



REVIEW ARTICLE

Enhancing Enteral Nutrition Safety: A Review of Current Practices and Research Opportunities

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ABSTRACT

Ensuring the safe preparation and administration of enteral nutrition is a critical component of clinical care, yet manual processes remain prone to significant errors. This scoping review examined 41 publications—21 research studies and 20 regulatory or best practice guidelines—to evaluate the impact of centralized preparation and bar code scanning technology on patient safety across the lifespan. The review categorized enteral nutrition risks into three primary domains: microbial contamination, preparation inaccuracies, and misadministration. The review identified research reporting manual enteral nutrition error rates as high as 26% to 31%, highlighting the significant risk associated with non-automated workflows.

Research outcomes revealed that transitioning from bedside preparation to a centralized location staffed by dedicated technicians significantly reduces microbial growth. Specifically, facility-prepared formulas were 24 times more likely to show contamination when handled at the bedside. Furthermore, the integration of bar code scanning technology emerged as the most effective barrier against errors, with studies identifying a high volume of "near misses" that may have otherwise gone undetected. Technology also delivered measurable operational benefits, including improved documentation accuracy (rising from 60% to 100% in one study) and substantial time savings for nursing staff, which allowed for more direct patient care.

The review highlights a transformative shift in the regulatory landscape, particularly with the adoption of Regulation (EU) 2024/1938 (the SoHO Regulation). This legislation mandates rigorous standards for the traceability and handling of human milk, requiring European facilities to adopt automated systems, 30-year data retention protocols, and the Single European Code (SEC) by 2027. Despite the clear benefits of these interventions, the review identified a significant geographical gap, as all 21 research studies were conducted in the United States. Future research should prioritize European-based clinical studies, formal cost-benefit analyses across diverse hospital settings, and the impact of these safety frameworks on long-term clinical outcomes such as reduced rates of necrotizing enterocolitis. Ultimately, the transition from manual, reactive processes to proactive digital frameworks is essential for clinical excellence and regulatory compliance in enteral nutrition management.

Introduction

The safe preparation and administration of enteral nutrition (EN) within the healthcare environment is paramount for maintaining patient safety, particularly for the vulnerable population receiving enteral support across the lifespan.¹⁻⁸ Ensuring the safety and accuracy of EN delivery—whether utilizing ready-to-feed (RTF) formulations, facility-prepared formulations, or human milk (expressed or pasteurized donor human milk)—requires meticulous attention to detail to mitigate potential errors.^{1-5,7-12}

CLASSIFICATION OF ENTERAL NUTRITION RISKS

Risks associated with EN can be broadly categorized into three domains: microbial contamination, preparation accuracy, and misadministration.^{6,7,13}

- **Contamination Risks:** These primarily involve microbial proliferation resulting from inappropriate handling or storage protocols, inadequate sanitization of delivery components, and/or the absence of effective recall response mechanisms for contaminated products.^{1,4-7,10,14}
- **Preparation Accuracy Risks:** This category encompasses arithmetic inaccuracies in calculating recipes for facility-prepared EN, inadequate systems for lot number tracking to prevent the use of recalled products, insufficient controls to prevent the use of expired products, and procedural failures leading to the selection of incorrect product components during preparation.^{1,4,6,7,13}
- **Misadministration Risks:** These involve the administration of an incorrect feeding to the designated patient. Examples include the use of the wrong expressed human milk specimen, the incorrect facility-prepared formula, or the wrong RTF product.^{3,4,6-8,13,15}

PROFESSIONAL GUIDANCE AND RESEARCH TRENDS

Numerous international professional organizations have disseminated evidence-based recommendations aimed at reducing patient risk with EN.^{1-5,9-12} Key strategies advocated include implementing a centralized EN preparation area for facility-prepared feedings, utilizing dedicated personnel for preparation, and integrating technological solutions such as bar code scanning to automate tracking and error prevention.^{1-5,9-12} In response to these recommendations, there has been a notable increase in scientific publications investigating EN-related risks and assessing the impact of various interventions on patient safety and outcomes.^{8,13,15,17,18}

The regulatory landscape for EN safety in Europe is being fundamentally reshaped by the adoption of Regulation (EU) 2024/1938 on standards of quality and safety for Substances of Human Origin intended for human application (SoHO Regulation).¹⁶ Officially adopted on May 27, 2024, and scheduled for full implementation by August 7, 2027, this legislation moves beyond professional recommendations to impose rigorous legal requirements for the handling, traceability, and utilization of human milk within clinical settings.¹⁶ This shift necessitates a move away from manual processes toward standardized, digital safety frameworks to ensure full compliance and patient safety.¹⁶

Objectives of this Review

This narrative review aims to discuss existing published best practices and evaluate the current literature on EN safety. The objectives include identifying emerging trends, highlighting knowledge gaps, and proposing avenues for future research in this critical domain of clinical care.

Methods

DECISION TO USE A SCOPING REVIEW

A scoping review methodology was chosen over a systematic review to explore the breadth and nature of available research as well as regulatory and best practice publications on this topic. This approach allowed the authors to map the scope of existing evidence and recommendations, providing a comprehensive overview of the topic landscape. The goal was to identify the volume, nature, and characteristics of studies in this field, which will ultimately inform the direction of future research. The scoping review framework also permitted the inclusion of a wide range of study designs and methods.

IDENTIFYING THE RESEARCH QUESTION

The scoping review was designed to evaluate the broader question: What is the impact of centralized handling and use of bar code scanning technology for enteral nutrition (EN) within the hospital setting with regards to patient safety?

ELIGIBILITY CRITERIA AND DATA SOURCES

A literature search was conducted using the NICU Healthcare Databases Advanced Search website (<https://www.nice.org.uk/>) and PubMed website (<https://pubmed.ncbi.nlm.nih.gov/>). To ensure comprehensive coverage, supplementary searches were performed on the official websites and publication repositories of professional organizations specializing in enteral nutrition and healthcare quality improvement. This targeted approach aimed to uncover all relevant guidelines, reports, and literature not indexed in the primary databases.

The following criteria guided the inclusion in this review:

- Language: Published in English.
- Topic: Publications must have discussed:
 - The use of centralized preparation of any EN (e.g., expressed human milk, pasteurized donor human milk, formulas, or modulars) in the hospital setting.
 - The use of bar code scanning technology in the preparation and/or administration of EN in the hospital setting.
- Population: Publications evaluating patients of all ages (from preterm infants to geriatrics) were included.

Results

The review process yielded 41 publications that met the inclusion criteria. All 41 full-text publications were subsequently evaluated and included in the final review.

PUBLICATION TYPES AND DISTRIBUTION

The included publications comprised two main categories:

- Research Studies: 21 publications.
- Regulatory or Best Practice Publications: 20 publications.

GEOGRAPHICAL ORIGIN

- All 21 research studies were conducted in the United States. No eligible research studies conducted in other countries were identified.
- The geographical distribution of the 20 regulatory or best practice publications was as follows:
 - North America: 15
 - European Union (EU): 3
 - United Kingdom (UK): 1
 - International Consensus Statement: 1 (with participating authors/organizations from Europe and North America).

RESEARCH OUTCOMES

Research indicates that manual processes for dispensing and administering EN are consistently associated with high error rates, ranging from 26 to 31%.^{17,18} To address this, several healthcare institutions have leveraged process improvement methodologies, specifically Failure Mode and Effects Analysis (FMEA) and LEAN Six Sigma, to evaluate their current practices and implement risk-reducing changes.^{6,7,19-22}

Identified Opportunities for Risk Reduction

Hospitals employing these process analyses identified several key areas for intervention: ^{6-8,13-15,19-28}

- **Dedicated Preparation Space:** Establishing a specific area for feeding preparation. ^{6,7,13,14,19-27}
- **Dedicated Technicians:** Adding or increasing the number of specialized technicians for feeding preparation. ^{6,7,13,14,19,21-28}
- **EHR Optimization:** Updating feeding orders within the Electronic Health Record (EHR) to prioritize discrete data entry over free-text. ^{6,19,21}
- **Automated Calculation:** Utilizing technology for automated recipe calculation based on the order for facility-prepared feedings. ^{6,7,13}
- **Bar Code Scanning Technology:** Implementing bar code scanning to verify correct products, prevent the use of expired or recalled items, and facilitate lot number tracking. ^{6,7,8,13,15,19,21-23,26,27}

Consistently, the introduction of dedicated technicians and/or bar code scanning was found to reduce the risk of contamination, preparation errors, and misadministration. ^{6-8,13-15,21-27} Notably, one study focusing on the neonatal intensive care unit (NICU) found that using dedicated technicians for feeding preparation reduced the time to achieve full enteral feedings for preterm infants (≤ 31 weeks at birth) from 32 days to 19 days.²⁵ A summary of the research outcomes is provided in Table 1.

Table 1: Enteral Nutrition Safety Research Outcomes and Recommendations

Reference (Study)	Key Outcomes / Findings	Recommendations & Key Implementation Steps
Steele & Albert (2025)⁸	Barcode scanning (BCS) prevented the wrong enteral formula from being administered in 2.9% of EN administration attempts or an average of 48 errors per month (1.6 times per day)	Implement BCS for EN administration in pediatric hospitals to prevent feeding errors
Alessi, et al (2025)¹⁵	BCS prevented the wrong infant formula from being administered in 1.1% of feeding administration attempts (average of 3.5 times per day)	Use BCS for infant formula administration to prevent feeding errors
Steele & Smith (2025)³⁰	Time required for feeding preparation and administration verification tasks (confirming items, calculating and verifying recipes, and documenting lot numbers) decreased by 33% for human milk (HM) feedings and 50% for formula feedings	Automate verification, calculation, and documentation tasks through BCS to improve safety by reducing risk of manual errors while improving staff efficiency
Steele & Alessi (2024)¹³	BCS prevented errors from reaching the patient 4% of the time when nurses were responsible for feeding preparation; addition of dedicated technicians reduced risk of error by 87% (with BCS preventing errors from reaching the patient 0.5% of the time)	Use BCS to prevent errors from reaching the patient and adopt a centralized preparation room with dedicated technicians to further reduce risk
Citty, et al. (2024)¹⁸	Review of 691 adult EN feeding errors found a 26% error rate	Adopt BCS to prevent EN errors
Chew, et al. (2023)³¹	Using BCS with adult EN improved documentation with 60% of EN documented as reviewed/administered prior to BCS and 100% documented as reviewed and either administered or held with appropriate reason after BCS implemented	Adopt BCS to improve EN documentation
Schwarz, et al. (2023)¹⁷	Review of 1,045 adult EN data points found a 26% error rate with approximately 50% of those being administration errors	Use BCS to prevent EN errors

Reference (Study)	Key Outcomes / Findings	Recommendations & Key Implementation Steps
Steele & Bixby (2022) ⁷	BCS prevented 3,329 HM errors (wrong or expired HM) in 7 years and 480 product errors in 2.5 years and ensured regulatory compliance during an unannounced US Food and Drug Administration site visit following a formula recall	Use BCS for HM and formulas during preparation and administration to prevent errors and for recall readiness
Oza-Frank, et al. (2017) ²³	BCS prevented 97 errors per 1,000 bottles when nurses were responsible for feeding preparation; addition of dedicated technicians reduced risk of error by 86% (preventing 14 errors per 1,000 bottles)	Use BCS to prevent errors from reaching the patient and adopt a centralized preparation room with dedicated technicians to further reduce risk
Brock, et al. (2016) ²⁵	Implemented dedicated technicians in a centralized preparation room which resulted in time savings for the nurse and a reduction in the average length of time to full feedings for preterm infants ≤ 31 weeks gestation at birth from 32 to 19 days	Implement use of dedicated technicians in a centralized location to save bedside nurse time and potentially reduce length of time to full feedings
Dumm, et al. (2016) ²⁸	Hospital partnered with a community college to create a formula technician training program which resulted in a decrease of formula errors from 0.9% pre-training to 0.7% in the first quarter post training to zero for the next 3 years	Utilize formalized, comprehensive training for technicians to reduce risk of preparation errors
Steele, et al. (2015) ²⁹	Addition of BCS saved 1,052 hours in the centralized preparation room and an estimated 953 hours of nursing time for verification and documentation tasks	Automate verification, calculation, and documentation tasks through BCS to improve safety by reducing risk of manual errors while improving staff efficiency
Luton, et al. (2015) ²¹	Used Six-Sigma process to evaluate HM handling and administration resulting in increasing centralized preparation room staff, updating orders in the electronic health record, limiting ready-to-feed formulas to single use, and updating thawing and delivery processes for better temperature control to improve patient safety	Recommended the changes implemented as well as longer term goals of changing from delivery of facility-prepared feedings in bulk to unit-dose, combining the hospital HM preparation room and formula preparation room into a single Nutrition Center, and adding BCS to improve patient safety
Paul (2015) ²⁴	The centralized feeding preparation room with dedicated technicians added multidisciplinary daily and weekly rounds to review orders and provide enhanced communication between the technician and the nurse preventing near-misses from reaching the patient in 8.6% of all feedings	Utilize multidisciplinary rounds between dedicated feeding preparation technicians and bedside nurses to improve communication and prevent feeding preparation errors
Steele & Bixby (2014) ⁶	Conducted Failure Mode and Effects Analysis (FMEA) to evaluate HM handling processes and implemented centralized preparation with dedicated technicians and BCS which prevented 182 HM errors (wrong or expired HM) in 6 months	Use the FMEA process to identify improvement opportunities and implement centralized preparation with dedicated technicians and BCS to reduce risk of error
Zhang, et al. (2014) ¹⁹	Conducted FMEA to quantify risks during HM preparation and administration and made recommendations estimated to reduce risk by 84.4%	Recommended a separate space with dedicated technicians for HM handling and larger HM storage refrigerators, enhancing existing BCS system, and standardizing the HM administration record
Wolford, et al. (2013) ²⁶	Implemented BCS which reduced risk in one year of wrong HM (541 times), expired HM (1,992 times), and wrong fortification (224 times); addition of dedicated technicians further reduced error rates	Use BCS to prevent HM errors from reaching the patient and add dedicated technicians to further reduce risk
Gabrielski, et al. (2011) ²⁷	Implemented centralized HM preparation with dedicated technicians and BCS (in the preparation room only) which resulted in standardizing practices and proving BCS was 100% reliable in preventing errors leading to follow up recommendation of expanding BCS hospital-wide	Use BCS and centralized preparation with dedicated technicians to reduce risk of error

Reference (Study)	Key Outcomes / Findings	Recommendations & Key Implementation Steps
Dougherty & Giles (2009) ²²	Addition of BCS to current process of centralized HM preparation with dedicated technicians reduced errors by 82%	Add BCS to centralized preparation operations with dedicated technicians to further reduce error rates
Steele & Short (2008) ¹⁴	Bedside preparation of infant feedings was 24 times more likely to show microbial growth than centralized preparation with dedicated technicians	Adopt a centralized preparation room with dedicated technicians for infant feeding preparation to decrease microbial contamination risk
Drenckpohl, et al. (2007) ²⁰	Utilized Six-Sigma process to evaluate HM handling and create process change which resulted in no errors reported post intervention	Implement standardized system for intake, storage, preparation, distribution, and administration of HM to reduce risk of error

Contamination

Contamination rates were significantly reduced by transitioning from bedside preparation to a centralized, dedicated process.¹⁴ Specifically, EN prepared by bedside nurses was 24 times more likely to show microbial growth compared to preparation in a dedicated, centralized space with dedicated technicians.¹⁴

- **Facility-Prepared Formulas (from powders):** This type of formula was the most affected, with microbial growth rates of 43.7% with bedside preparation compared to only 4% with centralized preparation.¹⁴
- **Commercially Sterile Liquid Formulas:** Even with sterile liquid formulas, bedside handling resulted in higher microbial growth (6.3% of feedings sampled) compared to centralized handling by dedicated technicians (0% of feedings sampled).¹⁴

Preparation and Administration Errors

The use of dedicated technicians was repeatedly shown to reduce EN preparation errors across multiple hospitals.^{6,7,13,23,27}

Hospitals that implemented bar code scanning technology for product verification at both the preparation and administration stages observed a higher number of "near misses" (attempts to use incorrect, expired, or recalled items) than reported error data prior to scanning.^{6-8,13,15,21-24,26,27} This finding suggests that errors may have previously occurred but went unidentified before the implementation of this technology.^{7,15}

Further research identified that multidisciplinary rounds to discuss EN orders and comprehensive, formal training for feeding preparation technicians also resulted in fewer EN errors.^{24,28}

Staff Efficiency and Documentation Accuracy

Several studies evaluated the impact of these changes on staff efficiency and accuracy.^{25,29-31}

One study found that the use of dedicated technicians for EN preparation saved bedside registered nurse time allowing that time to be allocated for other patient care duties.²⁵

Two studies specifically assessed the time savings realized by using bar code scanning instead of manual processes for tasks such as product verification, lot number tracking, recipe calculation, and charting EN in the EHR.^{29,30}

- One hospital eliminated a half-time position in their EN preparation room and saved 1,340 nursing hours annually when transitioning from manual processes to bar code scanning, redirecting this time to other patient care duties.²⁹
- Another study found that bar code scanning resulted in significant time savings for verification tasks: 33% for human milk feeding preparation and administration and 50% for formula feeding preparation and administration.³⁰

In an adult hospital setting, documentation accuracy was markedly improved with bar code scanning:³¹

- **Prior to scanning:** Only 60% of EN was documented correctly as reviewed and administered.³¹
- **After implementation:** 100% of EN was documented as reviewed and either administered or held with an appropriate reason.³¹

BEST PRACTICE RECOMMENDATIONS

Current research has informed the development of best practice recommendations for handling EN within healthcare settings, leading to publications from numerous regulatory agencies and professional organizations.^{1-5,9-12,32-36} Additionally, four summary articles have been specifically published concerning processes in the Neonatal Intensive Care Unit (NICU).³⁷⁻⁴⁰

A review of these best practice publications and summaries reveals several common, recurring themes.^{1-5,9-12,16,32-40} A synthesized coalition of these guidelines includes the following core recommendations:^{1-5,9-12,16,32-40}

- **Risk Assessment:** Evaluate current EN practices to identify potential failure points using systematic methodologies such as FMEA or Hazard Analysis Critical Control Point (HACCP).
- **Error Reporting:** Ensure robust systems are in place for the reporting of both actual errors and near misses.
- **Recall Planning:** Develop and maintain a plan for responding to EN product recalls, ensuring the ability to manage and execute the response appropriately.
- **Centralized Preparation:** Implement centralized handling for any facility-prepared EN, utilizing a dedicated space and dedicated technicians.
- **Component Verification:** Ensure proper verification of all EN components (including expressed human milk, pasteurized donor human milk, formulas,

fortifiers, and additives) at both the time of preparation and the time of administration.

- **Technology Integration:** Utilize bar code scanning and other technologies to eliminate manual processes and mitigate the risk of human error.
- **Universal Application:** Ensure that safety processes are established and consistently followed for patients across all age groups.

Additionally, the review identified a significant shift in the European regulatory landscape with the adoption of Regulation (EU) 2024/1938 on standards of quality and safety for substances of human origin intended for human application (SoHO Regulation).¹⁶ This legislation transitions many voluntary best practices into mandatory legal requirements for healthcare facilities.¹⁶ While the

regulation primarily focuses on substances intended for administration to another person—directly regulating donor human milk (DHM)—it establishes an overarching quality framework that indirectly informs and elevates best practices for the handling of expressed human milk (EHM) within the healthcare continuum, even though EHM use for a mother's own infant is not the primary regulated substance.^{16,41,42} Notably, the regulation is designed to be flexible by acknowledging rapid scientific and technological advances, thereby encouraging innovation within human milk banking practices while ensuring that safety remains paramount.⁴¹⁻⁴⁴

A detailed summary of the guidelines from each source reviewed may be found in Table 2.

Table 2: Best Practice Guidelines for Enteral Nutrition Safety in the Healthcare Setting

Source	Best Practice Recommendation Summary
British Dietetic Association (BDA)¹	• Prepare enteral nutrition in a dedicated space away from patient bedside that supports aseptic technique with no other activity occurring in the space • Trained staff with food hygiene training • Bar code traceability with inbuilt safety checks for human milk (HM) feedings • Traceability of pasteurized donor human milk (DHM) noting that bar code scanning allows for full traceability
A Consensus Statement From the European Milk Bank Association (EMBA)⁴²	• Proper labeling of DHM to include unique identifiers and expiry dates • Full traceability of all DHM including unique donation identifiers, volumes, dates, and other relevant information
European Commission's Health & Food Safety - Commission Directive (EU) 2015/565⁴¹	• Ensure full traceability of tissues, including DHM, from donor to recipient and vice versa through documentation and unique coding • Apply the Single European Code (SEC) to all DHM containers distributed for clinical application to standardize identification across borders • Utilize split-numbering within the SEC to uniquely identify multiple containers originating from a single donation • Incorporate precise expiry dating in an eye-readable format on all labels to prevent the use of outdated products • Maintain permanent records of all traceability data for a minimum of 30 years using a readable storage medium
Regulation (EU) 2024/1938 Standards of Quality and Safety for Substances of Human Origin¹⁶	• Maintain full traceability of pasteurized DHM by linking donor(s) to recipient(s) for a minimum of 30 years post-clinical application • Register quality and safety data for all DHM within a centralized digital platform • Assign unique identifiers, specifically the SEC using ISBT 128 standards, to every DHM donation to facilitate cross-border tracking • Obtain SoHO Establishment Authorization for any facility engaged in the processing and storage of DHM • Implement quality-driven Standard Operating Procedures (SOPs) for every phase of DHM handling • Investigate and report Serious Adverse Occurrences (SAO), including misadministration of donor milk or infectious disease transmission
Infection Prevention and Control Canada (IPAC) Paediatric and Neonatal Interest Group²	• Dedicated centralized space for human milk and formula preparation is required • At a minimum, a double check mechanism should be used at the time of administration to avoid errors; consideration should be

Source	Best Practice Recommendation Summary
	given to automated systems such as bar coding to prevent administration errors
Consensus Development Conference—EXPO 2015, Milan, Italy ³⁷	- Centralized preparation of HM in a dedicated space that supports aseptic technique by a qualified trained technician - Bar code scanning to reduce risk of misadministration and feeding of expired HM
Institute for Safe Medication Practices (ISMP) ³	- Implement centralized preparation of enteral nutrition (EN) with dedicated technicians - Use bar code scanning during the preparation and administration to confirm all EN products are correct, not expired, and not recalled - Select technology that can document the product's lot number and expiration date - Plan for recalls - Analyze near miss and error data
Academy of Nutrition and Dietetics, Pediatric Nutrition Practice Group ⁴	- Designate space solely for the purpose of feeding preparation that supports aseptic technique - Use of dedicated preparation technicians to provide accurately prepared products is recommended - Ensure processes to identify and respond to product recalls - Use technology for automated recipe calculations - Use bar code scanning at each step in the feeding preparation and administration process to prevent misadministration, use of expired items, and use of recalled items - Use bar code scanning technology to automatically track product lot numbers for DHM and infant/enteral formulas
American Society for Parenteral and Enteral Nutrition (ASPEN) ^{5,10,36}	- Implement centralized preparation with dedicated technicians - Ensure technicians follow strict aseptic technique for EN preparation - Use bar code scanning for all EN to prevent misadministration and use of expired or recalled items - Select technologies that allow for automatic tracking of lot numbers in the event of a recall
The Joint Commission (TJC) ³²	- A minimum of 2 patient identifiers should be confirmed when providing any care, treatment, or service either through manual two-person verification or bar code scanning - The hospital must have the ability to respond to product alerts from the Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), and manufacturers
American Academy of Pediatrics (AAP) ⁹	- All neonatal intensive care units (NICUs) will provide a specialized area or room, with limited access and away from the bedside, to accommodate mixing of formula or additives to HM - The facility must have procedures in place for accurate verification and administration of HM and formula to avoid misappropriation
U.S. Food and Drug Administration (FDA) ³³⁻³⁵	- Hospitals must be able to identify and track all recalled "critical foods" (infant formula and medical foods) - Hospitals must maintain meticulous records for FDA inspection
Human Milk Banking Association of North America (HMBANA) ¹¹	- Prepare fortified HM in a dedicated location that is separate from patient care areas to reduce risk of contamination - Use two-person verification or bar code scanning to confirm the correct HM and fortifiers are used
Facility Guidelines Institute ¹²	All NICUs should have a separate feeding preparation room that ensures the flow of materials from clean to soiled to maintain an aseptic preparation space
Steele C. Neonatal Intensive Care 2020 ³⁸	- Handle HM in a centralized preparation location - Use of dedicated staff is shown to reduce risk of errors

Source	Best Practice Recommendation Summary
	• Use bar code scanning to prevent HM and fortifier administration, prevent use of expired items, prevent administration of expired feedings, automatically calculate feeding recipes, and automatically track lot numbers of DHM and fortifiers in the event of a recall
Matus BA, et al. <i>Adv Neonatal Care</i> 2019⁴⁰	• Centralized preparation errors reduce risk of contamination and errors • Use training technicians for feeding preparation • Implement bar code scanning to ensure proper labeling, prevent preparation and administration errors, and monitor expiration dates/times
Steele C. <i>Frontiers in Nutrition</i> 2018³⁹	• Prepare HM feedings in a dedicated space that is separate from patient care areas; HM or DHM feedings should not be prepared in any patient care area including the patient's bedside • Use dedicated staff well trained in aseptic technique for HM handling and fortification • Use bar code scanning to ensure correct HM and products are used and to prevent use of items beyond expiry date and time • Use bar code scanning to automatically track lot numbers for DHM, fortifiers, and additives for efficient tracking in the event of a recall

Discussion

The safe delivery of EN is a cornerstone of patient care, yet the process is inherently complex and prone to human error, as evidenced by reported manual error rates consistently ranging between 26-31%.^{17,18} This narrative review synthesized current evidence and professional guidelines to confirm that the three primary risk domains—microbial contamination, preparation accuracy, and misadministration—are significantly mitigated by the adoption of centralized processes and technological intervention.^{1-15,17-29,37-40}

THE IMPACT OF CENTRALIZATION AND DEDICATED PERSONNEL

A pivotal finding of research reviewed is the dramatic reduction in microbial contamination achieved by shifting EN preparation from the bedside to a dedicated, centralized space staffed by specialized technicians.¹⁴ The data showing facility-prepared formulas were 24 times more likely to show microbial growth when prepared at the bedside provides compelling justification for this transition.¹⁴ This risk reduction extends even to commercially sterile liquid formulas, underscoring that contamination risk may be less about the starting product and more about the environment and procedural rigor of the handling process.¹⁴

Beyond microbial safety, the introduction of dedicated preparation technicians and centralized services also addresses preparation and misadministration risks. These personnel become experts in recipe calculation, component verification, and documentation, tasks often peripheral to a bedside nurse's primary focus. The subsequent reduction in preparation errors reported across multiple studies confirms the value of this specialization.^{6,7,13,23,27} This change also offers operational benefits, demonstrated by the reduction in nurse time spent on preparation, allowing for redeployment to direct patient care and, in one notable

instance, a quicker achievement of full enteral feedings for vulnerable preterm infants.²⁵

TECHNOLOGY AS THE ULTIMATE SAFETY BARRIER

While centralized preparation and dedicated staff are foundational improvements, the research overwhelmingly supports the integration of bar code scanning technology as the most effective final barrier against both preparation and administration errors.^{6-8,13,15,21,23,24,26} The frequent reporting of "near misses" after implementation strongly suggests that this technology is actively preventing errors that previously went undetected and undocumented.^{6-8,13,15,21,23,24} Bar code scanning technology that enables automated verification of product selection, patient identity, expiration dates, and lot number tracking, directly addresses all three major risk categories identified in this review.

Furthermore, the data on staff efficiency and documentation accuracy reinforce the positive operational impact of technology.²⁹⁻³¹ Significant time savings were realized by eliminating manual verification and charting processes, and one hospital setting saw documentation accuracy improve from 60% to 100% after implementation.²⁹⁻³¹ This transition supports both enhanced patient safety and improved clinical workflow and regulatory compliance.

ENSURING NUTRITIONAL PRECISION WITH AUTOMATED RECIPE CALCULATION

While bar code scanning ensures the selection of the correct product, the integration of an automated recipe calculator directly addresses the arithmetic inaccuracies identified as a primary preparation risk. Automated systems eliminate the reliance on manual calculations, which are prone to human error and can lead to serious health consequences such as feeding intolerance or electrolyte disturbances caused by under- or over-feeding.^{6,7,13} By providing precise, sophisticated

calculations for all components directly from the provider order, these technological guardrails transform a high-risk manual task into a standardized clinical protocol and a more efficient digital process.^{4,29,30}

REGULATORY AND FUTURE CONTEXT FOR SAFETY AND STANDARDIZATION

The best practice recommendations synthesized from professional guidelines largely align with the successful strategies identified in the research—advocating for centralized preparation, dedicated staff, and technology integration for the preparation and administration of EN in the healthcare setting.^{1-15,17-29,37-40} This alignment has moved from a recommendation to a clinical necessity with the adoption of Regulation (EU) 2024/1938 on standards of quality and safety for substances of human origin intended for human application (SoHO Regulation).^{16,41,42}

This regulation introduces a critical layer of oversight specifically concerning human milk within the healthcare setting, which is now formally classified as a Substance of Human Origin (SoHO).¹⁶ While the regulation directly governs the handling, processing, and facility requirements for pasteurized donor human milk, its stringent standards establish a non-negotiable quality framework for the entire sector.^{16,41,42} Although the regulation does not directly apply to EHM used for a mother's own child, the requirement for meticulous tracking and safety for donor milk will undoubtedly inform and elevate the standards applied to all human milk handling within hospitals.^{16,41,42} This regulatory push will likely accelerate the adoption of advanced tracking technologies, such as bar code scanning, within human milk banks and neonatal intensive care units (NICUs) to meet compliance requirements.

In addition, recent U.S. Food and Drug Administration (FDA) mandates reflect a growing international shift toward replacing manual processes with digital technologies to enhance operational efficiency and patient safety.^{34,35} Under the Food and Drug Omnibus Reform Act of 2022, hospitals are already required to track all recalled "critical foods"—including infant formula and medical foods—while maintaining rigorous records for FDA inspection.³⁴ This regulatory landscape is further changing with the Food Safety Modernization Act Section 204 (The Food Traceability Rule). While this primarily mandates enhanced traceability for items on the FDA's Food Traceability List (FTL) for manufacturers and distributors, it has established a new industry benchmark for safety and data transparency.³⁵ Within high-stakes clinical environments, waiting for legal mandates to catch up with clinical risk is not a viable strategy when patient safety is at stake. By adopting this level of digital readiness—including the capability to provide a sortable, electronic traceability spreadsheet to the FDA within 24 hours of a request—healthcare leaders move beyond "best effort" tracking to a state of total audit readiness and proactive patient protection. These evolving requirements underscore the urgent need for robust EN traceability systems to ensure rapid compliance during audits or product recalls.

KEY COMPLIANCE MANDATES FOR EUROPEAN HEALTHCARE FACILITIES

To meet these new requirements, facilities must transition from manual, reactive processes to a proactive digital framework.¹⁶ The core mandates enforceable by August 7, 2027 include:

- **Automated Traceability:** Facilities must establish robust, automated systems to track substances from donor to recipient, as manual processes are no longer considered viable for modern compliance.¹⁶
- **30-Year Data Retention:** A mandatory record-keeping requirement for all traceability data to be maintained for a minimum of 30 years after clinical use.¹⁶
- **The Single European Code (SEC):** Every donation must be assigned a unique SEC, comprising a Donation Identification Sequence (origin) and a Product Identification Sequence (processing/expiry) to facilitate safe cross-border exchange.^{16,43}
- **Standardization via ISBT 128:** The integration of the Global ISBT 128 Standard for coding and labeling is recognized as the most effective path to eliminate human error and language barriers while ensuring global traceability.^{16,44}
- **Authorization and Oversight:** Facilities involved in the processing, storage, release, or import/export of human milk must obtain a "SoHO establishment authorization." Compliance will be overseen by the newly established SoHO Coordination Board, which will conduct inspections to ensure harmonized rules across Member States.^{16,41,42}

DIGITAL SAFETY BARRIERS AND OPERATIONAL RETURN ON INVESTMENT

This regulatory push is expected to accelerate the adoption of advanced tracking technologies, such as bar code scanning, within human milk banks and NICUs. Such technology serves as the ultimate safety barrier, allowing hospitals to adapt the 5 Rights of Medication Safety to enteral nutrition safety: Right Patient, Right Product, Right Dose (via automated recipe calculation), Right Route, and Right Time.¹⁶

The transition from manual to digital processes represents a fundamental improvement in the institutional safety culture by providing an authoritative check against human fallibility. Beyond the immediate enhancement of clinical safety, the implementation of barcode scanning and automated tracking delivers measurable operational advantages:

- **Workflow Optimization:** By automating verification and charting, facilities can significantly reduce the labor burden associated with manual double-verification and documentation.²⁹ This optimization allows for the strategic redeployment of clinical staff—particularly bedside nurses—to direct patient care, thereby improving overall department efficiency.
- **Risk Mitigation and Resource Stewardship:** Longitudinal evidence confirms that these technologies intercept thousands of potential errors before they reach the patient, including the use of incorrect or expired products.^{6-8,13,15,23,26} In doing so, a digital framework effectively mitigates the severe

financial, legal, and regulatory risks inherent in manual administration while reducing costs associated with product waste and adverse event management.

KNOWLEDGE GAPS AND FUTURE RESEARCH OPPORTUNITIES

Despite the clear consensus on the efficacy of centralized preparation and bar code scanning, several knowledge gaps remain:

1. **Cost-Benefit Analysis Across Settings:** While efficiency data exists, more formal economic analyses are needed to demonstrate the long-term return on investment (ROI) of implementing centralized EN preparation and technology across diverse hospital settings (e.g., pediatric vs. adult, small community hospitals vs. large academic centers).
2. **Global Applicability of Research:** All identified research studies originated in the United States. Future research must evaluate the transportability and effectiveness of these interventions within different international healthcare systems, especially in light of forthcoming European regulations. There is a critical need for European-based clinical research. The forthcoming implementation of the SoHO Regulation (EU) 2024/1938 provides the perfect impetus for European investigators to fill this geographical gap and validate the efficacy of digital safety frameworks within the EU's unique regulatory ecosystem.
3. **Impact on Long-Term Outcomes:** Most studies focused on immediate error reduction and efficiency gains. Future research should correlate these safety improvements with hard clinical outcomes, such as

reduced rates of necrotizing enterocolitis (NEC), feeding intolerance, or length of stay, particularly in vulnerable populations such as preterm infants.

4. **Technological Evolution:** Research must keep pace with the evolution of technology, evaluating the safety and efficacy of emerging tools such as smart pumps, automated compounding systems, and radio-frequency identification (RFID) tags in EN delivery.

Conclusion

In conclusion, this review confirms that enhancing enteral nutrition safety requires a systemic approach that moves beyond reliance on manual double-verification. The research overwhelmingly supports a transition toward centralized preparation, dedicated expertise, and the integration of digital tracking technologies to minimize inherent risks in microbial contamination, preparation accuracy, and misadministration.^{6-8,13-15,19-31}

Furthermore, the adoption of Regulation (EU) 2024/1938 (SoHO Regulation) creates legal mandates for the handling and administration of pasteurized donor human milk within European healthcare facilities.⁴¹ The requirements for automated traceability, the application of the Single European Code (SEC), and 30-year data retention necessitate the immediate adoption of dedicated scanning software platforms. This regulatory shift serves as a timely reminder that the highest standards of safety and quality must be universally applied to protect the most vulnerable patient populations. Ultimately, the move from manual, reactive processes to proactive digital frameworks is the definitive path toward clinical excellence and regulatory compliance in enteral nutrition management.

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