because it was a true P.D.S.A. cycle that we did: Plan. Do. Study. Act.

SET: For anyone unfamiliar with that kind of cycle, what does it involve?

Mark Schorr, RRT: You plan out the change you're going to make—for us, that was to implement monitors on all of our babies—then we wrote out the process and did it. We collected data. We studied it. If we found that parts of the protocol were not being followed, we'd go back, meet, make a decision and ask: "What can we do about that?" And then we'd make the change; we'd act. You can do that with any process.

Meagan Dexter, RNC-NICN: As a nurse, you want to throw as many things as possible at whatever the problem is to fix it, but you're never going to know what fixed the problem unless you set out with a plan and test what changes. You have to (a) make sure that the changes that you are making are replicable, and (b) you have to know which change actually made the difference.

Shifting Culture

SET: For both nursing and respiratory departments did you have to make sure that, as a quality improvement initiative, the plan and the "*why*" was communicated? Was that a big factor in improving compliance to a new change or a new initiative?

"If that was your baby… and your baby had 10 sticks you could avoid, wouldn't that be of value to you?"

Mark Schorr, RRT: Definitely. I've worked in other industries where the boss says something, puts an email out, and that's the way it's got to be. But just because you say something doesn't mean it's going to happen. The change happens because of, like you said, *the why* and communicating it to the staff.

SET: We want to ask about cultural shifts. A lot of people in the NICU might consider blood draws an unfortunate but necessary process. How do you shift toward the idea that, in a lot of cases, this is unnecessary harm, and there are alternatives?

Mark Schorr, RRT: That's a great question. I think we still do a lot of blood draws, and for other things I wish we could reduce. I wish we had the technology to reduce a lot of different labs that we draw, but we're just not there yet. But to me, even if it is one [blood draw you're avoiding], then that matters, because if it was your baby, it would matter. And that's what I would say to anybody. If that was your baby and your NICU stay and your baby had 10 sticks you could avoid, wouldn't that be of value to you?

Meagan Dexter, RNC-NICN: To me, it's an educational journey. When I first started back in 2003, we did the micro preemie flip—so you picked up your baby and flipped them. We don't do that anymore. I didn't know the impact of flips until I was educated on the 10 or 15 years of data that showed us what we thought was a good thing was actually harming these babies. It made a huge difference. Once I got that knowledge and was able to pass that knowledge on to the rest of the staff… and the data actually supports what we're doing. As a nurse, if I understand the impact, then yeah, I'm going to do what I have to do, but I'm going to do it with a conscious effort to minimize negative impacts on my patient.

Building a More Collaborative Team

SET: Mark, you mentioned since 2015 or 2016 that you really started this initiative of reducing pain in the NICU. Do you feel like having these initiatives has helped create a more cohesive working relationship between RTs and nurses?

Mark Schorr, RRT: I think the transcutaneous implementation was a very cohesive process between the nurses and the RTs. I didn't realize how much it was going to be, but it was probably the most unified initiative of all of the projects that I've worked on.

SET: So this was an RT-focused initiative that brought the nurses in more to care about ventilation and understand how management and the ventilator can affect CO_2. Do you feel like there's been a nursing initiative that has resonated pretty well with the RTs the other way around?

Meagan Dexter, RNC-NICN: When we started our small baby protocol, everybody had to go through the PowerPoint, the education, all those things. And I think it was an awakening for both sides because you didn't know what you didn't know and how you were affecting babies. It was a good unified effort on that part as well.

Mark Schorr, RRT: I think having that continuous CO_2 number in the room, on the baby [has created cohesion] because everybody in the room knows what that number is related to. Everybody who enters the room is seeing the whole [ventilation] picture, and they're seeing it continuously. The nurses are primarily at the bedside more than the RTs. The RTs are assigned to more patients and are moving in and out So it lets nurses become really aware of the ventilator connection. That's what has been added by transcutaneous. They see when the CO_2 starts to climb, they see they need to call the RT to discuss what's happening, and it's been brought about by this continuous monitor.

Meagan Dexter, RNC-NICN: Right? It's in your face. It's right there. You can't ignore it.

Final Reflections

SET: What would you want any readers to take away from this conversation, or from your white paper, if you could have them understand just one thing?

Mark Schorr, RRT: Well, I know the financial cost of TCOM is a factor, but the value of it is tremendous. I don't know

how common transcutaneous monitoring is now throughout other patient care areas, but for me as a respiratory therapist, the future is TCOM. The future is CO_2. I know that, today, transcutaneous is primarily in the NICUs, but we're mandating CO_2 monitoring on post-operative adult patients now. CO_2 is telling you everything about the patient, not pulse ox. CO_2 is everything. So I hope more respiratory therapists see it and voice it, and that hospital administrators understand it.

SET: Meagan, is there anything you'd want readers to take away?

Meagan Dexter, RNC-NICN: I'd want them to not write off new technology that is reliable if you have the right process in place. Work with other disciplines and be an advocate for your patient to enable those processes to work like they should.

From Isolation to Inclusion: A Case Study on Transforming Family Engagement and Clinical Connection

Tara Lyngaas, RNC-NIC, NE-BC and Jaylee Hilliard, MSN, RN, NEA-BC, CPXP

Background: Setting the Stage

Innovations in the Neonatal Intensive Care Unit (NICU) frequently focus on advancing clinical modalities; however, technologies that reshape the lived experience of families have proven equally transformative. Bedside camera systems—once considered luxury adjuncts—are emerging as essential infrastructure for family-centered care. The authors share their unique perspectives—Tara Lyngaas, as a seasoned NICU Manager who led the October 2023 bedside camera rollout at her Level IV NICU, and Jaylee Hilliard, as a former director, two-time NICU mom, and clinical strategist—and a blueprint for elevating family engagement, optimizing staff workflows, and driving measurable gains in satisfaction and discharge readiness.

The Problem: Parent Isolation & Team Limitations

In March of 2021, when Jaylee's first daughter was admitted to the NICU, there were no bedside cameras. This was her first baby—and the harsh reality of the NICU felt nothing like what she had hoped and dreamed motherhood would be. She was trying to stabilize her blood pressure, navigate the anxiety and depression that came during the COVID-19 pandemic, and make sense of the fear and sleep deprivation that blurred those early days. But what took the deepest toll was the feeling that she was abandoning her baby every time she left her child's bedside. The guilt became so overwhelming that she began to dread even visiting, knowing she would have to leave again. Despite being a NICU nurse, the feelings of helplessness and distance were too real; she was unable to fully step into the role of mother.

Before bedside cameras or a digital family engagement solution were available, parents experienced profound isolation and anxiety. Staff had to respond to a high volume of family update requests—reflecting their deep need for connection—which frequently interrupted critical clinical workflows.

The Transformation: A Better Experience for Families and the Care Team

In October 2023, McLane Children's Baylor Scott & White Health implemented comprehensive digital family engagement technology, including secure, live-streaming video, HIPAA-compliant one-way photo/video/text messaging, and automated family education. With that one change, when Jaylee's second daughter was admitted to the same NICU, everything felt different. This time, she received photos and video updates from the care team, as well as educational content that supported the child's care journey and helped prepare Jaylee for her baby's discharge. Most importantly, the constant connection allowed Jaylee to *see* her fragile infant whenever she couldn't be there in person. She never felt like she had to say "goodbye." That ongoing visual connection—whether from the hospital bed, home, or anywhere in between—gave her peace of mind, allowing Jaylee to remain present, even when not at the bedside. It didn't erase the fear or uncertainty, but it transformed how she experienced them; she could stay connected, informed, and engaged as her new infant's mom—something she didn't realize was missing until she finally had it.

> "Families wanted updates constantly—and understandably so. We did everything we could, but without visual connection, our best efforts still fell short."
>
> – NICU Nurse

With the new technology, parents reported feeling continuously connected—no longer compelled to say "goodbye"—and staff feedback reflected an increase in perceived trust and communication efficiency between parents and the care team, enabling nurses to devote even more attention to direct patient care.

By the following year, the NICU leadership team had captured ongoing, real-time feedback by utilizing AngelEye's built-in survey module, which automatically sends brief questionnaires to families at key points during their stay (e.g., admission, every 4–10 days thereafter). Any family indicating their needs are not being met triggers a follow-up, often an in-person check-in by leadership or bedside staff. This just-in-time approach replaced the previous manual rounding process, boosting response reliability and enabling proactive interventions at the first sign of concern.

Tara Lyngaas is the NICU Manager, McLane Children's Baylor Scott & White Health.

Jaylee Hilliard is the Vice President of Clinical Strategy at AngelEye Health, revolutionizing patient and family support through advanced technology.

Figure A. Implemenation Approach - A four-phase rollout to ensure staff adoption, optimize workflows, and capture early wins.

Phase 1: Camera Installation, Privacy Protocols & Expectation Setting

OBJECTIVE

Introduce bedside cameras while establishing privacy safeguards and crystal-clear family expectations.

ACTIVITIES

- Family Orientation - at admission (or camera "go live" day), every family receives a concise, multilingual "How-To" overview
- Staff participate in hands-on role-play workshops using a unified script they helped develop within their shared governance councils.
- Staff scripts at the bedside and in the patient admission packet ensure every team member delivers the same message at the bedside.
- Installed cameras at every bedside in our open unit, paying special attention to where they were mounted to ensure they could easily be paused during cares/procedures with a digital "Your baby is receiving care" display.
- Implemented roaming in-services to meet staff where they were and educate them on HIPAA compliance, camera operation, and compassionate communication.
- Leaders integrated daily camera checks during daily rounds to ensure proper use and protocol adherence.

Phase 2: Digital Education Automation

OBJECTIVE

Streamline family orientation, discharge teaching, and resource distribution via the platform's education system.

ACTIVITIES

- Updated and uploaded unit-specific education and local resources
- Activated educational content was made available through the platform after it was reviewed and vetted
- Set up automated content to be "pushed" to families and noted which content was recommended versus required

Phase 3: One-Way Messaging & Engagement Incentives

OBJECTIVE

Deepen family connection through secure, one-way photo, video, and text messaging.

ACTIVITIES

- Rolled out one-way messaging to nurses, physicians, and allied-health staff (lactation consultants, social workers).
- Launched the "Care Connection Challenge" – a monthly contest recognizing the teams sending the most updates (milestones, general updates, educational reminders).
- Collected feedback during daily huddles to refine message templates and streamline workflows.

Phase 4: Digital Rounding & Feedback Surveys

OBJECTIVE

Capture real-time family experience and identify families in need of extra support.

ACTIVITIES

- Automated family-experience surveys to all families
- Defined a "Rapid Response Rounding" protocol: any family identified as less than satisfied triggered a personalized follow-up visit or call.
- Integrated survey analytics into weekly leadership dashboards to track trends and spotlight areas for improvement.

Charting the Course: Implementation Journey (Methodology)

Under Tara Lyngaas's direction, the Level IV NICU implemented a four-phase rollout, each phase lasting approximately three months (see *Figure A: Implementation Approach*). The staged approach allowed clinicians to master a small, clearly defined set of tasks before progressing, kept the workload manageable, and created early "wins" that the team could celebrate.

To verify that bedside-camera adoption produced measurable benefits, the evaluation team tracked four indicators—patient-family satisfaction, staff engagement, feeding outcomes, and operational efficiency—using each metric's pre-rollout benchmark (e.g., FY 2023 Press Ganey scores, May 2023 pulse-survey results) and then pulling the same data at regular intervals from automated dashboards, in-app micro-surveys, and EHR exports. Any time a metric stalled or trended unfavorably for two consecutive reporting cycles, a rapid-response quality-improvement huddle was triggered to identify the barrier and adjust workflows before the next review period.

Barriers to improvement were flagged whenever a metric plateaued for two successive data pulls or trended opposite to target. The quality-improvement (QI) council then:

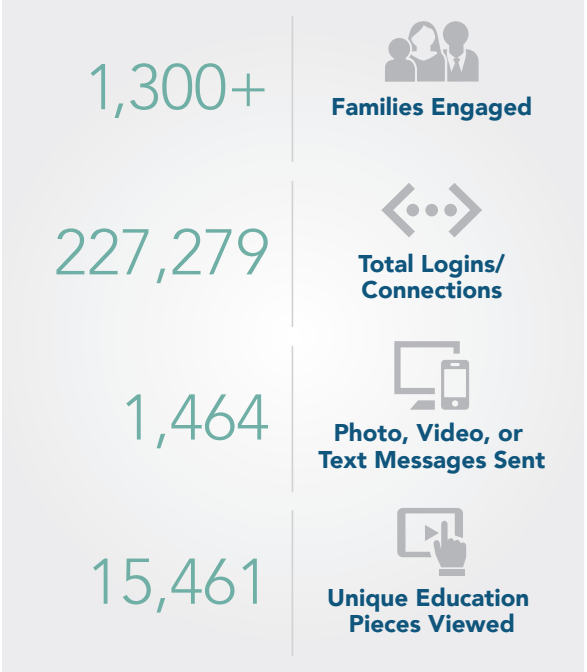
1. **Reviewed raw data** within seven days.
2. **Performed root-cause mini-huddles** with bedside teams.
3. **Issued countermeasures** (e.g., refresher huddles, workflow tweaks) logged in the QI tracker.

This continuous feedback loop ensured the rollout remained data-driven while still responsive to frontline realities—ultimately linking bedside-camera adoption to measurable gains in satisfaction, engagement, feeding success, and efficiency.

The Results: Platform Utilization & Digital Resource Engagement

Utilization Metrics

Since launching in November 2023, this Level IV NICU has embraced AngelEye Health's platform with remarkable engagement from both families and staff. Over 1,300 families have actively used the system, generating more than 227,000 secure logins between July and May (a period of 10 months)—evidence of a consistent, ongoing connection. The live-streaming feature alone has delivered over 1,770 hours of viewing time, allowing parents to remain visually connected to their infants even when they can't be at the bedside. Staff have also contributed meaningfully to family engagement, sending more than 1,460 secure one-way messages—photos, videos, and texts—to keep parents informed and emotionally supported throughout their NICU journey.



> "Technology alone didn't transform our unit; purposeful use with compassion and transparency did."
>
> – Tara Lyngaas

Families viewed 15,461 unique pieces of on-demand content—from high-impact topics like Infant Choking First Aid (1,775 views), Coping With Crying at Home (1,629), and Infant CPR (1,316) to diagnosis overviews, formula-mixing instructions, procedural guides, and competency checklists for G-Button and NG-tube care. Available in multiple languages, this digital library eliminated the time staff spent searching for paper handouts, printing materials, and coordinating interpreter services. Interpreter-mediated teaching sessions declined, and overall discharge-teaching time was noticeably reduced, freeing nurses for direct patient care and hands-on family instruction, while families maximized their precious in-unit time with their infants.

High usage across streaming, messaging, on-demand education, and embedded family surveys demonstrates that both families and staff have fully integrated AngelEye into their daily routines. These multiple touchpoints—visual connection, digital resources, just-in-time updates, and rapid feedback loops—directly supported the gains in patient satisfaction, staff engagement, feeding outcomes, and operational efficiency detailed above.

The Outcomes

The results described reflect a collection of quality-improvement efforts that align closely with the phased rollout and demonstrate that the AngelEye Health platform was a significant enabler.

Patient & Family Satisfaction **+6%**

During FY 2024, the NICU modestly exceeded its Press Ganey patient and family satisfaction target of 79.7, achieving a score of 80.6. In FY 2025, satisfaction continued to climb, surpassing the goal of 80.7 and reaching 85.8. This sharp upward trajectory coincided with the phased rollout of the AngelEye digital engagement platform, suggesting that continuous video access, on-demand education, and real-time feedback loops made a meaningful contribution to families' overall experience.

In addition to continuous video access and digital updates, leaders utilized AngelEye's built-in survey feature, which

captured real-time family feedback (even from off-site locations) for rapid intervention. At the same time, app-based education freed parents to spend more meaningful time at the bedside, together driving scores above target.

Staff Engagement

+11%

Between May 2023 and December 2024, staff engagement scores rose steadily, up 3% from May to December 2023, followed by an additional 4% increase over the next five months. By December 2024, the increase in satisfaction scores rose by over 11 percent during the 18-month period surveyed. According to the NICU's pulse surveys, this upward trend was driven in large part by improved work–life balance, a reduction in on-shift workload, and the streamlined communication and education workflows enabled by the AngelEye platform. These tools provided nurses and providers with the time and confidence to focus on patient care, thereby reinforcing overall engagement and job satisfaction.

Staff surveys indicated that improved work–life balance, reduced in-shift workload, and having dedicated tools to streamline communication and education were key drivers of this engagement boost.

Mom's Own Milk at Discharge

+6%

Mother's own milk at discharge rose from 61% (CY 2023) to 67% (CY 2024). This improvement was supported not only by reinstating three full-time NICU lactation consultants in December 2024 but also by the use of AngelEye's secure messaging to confirm lactation consults, provide words of encouragement, and share targeted educational content. Of particular help was the platform's digital education modules on the importance of providing breastmilk, as well as real-time video streaming, which allows mothers to see their infants during pumping sessions, encouraging additional nighttime pumping.

Parent Engagement

Discharge Teaching Time

Nurses observed that parents engaged in caregiving tasks (feeding and hands-on care) sooner and with greater confidence. Parents who consistently used the AngelEye app for educational purposes and discharge preparation felt more prepared when taking their baby home.

It is important to note that while broader initiatives (workflow standardization, nursing incentives for morale, and lactation program enhancements) contributed to these improvements, the timing, survey insights, and qualitative feedback strongly indicate that the AngelEye digital engagement platform was a significant catalyst for these outcomes.

Qualitative Findings

Methods

During the process, the NICU leadership team wanted to monitor not just the hard numbers, but what mattered to staff. To capture frontline clinician perspectives, a digital SurveyMonkey questionnaire was sent to all NICU staff in June 2025, with reminders sent over a 72-hour window to encourage rapid completion. A total of 47 team members (approximately one-third of the total staff) responded, providing timely and representative feedback across both day and night shifts. See Figures B and C.

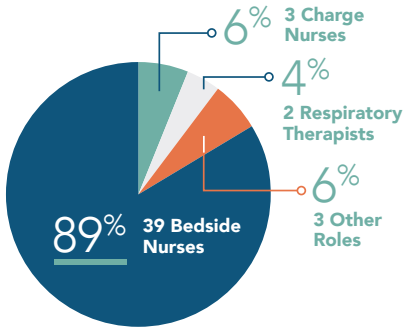


Figure B. Staff Role Breakdown.

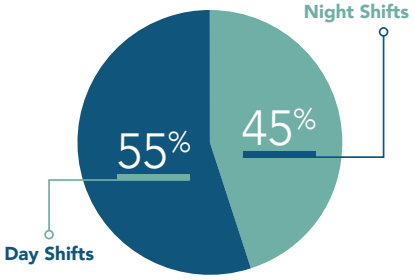


Figure C. Shift Distribution.

The balanced shifts and predominance of bedside nurses demonstrate that the survey primarily captures direct caregiving experiences, with input from leadership and ancillary staff supplementing our thematic analysis and grounding key takeaways in representative team feedback.

Qualitative Feedback

The NICU's clinical team reports that AngelEye solutions contributed substantially to improved communication and engagement:

- **Efficient Updates:** Fellows and attendings provide daily digital updates, ensuring consistency even when in-person contact is limited.
- **Capturing Milestones:** Staff record holiday events, milestones, and other memorable moments when families are unable to be present.
- **Digital Education Impact:** On-demand, multilingual modules empower families to learn at their own pace.
- **Proactive Support:** Survey data guide targeted follow-up with families who were not present during daily patient and family experience rounds.
- **Staff Morale:** "Care Connection" contests and positive feedback reinforced a culture of pride and connection.

Overcoming Resistance & Building Trust

Initial staff concerns regarding bedside cameras—ranging from privacy to potential workflow disruptions—were real and valid. Some feared added responsibilities; others worried about constant observation. Addressing these head-on through transparency, workflow alignment, and consistent messaging was essential.

Within just 4–6 weeks, the tone of the unit started to shift. "Once nurses were more comfortable with their workflow and realized how engaged and happy the parents were with being able to see their baby from home, they became advocates," Tara shared. Today, the cameras are embraced as an integral part of the NICU's family-centered care model, not an add-on.

> "Once nurses realized cameras didn't slow them down—and that families loved the photos and videos—they championed the system themselves."
>
> – Tara Lyngaas

Thematic Insights

Staff Perspectives were organized by theme and each paired with a key takeaway to illustrate frontline impact.

Equity & Access Initiatives

Ensuring equitable access to family engagement tools was a guiding principle from day one. The leadership team made a conscious decision to remove barriers—technological, linguistic, and logistical—so that all families, regardless of background or circumstance, could experience the connection, peace of mind, and empowerment the CameraSystem provides.

- Embedded CameraSystem orientation into admission workflows
- Provided multilingual quick-start guides for families
- Delivered content at a 5th-grade literacy level, translated into more than 70 languages through the AngelEye platform
- Bridged transportation and access barriers that many families face during their NICU journey with the camera technology, ensuring that all parents can stay connected to their infant.

Conclusion: Toward a Smarter, Integrated Future

Tara shared one last thought for her colleagues – "Our experience confirms that bedside camera systems are foundational to modern NICU care. A phased, staff-centered implementation—prioritizing privacy, equity, and engagement—yields measurable improvements in family satisfaction, staff morale, and clinical readiness. We encourage other units to adapt this blueprint to their workflows, thereby redefining the NICU journey and strengthening support for families from admission through discharge and beyond."

1. Emotional Well-Being & Anxiety Reduction

"I have seen parents who would have otherwise been unable to physically leave the bedside…be able to go home and get some much-needed rest."

KEY TAKEAWAY

Real-time video access meaningfully reduces separation anxiety and supports parental rest and maternal recovery—even overnight.

2. Enhanced Family Connection & Inclusion

"I had a family that was able to show off their baby to grandparents who were out of the country."

KEY TAKEAWAY

Multi-user access enables parents to include friends, family, and distant relatives in their baby's care journey, bolstering emotional support networks

3. Maternal Support & Milk-Production Benefits

"A mom told me that her milk supply increased once she was able to visualize baby while pumping."

KEY TAKEAWAY

Maintaining visual contact during pumping sessions can enhance lactation confidence and increase milk output.

4. Trust-Building Through Transparent Communication

"Parents love getting pictures and videos of their babies. They love the little updates and I think it gives them peace of mind when they can't be here."

KEY TAKEAWAY

One-way messaging and milestone snapshots promote unit transparency, foster stronger parent–caregiver relationships, and support the development of parental trust in the care team – a challenging outcome to achieve.

> "We insisted this be a standard offering—not a privilege—so every family reaps the benefits."
>
> – Tara Lyngaas

By uniting technology with compassion, this Level IV NICU has redefined family engagement as a core pillar of neonatal care. The leadership team invites other units to adopt the four-phase blueprint and join them in making every NICU a place of connection—until no family ever has to say 'goodbye' again.

As a next step in expanding family-centered care for their NICU, Tara and her team are particularly excited about the upcoming implementation of NICU2Home, AngelEye's evidence-based NICU navigation and discharge coordination solution, which will further streamline staff workflows and unlock additional time savings by bringing discharge planning and education into a single, user-friendly interface. NICU2Home enables intelligent, automated assignment of tailored educational modules and features a visual discharge roadmap—empowering parents to take the lead on preparation and transition home while ensuring clinical teams maintain full oversight.

AngelEye Health's strategic integration of AI across the platform—from predictive alerts to advanced analytics in the CameraSystem and NICU2Home—will surface real-time clinical insights that bolster care team decisions, strengthen family engagement, and ultimately drive improved patient outcomes throughout the NICU-to-home continuum.

By placing families at the heart of every decision—and equipping staff with tools that inspire trust, efficiency, and equity—this NICU has not only reimagined the care journey from admission to discharge, but has created a model for the future of neonatal care: connected, compassionate, and powered by purpose-built technology.

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Evolving Approaches to Infection Prevention in Neonatal Intensive Care

Aligning medical equipment manufacturers' IFUs, hospital protocols and accreditation compliance with disinfectant agents to help reduce risks and help protect babies.

Anduin Anderle, RN and Kara L Nadeau

Infection prevention (IP) in neonatal intensive care units (NICU) is a critical aspect of patient safety, as newborns, particularly premature and medically fragile infants, are highly susceptible to healthcare-associated infections (HAIs).[1,2] Every object in the NICU, including medical equipment, can serve as a potential reservoir for harmful pathogens—necessitating rigorous cleaning and disinfection protocols.[3]

However, aligning infection prevention (IP) practices with accreditation requirements, manufacturers' instructions for use (IFU), disinfectant agent IFUs, and hospital protocols can present challenges for NICU clinicians, supply chain teams and value analysis professionals alike.

In this introductory article—part of a multi-part series—readers will learn:

- The unique disinfection needs of the NICU environment
- Common challenges in aligning disinfectant agents with accreditation and equipment manufacturer IFUs
- Key considerations for disinfectant selection ahead of accreditation inspections

Infection risks in the NICU

NICUs face unique challenges in infection prevention due to the vulnerability of fragile newborns.[4] Research has found hospitalized neonates are highly vulnerable to healthcare-associated infections (HAIs).[5] Nosocomial infections are relatively common and increase morbidity and mortality, particularly in the smallest and most fragile infants.[6]

HAIs can also impact NICU length of stay and costs, with the estimated cost of a single healthcare-acquired bloodstream infection (HA-BSI) in neonates ranging from $1,642 to $160,8045.[7,8] Furthermore, private and public insurers, including the Centers for Medicare & Medicaid Services (CMS) under its Hospital-Acquired Condition (HAC) Reduction Program, often do not reimburse hospitals for certain HAIs.[9]

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About The Joint Commission (TJC)

The Joint Commission (TJC) accredits and certifies over 22,000 healthcare organizations and programs in the US, including both acute and non-acute facilities. Its accreditation process provides an objective evaluation that helps organizations improve performance and deliver safe, high-quality care.

Accreditation is granted following an unannounced, on-site survey by trained surveyors. These surveyors assess compliance with TJC standards by reviewing patient records, observing care, and speaking with staff and patients to trace the patient care experience.

Because NICUs present high risk for HAIs, frequent cleaning of the environment is critical, including disinfection of surfaces, which can serve as reservoirs of potential pathogens.[10] Research has shown "Generally, all objects and equipment used in the NICU environment constitute a reservoir for microbial transmission."[11]

Equipment disinfection responsibilities

Both medical equipment manufacturers and end user hospitals can bear responsibility for effective cleaning and disinfection of reusable medical equipment used in NICUs and other patient care areas.[12,13]

Medical equipment manufacturers

The US Food and Drug Administration (FDA) regulates manufacturers of medical equipment used in hospitals and other care settings. An element of this oversight is guidance to manufacturers of reusable devices that they "should consider device designs that facilitate easy and effective cleaning, as well as any necessary disinfection or sterilization by the users."[14]

The FDA requires manufacturers to include in their equipment instructions for use (IFU), recommended "cleaning agents or classes of agents that were used during the cleaning validation studies, that have been demonstrated to be compatible with the device and are effective in cleaning the device."[15] The IFU "should address both cleaning and disinfection if both are intended and should be clear regarding the difference between cleaning and disinfection, and the products used for each step."[16]

> "While we understand that adherence to strict cleaning, disinfection, and sterilization practices is essential for patient safety, we also understand that the current IFU process is inherently flawed."
>
> – APIC letter to TJC, May 19, 2025

Additionally, the manufacturer of the disinfection product specified in the equipment manufacturer's IFU must include in its own IFU instructions to help ensure efficacy and/or confirmation that cleaning, disinfection or sterilization cycles are successful.[17]

Hospitals

Hospitals accredited by The Joint Commission (TJC) must demonstrate compliance with equipment and disinfectant manufacturers' IFUs during TJC accreditation surveys.[18] Surveyors evaluate whether medical equipment disinfection practices—including agent type, dilution, contact time, and temperature—adhere to manufacturer guidelines.[19]

To maintain accreditation status, hospitals must undergo an on-site survey at least every three years.[20] A survey includes an "objective evaluation" of "organizational compliance to performance standards," including equipment disinfection practices.[2,22]

IFU compliance challenges and complexities

Hospitals face significant barriers in achieving IFU compliance due to:[23]

- A wide array of medical equipment with varying disinfectant requirements
- Pressure to standardize products for cost, storage, and usability
- Disinfectants specified in IFUs becoming unavailable, recalled, or unsafe for staff
- Newer disinfectants (e.g., broad-spectrum wipes) lacking validation in equipment IFUs

Push for supply standardization

Faced with increased pressures to reduce the risk for HAIs alongside cost pressures to standardize supply purchases for greater cost savings, hospitals report challenges adhering to use of medical equipment manufacturers specified disinfectant agents.[24]

Given the broad range of medical equipment used across patient care units in hospitals, including NICUs, the procurement and effective use of IFU specified disinfectant agents for each individual piece of equipment can present complexities and costs that can be burdensome for most healthcare organizations to manage.[25]

Supply chain professionals, value analysis committees, and clinicians striving for supply standardization and the associated stocking, storage, usability and cost benefits, many struggle with the compliance challenges presented by accreditation requirements around IFU adherence.[26]

Disinfectants entering–and exiting–the market

Additionally, the COVID-19 pandemic spurred the development of many new broad-spectrum disinfectants that medical equipment manufacturers have not tested with their products.[27] It may not be feasible for equipment manufacturers to test and validate every new disinfectant agent and update their IFUs accordingly.[28]

Common types of disinfectants include:[29,30]

- Reconstituted agents
- Wipes
- UV light

Adding to hospital challenges in disinfectant procurement and use aligned with equipment manufacturers' IFUs, the disinfectant agent the manufacturer has specified in its IFU could be subsequently taken off the market due to adverse events or a recall.[31] For example, one commonly used and approved agent is involved in a class action lawsuit due to reports of side effects such as skin burns, asthma and respiratory issues among healthcare workers.[32]

Different components, different disinfection methods

Adding to the complexity, a piece of medical equipment might be comprised of multiple components that each require different disinfection agents and processes, as specified in the manufacturer's IFU. Depending on the agent/process, disinfection could be performed by any number of healthcare stakeholders, including environmental services (EVS) staff members, bedside clinicians or sterile processing (SP) technicians.

For example, a NICU incubator's manufacturer might specify that surface cleaning can be performed with disinfectant wipes, something commonly available and easily used in clinical units. On the other hand, the incubator's reservoir for its humidification system might require a washer/disinfector machine cycle, with this mode of reprocessing handled by SP technicians in their department.

Performing a risk assessment

"Hospitals should assess the risks associated with equipment that does not align with standardized disinfectants," according to Vizient. "This assessment should focus on the following three key factors to determine the appropriate compliance approach and ensure patient safety."[33]

1. Determine whether the equipment comes into direct contact with a patient. Devices involved in direct patient care pose a higher risk and require stricter compliance measures.
2. Evaluate the prevalence of these items within the facility. If a device or piece of equipment is widely used or exists in large quantities, ensuring compliance becomes a higher priority.

How Often Should My Hospital Reprocess Medical Equipment?

In its IFU, a medical equipment manufacturer will specify how often its product should be reprocessed – components dissembled, disinfected (and sometimes sterilized) and reassembled for patient use.

Frequency and steps for adequate reprocessing will be defined in your device IFU. Frequency can vary between product types and manufacturer recommendations.

3. Lastly, determine how closely the available disinfectant aligns with IFU requirements.

APIC calls for changes in TJC's assessment of IFU compliance

A letter from the Association for Professionals in Infection Control & Epidemiology (APIC) CEO Devin Jopp, EdD to TJC president and CEO Johnathan B. Perlin, dated May 19, 2025, highlights challenges faced by hospitals when TJC assesses IFU compliance during surveys. Jopp referenced APIC member surveys and focus groups, which found:[34]

- 42% of participants indicated that their facility had been cited by a surveyor for failure to follow an IFU (including both regulatory and accrediting surveys)
- 54% percent of those who had been cited reported not being able to successfully challenge the citation by providing evidence for their practice
- 84% of respondents indicated that they had reached out to a manufacturer for clarification on an IFU in the past, and eight percent went as far as reaching out to the FDA directly

Jopp goes onto provide APIC's recommended modifications to TJC's approach, which include: [35]

- A differentiation be made between simple non-compliance with policy or stated practice and a commonly used approach where a facility has conducted a risk assessment and determined that an alternative cleaning, disinfection, and/or sterilization method is appropriate.
- IFU-related findings no longer be assessed under the "Infection Prevention and Control" chapter of the TJC standards and instead be housed under either "Environment of Care" or "Leadership" as the "burden of reconciling IFUs falls to the Infection Prevention and Control department, rather than the team that owns, operates, and maintains the equipment."

The letter concludes, "While we understand that adherence to strict cleaning, disinfection, and sterilization practices is essential for patient safety, we also understand that the current IFU process is inherentlyflawed."[36]

Aligning effective NICU infection prevention practices with industry requirements

Many NICU clinicians, IP practitioners and other hospital stakeholders are aligned in their commitment to protect tiny and fragile newborns from the risks of contracting HAIs. Despite this, they still may face the challenge of adhering to disinfectant agents specified in medical equipment manufacturer's IFUs.

When a hospital that has standardized on a disinfectant agent that is not specified in the manufacturer's IFU or switched to a new agent that has come to market, or the disinfectant specified in the IFU is unavailable or questionably safe for workers to use,

> "APIC recommends that some degree of flexibility be given to facilities to determine safe, effective alternatives when compliance with the manufacturer's IFUs is not feasible or does not meet infection prevention standards."
>
> – APIC letter to TJC, May 19, 2025

4 Key Questions to Ask About Your Hospital's Chosen Disinfectant Agent Ahead of a JACHO Inspection

1. Is it efficacious in neutralizing microorganisms of concern in the NICU environment?
2. Does it not prematurely erode or compromise medical equipment surfaces and components?
3. Is it used according to the disinfectant's IFU, including specified "wet time"?
4. Does it follow the medical equipment manufacturer's recommendations for rinsing parts following the specific "wet time" to maintain component integrity?

NICU and IP teams can be left scrambling to comply with TJC requirements.[37,38]

According to TJC's Environmental Cleaning Assessment, it is essential for organizations to follow manufacturer's IFUs for proper use of cleaning and disinfecting products, including aspects such as dilution, contact time, material compatibility, storage, shelf-life, safe use and disposal.[39]

When information from manufacturers is limited regarding the selection and use of agents for specific microorganisms, environmental surfaces, or equipment, TJC advises that "cleaning and disinfecting policies should be guided by the best available evidence and careful consideration of the risks and benefits of the available options."[40]

Preparing for an accreditation survey with proactive testing and validation

Ahead of an accreditation survey, hospital NICU teams in collaboration with IP practitioners and environmental service (EVS) staff members should conduct testing to demonstrate their chosen disinfectant agent:[41]

- Is efficacious in neutralizing microorganisms of concern in the NICU environment
- Does not prematurely erode or compromise medical equipment surfaces and components
- In used according to the disinfectant's IFU, including specified "wet time" (which is included in every disinfectant agent's IFU)
- Follows device manufacturers' cleaning instructions avoiding skipping steps such as wiping residual disinfectant from device after recommended "wet time"

A proactive approach to testing and compliance positions NICU teams for success and ultimately can contribute to greater safety for NICU babies.

Conclusion

Effective infection prevention in the NICU requires a careful balance between compliance with regulatory and accreditation standards and the practical realities of hospital operations. Medical equipment manufacturers' FDA IFU recommendations can create challenges for hospitals striving for standardization and cost efficiency. Those healthcare organizations that take proactive measures, such as conducting efficacy and compatibility testing, can help bridge the gap.

Hospitals can implement evidence-based disinfection practices that help protect vulnerable newborns and staff while

maintaining compliance with accreditations requirements. Ultimately, a well-coordinated approach to IP can help reduce the risk of HAIs, promote patient and staff safety in compliance with accreditation requirements, and reduce reprocessing time, staff resources and costs.

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Prediction of Peri-Operative Mortality in Care of Preterm Children in Non-Cardiac Surgery

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Abstract

Background The aim of this study was to develop a risk calculation model for peri-operative 30-day-mortality in preterm infants in non-cardiac surgery.

Methods Retrospective monocentric follow-up cohort-study of 27,453 pediatric anesthesias at a German university hospital and level one perinatal center between 2008 and 2021 for non-cardiac surgeries. Inclusion criteria were age < 37 post-menstrual weeks at the time of surgery. The primary endpoint was 30-day-mortality after surgery. For statistical analysis, stepwise backwards logistic regressions were performed to identify predictors for 30-day mortality after surgery.

Results Between 2007 and 2021, 278 preterm infants underwent surgery. The 30-day-mortality was 8.6% (24/278; CI95%:5.6–12.6). A preselection of potential risk factors was based primarily on prior knowledge available from the literature and the results of previously published studies. The final prediction model using a multivariable logistic regression revealed lower post-menstrual age (odds-ratio(OR): 0.67; CI95%: 0.54–0.83) and lower body weight at the time of surgery for extremely preterm infants (OR: 0.024; CI95%: 0.003–0.22), administration of dopamine or norepinephrine or epinephrine (OR: 11.6; CI95%: 3.58–37.7), and life-threatening emergencies between 10pm-7am (OR: 10.1; CI95%: 2.36–43.5) as significant independent risk factors for 30-day-mortality. The Area-Under-The-Receiver-Operating-Characteristic-Curve (0.90; CI95%: 0.85–0.96) showed a good discrimination of the final model. The investigation of the calibration curve (p = 0.99, Spiegelhalter test) and the goodness of fit test (p = 0.85, Hosmer-Lemeshow test) indicated no significant discrepancies between estimated and observed probabilities for the peri-operative 30-day mortality.

Conclusions Peri-operative 30-day-mortality of preterm infants during non-cardiac surgery is high. The prediction model with easily ascertainable factors as described could be a valuable tool for estimating 30-day-mortality in preterm infants and should be validated in larger populations.

Background

In the context of anesthesiologic peri-operative care, the care of preterm infants presents a particular challenge: This unique patient population has specific anatomical and physiological characteristics. Furthermore, congenital anomalies, for example cardiac, pulmonary, and/ or intestinal malformations, the immaturity of various organ systems as well as underlying diseases e.g. necrotizing enterocolitis or meconium-ileus yield a high risk for peri-operative cardiac arrest and mortality in the peri-operative setting.[1-7]

In recent years, several risk factors for peri-operative mortality and morbidity, such as peri-operative cardiac arrest, age less than one-year, American Society of Anesthesiologists (ASA) status ≥III, congenital defects, emergency surgery and preterm birth, have been identified in children.[6-9] Additionally, in neonatal care of preterm infants, risk factors for mortality include the degree of prematurity at birth, as well as co-factors such as infections and/or malformations.[6-9] However, these risk factors apply to almost every preterm infant, which complicates the individual risk assessment for mortality in this particular population.[6-9] Individual risk assessment is of particular importance for the attending physician, as the associated risks influence the timing and extent of surgery. From the perspective of the affected parents and their relatives, a differentiated and individualized risk assessment of the probability of a fatal outcome is important from a psychosocial point of view.

Various prognostic tools for predicting morbidity and mortality in adults show only limited validity in children. In paediatric anaesthesia the Paediatric-Risk-Assessment-Score was developed using a simplified five-variable objective score to predict mortality in neonates, infants and children undergoing non-cardiac surgery (age < 12 months, emergency surgical procedure, the presence of a neoplasm, of at least one comorbidity, and characteristics of critical illness).[10-12] Although it was easy-to-use and an accurate tool for estimating the mortality risk, a more differentiated assessment of the mortality risk is useful with regards to preterm infants.[12] Therefore, the aim of the present follow-up-study was to develop a risk calculation tool for 30-day-mortality in the context of peri-

operative anesthesiologic care of preterm infants in non-cardiac surgery.

Methods

The present study is a follow-up study of peri-operatively collected data focussing on mortality risk estimation for 30-day-mortality in preterm infants.[6,7] The study was approved by the Institutional Review Board of the University of Muenster, Germany (file reference 2019-398-f-S). Due to its retrospective nature, the requirement of written informed consent was waived by the Institutional Review Board. The manuscript adheres to the applicable STROBE-guidelines. The anesthesia database at the Protestant Hospital of the Bethel Foundation, Medical School OWL, Bielefeld University in Germany was scanned for the timeframe from 01.01.2008–31.12.2021. All anesthesia-relevant complications from the beginning of anesthesiologic care until 60 min after completion of anesthesia and/or sedation were recorded in the database.[13] The study centre is a perinatal and national trauma center with the highest level of care in each respective speciality. It cares for about 1% of all births in the Federal Republic of Germany. The center performs all surgical procedures on children with the exception of cardiac surgery.

Only infants that were deemed preterm at the time of surgery and underwent an anesthetic procedure were included.[6,7,13] If multiple operations were necessary during the hospital stay, only the first operation was included. Prematurity was defined as a post-menstrual age < 37 weeks of gestation at the time of surgery. The peri-operative period was defined from the onset of anesthesiologic care until 60 min after the end of anesthesia or sedation.[6,7,13]

Data were anonymized for evaluation. Exclusion criteria was post-menstrual age ≥ 37 weeks at time of surgery.

Demographic data (age, gestational age, post-menstrual age, age at time of surgery, sex), birth weight, weight classification according to classification of World Health Organisation (WHO) and weight on the day of anesthesia as well as existing congenital anomalies (central nervous system, airways, lungs, heart, vessels, gastrointestinal tract, kidneys) and comorbidities (central nervous system, airways, lungs, heart, vessels, blood and coagulation, gastrointestinal tract, kidneys, extremities, sepsis) according to their anatomical region were recorded. In addition, the occurrence of sepsis was recorded.[6,7]

Additionally, the pre-operative therapy with catecholamines (dobutamine, dopamine, epinephrine, norepinephrine) and the admission to the neonatal ICU were recorded.

In addition, the specific operation or intervention was recorded and assigned to a body region (intracranial, airways, thoracotomy, gastrointestinal, laparotomy, urogenital, vessels). The urgency of the surgical procedure was classified as vital (immediate), urgent (< 6 h) or elective according to surgical data. In addition, the time of day (beginning of surgery 7:01–15:00; 15:01–22:00; 22:01– 07:00) and the occurrence of peri-operative cardiac arrest (POCA) and peri-operative transfusion therapy was noted. POCA was defined as any condition that required the performance of chest compressions and/or defibrillation according to Utstein-Criteria.[6,7,14] The indication to perform chest compressions was declared by the anaesthetist in charge. Patient outcome was evaluated and recorded 30 days after resuscitation ("dead", "alive").

Statistical analysis

Data were collected in Microsoft Excel® (Version 2013). SAS 9.4 (SAS Institute Inc., Cary, NC, USA) and SPSS V.29.0 (IBM, New York, New York, United States of America) were used for statistical analyses. Mortalities and incidences were shown as % or relative frequencies per 10,000 performed preterm anesthetic procedures with indication of the 95% confidence intervals (CI95%). Confidence intervals were calculated using exact Clopper-Pearson method. Results are presented as mean ±standard deviation for continuous and percentages for categorical variables. Non-parametric tests, e.g. two-tailed exact Mann-Whitney test, Fisher's exact test and multivariable logistic regression models (backwards elimination) were performed; Receiver-Operating-Characteristic-Curves (ROC) and Area-Under-The-ROC (AUC) were calculated, and Hosmer-Lemeshow test and Spiegelhalter test were performed to check violations of goodness of fit of the logistic regression model. In addition, we performed a bootstrapping analysis (n = 1000) to check of the estimated regression coefficients.

Results

Out of 27,453 a total of 392 anesthetic procedures in 278 preterm infants were performed (1.4%; 95%CI:1.3–1.6) between 01/2008 and 12/2021. There were no relevant changes of anesthetic practice or the POCA mortality rates during the observation period.

Characteristics of preterm infants requiring surgery

All anesthetic procedures were performed in general anesthesia by specialists in anesthesia with clinical expertise in pediatric anesthesia.

According to the WHO classification, 111 (39.9%) of these children were extremely preterm (post-menstrual age < 28.weeks + 0 days), 61 (21.9%) very preterm (post-menstrual age 28. weeks + 0 days – 31. weeks + 6 days) and 106 (38.1%) were preterm (post-menstrual age 32. weeks + 0 days -≤36.weeks + 6 days). An extremely low birth weight (< 1.0 kg) was observed in 119 preterm infants (43.0%), 50 (18.1%) had a very low birth weight (1.0-<1.5 kg), 73 (26.4%) a low birth weight (1.5-<2.5 kg) and 35 (12.6%) a normal birth weight (≥ 2.5 kg).

Table 1 shows the characteristics, congenital anomalies, comorbidities, and surgical procedures of anesthesiologically treated preterm infants.

Peri-operative 30-day-mortality

Peri-operative 30-day-mortality in preterm infants was 8.6% (24/278; 95%CI:5.6–12.6) respectively 612.2 per 10,000 anesthesias (24/392 anesthetic procedures) in preterm infants. Peri-operative 30-day-mortality was highest in the extremely preterm infants at 12.6% (14/111; 95%CI:7.1–20.3), followed by very preterm at 9.8% (6/61; 95%CI:3.7–20.2) and preterm infants at 3.8% (4/106; 95%CI:1.0–9.4). According to the classification of birth weight, peri-operative 30-day-mortality was highest in preterm infants with extremely low birth weight at 13.4% (16/119; 95%CI:7.9–20.9), followed by preterm infants with low birth weight at 6.8% (5/73; 95%CI:2.3– 15.3), very low birth weight 4.0% (2/50; 95%CI:2.3–15.3) and normal birth weight at 2.9% (1/35; 95%CI:0.1–14.9).

Selection of potential risk factors

Potential risk factors for perinatal mortality identified in the literature (e.g. post-menstrual age at birth) and the results of

Table 1 Characteristics and surgical procedures of anesthesiologically treated preterm infants

	Overall [*n* = 278]	**Survivor [*n* = 254]**	**Non-survivor [*n* = 24]**	***p*-value**
Male sex [n (%)]	154 (55)	143 (56)	11 (46)	0.39
Age categories (mean ± SD))				
Post-menstrual age at birth [w] (missing *n* = 2)	30.0 ± 4.5	30.2 ± 4.4	27.6 ± 4.0	**0.003**
Age at time of surgery [d]	20.5 ± 22.1	20.9 ± 22.5	16.5 ± 17.1	0.77
Post-menstrual age at time of surgery [w]	32.2 ± 3.8	32.5 ± 3.6	28.9 ± 3.6	**< 0.001**
Preterm infant [n (%)]	106 (38)	102 (40)	4 (17)	**0.02**
Very preterm infant [n (%)]	61 (22)	55 (22)	6 (25)	
Extremely preterm infant [n (%)]	111 (40)	97 (38)	14 (58)	
Body measures (mean ± SD)				
Birth weight [kg]	1.465 ± 813	1.508 ± 821	1.013 ± 564	**< 0.001**
Weight at time of surgery [g]	1.633 ± 761	1.694 ± 753	0.999 ± 532	**< 0.001**
Weight at time of surgery (kg) differentiated by preterm, very und extremely preterm				
Preterm infant	2.329 ± 505	2.343 ± 506	1.990 ± 356	0.14
Very preterm infant	1.514 ± 486	1.560 ± 487	1.112 ± 229	**0.006**
Extremely preterm infant	1.026 ± 485	1.078 ± 495	0.667 ± 154	**< 0.001**
Congenital anomalies [n (%)]	141 (51)	131 (52)	10 (42)	0.40
Central nervous system	20 (7)	20 (8)	0 (0)	0.23
Airways	26 (9)	21 (8)	5 (21)	0.06
Lungs	28 (10)	24 (9)	4 (17)	0.28
Heart	28 (10)	25 (10)	3 (12)	0.72
Vessels	11 (4)	8 (3)	3 (12)	0.06
Gastrointestinal tract	115 (41)	110 (43)	5 (21)	**0.05**
Comorbidities [n (%)]				
Central nervous system	85 (31)	72 (28)	13 (54)	**0.018**
Airways	112 (40)	99 (39)	13 (54)	0.19
Lungs	180 (65)	160 (63)	20 (83)	0.**05**
Heart	33 (12)	31 (12)	2 (8)	0.75
Blood and coagulation	112 (40)	102 (40)	10 (42)	0.99
Gastrointestinal tract	164 (59)	114 (57)	20 (83)	**0.01**
Sepsis	140 (50)	124 (49)	16 (67)	0.13
Transfer from the neonatal intensive care unit	240 (91)	218 (90)	22 (100)	0.24
Pre-Existing therapy with catecholamines [n (%)]	82 (29)	63 (25)	19 (79)	**< 0.001**
Norepinephrine	28 (10)	18 (7)	10 (42)	**< 0.001**
Dobutamine	22 (8)	15 (6)	7 (30)	**< 0.001**
Epinephrine	16 (6)	10 (4)	6 (25)	**< 0.001**
Dopamine	44 (16)	33 (13)	11 (46)	**< 0.001**
Type of surgical procedure [n (%)]				
Intracranial	40 (14)	39 (15)	1 (4)	0.22
Airways	8 (3)	8 (3)	0 (0)	0.99
Thoracotomy	33 (12)	30 (12)	3 (12)	0.99
Laparotomy	213 (77)	189 (74)	24 (100)	**0.002**
Urogenital	10 (4)	8 (3)	2 (8)	0.21
Vessels	15 (5)	12 (5)	3 (12)	0.13
Emergency categories [n (%)]				
Elective	117 (43)	114 (46)	3 (13)	**< 0.001**
Urgent	62 (23)	58 (24)	4 (17)	
Vital	90 (33)	74 (30)	16 (70)	
Time of day [n (%)]				
7:01–15:00	203 (73)	191 (75)	12 (50)	**0.004**
15:01–22:00	47 (17)	42 (17)	5 (21)	
22:01–7:00	27 (10)	20 (8)	7 (29)	
Peri-operative Cardiac Arrest [n (%)]	10 (4)	5 (2)	5 (21)	**< 0.001**

Table 1 (continued)

	Overall [*n* = 278]	Survivor [*n* = 254]	Non-survivor [*n* = 24]	*p*-value
Peri-operative transfusion therapy [n (%)]				
Red blood cell concentrates	104 (38)	98 (39)	6 (25)	0.27
Fresh frozen plasma	111 (40)	105 (42)	6 (25)	0.13
Red blood cell concentrates or Fresh frozen plasma	137 (49)	128 (51)	9 (38)	0.29

d days, *g* gram, *SD* standard deviation, *w* weeks

p=two-sided *p*-values of the statistical tests for group comparison Survivor vs. Non-Survivor

The *p*-values should be interpreted with caution, as no adjustment of the α-error was performed. Univariate *p*-values < 0.05 should not be interpreted in terms of statistical significance but might indicate a potential predictor

The statistical evaluation was performed by two-tailed exact Mann-Whitney test or Fisher´s exact test. Emergency categories were tested by Mantel-Haenszel Chi-square test of trend

Body weight at time of surgery was missing in *n*=3

Bold emphasize the significant *p*-values

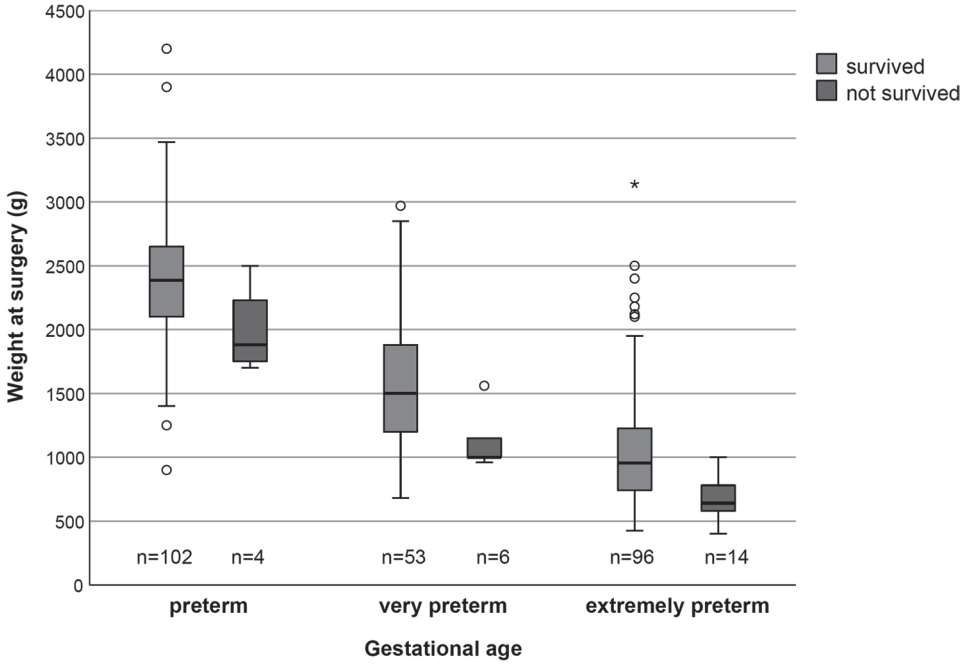

Figure 1. Impact of weight at the time of surgery and prematurity differentiated by perterm, very and extremely preterm on 30-day-mortality (body weight at time of surgery was missing in n=3).

univariate analysis of our data (Table 1) were used to determine a list of potential predictors of 30-day-mortality in preterm children in non-cardiac surgery.

In the previous study, lower body weight at time of surgery was identified as a strong, respectively the strongest risk factor in this patient group.[6,7] However, Figure 1; Table 1 indicate that the impact of body weight at the time of surgery was particularly evident in very and extremely preterm infants. Therefore, the body weight at the time of surgery was differentiated between premature, very premature and extremely premature infants. Furthermore, both the time of surgery between 10pm-7am (25.9%) and the emergency category "vital" (17.8%) were strongly associated with increased mortality. However, the vast majority (80.8%) of surgeries at night (10pm-7am) were life-threatening emergencies, these were summarized in a combined risk factor "nocturnal vital emergency" (0 = surgery between 7am-22pm *or* non-vital emergency, 1 = vital emergency between 10pm-7am). This combined risk factor has a stronger impact on mortality (28.6%; Odds Ratio [OR] = 5.27, 95%CI:1.82–15.2) than either risk factor "time of surgery" or "emergency" (see Supplement 1). In summary, body weight at the time of birth, body weight at time or surgery (differentiated by preterm, very preterm, preterm infants), post-menstrual age at the time of birth, post-menstrual age at the time of surgery, pre-operative norepinephrine, dobutamine, epinephrine, dopamine, catecholamines, nocturnal vital emergency, and laparotomy were included as potential predictors in a stepwise (backwards, p_{out}=0.15) multivariable logistic regression model. This regression model revealed post-menstrual age at time of surgery (OR:0.66; CI95%:0.53–0.83), body weight at time of surgery only in extremely preterm infants (OR:0.34; CI95%:0.004–0.326), application of dopamine (OR:4.48; CI95%:1.51–14.8), norepinephrine (OR:4.72; CI95%:1.51–14.8), the occurrence of epinephrine (OR:3.51; CI95%:0.80–15.5) and nocturnal vital emergency between 10pm-7am (OR:6.81; CI95%:1.63–28.4) as significant independent risk factors for 30-day-mortality. All included risk factors were statistically significant ($p < 0.01$), except epinephrine ($p = 0.097$). Supplement 1 shows the results in detail.

Development of the final prediction model

The discrimination assessed with AUC under the ROC was 0.90

Table 2 Included variables in the final multivariable logistic regression model

Predictors	b	S.E.	Wald	Sig.	Odds ratio	95% CI odds ratio
Post-menstrual age at time of surgery [weeks]	-.406	.110	13.746	.000	.666	.538.826
Weight at time of surgery [kg] in extremely preterm infants	-3.725	1.124	10.989	.001	.024	.003-.218
Nocturnal vital emergency	2.317	.743	9.712	.002	10.142	2.362-43.54
Preoperative Catecholamines	2.454	.601	16.694	.000	11.631	3.585-37.74
Constant	9.848	3.509	7.876	.005	n.a.	n.a.

b regression coefficient, *S.E.* standard error, *95% CI* 95% confidence interval, *n.a.* not applicable, Catecholamines = dopamine, norepinephrine and/or epinephrine

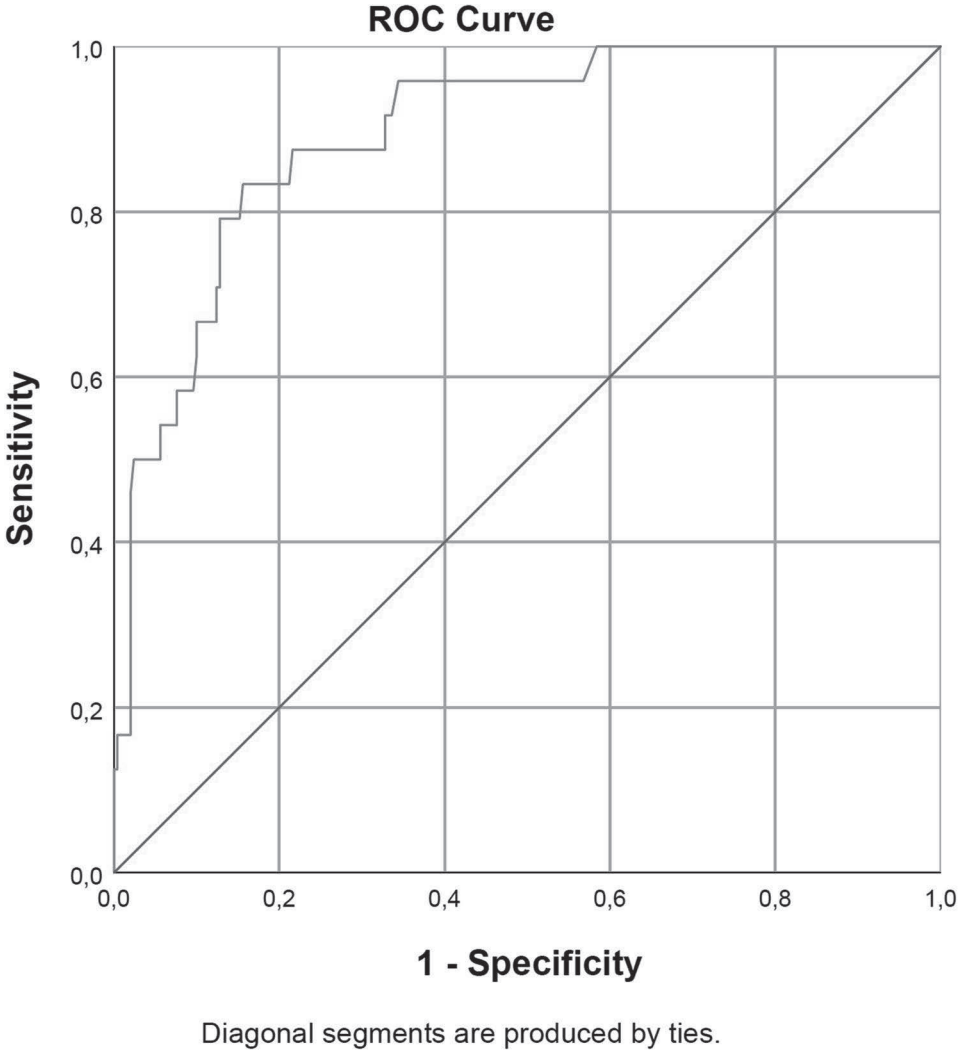

Figure 2. Receiver-Operating-Curve (ROC) (final model) [Area-under under the ROC = 0.90 (CI95%:0.84-0.96)].

(CI95%:0.84–0.96). Because the number of predictors was high (n = 6) (in relation to the total number of infants in this study, we checked whether the prediction model could be simplified if the three predictors norepinephrine [y/n], dopamine [y/n], and epinephrine [y/n] are replaced by one combined predictor '(3) Catecholamines' (norepinephrine or dopamine or epinephrine [y/n]). This simplified multivariable logistic regression model (backwards, p_{out}=0.15) confirmed the significance of the combined predictor (norepinephrine or dopamine or epinephrine [y/n]) (OR: 11.6, CI95%:3.59–37.7, $p < 0.01$).

Table 2 shows the results of the final (simplified) prediction model, i.e. the multivariable logistic regression model includes four predictors: post-menstrual age at time of surgery, body weight at time of surgery only in extremely preterm infants, presurgical application of catecholamines (dopamine or norepinephrine or epinephrine), and nocturnal vital emergency.

The discrimination of this final prediction model assessed with AUC under the ROC was 0.90 (CI95%:0.84–0.96) (Figure 2). The investigation of the calibration of the logistic regression model (visual inspection and non-significant Spiegelhalter test; p = 0.99) showed no significant discrepancies between estimated and observed probabilities for mortality (see Supplement 2: Calibration curve). Hosmer-Lemeshow test also indicates no significant violation of goodness of fit of the final logistic regression model (p = 0.84). Based on the estimated regression coefficients (Table 2), the linear predictor, abbreviated as "risk

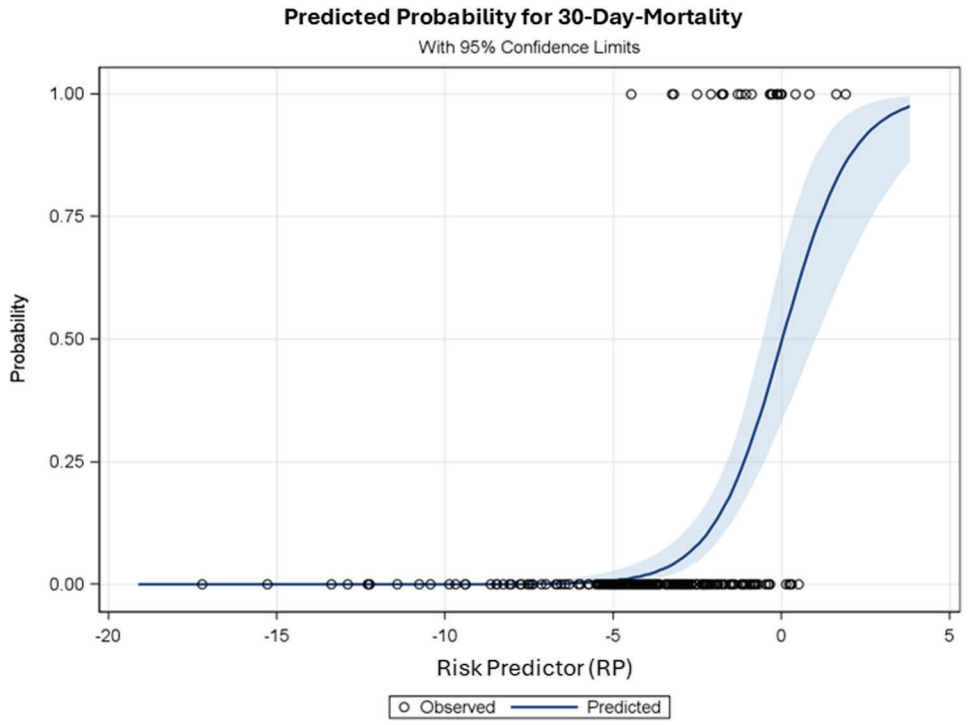

Figure 3. Relationship between risk predictor "RP" and the predicted probability of 30-day-mortality.

predictor" (RP), is calculated as:

$$RP = 9.848 - 0.406x_1 - 3.725x_2 + 2.454x_3 + 2.317x_4$$

x_1 = post-menstrual age at time of surgery (weeks)
x_2 = body weight (kg) at time of surgery in extremely preterm infants
x_3 = pre-operative application of dopamine, norepinephrine or supra (yes = 1, no = 0)
x_4 = nocturnal vital emergency between 10pm-7am (yes = 1, no = 0)

According to the logistic function, the probability of 30-day-mortality is calculated as exp(RP)/(1 +exp(RP)). The relationship between the predictor RP and predicted probability of 30-day-mortality is shown in Figure 3. In addition, the CI95%-limits indicate the accuracy of the estimated probability of 30-day-mortality.

The results of the bootstrapping procedure (significance of regression coefficients, all $p < 0.002$) and CI95% (not including '1') confirmed the regression coefficients estimated by the final prediction model (Supplement 3).

The probabilities for peri-operative 30-day-mortality differentiated by extremely preterm, very preterm and preterm infants are shown in Figure 4. Figure 4 illustrates the influence of the individual factors, e.g. catecholamines, on mortality. In particular, Figure 4 can be used to roughly estimate the probability of mortality without tools (such as calculators, etc.).

30-day-mortality in extremely preterm infants (age at birth < 28 weeks)

The 30-day mortality rate was highest in this group at 12.6% (14/111). 12 (85.7%) of the 14 deceased infants were treated with dopamine, norepinephrine or epinephrine before surgery and 4 (28.6%) as a nocturnal vital emergency. Of the 97 survivors, 35 (36.1%) were treated with dopamine, norepinephrine or epinephrine and 10 (10.3%) as nocturnal vital emergencies. However, it is worth noting that from a gestational age > 30 weeks at the time of surgery, the probability of death in this group was very low.

30-day-mortality in very preterm infants (age at birth: week 28 - < 32)

The 30-day mortality rate in this group was 9.8% (6/61). 5 (83.3%) of the 6 deceased infants were treated with dopamine, norepinephrine or epinephrine before surgery and none was treated as nocturnal vital emergency. Of the 55 survivors, (only) 4 (7.3%) were treated with dopamine, norepinephrine or epinephrine and 3 (5.7%) as nocturnal vital emergencies.

30-day-mortality in preterm infants (age at birth: week 32 - < 38)

The 30-day mortality rate was lowest in this group 3.8% (4/106). 1 (25%) of the 4 deceased infants was treated with dopamine, norepinephrine or epinephrine before surgery and 2 (50%) were treated as nocturnal vital emergencies. Of the 102 survivors, only 7 (6.9%) were treated with dopamine, norepinephrine or epinephrine and only 2 (2.0%) were treated as nocturnal vital emergencies.

Discussion

The present study investigated 30-day-mortality and its risk factors in 278 preterm infants in a German level-one-perinatal-center. 30-day-mortality was 8.6%. The multivariable prediction model showed that lower postmenstrual age and lower body weight at time of surgery especially in extremely preterm infants, application of catecholamines like dopamine, application

< 0.01	0.01 – 0.025	0.025 – 0.05	0.05 – 0.10	0.10 – 0.2	> 0.2

Age at OP (week)	Body weight (g)	Estimated probability for death	Estimated probability for death with catecholamine	Estimated probability for death with nocturnal vital emergency
Probability for 30-day mortality in **extremely preterm infants** (age at birth< 28 weeks)				
25	400	0.143	0.660	0.628
25	500	0.103	0.572	0.538
25	600	0.073	0.479	0.445
25	700	0.052	0.388	0.356
25	800	0.036	0.304	0.276
26	400	0.100	0.564	0.530
26	500	0.071	0.471	0.437
26	600	0.050	0.380	0.348
26	700	0.035	0.297	0.269
26	800	0.024	0.225	0.202
26	900	0.017	0.167	0.149
27	400	0.069	0.463	0.429
27	500	0.048	0.372	0.341
27	600	0.034	0.290	0.263
27	700	0.024	0.220	0.197
27	800	0.016	0.162	0.145
27	900	0.011	0.118	0.104
27	1000	0.008	0.084	0.074
28	600	0.023	0.214	0.192
28	700	0.016	0.158	0.141
28	800	0.011	0.114	0.101
28	900	0.008	0.082	0.072
28	1000	0.005	0.058	0.051
28	1100	0.004	0.041	0.036
29	700	0.011	0.111	0.098
29	800	0.007	0.079	0.070
29	900	0.005	0.056	0.049
29	1000	0.004	0.039	0.034
29	1100	0.002	0.027	0.024
29	1200	0.002	0.019	0.017
30	800	0.005	0.054	0.048
30	900	0.003	0.038	0.033
30	1000	0.002	0.027	0.023
30	1100	0.002	0.018	0.016
30	1200	0.001	0.013	0.011
30	1300	0.001	0.009	0.008
Probability for 30-day mortality in **very preterm infants** (age at birth: week 28 - < 32)				
29		0.127	0.629	0.597
30		0.089	0.530	0.496
31		0.061	0.429	0.396
32		0.041	0.334	0.304
33		0.028	0.250	0.226
34		0.019	0.182	0.163
35		0.013	0.129	0.115
36		0.008	0.090	0.079
37		0.006	0.062	0.054
Probability for 30-day mortality in **preterm infants** (age at birth: week 32 - < 38)				
33		0.028	0.250	0.226
34		0.019	0.182	0.163
35		0.013	0.129	0.115
36		0.008	0.090	0.079
37		0.006	0.062	0.054
38		0.004	0.042	0.037

Figure 4. Probability for 30-day mortality.

of norepinephrine, and nocturnal vital emergency between 10pm-7am were important risk factors for predicting mortality. The prediction model showed a good discrimination between survival and death within 30 days after surgery. The calibration curve showed no significant discrepancies between estimated and observed probabilities for mortality.

Despite the progress in peri-natal medicine in recent years, the morbidity and mortality of preterm children has remained high: Within the first year of life for children peri-operative 30-day-mortality ranges between 0 and 180 per 10,000 pediatric anesthesias. Particularly high mortality rates could be observed when considering only preterm infants. Common serious congenital anomalies and/or perinatal complications requiring surgical care make this a high risk patient collective.[6,7,13,15,16] In the prospective multicenter NECTARINE-study, which investigated morbidity and mortality after anesthesia in neonates and children in 165 centers in 31 european countries, a 30-day-mortality of 4.1% was found in the subpopulation of neonates < 28 days post birth, mainly caused by sepsis and multiorgan failure.[17] Although NECTARINE showed that the relative risk of 30-day-mortality increased with decreasing post-menstrual age, NECTARINE does not provide any differentiated information on the mortality in the group of preterm children within the different categories.[17] Therefore, the present data gives an insight into the outcomes of neonatal surgery at a German university hospital with approximately 20 preterm neonates per year or one every other week in the real world, confirming the existing risk factors in this unique population and therefore is an interesting addition to previous studies such as NECTARINE.

Various risk factors influencing peri-operative mortality in children have been described which apply to preterm infants in the peri-operative setting anyway: ASA physical status, neonatal age, age at surgery, congenital anomalies, comorbidities e.g. sepsis, preoperative organ dysfunction and organ support, preoperative blood transfusion, emergency category of the surgery, surgery in the off hours, pre-operative and peri-operative cardiac arrest as well as the presence of a do-not-resuscitate order and many others. However, some of these risk factors only manifest themselves in the intra- or post-operative course and are therefore not available pre-operativelyIn addition, it is sometimes difficult for relatives to interpret effect estimates, especially if several risk factors are present in combination.[18-26]

Therefore, a differentiated multivariable prediction model for peri-operative mortality appears to be useful for various reasons: From the parents/guardians' perspective an appropriate prognosis assessment tool enables a transparent understanding of risk with realistic expectations of the post-operative outcome, the definition of treatment limits, and, if necessary, alleviate feelings of anxiety as well as psychological support and the preparation of religious rituals. With regards to the healthcare professionals involved, an improved assessment of 30-day-mortality and associated risk factors may facilitate care of this very special cohort. It may provide increased precision of the prognostic evaluation and streamline the assessment of procedural risk. Furthermore, precise risk estimation ensures the allocation of adequate resources such as monitoring, equipment and the presence of experienced specialists along with appropriate post-operative follow up care.[27-29]

For neonatal intensive care several prognostic calculators have been developed to estimate mortality. However, although the AUC in these scores ranged from to 0.96 their transferability is limited because they were not evaluated in the peri-operative setting.[18-26] Therefore, the present prediction model evaluates peri-operative mortality risk in a more differentiated manner, focusing on the peri-operative care of preterm infants in the context of non-cardiac surgery based on factors that are easy to collect combining the peri-operative risk with the risk of neonatal intensive care, demonstrating a good discrimination (AUROC:0.90; CI95%:0.84–0.96). Since an excessive variety of variables to be collected is likely to increase the accuracy of the assessment tool, but also reduces user-friendliness, one advantage of the risk assessment tool on which the present work is based, is the assessment on the basis of simple factors to be collected in a manageable framework at the bedside.[30] User-friendliness can be increased by programming an application, like the American College of Surgeons NSQIP Pediatric Surgical Risk Calculator, or a special calculator programmed in the electronic patient file.[31]

Limitations

The limitations of this study include its retrospective and monocentric design. Since the university hospital conducting the study is a perinatal center with the highest level of care and one of the biggest pediatric surgery centers in Germany, it is quite possible that local expertise and higher standards could have distorted the value. Although preterm infants in Germany are being treated at such centres, the present study may not be representative of the general population of preterm infants undergoing surgery. So far, no external validation of the developed prediction model has been carried out. Ideally this should be carried out as part of a multicentric international study. However, the peri-operative care of preterm infants is rare, as was already demonstrated in NECTARINE. Although only a few risk scores for children have been externally validated so far, the publication of this prediction model may encourage some centres to provide validation. It may also be possible to use this validation to develop a scoring system in order to weigh the various influencing factors against each other. The present prediction model was not developed for the prediction of mortality in children undergoing cardiac surgery, traumatized children, or children undergoing solid organ transplant. These specific patient populations need a specific risk assessment tool and special validation. The present study only evaluates the prediction of mortality, so that morbidity is not taken into account. Possibly, the use a combination of mortality and major morbidity as the outcome, could increase the applicability of the predictive model and the clinical value. Furthermore, the small number of preterm infants may have biased the results. However, the number of preterm infants even in large and international multicenter studies is typically low. Accordingly, the fact that the present study is the largest within the collective of preterm infants to date must be recognized.

Conclusions

Lower post-menstrual age and body weight at time of surgery, especially in extremely preterm infants, application of catecholamines like dopamine, norepinephrine or norepinephrine and nocturnal vital emergency are relevant risk factors for 30-day-mortality. The prediction model "PrEdiction of MortAlity in peri-operative Care of preterm cHildren" (PEACH) developed on the basis of these influencing factors could prove to be important for peri-operative risk assessment, rational risk education for parents, optimizing timing of surgery

and ensuring optimum peri-operative care by the experienced specialist teams.

Abbreviations

AUC	Area-Under-The-ROC
CI95%	95% confidence intervals
ICU	Intensive Carew Unit
OR	Odds Ratio
POCA	Peri-operative Cardiac Arresr
ROC	Receiver-Operating-Characteristic-Curves
WHO	World Health Organisation

Authors' contributions

GJ has made substantial contributions to the conception, design of the work; the acquisition, analysis, interpretation of data; and drafted the work. LI has made substantial contributions to the conception; the acquisition, analysis, interpretation of data; and substantively revised the work. JH has made substantial contributions to the analysis, interpretation of data; and substantively revised the work. SJ has made substantial contributions to the analysis, interpretation of data; and substantively revised the work. JP has made substantial contributions to the analysis, interpretation of data; and substantively revised the work. SWR has made substantial contributions to the analysis, interpretation of data; and substantively revised the work.

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Data availability

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

Ethics approval and consent to participate

The study was approved by the Institutional Review Board of the University of Muenster, Germany (file reference 2019-398-f-S). Due to its retrospective nature, the requirement of written informed consent was waived by the Institutional Review Board. The study adheres to the Declaration of Helsinki.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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