Probiotics & NEC: Family-Clinician Communication is Key

The NEC Society is a patient-led organization that works in partnership with clinicians and scientists to advance NEC research, education, and advocacy. Recognizing the value and power of the patient-family perspective is fundamental to the NEC Society’s vision of building a world without necrotizing enterocolitis. Patient-families must be integrated in the healthcare, research, and practice decisions that affect their lives. The NEC Society is committed to elevating the patient-family voice.

In the NICU, families need access to information to serve as partners in their child’s care. Too often, healthcare providers hesitate to share information because they don’t want to overwhelm or scare families. Yet, what is overwhelming and terrifying for families is not understanding or knowing what is happening to their child, nor how to contribute to their care. Families must have a voice in what is considered an acceptable risk or benefit in the NICU. Communication is critical and it is important to recognize that providing this type of information does not further overwhelm families.

NICU families should be informed about interventions that are relevant to their child’s health. Recently, the American Academy of Pediatrics released a thoughtful statement recommending against the routine use of probiotics in preterm infants. Considering the increased use of probiotics across centers in the United States as well as statements supporting their use to help prevent NEC from the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition and American Gastroenterological Association, families should be informed about the risks and benefits of probiotics, as highlighted in the AAP statement. Given the state of probiotic research, awareness, and use, clinicians should be prepared to share the evidence supporting their center’s decision on probiotics so that families can understand the rationale behind their unit using or not using probiotics.

The NEC Society’s consideration of probiotics elevates patient-families while simultaneously encouraging counsel from clinicians, researchers, and other stakeholders. The NEC Society recognizes that there have been at least 56 randomized controlled trials and 30 observational studies, totaling 87,830 neonatal patients, focused on probiotic use in the NICU. However, additional research is still required to:

- Better understand the effectiveness of probiotics in preventing NEC and other outcomes
- Identify whether certain subsets of infants benefit most from probiotics and under what clinical circumstances
- Resolve uncertainties around optimal probiotic strain or combination of strains
- Confirm optimal dose and duration of treatment

Despite these knowledge gaps, NICUs across the United States and elsewhere in the world have implemented the routine use of probiotics as a strategy to reduce the risk of NEC and death at their centers. It is essential for centers using probiotics or considering use to follow guidelines to ensure consistency in practice. Local data surveillance should be used to assess the impacts of probiotic supplementation on outcomes such as NEC and adverse events such as uncommon infections.
from the probiotic organism or the rare possibility of contamination of a product.

Too many infants die from NEC every year in the US. The lack of US-Food and Drug Administration (FDA) approval for any probiotic product in the US for the prevention of death or NEC remains a concern given past evidence that some over-the-counter probiotic products may not contain the advertised strains in the advertised amounts or contain other non-disclosed strains. These data partially contribute to the lack of universal adoption of probiotic use. We encourage collaboration among physicians, industry, and the FDA to pursue an FDA-approved, pharmaceutical grade probiotic to ensure the safety of use in this vulnerable population. Until then, the use of probiotics requires a risk-benefit analysis that is unique to each NICU. Clinicians should be aware of current regulation of probiotic preparations as dietary supplements, including the rare possibility of contamination with pathogenic species. NICU-level decisions on whether to adopt probiotic therapy should involve NICU family advisors, and clinicians should be prepared to share information with NICU parents who have questions and want to gain a better understanding of this therapy. We will build a world without NEC by centering patient-families and integrating them in decisions that have life-altering implications.

Patient-families intimately understand the devastating impacts of NEC and recognize the urgency of this work. Given the menacing nature of NEC and the current science, the NEC Society urges centers, professional associations, and clinicians to integrate families into the decision-making process regarding the use of probiotics in preterm infants.

This statement was developed collaboratively and is supported by 100% of the NEC Society Board, Council, Staff, and Leadership, consisting of 13 patient-families who have been personally affected by NEC, 13 clinician-researchers, and six Board Members, who unanimously advise:

- Probiotics can be considered as a strategy to help reduce the risks of NEC and death in very low birth weight infants (VLBW).
- There is a growing awareness of probiotics due to marketing, media coverage, and research. Accordingly, families of VLBWs should be better informed about the potential risks and benefits of probiotic use to prevent NEC and death.
- Clinicians should be prepared to help parents understand their unit’s rationale for offering or not offering probiotics in their NICU.
- Detailed implementation and careful data collection are essential to continuously track and understand the effect of probiotic use or the lack thereof.

In the coming months, the NEC Society will publish a toolkit that provides resources to assist centers in discussing NEC and probiotics with families, as well as important considerations and steps for centers interested in implementing probiotics.

Stay tuned and connected with the NEC Society by joining us.

All NEC Society Board, Council, Staff, and Leadership reviewed the NEC Society’s Conflict of Interest Policy and completed the organization’s Conflict of Interest form. Some members reported financial conflicts and COI forms are available by contacting jennifer@necsociety.org.

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References


