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Enhanced Recovery After Surgery (ERAS) Society Recommendations for Neonatal Perioperative Care

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IMPORTANCE Neonates requiring surgery are often cared for in neonatal intensive care units (NICUs). Despite a breadth of surgical pathology, neonates share many perioperative priorities that allow for the development of unit-wide evidence-based Enhanced Recovery After Surgery (ERAS) recommendations.

OBSERVATIONS The guideline development committee included pediatric surgeons, anesthesiologists, neonatal nurses, and neonatologists in addition to ERAS content and methodology experts. The patient population was defined as neonates (first 28 days of life) undergoing a major noncardiac surgical intervention while admitted to a NICU. After the first round of a modified Delphi technique, 42 topics for potential inclusion were developed. There was consensus to develop a search strategy and working group for 21 topic areas. A total of 5763 abstracts were screened, of which 98 full-text articles, ranging from low to high quality, were included. A total of 16 recommendations in 11 topic areas were developed with a separate working group commissioned for analgesia-related recommendations. Topics included team communication, preoperative fasting, temperature regulation, antibiotic prophylaxis, surgical site skin preparation, perioperative ventilation, fluid management, perioperative glucose control, transfusion thresholds, enteral feeds, and parental care encouragement. Although clinically relevant, there were insufficient data to develop recommendations concerning the use of nasogastric tubes, Foley catheters, and central lines.

CONCLUSIONS AND RELEVANCE Despite varied pathology, neonatal perioperative care within NICUs allows for unit-based ERAS recommendations independent of the planned surgical procedure. The 16 recommendations within this ERAS guideline are intended to be implemented within NICUs to benefit all surgical neonates.

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Supplemental content

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Enhanced Recovery After Surgery (ERAS) guidelines provide health care practitioners with evidence-informed recommendations designed to be implemented as a synergistic care bundle to standardize and improve perioperative care.[1] The guidelines and their respective components are intended to minimize the physiologic stress of surgery and the resultant catabolic state that contributes to adverse surgical outcomes. ERAS guidelines currently exist for over 20 adult surgical populations.[2-5] Recommendations relating to preoperative optimization, intraoperative fluid management, and analgesia-related recommendations are similar across a number of specialty-specific guidelines. In adults, ERAS care pathways have been shown to reduce complications, reduce postoperative length of stay (without increasing readmissions), and reduce costs.[6]

Pediatric patients, and particularly neonates, are especially vulnerable to surgical stress. At present, the ERAS Society Guideline for the treatment of neonates undergoing intestinal resection is the only neonatal guideline.[4] Given the imperative to produce evidence-based care pathways for the neonatal population, a series of subspecialty-based guidelines would be cumbersome, and thus, this model of replicating the adult guidelines was rejected. Instead, there is a recognized set of commonalities between neonates requiring surgery that can be used to develop broadly applicable guidelines. It is with this tenet in mind that this guideline was created. We sought to reevaluate the recommendations for neonates undergoing intestinal resection and update and expand these guidelines to apply to a broader population of all surgical neonates. These guidelines are intended to be implemented within the neonatal intensive care unit (NICU) to create a shared evidence-based care model for multidisciplinary and multiprofessional teams.

Methods

The guideline was developed following the approach outlined by the ERAS Society's standards for guideline creation and has been endorsed by the ERAS Society.[7]

Guideline Development Committee

An international guideline development committee (GDC) was established, including pediatric general and thoracic surgeons, pediatric anesthesiologists, neonatologists, neonatal nurses, and ERAS methodology experts. An additional advisory team of ad hoc consultants was approached for specific recommendations (members included representatives from dietetics, pharmacy, and subspecialty surgery). Parent representatives were consulted throughout.

Scope Determination and Literature Search

A modified Delphi technique was used to create a consensus definition for the scope of included patient population and procedures and then to develop and refine the topic areas and specific recommendations. Consensus was predefined as greater than 70% agreement with the proposal by GDC members with serial Qualtrics surveys being used to measure consensus. A combination of virtual consensus meetings and circulated working documents were used until universal consensus regarding the population and included topic areas was attained.

Analgesia-related topics were considered by an alternate working group and not included in these recommendations.

Literature Search

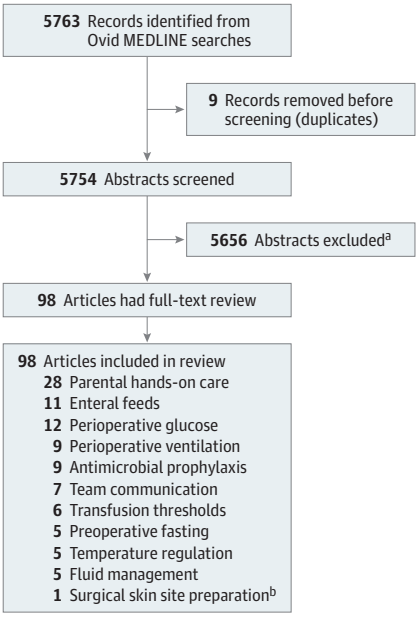
Within the topic areas, working groups proposed new recommendation (s) or recommendation amendments, and search strategies were developed in consultation with a research librarian. The primary literature from the 2020 Intestinal Resection Guideline[4] was reviewed together with a focused literature review of each topic from 2017 to 2022 to identify updated data and reevaluate the evidence base behind prior recommendations for the broader neonatal population. Searches were performed using Ovid MEDLINE and limited to the English language. Each working group was provided with literature and encouraged to further snowball search the literature as required. JBI (formerly Joanna Briggs Institute, a research organization that develops evidence-based information) quality assessment was performed for all included full-text studies and the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach was used to summarize the certainty of evidence for each recommendation and determine the strength of the recommendation (**Table 1**).[8,9] The proposed recommendations were then circulated to the broader GDC alongside proposed strength of recommendations and grade of evidence. Iterative amendments occurred until there was (1) consensus (>70% agreement) to include the recommendation, (2) support of the strength of recommendation, and (3) the appropriate grade of evidence quality. All 18 GDC members completed each round of the modified Delphi and approved the final recommendations.

Table 1. Grading of Recommendations Assessment, Development, and Evaluation Method for Rating Quality of Evidence and Strength of Recommendation

Measure	Quality/ strength level	Meaning
Evidence quality	High	Further research very unlikely to change the GDC's confidence in the estimate of effect
	Moderate	Further research is likely to have an important impact on the GDC's confidence in the estimate of effect and may change the estimate
	Low	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate
	Very low	Any estimate of effect is very uncertain
Strength of recommendation	Strong	The desirable effects of an intervention clearly outweigh the undesirable effects, or clearly do not
	Weak	The trade-offs are less certain—either because of low-quality evidence or because evidence suggests that desirable and undesirable effects are closely balanced

Abbreviation: GDC, guideline development committee.

Figure. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Diagram



[a]The reasons for exclusion were that the population, setting, or study type (review, editorial, or study protocol) was wrong or the article was retracted.

[b]Included recent systematic review.

Results

The patient population was defined as neonates (within the first 28 days of life) undergoing a major noncardiac surgical intervention while admitted to the NICU. The GDC elected not to specify any patient-related exclusion factors (eg, prematurity, comorbidities); rather, clinicians were encouraged to use these recommendations for any patient within the NICU and to modify using clinical judgment. There were 42 potential topics identified, 17 of which were taken from the neonatal intestinal resection guideline.[4] After 2 rounds, a total of 21 topics were selected for search strategy development. Working groups contributed to the development of search strategies yielding a total of 5763 identified abstracts. After abstract screening, 98 articles were included in full-text review, which were considered alongside the relevant 58 articles from the ERAS Society Guideline for Neonatal Intestinal Surgery Guideline[4] (**Figure**). Using the JBI critical appraisal tool specific to each study design, each of these articles was assessed for the quality of evidence.[8] The GDC

Table 2. Consensus Guidelines for Neonatal Perioperative Care: Enhanced Recovery After Surgery (ERAS) Society Recommendations for Neonatal Intensive Care Units

Topic	Recommendation	Quality	Strength
Team communication	Implement perioperative multidisciplinary team communication using a structured process and protocol (eg, preoperative and postoperative huddles).	Moderate	Strong
Preop fasting	For neonates who are not otherwise nothing by mouth, offer formula or breast milk (with fortification removed) for up to 6 h and 4 h, respectively, preoperatively, and clear fluids up to 1 h preoperatively to minimize fasting.	Moderate	Strong
Temperature regulation	Continuously monitor intraoperative core temperature and take preemptive measures to prevent hypothermia (<36.5 °C) and maintain normothermia beginning before transfer from the NICU.	Moderate	Strong
Antimicrobial prophylaxis	Administer appropriate preoperative antibiotic prophylaxis within 60 min of skin incision for clean-contaminated, contaminated, and dirty cases.	Low	Weak
	Discontinue prophylactic postoperative antibiotics within 24 h of surgery unless ongoing treatment is warranted.	Low	Weak
Surgical skin site preparation	Use chlorhexidine-based skin preparation to prepare the surgical site in neonates and infants >35 weeks' gestation and >1500 g.	High	Strong
Perioperative ventilation	Use a lung-protective strategy (eg, 4-8 mL/kg, not >10 mL/kg and PEEP approximately 5). Ensure tidal volumes are measured intraoperatively and monitor carbon dioxide levels.	Low	Weak
	Consider using cuffed tracheal tubes for appropriately sized neonates to optimize ventilation and decrease the risk of reintubation. Consider the use of LMAs for appropriately sized infants for uncomplicated procedures where the anesthesia practitioner has access to the airway in case of need to rescue.	Low	Weak
	Aim for early postoperative extubation as soon as feasible, considering gestational age, risk for respiratory failure and type of surgical repair.	Moderate	Weak
Fluid management	Titrate perioperative fluids to maintain tissue perfusion and prevent hypovolemia, fluid overload, and hyponatremia.	Moderate	Weak
Perioperative glucose control	Ensure adequate perioperative glucose intake to avoid hypoglycemia which can be associated with adverse outcomes; tight glucose control with insulin infusions is not routinely recommended.	Low	Weak
Transfusion threshold	Restrict transfusions to maintain a hemoglobin level >90 g/L for a term neonate with no oxygen requirements. Term neonates within the first week of life, either intubated or with an oxygen requirement, should be transfused to maintain a hemoglobin level >110 g/L.	Low	Weak
	Use written transfusion guidelines that take into account the target hemoglobin threshold and coagulation profile as well as the clinical status of the neonate and local practice.	Low	Weak
Enteral feeds	Use breast milk as first choice for enteral nutrition.	High	Strong
	Use postoperative feeding protocols to promote early enteral feed introduction and advancement.	Low	Weak
Parental hands-on care	Facilitate hands on care and purposeful practice by parents that is individualized to meet the unique needs of parents and infants early during the admission. Build parental knowledge, skills, and confidence to take on a leading role and facilitate caregiver readiness for safe transition or discharge from the NICU.	High	Strong

Abbreviations: LMA, laryngeal mask; NICU, neonatal intensive care unit; PEEP, positive end-expiratory pressure.

SI conversion factor: To convert hemoglobin to grams per deciliter, divide by 10.

determined that there was adequate evidence to create recommendations in 11 defined topic areas. Between 1 and 3 recommendations were created per topic area, resulting in a total of 16 final recommendations (**Table 2**). Evidence tables are included in the eAppendix in the Supplement.

Team Communication

Surgical handovers are particularly vulnerable to communication breakdown and can lead to patient safety events.[10] Structured communication using checklists such as the World Health Organization Surgical Safety Checklist,[11] standardized postoperative checklists,[12] and hypothermia checklists[13] have been shown to be effective in neonates in multiple international large-scale studies. Enhanced communication can build collaborative teams and improve health care practitioner satisfaction.[14] Although the body of evidence in neonates is still somewhat limited, this is a strong recommendation given the body of indirect evidence and expert agreement of the small risk of harm.

Recommendation: Implement perioperative multidisciplinary team communication using a structured process and protocol (eg, preoperative and postoperative huddles).

Evidence quality: Moderate

Recommendation strength: Strong

Preoperative Fasting

Minimizing fasting time to reduce the catabolic response is a core component of ERAS recommendations. There is a large body of high-quality evidence that demonstrates its importance.[15] Neonates are particularly vulnerable to prolonged fasting as they have reduced reserves; therefore, despite there only being a moderate amount of evidence in neonatal patients, there is a strong recommendation to

minimize fasting. Anesthesia guidelines have increasingly recognized the safety evidence permitting clear fluid intake up to 1 hour before surgery.[16-18] The group recommends the development of local protocols to minimize fasting and encourage clear fluid intake up until 1 hour before surgery.

Recommendation: For neonates who are not otherwise nothing by mouth, offer formula or breast milk (with fortification removed) for up to 6 hours and 4 hours respectively preoperatively, and clear fluids up to 1 hour preoperatively to minimize fasting.

Evidence quality: Moderate

Recommendation strength: Strong

Temperature Regulation

Neonates with perioperative hypothermia have additional adverse respiratory events and are more likely to require thermoregulatory, respiratory, and cardiac interventions than normothermic neonates.[19] Transportation of neonates is often a time of heat loss,[20,21] and perioperative protocols including standardized handovers addressing thermoregulation have been demonstrated to improve maintenance of normothermia.[12,13,22] There is moderate evidence from multiple prospective studies that a multifaceted approach to heat preservation and active warming is required to prevent hypothermia during transfer and while in the operating room.

Recommendation: Continuously monitor intraoperative core temperature and take preemptive measures to prevent hypothermia (temperature <36.5 °C) and maintain normothermia beginning before transfer from the NICU.

Evidence quality: Moderate

Recommendation strength: Strong

Antimicrobial Prophylaxis

Surgical site infections (SSIs) are a major cause of morbidity after surgery.[23] Rates of neonatal SSI are increased in younger neonates undergoing abdominal surgery.[24] A number of single-center cohort studies of infants have demonstrated the benefit of preoperative antibiotics in reducing the rates of SSI in clean-contaminated, contaminated, and dirty cases.[25,26] Several small cohort studies in infants younger than 1 year have not demonstrated any benefit of antibiotic prophylaxis in clean procedures.[27,28] Although the quality of evidence in neonates is low, the guideline committee has recommended appropriate prophylactic antibiotics given the congruency of findings in small cohort studies with high-quality data in older patients.

Recommendation: Administer appropriate preoperative antibiotic prophylaxis within 60 minutes of skin incision for clean-contaminated, contaminated, and dirty cases.

Evidence quality: Low

Recommendation strength: Weak

The extended use of prophylactic antibiotics has not been shown to reduce the risk of SSI in adult or pediatric patients undergoing clean or clean-contaminated procedures.[29] If ongoing treatment is required (due to necrotizing enterocolitis, incomplete source control, etc), the antibiotic duration should be guided by clinical context. Given the low quality of evidence specifically within the neonatal population, this is a weak recommendation.

Recommendation: Discontinue prophylactic postoperative antibiotics within 24 hours of surgery unless ongoing treatment is warranted.

Evidence quality: Low

Recommendation strength: Weak

Surgical Site Skin Preparation

The use of skin antisepsis to prepare the surgical site is a central tenet of surgical site preparation to reduce the burden of skin pathogens before incision. High-quality evidence supports the superiority of chlorhexidine-based solutions in reducing the risk of SSI in adults.[30,31] There was initially some hesitancy in applying this to the neonatal population given the increased susceptibility to skin burns.[32] A recent prospective quality improvement initiative demonstrated that chlorhexidine-based skin preparation in infants (aged >35 weeks and weighing >1500 g) was not associated with any adverse skin reactions.[33] Indirect adult and pediatric data are coupled with recent prospectively collected safety data for the term and late-preterm neonatal population.[33]

Recommendation: Use chlorhexidine-based skin preparation to prepare the surgical site in neonates and infants older than 35 weeks' gestation and weighing more than 1500 g.

Evidence quality: High

Recommendation strength: Strong

Perioperative Ventilation

Neonates are at higher risk of airway or pulmonary complications related to perioperative ventilation. Their small airways and fragile lungs are susceptible to airway stenoses and barotrauma. Appropriate monitoring including capnography and tidal volumes are required to deliver lung-protective ventilation strategies.[34-36] Despite these practices being widespread, there are relatively few primary sources of high-quality evidence, and thus, this is a weak recommendation.

Recommendation: Use a lung-protective strategy (eg, 4-8 mL/kg, not greater than 10 mL/kg and positive end-expiratory pressure of approximately 5 cm H_2O). Ensure tidal volumes are measured intraoperatively and monitor carbon dioxide levels.

Evidence quality: Low

Recommendation strength: Weak

The risks of unplanned extubation and consequent reintubation can be high.[37] The use of cuffed endotracheal tubes (ETTs) remains controversial in neonates.[38,39] A nonblinded randomized clinical trial (RCT) comparing cuffed and uncuffed ETTs in the NICU demonstrated fewer reintubations to optimize ETT size and fewer episodes of atelectasis with a cuffed tube with no difference in postextubation complications or subglottic stenosis.[40] In a select group of neonatal patients, the use of a laryngeal mask can be considered due to ease of use, fewer hemodynamic changes while capturing the airway, and minimal postoperative complications.[41-43]

Recommendation: Consider the use of cuffed tracheal tubes for appropriately sized neonates to optimize ventilation and decrease the risk of reintubation. Consider the use of laryngeal masks for appropriately sized infants for uncomplicated procedures where the anesthesia practitioner has access to the airway in case of need to rescue.

Evidence quality: Low

Recommendation strength: Weak

Early extubation has been associated with decreased morbidity and shorter ICU and hospital lengths of stay.[44] In neonates who were intubated for noncardiac surgery, those who were extubated early (within 24 hours of surgery) had lower adverse respiratory events and a shorter length of stay.[45] However, in 1 study,[46] the extubation of neonates in the recovery room was associated with higher adverse respiratory events. A weak recommendation is made to encourage neonatal units to develop protocols to facilitate early extubation when feasible given the variable factors that impact risks of reintubation (eg, recent esophageal anastomosis, need for positive pressure, etc).

Recommendation: Aim for early postoperative extubation as soon as feasible, considering gestational age, risk for respiratory failure, and type of surgery.

Evidence quality: Moderate

Recommendation strength: Weak

Fluid Management

Neonates require careful titration of intravenous fluid intake particularly in the first few days of life.[47] There are pediatric guidelines for intraoperative fluid administration, but guidelines for neonates do not yet exist.[48] Fluid choice should be driven by the infant's preoperative fluid status, intraoperative stress and volume loss, and urine output with a target of euvolemia and the avoidance of hyponatremia. Hypotonic solutions must be used with caution as they may contribute to hyponatremia in neonates.[49] This is a weak recommendation as there is relative paucity of primary evidence primarily from small, single-site studies, and specific fluid resuscitation regimens cannot be recommended.

Recommendation: Titrate perioperative fluids to maintain tissue perfusion and prevent hypovolemia, fluid overload, and hyponatremia.

Evidence quality: Moderate

Recommendation strength: Weak

Perioperative Glucose Control

Neonates require a continuous supply of glucose to support brain development and are susceptible to neurodevelopmental sequelae with prolonged hypoglycemia. Perioperative euglycemia is the target for neonates who are susceptible to complications of both hypoglycemia and hyperglycemia for which intraoperative and postoperative monitoring is recommended.[50] Tight glycemic control with an insulin infusion was associated with a higher risk of infection in infants younger than 60 days in a post hoc analysis of children undergoing cardiac surgery[51] and was not shown to affect neurodevelopmental outcomes.[52] Overall, the evidence for this recommendation came from small, single-site studies including RCTs focused on specific aspects of glucose management (ie, tight vs lenient glycemic control).

Recommendation: Ensure adequate perioperative glucose intake to avoid hypoglycemia, which can be associated with adverse outcomes; tight glucose control with insulin infusions is not routinely recommended.

Evidence quality: Low

Recommendation strength: Weak

Transfusion Thresholds

Both anemia and blood product transfusion have potential detrimental effects on neonates, and a careful balance is required to guide transfusion practices.[53] Anemia and thrombocytopenia in neonates are common, and the majority of preterm infants will receive at least 1 blood transfusion while admitted to the NICU.[54] The Canadian Pediatric Society Position article[55] includes postnatal age and the need for respiratory support when determining thresholds. Most advocate for conservative transfusion thresholds given the lack of any difference in large RCTs between restrictive and liberal transfusion regimes in neonates.[56-58] In order to create consistency in the NICU, an institution-specific guideline is recommended to promote consistency in transfusion parameters that take into account relevant clinical variables.

Recommendation: Restrict transfusions to maintain a hemoglobin level greater than 90 g/L (to convert to grams per deciliter, divide by 10) for a term neonate with no oxygen requirements. Term neonates within the first week of life, those who are intubated, or those with an oxygen requirement should be transfused to maintain a hemoglobin level greater than 110 g/L.

Evidence quality: Low

Recommendation strength: Weak

Recommendation: Use written transfusion guidelines that take into account the target hemoglobin threshold and coagulation profile as well as the clinical status of the neonate and local practice.

Evidence quality: Low

Recommendation strength: Weak

Enteral Feeds

Breast milk is the first-choice enteral feed for preterm and term infants in the NICU who do not have a contraindication for enteral feeds.[59] The evidence for this recommendation comes from high-quality studies, including a multisite RCT. For term infants, breast milk has been shown to reduce severe diarrhea, acute otitis media, lower respiratory tract infections, and obesity.[60] In preterm infants, there is a reduction in necrotizing enterocolitis, late-onset sepsis, chronic lung disease, retinopathy of prematurity, and improved neurodevelopmental outcomes.[61] Postoperative patients, including patients with gastrointestinal tract anomalies such as gastroschisis, may have an earlier resumption of enteral autonomy when given breast milk exclusively.[62] Mechanisms already in place with the NICU can be applied to surgical neonates across the unit.[59,60]

Recommendation: Use breast milk as first choice for enteral nutrition.

Evidence quality: High

Recommendation strength: Strong

Early enteral feeding is supported and can reduce length of stay and infectious complications in appropriate patients.[63-65] Given the wide variability in patients included within this guideline, no specific recommendation regarding timing of postoperative feeds is made. There is evidence from small, single-site studies to support a structured feeding protocol postoperatively to reduce time to

enteral autonomy and reduce incidence of intestinal failure–associated liver disease.[66-68] Feeding protocols standardize readiness criteria for introduction of trophic feeds and provide structured criteria for advancement toward full enteral feeds to minimize practitioner variability. Unit-based guidelines to standardize the introduction and advancement of feeds are recommended to reduce both the duration of parenteral nutrition and central line use by reaching goal enteral feeds more quickly.

Recommendation: Use postoperative feeding protocols to promote early enteral feed introduction and advancement.

Evidence quality: Low

Recommendation strength: Weak

Parental Hands-On Care

Parents and other identified caregivers should be considered integral members of their infant's care team rather than merely visitors to the NICU.[69] Family-centered care has been associated with improved weight gain, decreased length of stay, and decreased readmission rates in multiple well-designed studies.[70] Parental involvement is often already integrated within many neonatal units: benefit has been shown by involving parents in delivering developmentally appropriate sensory stimulation,[71] participating in Beads of Courage memory making,[72] and engaging in family-integrated care.[73] Parents of neonates and infants who have undergone surgery require additional coaching to help them comfortably participate in their child's care. Early hands-on practice with skills such as nasogastric tube feeds, dressing changes, and management of colostomies are necessary to develop a readiness to leave the NICU.[74] Parental discharge teaching can be associated with a reduction in health care utilization,[75] and discharge simulations can increase parental preparedness.[76] Each of these interventions can be adapted to the perioperative recovery and are ideally implemented unit-wide, thus, a strong recommendation is made to involve parents early.

Recommendation: Facilitate hands-on care and purposeful practice by parents that is individualized to meet the unique needs of parents and infants early during the admission. Build parental knowledge, skills, and confidence to take on a leading role and facilitate caregiver readiness for safe transition or discharge from the NICU.

Evidence quality: High

Recommendation strength: Strong

Discussion

Although the GDC considered 21 potential topic areas, evidence-based recommendations could only be supported in 11 of these areas at the current time. Eight of the resultant 16 recommendations are supported by low-quality evidence. Rather than exclude these topics while waiting for stronger evidence, the GDC felt it was necessary to include these weak recommendations to highlight areas in need of further audit and research. Surgical neonates are an understudied population. Neonatal surgical units are encouraged to develop implementation and audit tools to measure outcomes and contribute to stronger recommendations. Working groups were developed to explore the use of Foley catheters, nasogastric tubes, and central lines as they were felt to be relevant topics for ERAS protocol development; however, there were insufficient data to support any recommendation for or against their use. The GDC felt that it was important to highlight these areas in the hope that future iterations of this guideline will be able to draw on new primary data concerning these topic areas that would be helpful additions to a neonatal ERAS protocol. Patient characteristics including patient sex were not considered in the recommendations due to the lack of rigorous evidence and are worthy of attention in future studies.

Conclusions

ERAS guidelines have historically been designed for the care of patients undergoing specific surgical procedures (eg, pancreaticoduodenectomy) or related procedures (eg, colorectal resections). This new guideline provides recommendations based on the best available evidence for the perioperative care of neonates undergoing a variety of noncardiac surgical procedures. It is designed for unit-wide implementation to reduce variability in care, enhanced evidence-based practice, while allowing clinicians to modify and select the appropriate recommendations as appropriate. It is hoped that by implementing ERAS on a unit-wide level, more infants can benefit from the principles of enhanced recovery after surgery without waiting for specific procedure-based guidelines.

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Author Contributions: Dr Pilkington had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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