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Section 5. Procure, Select/Prepare, Label, and Dispense EN

Background

With a wide variety of available EN products on the market, each organization makes clinical and fiscal decisions to establish an EN formulary. Each EN product, including human breast milk (HBM), procured and stocked within a facility, needs to be uniquely recognized by clinicians involved in EN therapy. Selection errors can occur when products have similar names or product labels. Whether dispensed from a central location or stocked on a patient care unit, EN products must be labeled to identify the intended patient, date of feeding, and duration of feeding. Some patients receive EN products that require preparation from powdered form, which increases the complexity and safety risk of EN use.

Question 5.1. How is a clinically appropriate and cost-effective formulary developed, and which experts should be involved in its development?

Question 5.2. How are EN product shortages and substitutions managed?

Practice Recommendations

1. Establish a formulary of available EN formulas specific to the needs of the institution's patient population.
 - a. Base the size of the enteral formulary on the specific needs of the facility, but limit the size to avoid product duplication, decrease inventory management, and lower costs.
 - b. Prioritize formulas that meet the estimated nutrient needs of patients rather than the patient's diagnosis. Use evidence-based research to evaluate the inclusion of specialty formulas on the formulary.

- c. Consider whether competitive bidding, group purchasing organizations, or the selection of all products from the same manufacturer can be cost-effective. If the facility participates in a corporate buying group, optimize the contractual agreement to allow for the purchase of a formula outside of the formulary if it better meets patients' nutrition needs.
2. Develop a multidisciplinary formulary selection committee of clinicians and administrators, including dietitians, nurses, pharmacists, and physicians.
3. Generate a substitution list for each EN formula during the development or restructuring of the EN formulary, which can be implemented in the case of product shortages.
4. Allow enough flexibility in the EN process to respond to manufacturer revisions to their product lines, as well as product shortages or outages.

Rationale

Over 200 different commercially prepared EN formulas are available for neonatal, pediatric, and adult use. Beyond standard formulas, a myriad of specialty formulas are marketed for specific disorders and disease states. As it is not practical or cost-effective to provide all available formulas, healthcare facilities create enteral formularies to control inventory and cost. In one study published in 1989, more than 75% of the hospitals had developed EN formularies. The documented reasons were cost containment, decreased product duplication, staff education, and inventory management.¹ Another method to control costs is participation in a group purchasing organization. Group purchasing may allow healthcare facilities to control costs while providing the best patient care. Typically, an established commitment level is set for institutional compliance and results in benefits for the purchase of products and services at lower costs.^{2,3} Organizations can request a clause in the contract to allow for the purchase of a noncompeting product without penalty if it better meets the patients' needs.

The multidisciplinary formulary selection committee will represent the perspectives of dietitians, nurses, pharmacists, physicians, and administrators. The committee evaluates the institution's patient population and its specific nutrition needs to identify the enteral formula categories needed.⁴ When available formulas in each category are evaluated, formulas that will meet the estimated nutrition needs of the patient are usually preferred to those tailored to specific diagnoses.⁵ Evidence-based research can inform the selection of products and is especially helpful when considering specialty and disease-specific formulas.⁶ Specialty formulas are considerably more expensive than standard formulas, and research to support the increased cost may be lacking. Evidence-based guidelines from the American Society for Parenteral and Enteral

Nutrition and the Evidence Analysis Library from the Academy of Nutrition and Dietetics can be utilized to identify indications and appropriate use for disease-specific formulas.

Although shortages of enteral formulas have not been as common as recent PN shortages, certain EN formulas may sometimes be unavailable due to demand, manufacturing issues, or disaster. By identifying which products have similar nutrient profiles and indications, the formulary selection committee can develop a substitutions list to systematically identify appropriate alternative formulas to use if a shortage occurs. This can then be implemented and communicated in a timely manner when needed. The substitutions list can also be used to select products for patients whose home formula is not available on the institution's current formulary.

Question 5.3. How should human breast milk (HBM) be managed as an enteral formula?

Practice Recommendations

1. Use HBM for infant feeding whenever possible and when there are no medical contraindications.
2. If maternal human milk is not available, use pasteurized donor human milk for premature infants.
3. Donor milk should come from an accredited (Human Milk Banking Association of North America [HMBANA]) milk bank or commercial company that uses HMBANA or more stringent guidelines. Do not purchase HBM from individuals or through the Internet.
4. Develop at the healthcare organizational level policies for the collection, receiving, storage, labeling, and feeding of HBM. Storage recommendations are described in Table 2.
5. The recommended length of time that milk can be frozen at -20°C (-4°F) should be shortened to 3 months.
6. HBM should not be preheated for feeding to a temperature greater than 40°C (104°F).
7. Use fortified HBM for premature infants.
8. Use sterile products to fortify HBM, whenever possible.
9. Fortify HBM in a milk lab under sterile conditions. The optimal timing between human milk fortification and feeding is not known.
10. Educate all mothers expressing HBM regarding lactation science, as well as human milk collection and storage, including cleaning of the breast pump.

Rationale

Human milk is the feeding of choice for infants.⁷ Use of HBM offers many benefits to mothers and infants, including premature infants.^{8,9} However, the nutrient profile of unfortified HBM is not adequate to support the growth of premature infants; therefore, HBM for premature infants must be fortified.⁸⁻¹¹

Table 2. Recommendations for Human Breast Milk Storage for Hospitalized Infants.

Storage Method and Temperature	Recommended Storage Time
Freezer (home combined with refrigerator)	3 months; new evidence would suggest shortening this time
Freezer (−20°C, −4°F)	6–12 months; new evidence would suggest reducing this to 3 months
Freezer (−70°C, −94°F)	>12 months
Refrigerator (4°C, 40°F), fresh milk	New evidence would suggest lengthening this from 48 to 72 hours unit dosed, single entry 96 hours
Refrigerator (4°C, 40°F), thawed milk	24 hours
Refrigerator (4°C, 40°F), fortified milk	24 hours
Refrigerator (4°C, 40°F), thawed pasteurized donor milk	48 hours
Cooler with ice packs (15°C, 59°F) fresh milk	24 hours
Room temperature (25°C, 77°F)	<4 hours

Adapted with permission from Lessen R, Sapsford A. Expressed human milk. In: Robbins ST, Meyers R. *Infant Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities*. Chicago, IL: American Dietetic Association; 2011:47.

Guidelines for use of HBM from mothers who abuse drugs. The Academy of Breastfeeding Medicine and the American Academy of Pediatrics have guidelines regarding the use of HBM from mothers who admit to abusing drugs.¹² Milk from adequately nourished mothers who are HIV negative, who have had consistent prenatal care, and who are participating in a treatment program can be used.¹²

Use of donor human milk. If maternal HBM is unavailable, the use of donor HBM is recommended for premature infants by the American Academy of Pediatrics and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition.^{7,13} Because the protein content of donor HBM depends on the stage of lactation, various fortification strategies may be needed to ensure the protein content of all donor HBM is sufficient.^{14,15} Organizations can acquire donor milk from an accredited Human Milk Banking Association of North America (HMBANA) human milk bank or a commercial company that uses similar stringent donor selection and HBM preparation guidelines. Buying HBM from the Internet is not safe.¹⁶ The U.S. Food and Drug Administration recommends against feeding infants HBM acquired directly from individuals or through the Internet.¹⁷

Fortification of human milk. Powdered products can never be completely sterile. Therefore, it is recommended that liquid sterile products be used to fortify HBM whenever possible.¹⁵ It is best to fortify HBM away from the bedside, in a sterile milk lab. The optimal time between HBM fortification and feeding is not known. It is suggested that this time be as short as feasible to limit the breakdown of nutrients in HBM. Articles using prior renditions of the current human milk fortifiers reported an increase in osmolarity over time.^{18,19}

Human milk storage and handling. The Academy of Nutrition and Dietetics published recommendations for HBM storage for hospitalized infants in 2011.²⁰ More recent literature

raises concerns about long-term freezing of unpasteurized HBM at −20°C (−4°F).²¹ The dornic activity is a measure of the acidity of HBM and is used as an indirect method of assessing milk quality and bacterial contamination.²¹ Lipoprotein lipase maintains its activity at this temperature, and this activity increases when HBM is frozen for more than 3 months, which is thought to result in a breakdown of triglycerides to free fatty acids that could damage the intestinal epithelial cells.²²

Slutzah and colleagues²³ have recommended that fresh HBM can be refrigerated for up to 96 hours; however, their study was not conducted in a real-time environment with multiple entries of HBM into the same bottle. According to the Academy of Nutrition and Dietetics recommendations, refrigeration for 96 hours is acceptable with unit-dosed, single-entry access.²⁰ In a unit with multiple entries, it seems reasonable to be more conservative about refrigeration storage times, limiting refrigerated storage to 72 hours.

In 2015, Bransburg-Zachary and colleagues²⁴ raised concern about the heating of HBM for infant feeding. HMBANA advocates for the warming of human milk for premature infants to body temperature.²⁵ Term infants may have milk directly from the refrigerator or at room or body temperature.²⁵ At temperatures greater than 40°C (104°F), the nutritional and immunological properties of HBM begin to deteriorate. The amount of time that HBM is kept warm is also important; at 38°C (100.4°F), lipolysis is rapid with a 440% increase in free fatty acids in an hour.²⁶

Published reports of infants becoming ill as a result of HBM contamination are few; however, contamination can be a problem. HBM expressed using breast pumps has a higher rate of contamination than HBM expressed by manual expression.²⁷ Educational intervention may decrease the prevalence of contamination.

Question 5.4. What are the best ways to determine clinical advantages/disadvantages of the closed EN system?

Practice Recommendations

1. Select an open or closed system for EN delivery based on the following factors of each system and the needs of the institution:
 - a. Cost: The use of a closed system can potentially save money because it requires fewer nursing resources and lowers the risk of infections due to bacterial contamination.
 - b. Safety: If an open system is used, facilities must be willing and able to implement protocols and diligently monitor compliance with all EN product handling and administration procedures, including hand hygiene, proper handling of enteral feedings and sets, and hang-time limits.

Rationale

Over the years, many healthcare institutions have transitioned from open enteral systems (in tetra-packs, bottles, or cans) to closed enteral systems (in bags or rigid containers) in efforts to reduce infection from contaminated enteral formulas and to reduce nursing time. Commercially available liquid EN products are sterilized before distribution but can become contaminated when used at the facility. Contamination of enteral formulas can cause abdominal distension,²⁸ diarrhea,^{29–31} and bacteremia following administration.³² Several studies have shown that the risk of contamination is greater with open systems because these systems increase physical handling of EN.^{33–37} Closed systems can decrease manipulation and human contact with enteral formulas and feeding administration sets, which in turn reduces the risk of contamination.^{38–43} However, some studies have shown that open systems can be safely used when staff practice good hygiene and comply with proper handling procedures.^{44–46} Multiple studies have demonstrated that using a closed system reduces nursing time.^{46–48}

Closed systems can be costly because of formula packaging and waste from unused formula (closed system products come in 1000-mL or 1500-mL containers, whereas open-system products come in 237-mL or 250-mL containers). Closed containers have an increased hang time of up to 48 hours (compared to 4–8 hours with open systems); however, most closed containers are discarded after 24 hours due to current manufacturer recommendations to change enteral feeding sets every 24 hours and to spike each closed container only once.⁴⁹ Nevertheless, studies have found that using closed systems with increased hang times reduces waste and costs.^{49,50} A 2013 cost-analysis study showed that a closed system was more expensive than an open system when accounting for waste (\$4.80 per patient day compared to \$4.21 per patient day).⁴⁹ However, when nursing time was factored into the costs, the expense of the open system increased to \$9.83 per patient day.

Pediatric Open Systems

Open systems will likely need to continue to be utilized in the pediatric population because many products are only available in powdered form. Powdered infant formulas are not sterile upon manufacture. In 2004, an infant died as a result of a *Cronobacter*, formerly called *Enterobacter sakazakii*, infection that was found in the infant's reconstituted powdered infant formula.⁵¹ The organism was also found in unopened cans of the formula. Ready-to-feed and concentrated liquids are sterile products, but not all formulas come in this form as noted above. Therefore, it is recommended that powdered formula not be used for immune-compromised infants, if other options are available.

Over time, infant formula manufacturers have converted many products, such as human milk fortifiers, from powder to liquid forms. However, certain products are only available in powder, such as products for infants with inborn errors of metabolism, infant and pediatric elemental formulas, and a specialty infant renal formula. Some formulas only come as ready-to-feed or powder products and are not supplied in concentrated liquid form. If the clinician wants to use these formulas at a higher calorie density, nonsterile powder is commonly added to ready-to-feed formula, which increases the risk of contamination.

HBM is the preferred nutrition for infants. If mother's own milk is not available, donor human milk may be used. Donor milk is pasteurized, which diminishes the immunoprotective nutrients. Compared to fresh or frozen HBM, proliferation of bacterial pathogens in pasteurized HBM was 1.8–4.6 times.⁵²

In 2011, the Academy of Nutrition and Dietetics issued guidelines for hang times for infant feedings,⁵³ and these stringent guidelines are recommended for neonates and immunocompromised infants until there is sufficient further evidence. In a prospective, descriptive study of 30 pediatric patients, Lyman et al⁴⁴ found that "decanted enteral formula administered continuously over 12 hours in a pediatric hospital setting has a lower than expected rate of bacterial growth when recommended handling practices are followed." This evidence might influence the Academy of Nutrition and Dietetics to revise the hang-time guidelines to 12 hours for pediatrics; however, there is no evidence at this time that guidelines for immunocompromised or neonatal patients should be altered.⁴⁴

Question 5.5. What are the critical elements of the EN order that need to be transmitted to ensure safe product preparation?

Practice Recommendations

1. Develop and design standardized EN orders (CPOE or editable electronic templates, or paper as a last resort) for adult and pediatric EN regimens to aid prescribers in meeting each patient's nutrition needs and to improve order clarity.

2. Include all critical elements in the EN orders: (1) patient identifiers, (2) the formula name, (3) the EAD site/device, (4) the administration method and rate, plus (5) water flush type, volume, and frequency. Incorporate the feeding advancement order, transitional orders, and implementation of complementary orders into protocols. All elements of the EN order must be completed when EN is modified or reordered.
3. Avoid the use of unapproved abbreviations or inappropriate numerical expressions.
4. Encourage the use of generic terms to describe EN formulas. All elements of the EN order must be completed when EN is modified or reordered.
5. Provide clear instructions related to modular products, including product dose, administration method, rate, and frequency.
6. Establish and enforce policies and procedures that clearly describe the preparation of powdered EN products, including who will evaluate compatibility, measure the dose, reconstitute the product, what diluent and source will be used, the location of preparation, labeling including beyond use date and time, and storage.

Rationale

Many problems associated with EN orders often result in inadequate delivery of formula to patients in critical care settings. These problems are attributed to underordering, frequent cessation of the enteral infusion, and slow advancement of the EN to goal rate.^{54,55} EN protocols,^{54,56–58} algorithms,⁵⁹ and clinical practice guidelines⁶⁰ have been developed to standardize enteral feeding practice, and many have resulted in an improvement in the delivery of enteral feedings to patients. One group developed a protocol that standardized ordering, nursing procedures, and rate advancement and also limited interruptions to EN administration. Use of the protocol improved delivery of goal volumes, although there was physician resistance to using a standard order.⁵⁵ A Canadian group improved delivery of the required formula volume using a protocol.⁵⁶ Woien and Bjork⁵⁹ reported on a feeding algorithm that was developed to increase the likelihood of meeting nutrition requirements in intensive care. The algorithm also resulted in an increased utilization of EN (rather than PN) and in the number of patients who met EN administration goals. Another study described a stepwise process to develop and implement a tailored action plan that could be adopted in ICUs with differing characteristic and used to help identify barriers to adequate provision of EN in critically ill patients (eg, EN formula and feeding pump availability on units, use of a protocol to reduce interruptions, an algorithm for managing diarrhea) and help those facilities tailor interventions to improve nutrition practice.⁶¹

Patient-specific EN orders should include all critical elements: (1) patient demographics, (2) the formula name, (3)

delivery site and access device, and (4) administration method and rate, plus water flush type, volume, and frequency. Orders can be provided as a single order representing a specific prescription, or they can be part of a larger protocol that directs advancement of EN from initiation to a goal rate or volume that represents a nutritionally adequate end point. Specific preparation or administration instructions can also be included in these protocols. Such instructions are especially important for safe use of modular products or reconstituted powdered products to meet patient requirements. The inclusion of transitional orders will direct weaning from EN, and ancillary orders may address various patient care issues. Orders may be communicated through a CPOE system or via editable templates in electronic format, with paper forms clearly being a last resort or for when electronic systems are down.

Patient identifiers: The order should clearly state the patient's name, date of birth, location, and medical record number (MRN).

Formula: The formula should be clearly identified in the order by a generic name as well as by the specific product brand depending on institutional policy. For example: A formula that contains 1 calorie per mL can be generically identified as "isotonic" or "standard"; formula that contains 2 calories per mL can be generically identified as "calorie dense"; a partially hydrolyzed formula can be generically identified as "semi-elemental" or "peptide based." Formula orders may also include the administration of modular products used to enhance the protein, carbohydrate, fat, or fiber content of the enteral regimen. In the adult population, these products are usually administered directly to the patient via the EAD in prescribed amounts and frequency with specific administration guidelines but are most often not added to the enteral formula. In the neonatal and pediatric population, fluid tolerance limits are a greater concern; therefore, the base formula is often augmented with a modular macronutrient as compatibility allows. When this type of manipulation to infant formula is prescribed, the base formula, the modular product, and the base and final concentration of formula per 100 calories are all considered.^{62,63} If this is done in the home, it is important to teach the parents or caregivers the proper method to prepare a formula with additives.

Delivery site/device: The route of delivery as well as the access device for EN formula administration should be clearly identified in the order to prevent wrong-site administration. Enteral misconnections have been reported in the literature.⁶⁴ Identification of the infusion site (eg, jejunal port of gastrojejunostomy tube) also decreases the chance of inadvertent use of the wrong feeding port for enteral infusion.

Administration method and rate: Bolus, gravity, or continuous method (rate based or volume based): volume or rate of administration and timing of formula delivery within a specified period of time (24 hours or cyclic) should be clearly set forth in an EN order.

Supplementary orders: Orders that differ from the standard formula rate, route, and volume prescriptions. These can include:

Advancement orders: These orders direct the progression of an EN regimen from initiation through to an end point or goal formula volume infused over a specified time period. Increases in formula volume or rate of administration to achieve a goal should be clearly written. Protocols should visibly illustrate feeding adjustments when volume based feeds are utilized. Advancement orders also need to be coordinated with decreases in PN.⁶⁵

Transitional orders: The incremental decreases in formula volume over a period of time to accommodate for an increase in oral intake.

Ancillary orders: Routine or ancillary orders will depend on both the population and setting. These orders are based on institutional policies for care of the enterally fed patient, such as orders for HOB elevation, tube occlusion treatment, bowel management,⁶⁶ and monitoring laboratory parameters.

EN orders contain all the elements that should be part of an EN order plus suggestions for ancillary and transitional orders. Many institutional settings already utilize CPOE systems, and these systems should be designed with detailed order sets that promote safety by using EHR drop-down menus within each element of an EN order, including required fields. Such menus may facilitate standardized advancement of initial administrations to goal volumes, uniform enteral access device flushing volumes and methods, and population-specific ancillary orders. Orders for monitoring, flushing, and transitioning from tube feeding can also be included.

Question 5.6. What are the minimum requirements for the safe preparation of EN formulas that need to be decanted from small commercial containers or reconstituted from dry powder?

Practice Recommendations

1. Use competent personnel trained to follow strict aseptic technique for formula preparation.
2. Immediately refrigerate formulas reconstituted in advance. Discard unused reconstituted and refrigerated formulas within 24 hours of preparation.
3. Expose reconstituted formulas to room temperature for no longer than 4 hours. Discard unused formula after this time.
4. Use a sterile water source for formula reconstitution.
5. Use formula decanted from a screw cap instead of a flip top.

Rationale

Between 0% and 57% of enteral formulas prepared in the hospital and over 80% of those prepared in the home have been found to be contaminated with bacteria.^{39,67-69} EN preparation

may include the mixing, reconstitution, or dilution of modular products and formula with sterile water, and/or pouring the formula into an administration container. The sterility of the commercially available liquid EN products, as well as that of the sterile bags and administration sets, is disrupted by any manipulation, which increases the risk for contamination. Commercially available EN products manufactured in dry powder form are not required to be sterile and may be contaminated by the end of the production process prior to reaching the market. A study of powdered infant formulas across several European countries revealed *Enterobacter* species contamination in 53% of 141 samples.⁷⁰ Although these bacteria were found in amounts within the accepted maximal limits, the organism would be expected to multiply rapidly once these products are reconstituted with water, especially if at room temperature.⁷¹ A more recent study of EN powder formulas in the care of adults identified considerable contamination. Out of 28 samples of reconstituted powdered formulas, 27 (96%) had total viable bacterial counts greater than 10³ colony-forming units (CFU)/g.⁷¹ The CDC recommends that if a powder EN product is selected to meet a patient's needs, trained personnel should prepare it following strict aseptic technique.⁷² Reconstituted formula exposed to room temperature for more than 4 hours should be discarded. In addition, the reconstituted formula that is not immediately used must be promptly refrigerated, and any formula that remains 24 hours after preparation must be discarded. In the absence of a formula preparation room, the pharmacy can support reconstitution of powdered formula in a laminar airflow environment.

The water supply may be a source of potential contamination if purified water is not used. All water supplied for feeding preparation must at least meet federal standards for drinking water and not contain contaminants. For reconstitution of pediatric and neonatal formulas, the water needs to be sterile.^{53,72} This should also be considered for reconstituting formulas intended for adults. Weenk et al³⁵ compared various feeding systems and found a sterile glass bottle containing enteral formula to be associated with the lowest level of microbial growth from touch contamination. They also found that decanted formula poured from a container with a screw cap into a feeding bag was associated with lower levels of microbial growth than formula poured from a container with a flip top (similar to the type of top found on a soda can).³⁵

Question 5.7. What are the safety issues when using blenderized tube feedings and how can the risk of complications be reduced?

Practice Recommendations

1. Prepare blenderized tube feedings (BTF) using safe food-handling techniques, and store it at refrigerator temperature immediately after preparation. Discard any unused portion after 24 hours.

2. Limit the hang time of blenderized tube feedings (BTF) to 2 hours or less.
3. Give BTF only via a gastrostomy tube that is 14 Fr in size or greater.
4. Do not use BTF in patients who do not have a proven tolerance to bolus feeds, those who are medically unstable, or those who lack a mature gastrostomy site that is free of infection.
5. Involve a registered dietitian or nutrition support clinician in the development of the BTF formula to ensure adequate nutrient delivery.
6. Sanitize mechanical devices (eg, blenders) used to prepare BTF after each use with an established protocol.

Rationale

An alternative to commercial enteral formulas, BTFs use foods that are blended to a consistency that allows for ease of use with a feeding tube.⁷³ BTFs can be provided exclusively or in conjunction with a commercial formula. In addition, commercially prepared, ready-to-use, real-food blenderized formulas are available for those patients who do not want to make their own homemade formulas.

There is limited research on the safety and efficacy of BTF in home-fed patients. Several studies demonstrate some benefit with this technique in, for example, postfundoplication patients. However, more research is needed to demonstrate the benefit in additional patient populations generally maintained on partial or complete home nutrition support.^{74,75}

Home-prepared BTFs have a higher risk of cross-contamination and potential for foodborne illness than commercial EN products.⁷⁶⁻⁷⁸ High risk of contamination was a major reason why institutions moved away from using BTF in the hospital setting when commercial enteral formulas became available. In the home environment, care should be taken to prepare BTFs using safe food-handling techniques to prevent cross-contamination. Once prepared, the BTF should be immediately used or immediately refrigerated at appropriate temperatures.^{73,79} Access to adequate refrigeration, clean water, and electricity is imperative before considering a change to BTF.⁸⁰ Given the potential for infection associated with foodborne illness, use of BTF may not be appropriate among medically unstable patients, immunocompromised patients, or those without a mature feeding tube site.^{73,81} BTF should not be held at room temperature for more than 2 hours due to concerns about food safety and bacterial contamination; therefore, a bolus regimen instead of a continuous infusion is recommended.^{73,76} Patients with volume limitations or known intolerance to bolus feeds are not good candidates for BTFs. Refrigerated BTF formula that is not used within 24 hours of formulation should be discarded.

There may be an increased risk of tube occlusion with BTFs given their high viscosity. Therefore, BTFs are not recommended for patients with a feeding tube smaller than 14 French as smaller tubes are more likely to occlude.⁷⁵ A recent study was

conducted to determine the flow rate of BTFs through the new enteral (ENFit) connector system compared to various other available feeding tube components. In this study, ENFit and Cath-tip syringes flow and pressure requirements were essentially equivalent. If BTFs can go through the Cath-tip syringe, they should also be able to go through the ENFit connector.⁸² Another study by Mundi et al⁸³ observed a need for increased force with the ENFit connector to administer blenderized formulas compared to traditional connectors, but this study was conducted with device prototypes and not with FDA-approved products. Currently, the FDA and other independent labs are conducting flow and pressure studies with a variety of tubes and a variety of formulas, including blenderized diets.

Several studies have demonstrated that the macronutrient and micronutrient content of BTFs is highly variable and the energy content is often overestimated.^{76,78,83-85} Registered dietitians should be involved in development of the BTF composition to ensure adequate nutrient delivery in the home environment and help maintain consistency of the regimen to prevent underfeeding.^{74,76,86}

Questions 5.8–5.10. Does a standardized approach to labeling EN reduce errors and what are the critical elements of the EN order that need to appear on the patient-specific label? What elements on a commercial container must be present to meet the critical elements of the EN order/patient identification? How does one best avoid errors associated with sound-alike, look-alike product names and labels?

Practice Recommendations

1. Include all the critical elements of the EN order on the EN label: patient identifiers, formula type, enteral delivery site (route and access), administration method and type, and volume and frequency of water flushes.
2. Standardize the labels for all EN formula containers, bags, or syringes to include who prepared the formula, date/time it was prepared, and date and time it was started.
3. Express clearly and accurately on all EN labels in any healthcare environment what the patient was ordered. Given changes to administration rates/volumes, consider patient-specific labels that state:
 - a. “Rate not to exceed _____”
 - b. “Volume not to exceed _____”
4. Include on the label of HBM stored in the hospital: contents in container, infant’s name, infant’s medical record number, date and time of milk expressed, maternal medications, fortifiers added, and energy density.
5. State on the HBM label whether the milk is fresh or frozen, date and time the milk was thawed, and the appropriate expiration date. Bar codes, special colors, or symbols may be used to further identify the HBM.

Table 3. Components of the Formula Label.

Labeling of Enteral Formula	Labeling of Incoming Human Breast Milk
<ul style="list-style-type: none"> • Patient's name • Medical record ID number • Formula name and strength of formula, if diluted • Date and time formula prepared^a • Date and time formula hung^a • Administration route • Rate of administration expressed as mL/h over 24 hours if continuous administration or "Rate not to exceed _____" or "Volume not to exceed _____" • Administration duration and rates are to be expressed on the label if the EN is cycled or intermittent • Initials of who prepared, hung, and checked the EN against the order. • Appropriate hang time (expiration date and time) • Dosing weight if appropriate • "Not for IV Use" 	<ul style="list-style-type: none"> • Infant's name • Medical record ID number • Dosing weight • Date and time that milk expressed • Medication or supplements being taken by the mother • Specify whether milk is fresh or frozen • Contents in syringe/container (expressed breast milk) • If frozen, date and time milk thawed • Expiration date (based on whether the milk was fresh or frozen) • "Not for IV Use" • Fortified human breast milk also includes: <ul style="list-style-type: none"> ○ Name of fortifier ○ Final concentration ○ Date and time formula prepared ○ Initials of who prepared, hung, and checked the EN against the order

EN, enteral nutrition; ID, identification; IV intravenous.

^aDate-time formula prepared and date-time formula hung may be different, so note both.

6. Label commercial enteral containers "Not for IV Use" to help decrease the risk for an enteral misconnection.
7. Carefully check commercial enteral container labeling against the prescriber's order. Be aware of sound-alike or look-alike product names that may be mixed up on the order or during selection of the product.

Rationale

In any healthcare environment, patient-specific, standardized labels for EN express clearly and accurately what the patient is receiving at any time. Having standardized components on a label decreases potential confusion when a patient is transferred to a different unit within a facility or when a new staff member takes over a patient's care.⁸⁷ Clear labeling that the container is "Not for IV Use" helps decrease the risk for an enteral misconnection. Proper labeling also allows for a final check of that enteral formula against the prescriber's order.⁸⁸

Standardized labels can be affixed to all EN formula administration containers (bags, bottles, syringes used in syringe pump). Each label lists the 4 critical elements of the EN order: patient identifiers, formula type, enteral delivery site (route and access), and administration method (see Table 3). It also identifies the individuals responsible for preparing and hanging the formula as well as the time and date the formula is prepared and hung.^{88,89} See Figures 5 through 8 for examples of labels, which may also include nutrient information if the label is computer generated. Care should be taken in developing a label that is clear and concise and of a size that fits neatly on the container.

Special considerations regarding the labeling of HBM. Clear and concise labeling of HBM is essential to prevent errors in the delivery of HBM to the infant. The label of milk stored in the hospital should include the following information: contents in

container (HBM), the infant's name, the infant's medical record number, the date and time when milk was expressed, maternal medications, fortifiers added to the HBM, and the energy density of the HBM.⁹⁰ Additionally, the label should state whether the milk is fresh or frozen, date and time the milk was thawed, and expiration date based on whether milk is fresh or frozen.⁵³ If the mother is separating fore and hind milk, this designation should appear on the label. Unique identifiers may be used to describe other factors such as colostrum, transitional, and mature milk. Bar codes, special colors, or symbols may be used to further identify the HBM. Hospitals may use computer-generated or, at last resort, handwritten labels (see Figures 7 and 8).

Topics for Future Research

- Efficacy of methods and objectives for developing EN formularies
- Best practice for formulary decision-making process
- The cost-effectiveness of including specialty formulas in formularies
- The optimal size of formularies
- The costs and benefits of participating in corporate-buying organizations
- Safe storage and hang times for all categories of human milk, including the concern for the dornic activity of unpasteurized human milk during freezing
- The optimal feeding temperature for HBM for premature infants to promote digestion without altering the beneficial properties in human milk and the length of time HBM can safely remain at this temperature
- The optimal time between preparation and feeding the infant using the newer HBM fortifiers and modular additives



ENTERAL USE ONLY	
<i>Institution and Department Name – Contact Information</i>	
Patient Name _____ Patient ID _____ Room Number _____	
Human Breast Milk Contents	
Fresh or Frozen (circle)	
HBM Fortifier _____ cal/oz. and/or _____ to make _____ (as per prescriber order)	
Prepared by: _____ Date: _____ Time: _____	
Delivery Site	
	Route of Delivery: _____ Enteral Access Site: _____
	
Administration	
Method of Administration: Bolus Continuous	
Rate of Administration: _____ mL/h	
Formula Hung By: _____, Nurse Date: _____ Time: _____	
Expiration Date: _____ Time: _____	

Figure 7. Standard human breast milk label template (infant patient). HBM, human breast milk; ID, identification; IV, intravenous. Adapted from Bankhead R, Boullata J, Brantley S, et al. Enteral nutrition practice recommendations. *JPEN J Parenter Enteral Nutr.* 2009;33(2):122-167.

<i>Institution and Department Name – Contact Information</i>	
Patient Name _____ Patient ID _____ Room _____	
Pumped: Date _____ Time _____	
MEDICATIONS TAKEN:	
Expiration Date: _____ Time: _____	

Figure 8. Human breast milk storage label. ID, identification. Reprinted from Bankhead R, Boullata J, Brantley S, et al. Enteral nutrition practice recommendations. *JPEN J Parenter Enteral Nutr.* 2009;33(2):122-167.

- Ideal fortification for mother’s and donor human milk for the premature infant in and outside the hospital
- Methods to analyze and fortify human milk
- Best method of fortification for the infant who requires surgery or the infant with short bowel syndrome
- The safety and cost-effectiveness of the closed system on patient and nursing satisfaction

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Section 6. Administration: General

Background

The administration of EN therapy is a step in the process with significant potential for error. Errors can stem from incomplete evaluation of a patient’s tolerance for enteral feeding that increases the risk for aspiration or GI complications. Enteral misconceptions, poor positioning, pump misadventures, and contamination can all lead to less than optimal patient outcomes.

Question 6.1. What system-based measures can be implemented to enhance the safety of EN administration?

Practice Recommendations

1. Develop policy and procedure documents for evidence-based practices to standardize the approach to and the administration of EN in all patient populations.
2. Maintain competency as defined within the organization to maximize safety of the patient for all caregivers involved in the administration of EN.
3. Develop and use enteral feeding and related protocols with order sets and checklists to optimize nutrition delivery and promote safe and effective practice, from patient evaluation to pump programming.
4. Initiate and update protocols periodically based on best evidence, including national guidelines and recommendations to meet the needs of the specific patient populations.

5. Monitor performance of EN delivery and related care and have in-place systems to enhance practice in terms of efficacy and safety as indicated.
6. Encourage change champions, such as nutrition support team members, to guide EN practice.
7. Include knowledgeable nurses in decision making for selection and purchase of EN administration sets, feeding pumps, and access devices.
8. Commit to adequately staffing patient care units on which many patients receive EN with nurses having documented competency in EN administration.
9. Support both the physical and cognitive efforts of nurses and other caregivers involved in maintaining safe practices around EN administration. For example:
 - a. CPOE for EN orders with the full order available on the nursing medication administration record
 - b. Bar coding on EN containers and patient-specific labels
 - c. Prompts for documentation of essential steps in administration of EN as well as the care and monitoring related to feeding tube and EN use
10. Develop and implement interdisciplinary quality improvement programs, including systematic review and analysis of administration-related EN errors, then implement subsequent safeguards to address any identified errors in the process.

Rationale

A transparent and collaborative approach using guidelines, protocols, and standardized practice based on best evidence enhances patient care within the EN process. Guidelines are published periodically to provide recommendations for practice based on best available current evidence.¹⁻³ Although the practice of EN administration varies widely, protocols can standardize and guide practice toward safety. The benefit of using protocols to enhance clinical practice has been articulated.⁴⁻⁸ Heyland et al⁹ demonstrated that protocols can significantly improve nutrition practices. Racco¹⁰ discussed development of a protocol to help overcome barriers to achieving goal rate and guide staff in areas such as holding feeding for gastric residual volume (GRV). Protocol order set included starting EN rate, energy, protein, and fluid goals as set by the nutrition support clinician, bowel management program, prokinetic agent use as indicated, and education of this order set. Data collection revealed that 23 protocol patients achieved goal rate in one-third the time of 13 patients who received EN in the usual manner. Patients with elevated GRV reached goal 16 hours sooner when the protocol was used, and those with elevated GRVs started on prokinetic agents after 3 elevated GRVs 75% of the time. In an evidence-based implementation project with pretest-posttest measures, Kenny and Goodman¹¹ showed that EN protocols in a military hospital improved practices, such as keeping the head of the bed up, medication administration, and

tube-unclogging practices, and also increased provision of family education. Institutional protocols can guide practice in areas such as tube placement verification, hang time and feeding set changes, monitoring tolerance of EN, and adequacy of EN. A nurse-driven protocol to assess stool for *Clostridium difficile* as appropriate can also be helpful. Protocols may be institution specific. It is advisable to periodically review protocols and update them as warranted by new evidence.

Order sets can guide appropriate EN product selection, initiation rate and progression to goal, delivery route, and administration method. Additionally, they can prompt safety features in EN care and monitoring. For example, routine monitoring of laboratory values could be especially helpful for those at risk for issues such as refeeding syndrome or hyperglycemia. Order sets can prompt additional fluid administration and offer guidance for staff in areas such as HOB elevation, residual volume check, and abdominal assessment. Safety practices and protocols can be embedded in the order set to populate the EHR to schedule and remind staff of necessary clinical tasks. Elements of EN ordering that should also be included in the order set include demographics such as patient identifiers, and body weight might also be included or readily accessible.¹²

Accountability is optimized when the system process identifies who is responsible for what. Organizations can standardize safety practices for EN, such as those related to decreasing risk for enteral misconnections¹³:

- Tracing tubings and lines with reconnections at handoffs
- Training nonclinical staff to ask a qualified clinician to reconnect lines instead of attempting reconnection themselves
- Discouraging the modification or adaptation of IVs or EADs even if the availability of adaptors and connectors is reduced
- Labeling of tubes and connectors
- Identification and confirmation of solutions label and labeling of bags with bold statements in terms of contents
- Identification and minimization of conditions and practices that contribute to healthcare worker fatigue and mitigate risk
- Purchasing of appropriate, safe equipment that meets standards and guidelines such as those from American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI)
- Careful evaluation of purchasing decisions by an interdisciplinary task force
- Following manufacturers' guidelines to promote safe connections

Assessing barriers to guideline adherence is key to effective and consistent use of guidelines and protocols. The 2013 update to

the Canadian Critical Care Nutrition Guidelines discusses key strategies to promote their previous guidelines and explores 5 thematic domains in analyzing barriers as well as offering system-level quality improvement interventions.¹⁴ This guidelines update promotes evaluating and monitoring practice via performance improvement strategies to enhance nutrition care and improve patient outcomes. As noted earlier, Kenny and Goodman¹¹ have described the development and implementation of an evidence-based practice protocol for care of patients with EN tubes; after these performance improvement interventions, HOB elevation was achieved 100% of the time. Lyerla and colleagues¹⁵ used a modified interrupted time-series design to collect data on 43 patients and 33 nurses in a 12-bed critical care unit. They found that a nursing clinical decision support system integrated into the electronic flow sheet increased adherence to guidelines. Change champions have been shown to facilitate change processes to improve care.^{11,16} This is a role that can be played by appropriate staff who take an active interest in and accountability for enhancing practice.

Question 6.2. What are the essential components for EN administration to include in nursing policies, procedures, and practices?

Practice Recommendations

1. Define the quality control process for receipt, distribution, storage, preparation, handling, and administration of EN products.
2. Use sterile liquid EN formulations in preference to powdered, reconstituted, or blenderized preparations, whenever possible.
3. Administer EN by, or under the direct supervision of, competent personnel as defined by the organization. The personnel who administer EN will:
 - a. Either accept the delivery of the EN container identified with the patient-specific label or select the product from the unit-based inventory and places the patient-specific label (depending on the organizational model).
 - b. Visually inspect the product or preparation for damage to the container, altered formula characteristics, and expiration date limits.
 - c. Confirm that the EN container with the patient-specific label reflects what has been ordered by the prescriber. Verify patient identifiers, product name, and route (and rate) of administration.
 - d. Perform proper handwashing prior to entering the patient care area as well as prior to working with the feeding administration. Don clean gloves prior to working with the feeding tube and administration set.
 - e. Use aseptic technique in setting up and connecting the feeding administration set and related equipment.

- For example, use a small clean towel under the patient feeding tube connection to facilitate a clean area prior to working with the tube.
- f. Verify patient identifiers at the bedside matching those on the EN label, per institutional protocol, and verify appropriate patient positioning for feeding.
 - g. Trace tubing from point of the enteral access device that was described in the EN order and confirm that there has been no dislocation of that device.
 - h. Position the EN container appropriately for the patient and set up the administration set, priming it as indicated.
 - i. Flush EAD and attach administration set using aseptic technique. The EN container and administration set make up the EN “delivery device” and are attached together until discarded.
 - j. Cover the end with a clean cap for any disconnection, such as when the feeding is stopped and the distal end of the delivery device is disconnected as for nocturnal or gravity bolus feeding. If a pump is being used as for continuous feeding, program it based on the EN order.
 - k. Base any change to the administration rate on documented EN orders (including prescribed rates for advancement or weaning).
 - l. Do not interrupt feeding administration for routine care unless specifically ordered (as for medication administration). If the feeding must be interrupted, flush the tube to reduce the residue in the tube and decrease potential for clogging.
 - m. Ensure that administration of enteral medication via the EAD is reviewed and approved with documentation as indicated by a knowledgeable pharmacist.
 - n. Document EN processes in the patient’s EHR, with a second entry for any independent double-check performed. This includes documentation of tolerance and administration volumes, including hourly rates as well as amount of intake, and water flushes.

Rationale

The purpose of policies and procedures is to ensure that staff follow a consistent standard of care and quality at all levels.¹⁷ Policy statements guide practice by indicating what is to be done and by whom. They are often based on institutional protocol. Procedures describe the specific methods for following policies in practice. When staff understand the rationale for policy and procedures, they may be more likely to adhere to protocol and use critical thinking. Issues to address in policies and procedures related to EN delivery are listed in Table 4.

Table 4. Issues to Cover in Policies and Procedures for EN Delivery.

- How feeding tubes are to be inserted
- How verification of EAD placement is to occur and how EAD placement is monitored
- Care for enteral feeding tubes
- How to prevent or handle practice challenges such as tube dislodgement
- Elements necessary in a provider order for EN
- Administration of EN in terms of formula attainment and verification, labeling, administration route, and method (eg, pump use or gravity bolus feeding method)
- Rate or frequency of feedings
- Type, volume, and frequency of water flushes
- Hang times and equipment handling (eg, in terms of administration set changes)
- Medication delivery issues that involve or relate to EN or the enteral tube
- Issues related to safety in administration such as recommendations from The Joint Commission Sentinel Event Alert 53 and other safety issues such as head of bed elevation¹⁸
- How to optimize that the appropriate volumes of feeding product and fluid are actually delivered
- Methods to monitor for adequacy of EN as well as potential adverse effects, and identify who is responsible for overall and specific aspects of monitoring as well as patient/family education, especially when transition to the home setting when continued feeding is anticipated
- Frequency of residual assessment, what tubes are to be assessed, how assessment should be performed, and the rationale for the assessment (the rationale helps staff identify the need for abdominal and more global patient assessment as a guide for tolerance to EN instead of relying solely on gastric residual assessment)

EAD, enteral access device; EN, enteral nutrition.

Organizations can use a systematic plan to promote the periodic review of policies and procedures and the updating of policies and procedures based on relevant and current evidence as well as best practice for patients in the particular care setting or organization. By conducting quality or performance improvement, healthcare organizations can monitor practice and identify areas for improvement and then implement appropriate measures to address the findings. For example, Guenter¹⁹ has discussed areas for potential human error related to EN and suggested the need for nursing oversight to minimize complications and enhance practice. Kenny and Goodman¹¹ describe the use of change champions to increase nursing knowledge of procedures and issues related to the environment of care.

Policies and procedures for the ongoing care and routine assessment of EADs can help with early identification of complications and proper interventions. Policies regarding EAD care and assessment can cover correct tube placement, mucosal and skin surfaces assessment, and infection prevention.

Question 6.3. What are the essential steps in EN administration to prevent aspiration?

Practice Recommendations

1. Maintain elevation of the HOB to at least 30° or upright in a chair, unless contraindicated, and then consider reverse Trendelenberg position.
2. Monitor the patient at least every 4 hours for appropriate positioning. In pediatrics, it is recommended that infants under 1 year of age sleep on their back and not have the head of the bed elevated.

3. Minimize the use of sedatives because airway clearance is reduced in sedated patients.
4. In patients who have difficulty clearing secretions, follow instructions from appropriate staff regarding how to clear secretions (eg, by oral suctioning), especially prior to lowering of the head of the bed and prior to extubation.
5. Understand that the method of administration (bolus, intermittent, continuous) and optimal site (gastric, small bowel) of EN feeding will depend on the patient needs, medical conditions, tolerance and goals (eg, if home use is anticipated), and resources available.
6. Monitor patient status for tolerance using measures such as assessment for abdominal distention, firmness, and large gastric residual volume (GRV), feeling of fullness, or nausea that might lead to gastric reflux.
7. Monitor patients for appropriate feeding tube placement at least every 4 hours or per institutional protocol. Monitor visible length of tubing or marking at tube exit site (naris or stoma) and investigate placement when a deviation is noted.
8. Monitor tube placement and abdominal distention, firmness for stable patients with longstanding EN therapy.
9. Place infants under 1 year of age on their back for sleep and do not have the HOB elevated.

Rationale

Aspiration may be related to oral pharyngeal secretions and/or reflux of esophageal and gastric content, including EN. Critically ill patients and patients with impaired swallowing

may have difficulty protecting their airways. Frequent, good oral care and oropharyngeal suctioning, especially prior to lowering the HOB as for positioning, can reduce adverse events related to aspiration of oropharyngeal secretions.^{20,21} Metheny and colleagues²² compared usual care with an aspiration risk reduction protocol (ARRP), which included HOB 30° or higher unless contraindicated; distal small bowel feeding tube placement, when indicated; and use of an algorithmic approach for high GRVs. With usual care, 88% of patients aspirated compared to 39% with the ARRP protocol. In the usual care group, 48% of patients developed pneumonia vs 19% in the ARRP group. The authors concluded that combining HOB at least 30° and use of small bowel feeding site can reduce aspiration and aspiration-related pneumonia dramatically in critically ill, tube-fed patients. In an earlier article (2006), Metheny²³ reported that 25 of 201 critically ill patients had malpositioned enteral feeding tubes and significantly higher risk for aspiration than those with tubes appropriately positioned. Risk for aspiration may be increased with enteral tube ports in the esophagus, especially if there are other risk factors for regurgitation. Some standard NG tubes (when used to deliver EN for short-term use) have end holes spaced 3 inches apart, and the standard tube placement measurement of nose to ear lobe to tip of xiphoid (NEX) may be suboptimal in guiding gastric tube tip placement. A nose to earlobe to mid-umbilicus (NEMU) method to estimate appropriate nasogastric tube placement has been recommended to promote placement of the tube end holes in or closer to the gastric fluid pool.²⁴⁻²⁶ Appropriate location of the enteral tube's distal end must be ascertained prior to instillation of fluid or medication. It is recommended in infants aged 1 year or less that they sleep on their back and not have the HOB elevated. These recommendations are part of the American Academy of Pediatrics Safe Sleep Initiative, to reduce sudden infant death syndrome.²⁷

It is important to obtain, ascertain, and maintain optimal enteral tube placement to help reduce potential reflux of EN. Metheny et al²⁸ performed a retrospective analysis of 428 critically ill, mechanically ventilated patients and found that the percentage of aspiration was 11.6% lower when feeding tubes were in the first portion of the duodenum, 13.2% lower in the second/third portion, and 18% lower in the fourth portion of the duodenum or lower ($P < .001$). In a randomized controlled trial of 33 ventilated patients randomized to gastric vs transpyloric feeding, Heyland et al²⁹ found that feeding beyond the pylorus was associated with significant reduction in gastroesophageal regurgitation and there was a trend toward less micro-aspiration. In critically ill patients, small bowel feeding may be associated with less pneumonia than gastric feeding, but without differences in mortality or days on a ventilator.

The American Association of Critical-Care Nurses recommend the following to reduce the risk for aspiration: maintain the HOB 30°–45° unless contraindicated; use sedatives as

sparingly as possible; assess feeding tube placement at 4-hour intervals; observe for change in amount of external length of the tube; assess for gastrointestinal intolerance at 4-hour intervals; assess residual volume, patient, and abdominal status and advance the tube if indicated; avoid bolus feeding for those at high risk for aspiration; assess swallow before oral feedings are started for recently extubated patients after prolonged intubation; maintain endotracheal tube cuff pressure at an appropriate level; and ensure that secretions are cleared from above the cuff before it is deflated.²

Question 6.4. Can EN be administered safely in patients who require prone positioning?

Practice Recommendations

1. Assist the patient in clearing secretions as indicated and promote good oral hygiene.
2. Assess abdominal status every 4 hours and as indicated and monitor bowel status as a guide for GI motility status.
3. Consider short-term use of prokinetic agents if indicated clinically.
4. Consider transpyloric tube placement for patients who are at increased risk for aspiration or have persistently elevated GRVs.

Rationale

Evidence is limited, demonstrating the safety and tolerability of EN in the prone position, although the minimal available evidence does not suggest a substantial increase in complications compared to EN administered in a supine position. Strategies to increase enteral feeding tolerance in the supine position such as HOB elevation, small bowel feeding, and use of prokinetic agents may increase EN tolerance for patients in the prone position. When the patient's clinical situation favors positioning other than HOB elevation at 30° or greater, as in prone patients, the use of small bowel feeding and prokinetic agents with 25° HOB elevation has been shown to increase volume tolerance and progress toward feeding goals.³⁰

Linn et al³⁰ reviewed the literature related to administration of EN in adult patients in the prone position. Only 2 of the 4 studies that they found that met their inclusion criteria were designed to compare outcomes associated with EN administered in the prone vs supine position. The conclusions of these 2 studies were that GRVs of patients in the prone position were similar to those noted in patients in the supine position; also, EN delivered to prone-positioned patients did not appear to increase risk of vomiting or pneumonia in the 2 studies where this risk was specifically explored. The limited evidence in this area is highlighted by these authors. Fineman and colleagues³¹ compared 51 prone and 51 supine pediatric patients with acute

lung injury in terms of mechanical ventilation, airway management, and pain and sedation management, as well as EN. These authors determined that there was no difference in feeding complications between the supine and prone positions. They also noted that patients who were fed via the jejunal route reached feeding goal earlier than those fed via the gastric route; however, the study design monitored adverse effects as opposed to actively looking at outcomes.

Prokinetic agents (eg, erythromycin) and HOB elevation of 25° were specifically employed in prone patients who exhibited volume intolerance.³⁰ Delayed gastric emptying is reported in 50%–60% of critical care patients, and multiple factors, including use of vasopressors, and endogenous and exogenous catecholamines, can contribute to the delay. The efficacy of erythromycin as a prokinetic agent exceeds that of metoclopramide, although the effectiveness of erythromycin diminishes over time. Both agents may have a synergistic effect when combined. When the use of small bowel feeding tubes is feasible, it also may increase EN tolerance in prone patients.

The National Pressure Ulcer Advisory Panel (NPUAP) recommends limiting HOB elevation to 30° for an individual on bedrest, unless contraindicated by the patient's medical condition or feeding and digestive considerations. NPUAP also recommends that an individual not be positioned directly on a pressure ulcer.³² Schallom and colleagues³³ have compared research to prevent aspiration and pressure ulcers in critically ill patients and suggest that the optimal elevation to balance the risks for both of these issues is unknown. They recommend that until more evidence is available, caregivers should make HOB elevation decisions in the context of the patient's overall condition. They recommend HOB elevation of 45° for patients receiving EN who require mechanical ventilation or are heavily sedated, but lowering the head to 30° might be done periodically for patient comfort. They also stated that for critically ill at less risk for aspiration (eg, non-mechanically ventilated patients), it is recommended to maintain HOB at 30° and take pressure-relieving measures.

Questions 6.5 and 6.6. Is elevated HOB required for patients without significant aspiration risk? Are there modes of ventilator support that can increase the risk of aspiration (eg, high-volume flows, BIPAP, APRV)?

Practice Recommendations

1. Maintain elevation of HOB at 30° or more for gastric feeding. However, pump feeding interruption for short periods of time to lower the HOB may not be necessary or recommended unless contraindicated.
2. Consider carefully the indication for EN in the patient receiving high-flow modes of ventilation, especially if that patient is concomitantly receiving any sedation.

Rationale

When evaluating the research related to EN and aspiration risk, it is important to note that much of this research has been conducted in patients with critical care status, a factor that may already increase aspiration risk. However, non-critically ill patients may also be at risk for aspiration related to EN.

Patients requiring EN may not be able to protect their airway due to difficulty swallowing or other reasons, and aspiration from oropharyngeal secretions may occur more readily in the supine position. Patients in the supine position may be at greater risk of aspiration due to gastric reflux than those whose heads are elevated either in a bed or chair, while stopping a slow-drip feeding for a brief period to reposition the patient in bed may not be necessary and may even be counterproductive. Assessment of the patient's abdominal and bowel status to check adequate gastrointestinal motility is an ongoing priority in caring for the patient receiving EN. Returning the patient's HOB quickly to at least 30° is imperative.³⁴

High-flow ventilators and bag-valve-mask ventilations increase likelihood of aspiration. However, these therapies are essential in some situations because irreversible hypoxic brain injury trumps the risk of potential aspiration. High-flow volumes by noninvasive ventilation (NIV), noninvasive positive pressure ventilation (NIPPV), or other means can increase the risk of aspiration, and the risk is further increased in the sedated patient.¹⁶ EN is not always indicated in patients on high-flow volume NIV as some patients have learned to eat with high-flow volume NIV without incidence of pneumonia, including patients with neuromuscular diseases such as amyotrophic lateral sclerosis. Guidance from a speech and language pathologist may help determine risk of aspiration, although eating may be a quality-of-life issue for the patient who exercises self-determination and elects to eat and drink while aware of the risk of aspiration.

Meeting EN volume targets for patients with gastrostomy tubes who are receiving respiratory therapies, especially with high-pressure settings, is challenging. Patients who are receiving high-pressure respiratory support via NIV may experience gastric insufflation. A patient with normal muscular function may belch (eructate) to relieve the abdominal distention and then be able to eat or take EN. However, a patient with a weak diaphragm may be unable to belch and may experience gastric bloating and fullness due to aerophagia. This phenomenon happens when pressures to support respiration and the work of breathing force air into the stomach. Early satiety and gastric bloating may cause the patient to be unable to meet EN goals due to feeling sated, sometimes despite feeling hungry. Venting the gastric tube may relieve this condition and increase feeding tolerance toward goals. Some medical centers have developed aerodigestive clinics devoted to serving this client base. When aggressive manual venting (eg, via open syringe) is not adequate, a gastric decompression valve bag may provide additional relief and allow feeding toward volume goals.³⁵

Carron and colleagues³⁶ reviewed optimal head position and use of a nasogastric tube to ameliorate gastric distension, although this review was unrelated to EN use. They detail the sequelae whereby gastric distention compresses the lungs and decreases compliance, which in turn demands higher airway ventilation pressure. They suggest that airway pressures higher than 20–25 cm H₂O should be avoided. Moreover, considering recent evidence of the efficacy of high-pressure NIV in severe chronic hypercapnic COPD, this therapy should be carried out in an almost sitting position approximately half an hour after a meal or EN and with routine gastric decompression care.^{37,38}

Question 6.7. What factors determine the best duration or rate of the feeding to improve the likelihood that the full prescribed dose is received?

Practice Recommendations

1. Minimize interruptions to EN as much as possible to help ensure optimal nutrition delivery.
2. Evaluate brief “NPO” status (eg, for procedures) for need and minimize those interruptions as much as possible. For example, the amount of time that a jejunal feeding must be stopped for a procedure may be different from the duration required for gastric feeding.
3. Accommodate interruptions to feeding delivery when they are anticipated, and plan the feeding schedule to maximize delivery of the daily feeding volume. A volume-based feeding protocol may provide the nurse with latitude in modifying EN administration to meet the patient’s goal safely.
4. Consider patient condition factors and tolerance, lifestyle, goals and convenience, and placement of the distal end of the tube in formulating the feeding regimen to meet patient nutrition and fluid needs.

Rationale

Various scheduling techniques for EN may be used in clinical practice. Volume-based feeding protocols have been recommended to ensure that patients receive adequate nutrition in a given 24-hour period. In a pilot study, Heyland et al⁹ demonstrated improvement in nutrition delivery using volume-based enteral feedings or the delivery of a daily feeding volume target over a 24-hour period that prompts makeup of missed feeding within set guidelines. McClave et al³⁹ evaluated a volume-based feeding (VBF) protocol designed to adjust for delivery interruptions in a prospective randomized controlled trial compared to rate-based feeding (RBF) in which the physician determined a constant hourly rate. On days where feeding was interrupted, VBF patients received a mean of 76.6% of goal calories vs the RBF group, which received a mean of 61% of goal calories ($P = .001$); furthermore, VBF was not associated with vomiting, regurgitation,

or feeding intolerance. These investigators concluded that VBF is safe and improves EN delivery compared to RBF.

In a prospective controlled trial where 164 critically ill patients were randomly assigned to intermittent feeding (one-sixth of the feeding goal was administered every 4 hours) vs continuous feeding, both groups reached the feeding goal by day 7, but the participants in the intermittently fed group reached the goal faster and had a higher probability of being at goal than those fed continuously.⁴⁰ Lichtenberg et al⁴¹ found that 158 patients scheduled for a 20-hour rate to compensate for interruptions had a significantly reduced caloric deficit (and a higher level of overfeeding) compared to 110 patients fed for a 24-hour rate. Van den Broek and colleagues⁴² observed that administered feeding amounts were significantly lower than prescribed in a 4-month study of 55 patients who received continuous pump feeding, portion drip, or combined feeding schedules. A mean energy deficit 1089 kJ/d (range, -7955 to +795 kJ/d) was noted largely due to interruptions for procedures. The delivered feeding was in goal range only in critical care. They suggest adapting EN schedules to accommodate periods when patients are off feedings as well as the use of formulations with higher energy density.

Outcomes of these EN administration protocols may be difficult to demonstrate. de Araujo et al⁴³ studied 41 critically ill patients who received continuous vs intermittent (per pump) feeding and found no statistically significant difference in terms of calories received per day, bowel distention, or emesis for patients who had 6 hours off at night vs those fed for 24 hours per day. It has been suggested that feedings held for a 6-hour period might result in reduced gastric microbial growth due to increased gastric acidity during the off period.⁴⁴

Patient convenience, lifestyle, and preferences are factors to consider when creating the EN schedule, especially when EN is likely to continue postdischarge. A 24-hour feeding schedule is seldom needed, and periods without being connected to feeding may enhance patient lifestyle. It may therefore be advisable to individually assess the feeding schedule of each patient, including those in long-term care settings.

Although jejunal feeding may be better tolerated as periodic continuous feeding (eg, nocturnal feeding), the delivery schedule options are limited compared to gastric feeding. Nocturnal feeding may be used to encourage daytime oral intake; however, the patient’s appetite may still be dampened, and it may be challenging to determine the adequacy of meals and modify the EN volume accordingly. If oral intake is encouraged and a gastric tube is being used, postmeal gravity bolus feeding can be infused immediately after each meal to promote the patient’s appetite for the next meal, and the amount of feeding can be adjusted according to the adequacy of intake of each meal (eg, use half of the EN volume after half of the meal is eaten). When oral intake is discouraged (eg, because of marked dysphagia) but a patient is in an environment involving food, EN can be administered prior to encounters with people eating to dampen the patient’s appetite and reduce the desire to eat.

When continuation of EN into the home setting is anticipated, clinicians can implement the home schedule (such as gravity bolus meal-like feedings) in the acute care setting before discharge. This approach allows the acute care team to not only work toward the feeding goal and assess patient tolerance but also provide the patient or family as much assistance and training as possible before discharge.

Question 6.8. What practices maintain safety throughout EN administration in regard to pump issues?

Practice Recommendations

1. Purchase best-performing pumps and follow manufacturer recommendations for pump use and maintenance.
2. Ensure that institutional biomedical engineering departments periodically test, according to manufacturer recommendations, whether pumps continue to meet the accuracy rates and whether alarms function.
3. Consider a volume-based ordering system as opposed to a rate-based delivery when appropriate to optimize delivery of the total volume in a set time period.
4. Compare time of container initiation with completion of infusion of container in terms of expected delivery amounts as a double-check of accuracy of delivered volume.
5. Zero the volume delivery amount on the feeding pump at the beginning of a time period, such as usual intake and output assessment period. This can serve as a check of amount delivered, especially when that volume is the same as the expected delivery volume. When the volume delivered varies from expectations, additional investigation regarding the variance is in order.
6. Use lightweight, portable, user-friendly, and accurate pumps. For patients who may require continued pump use in the home setting, consider the simplicity of use and reliability of the pump. If possible, begin use of the pump to be used in the home care setting before the patient is discharged from acute care.

Rationale

Enteral feeding pumps are used to ensure accurate, consistent feeding delivery with an alarm designed to signal interruption or alteration to this delivery. Patients and caregivers who rely on and are responsible to account for this consistent delivery expect that an alarm will sound for any deviation from what is prescribed in terms of delivery and that the volume-delivered feature represents actual volume delivered in a specific time period. However, pumps have been shown to deliver rates and volumes that vary from the prescribed settings.⁴⁵ Accuracy in delivery is important for all who rely on enteral feeding pumps because even small variances over time can have a significant impact on

the patient's nutrition status. Particularly in vulnerable neonates and young children, small differences in the rate and volume of feeding can lead to major consequences.

White and King⁴⁶ discuss 4 areas for safety regarding the use of enteral feeding pumps: (1) the consistent and accurate delivery of formula, (2) the minimization of errors regarding tube misconnection, (3) the impact of feed delivery itself, and (4) the potentially toxic chemical composition of the casing used in pump manufacture, although sets free of di(2-ethylhexyl)phthalate (DEHP) are now marketed. They assert that accuracy, safety, and consistency are important for patient confidence and acceptance of feeding pumps.

The potential unreliability of pumps can be a source of stress not only for staff and caregivers but also for patients, including those in home settings, who may be concerned when fluid remains in delivery containers at the end of a programmed pump delivery period or, to the contrary, if feeding infuses more quickly than expected. In 1 study of home EN in 34 pediatric patients with inherited metabolic disorders, 75% of families of children surveyed reported sleep disturbances related to alarms, and 50% of home patients experienced faulty pumps that affected accuracy and, in 1 critical incident, led to underfeeding.⁴⁷ These authors published the review of enteral pumps, suggesting that formula delivery is accurate to within $\pm 10\%$ of what is programmed. Some pediatric and adult systems report adhering to deviance rates of only $\pm 5\%$.⁴⁶

Pump inaccuracy has been identified as a primary contributing factor in both underdelivery and overdelivery of feedings.⁴⁸ Tepaske et al⁴⁵ looked at 13 commercially available pumps tested in a laboratory setting in 12 sessions with different tubes and formulas. Formula delivery differed from preset to actual delivery over a 24-hour period, with deficits ranging from 0.5%–13.5%, and differences of +66 mL to –271 mL per 24 hours. Decreased accuracy was attributed to the feeding pump vs formula viscosity or resistance in delivery; however, only 1 pump of each type was tested in this study, and EADs varied between 6 and 16 Fr in diameter. Spronk et al,⁴⁹ who tested 14 feeding pumps (6 Kangaroo 324 pumps and 8 Kangaroo 224 pumps), noted that discrepancies of up to 24 mL/h below the preset volume occurred despite frequent calibrations by technical service using weight volume analysis. They discuss that differences in delivered volumes could be due to viscosities of formula or bending or twisting as the patient moves. They recommend monitoring pump function in various settings and conditions, suggesting that technical service, age, and depreciation of pumps influence their accuracy. For one brand of enteral feeding pump, a 2011 report was issued to warn that users who incorrectly pressed a certain key sequence might conclude that an inoperable pump was infusing and consequently be at risk of hypoglycemia due to lack of feeding.⁵⁰ Additionally, incorrect key presses may cause a particular type of pump to appear to be infusing even though an occlusion exists.⁵⁰ Older reports of inaccuracies exist from 2003 and prior, but these findings may not be generalizable to newer pumps.

Manufacturers establish accuracy rates for their specific pumps and generally fall within the accuracy rates as described above.⁴⁶ Low-flow rates combined with high-dose settings may exceed the life of the disposable set and should be replaced every 24 hours to maintain delivery accuracy, allow proper air and occlusion sensing, and prevent growth of bacteria. Therefore, avoid programming a rate and dose combination that exceeds a 24-hour feeding regimen. Pumps should be used exclusively for enteral formulas or human milk and not interchangeably for medications and EN. When using HBM in infants, syringe pumps are used to minimize the loss of HBM in a feeding bag.

Question 6.9. Can the EN feeding system be a source for contamination and infection and how can contamination in the EN feeding system be best prevented?

Practice Recommendations

1. Use a closed EN delivery systems when possible.
2. Follow the manufacturer's recommendations for duration of infusion through an intact delivery device (container and administration set).
3. Do not reuse the enteral delivery device for open or closed systems (container and administration set in excess of what is recommended by the manufacturer).
4. If open systems are used, follow recommended hang times and avoid topping off remaining formula, which may result in a continuous culture for exponential microbial growth.
 - a. Limit infusion time for open EN feeding systems to 4–8 hours maximum (12 hours in the home setting).
 - b. Limit infusion time for a reconstituted powder product or modular to 4 hours maximum.
 - c. Change the delivery device (container and administration set) according to the manufacturer's recommendations for open systems.
5. Be aware that the addition of modular units to an open feeding system may result in an unacceptable risk of contamination in hyperthermal environments.
6. To limit the risk of microbial growth and biofilm formation, avoid unnecessary additions to the EN administration set. If additional equipment, such as 3-way stopcocks, are used, follow manufacturer recommendations or facility protocol for change and cleaning practices.
7. Establish and follow protocols for preparation, handling, and storage of commercial and handmade EN.
 - a. Educate those who prepare and administer EN about hand hygiene (a critical point) and safe handling of EN preparation and administration;

- b. extend education to patients and family members/care givers who will continue this practice into the home setting.
- b. Use effective hand hygiene in all aspects of EN preparation and administration. When gloves are used, they must be clean gloves, not having been involved in other nonrelated tasks. The importance of hand washing in minimizing transference of microbial growth and preventing hospital-acquired infections cannot be overstressed.
- c. Give preference to selecting systems that require minimal handling.
- d. Use a clean work surface for EN preparation.
- e. Use equipment dedicated for EN use only.
- f. Store EN formula according to the manufacturer's instructions. Store prepared or opened ready-to-feed solutions in an appropriate refrigerator, discarding any used solutions within 24 hours of preparation or opening.
8. Periodically survey and regularly monitor adherence to the above-listed protocols. Document findings and take appropriate actions if protocols are not followed.
9. Reduce potential for touch contamination of EN-related equipment as well as risk of exposure to body fluids by reducing interruptions to the system, providing a clean work surface (eg, small clean towel under tube/administration connection) and when interruptions are necessary, and using only washed hands and gloves.
10. Keep all equipment, including syringes and containers for flush and medication administration, as clean and dry as possible. Store clean equipment away from potential sources of contamination.
11. Consider whether microbial growth related to EN might be implicated as part of the diagnosis when patients have adverse conditions such as diarrhea.

Rationale

Although microbial growth has been associated with EN in a variety of studies and in a variety of ways, contamination related to EN is an often overlooked source of bacterial infection.^{1,51} In discussing microbial growth, questions arise such as which types and what amount of microorganisms are harmful, what are the associated adverse effects of harmful microbial growth, and what areas related to EN are most strongly correlated with harmful microorganisms.⁵² Patients who require EN may be immunocompromised, at least until their nutrition status is improved, and they rely on healthcare professionals to minimize risk related to EN delivery.

Hospital-prepared EN poses the risk for foodborne illness or nosocomial infection.^{38,53,54} Blenders used in reconstituting formulas have been cited as a primary source of contamination.⁵⁵ Diluting formula hung for a period of time is no longer

recommended because additions to the EN system increase risk of microbial growth.

Water that is hung as a separate infusion to the EN delivery device may also serve as a source for exponential microbial growth, especially when the water is hung for extended periods (eg, >8–24 hours); however, reporting of well-designed research in this area is lacking.

In a prospective, descriptive study, cultures were taken from 30 pediatric patients every 4 hours as they were administered continuous feeding of decanted formula over a minimum hang time of 12 hours with formula added per “current practice.” Out of 111 usable cultures, 100 had no growth, 6 had growth below the FDA threshold for contamination, and 5 cultures in 2 patients grew coliforms with no evidence of bacterial gastroenteritis over the 48-hour data collection period.⁵⁶ In this study, decanted formula used for pediatric patients had a lower growth rate over a 12-hour period than anticipated when recommended handling procedures were followed.

Perry and colleagues⁵⁷ compared closed EN systems with open systems and open systems with modular additives in a critical care burn unit. No microbial growth was found in closed and open systems in the thermoneutral and hyperthermal critical care, nonpatient environment, although humidity was not reported. Microbial growth was noted in both temperature environments in the open system with modular additives. Significant growth in the open system with modular additives was noted in the hyperthermal environment, where 30% of samples exceeded FDA standards by 4 hours and CFUs were too numerous to count by 8 hours. These investigators concluded that the addition of modular units to an open feeding system may result in an unacceptable risk of contamination in hyperthermal environments.

A wide variety of organisms was recovered from neonatal feeding tubes in studies by Juma and Forsythe⁵⁸ and Hurrell et al.⁵⁹ In Juma and Forsythe’s study, some of the organisms were encoded for antibiotic resistance.⁵⁸ Hurrell and colleagues reported that a multitude of organisms, including antibiotic-resistant ones, was identified in 129 feeding tubes collected from 2 neonatal intensive care units (NICUs), and *Klebsiella pneumoniae* and *Serratia marcescens* caused infections in the 2 NICUs.⁵⁹ The significance of biofilm formation in enteral feeding tubes, which constitutes a risk factor for susceptible neonates, is highlighted in another report by this group of investigators.⁶⁰ Biofilm growth on 3-way stopcock valves used within the feeding delivery system can cause nosocomial infections; *Pseudomonas aeruginosa* was found to develop a bacterial biofilm in these valves within 3 days.⁶¹ These valves may be used with no routine change time or care practices and may be exposed to many interruptions and manipulations.

System design has been suggested to play an important role in reducing bacterial contamination. Retrograde spread of the patient’s own flora has been identified as a source of contamination in EN administration sets, and system design improvements (such as recessed spikes on administration sets) have been recommended to reduce potential touch contamination.⁶² Mathus-Vliegen et al⁵¹ reported that the large amount of

potentially pathogenic bacteria found in delivery sets was likely related to the endogenous vs exogenous route, potentially due to retrograde microbial growth.

In a study of EN-related equipment, clean, dry feeding equipment had less microbial growth than feeding equipment that retained moisture, feeding formula, and other media for microbial growth. Syringes stored for up to 5 days in a clean, dry fashion as 2 pieces (ie, piston being removed from the barrel of the syringe prior to storage) had less microbial growth than more newly obtained syringes (eg, 12 hours) that housed moisture where cultures exceeded standards for both type and amount of microbial growth. Also noted, feeding tubing administration caps taped upright to IV poles had significantly more adverse microbial growth cultured from them than caps that were stored in a manner to prevent moisture retention.⁵²

Ho and colleagues⁶³ found a strong correlation between cultures taken from staff hands and contamination of tube hubs, enteral feeding, and nasopharynx and gastric fluid, and the investigators noted a significant reduction in contamination in the group that received an infection control program (ICP). Hand contamination with methicillin-resistant *Staphylococcus aureus* (MRSA) was highly correlated with contamination of the EN system, and these authors recommend ICPs in long-term care settings. The effect of touch contamination has been demonstrated in syringes,⁶⁴ and healthcare professionals must take measures to avoid the transfer of microbial growth from hands to patient care items and areas, such as the inner aspect of a feeding tube. The importance of appropriate hand hygiene and clean glove use as indicated cannot be overstressed. Additionally, a clean surface (eg, a clean small towel under tubing prior to disconnections or manipulation) may reduce inadvertent touch contamination from less clean areas. Changing delivery systems at once is less risky than topping off the volume of formula.

Reuse of feeding bags for the home setting is sometimes considered a cost-saving measure. Oie and Kamiya⁶⁵ found that washing feeding bags with water and then 0.1% sodium hypochlorite (ie, bleach) solution significantly reduced microbial growth ($P < .01$) compared with washing with water alone. Rinsing of continuous EN sets used for 24 hours with tap water was not determined to decrease contamination when cultured at 8 and 16 hours in a 2-group comparison (rinse vs nonrinse).⁶⁶

Williams and colleagues⁶⁷ conducted a randomized controlled trial and concluded that aspirating GRVs less frequently in critical care was not correlated with increased patient risk of complications from EN but could potentially reduce the risk of contamination of the feeding circuit and the risk of exposure to body fluid. In another study, Williams et al¹⁶ identified other strategies to reduce interruptions to enteral feeding that might increase risks of contamination and negatively affect nutrition outcomes.

Adverse events related to microbial growth in EN have been addressed, but additional research in this area may prove to be of benefit. *Clostridium difficile* and associated diarrhea in hospitalized tube-fed patients have been correlated with EN, especially in those receiving postpyloric feeding.^{68,69} With the steady increase in this very serious

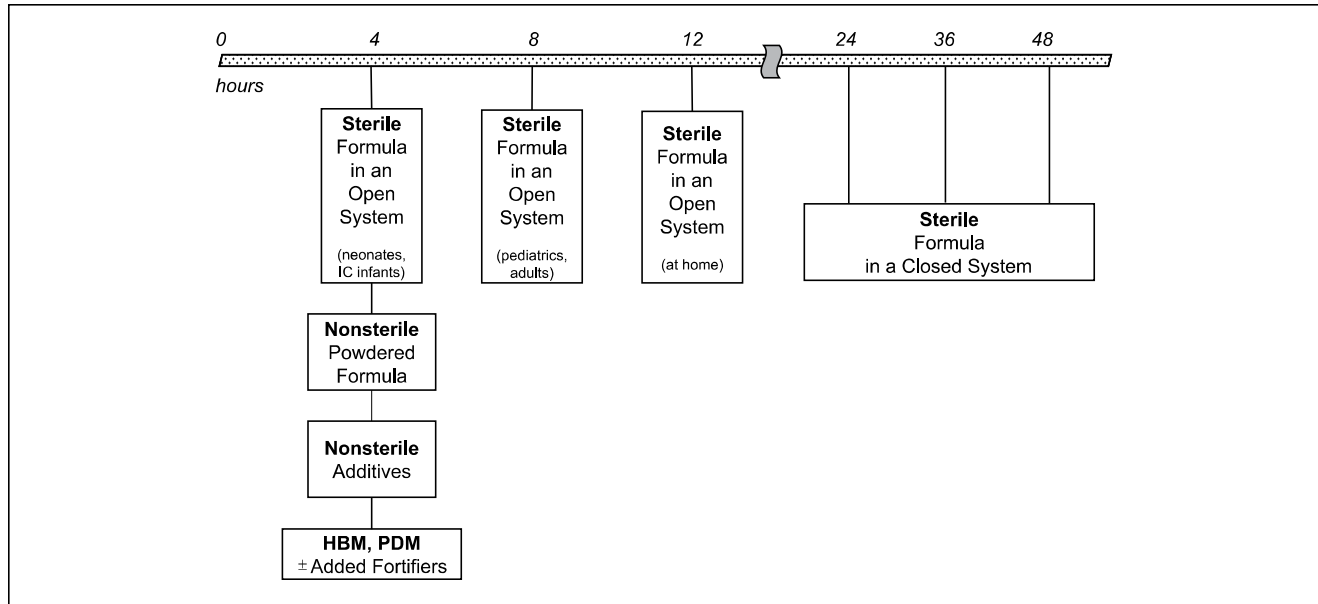


Figure 9. Hang times for enteral nutrition. HBM, human breast milk; IC, immunocompromised; PDM, pasteurized donor milk.

malady, every potential correlation must be considered, including medications, underlying disease, and prior status, but bacterial contamination must also be considered.⁷⁰ There are many potential causes of frequent and/or loose stools, including medications, underlying disease, and prior status, but bacterial contamination must be considered.⁷⁰ In an observational, retrospective study of EN use in 175 hospitalized poststroke patients compared 24-hour hang time vs 72- or 96-hour hang time, the 24-hour hang time was independently associated with a lower risk of diarrhea and longer diarrhea-free survival.⁷¹ Jack et al⁷² reported a 78% incidence of diarrhea in 55 patients using EN, and the frequency increased with longer periods of enteral feeding. They recommended that organizations use a diarrhea risk management algorithm. Hurt et al⁷³ suggested that incorporation of EN as a base strategy for stress ulcer prophylaxis to reduce the need for acid-suppressive therapy may reduce *C difficile* pseudomembranous colitis. Others have recommended allowing stopping EN for periods of time (eg, 6-hour break) to allow gastric pH to return to its more normal acidic pH to help reduce gastric microbial growth.⁴⁴

Healthcare organizations that follow national standards practice recommendations (eg, Hazard Analysis and Critical Control Point [HACCP] and National Institute for Health and Clinical Excellence [NICE] 2012) in training and monitoring staff who work with EN can reduce and contain microbial growth.^{74,75} For example, Oliveira et al⁵⁵ reported that a hospital reduced bacterial count from 10^5 CFU/mL to 10^1 CFU/mL by following HACCP guidelines for preparation, storage, and delivery of enteral feeds and using a flowchart and monitoring critical control points defined using a decision tree based on

HACCP guidelines. If using a threshold of 10^5 CFU/mL, then EN delivery sets should be used within 24 hours.⁶⁶ See Figure 9 for hang times for EN and Figure 10 for an overview of potential contamination points in EN.

Question 6.10. Under what circumstances (if any) should EN be held to improve patient safety (prior to transportation, prior to procedures, surgery, or extubation)?

Practice Recommendations

1. Avoid interruptions or holding EN for routine interventions, including endotracheal extubation and procedures where short periods of HOB lowering are needed.
 - a. Perform a thorough assessment for oropharyngeal secretion retention and potential for reflux of gastric fluid by a qualified professional.
 - b. Disconnection of EN equipment not only decreases nutrition delivery and increases potential microbial growth of related equipment but also increases the risk for tubing misconnection.
2. Consider risk vs benefit regarding disconnection of EN on an individual basis as it reduces needed nutrient delivery and may increase safety risk.
3. Follow the American Society of Anesthesiologists preoperative fasting recommendations⁷⁶:
 - a. Human milk—4 hours
 - b. Infant formula—6 hours
 - c. Nonhuman milk—6 hours

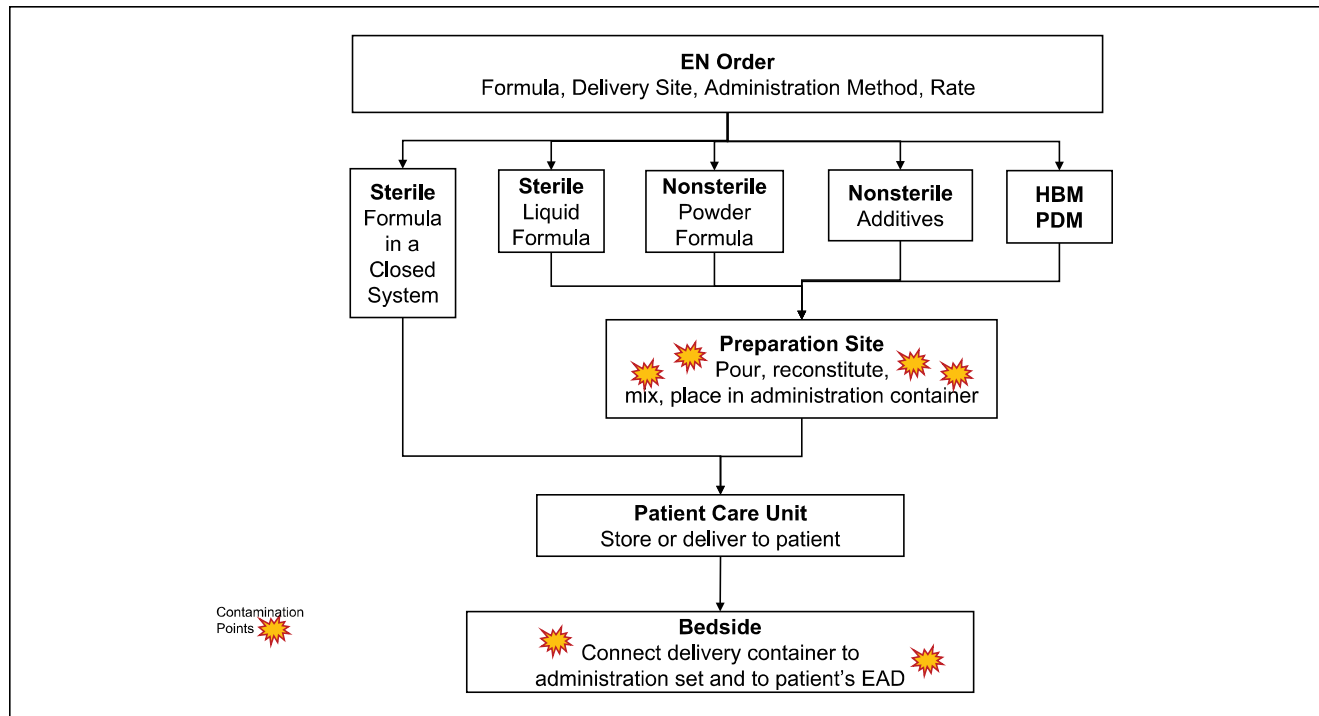


Figure 10. Contamination points in formula preparation. EAD, enteral access device; EN, enteral nutrition; HBM, human breast milk; PDM, pasteurized donor milk.

Rationale

Safety can be built into all aspects of patient care, and ownership for safety integration must be an expectation of all healthcare professionals. When EN is held for tests and procedures, patients are deprived of nutrition and fluid unless lost volume is effectively made up during the other hours of the 24-hour period. Peev et al⁷⁷ compared avoidable and unavoidable interruptions in EN and equated interruptions in EN delivery to undesirable outcomes such as underfeeding and prolonged length of hospitalization. Withholding feeding can be done as necessary, but decisions based solely on tradition are not advisable. Instead, clinicians are encouraged to use evidence and critical thinking to decide whether to interrupt feedings. Williams and colleagues¹⁶ have reviewed means to reduce avoidable interruptions.

Transporting patients between departments, areas, facilities, or care settings increases the potential for disconnection and misconnection of the enteral feeding system, delay of feeding resumption, and potential tube clogging, as well as deviation from usual preventive practices, such as maintaining HOB elevation. Intrahospital transportation has been identified as a risk factor for pneumonia. In a cohort-matched design study of critically ill ventilated patients, 118 patients were transported (primarily for radiologic procedures) and 118 were not. Of those who were transported, 26% developed ventilator-associated pneumonia (VAP), as opposed to 10% of those who were not transported.⁷⁸ Three independent risk factors for VAP were identified in this study: the need for reintubation, EN, and intrahospital transport. It was not clear whether alteration in HOB positioning was a factor in these

outcomes. During transport, appropriate hand-off between qualified personnel is essential. Documentation of line tracing and ready access provide resources if concerns or questions arise.

Depending on the context, turning continuous EN off for lowering the HOB for a brief time may be unnecessary and even counterproductive in terms of reduced feeding volume, risk of forgetting to turn the feeding back on, and increased potential for tube clogging. If the HOB must be lowered, it should be quickly reelevated to 30°, or preferably 45°, unless contraindicated.^{28,34} Another possible option is to reposition the patient in reverse Trendelenburg while feedings infuse. The patient clinical condition may be a more influential risk factor for reflux and aspiration than the small per-minute volume of feeding delivery. Oropharyngeal suctioning and assessment of patient condition, including abdominal assessment, may be more helpful in tempering aspiration risk than stopping small-volume feeding infusion for a short period for lowering the HOB.

The standard practice of NPO after midnight prior to procedures and surgery has been challenged and warrants patient-specific consideration regarding its appropriateness and risks and benefits.⁷⁹ For example, jejunal feeding may not need to be held for the same time period as gastric feeding, especially when gastric decompression may be an option prior to a procedure. In a study by Moncure and colleagues,⁸⁰ 46 patients with jejunal tube feeding that infused until they were transported to the operating room were compared to 36 patients who had jejunal feeding held for 8 hours prior to surgery. No aspiration was noted in either group, and the investigators concluded that jejunal feeding may safely continue until the time of surgery.

In a prospective, observational cohort study, critically ill, mechanically ventilated patients were fed via gastric tube until 45 minutes prior to selected operative and nonoperative procedures or via duodenal tube until the procedure started. Pousman and colleagues⁸¹ found a trend in the intervention group toward increased nutrition administration and faster attainment of target goals, with no statistically significant difference between the usual practice group and the patients with the reduced fasting protocol.

The American Society of Anesthesiologists have published practice guidelines for preoperative fasting timeframes for elective procedures. These include discontinuing various liquids prior to an elective surgical procedure. Those liquids pertinent to the patient receiving EN include human milk, infant formula, and nonhuman milk. A 2-hour fasting time period for those receiving human milk is recommended, a 4-hour time period is recommended for infant formula, and a 6-hour time fasting period is recommended for those receiving nonhuman milk.⁷⁶

The practice of holding EN for patient conditions also warrants critical appraisal. For example, McClave and Chang⁸² have concluded that “evidence of gastrointestinal bleeding is not an automatic contraindication” to EN; rather, EN may protect the gut mucosa and further reduce bleeding, increase the risk for rebleeding, or “serve as a moot point with no relation to further bleeding.” They discuss reasons to consider continuing or holding feeding for a period of time, depending on etiology of the bleeding. Other decisions about interrupting EN, such as whether to hold feeding for a period prior to endotracheal extubation or for medication administration, will also depend on the specific situation and the best evidence available to the clinician.

Question 6.11. What is the most accurate method to measure the amount of formula infused (ie, recorded I/O, marking the bottle or bag)? Who is responsible for monitoring whether the amount recorded was actually infused?

Practice Recommendations

1. Do not rely on pump rate and volume settings **alone** to determining the amount of feeding infused. Calculate the hourly rate multiplied by the hours infused, allotting for any downtime and use other methods to double check and ensure accuracy of volume infused. Compare that volume to the pump history of volume infused for an accurate measure of intake.
2. Document the volume of EN and other fluid administered and investigate when suboptimal nutrition and fluid seems to have been delivered. Serve as patient advocates to promote best nutrition and fluid delivery.
3. Monitor nutrition and fluid trends, including any gaps in delivery, and pursue methods to enhance delivery as indicated.
4. Implement methods to ensure that adequate nutrition is being administered for patients who continue EN after they transition from acute care to another setting.

5. Tailor ordering methods to help ensure that accurate nutrition volumes are delivered:
 - a. Consider volume-based feeding schedules where a specific volume is to be infused in a 24-hour period.
 - b. Use an easily measurable volume, such as one or two 1-liter containers/d or 2 cartons (cups) of feeding per EN “meal,” in orders for EN in the home care setting.
6. Institute systems to embed accountability and oversight for accurate delivery of nutrition intake, including methods of ordering and documenting actual intake. Have policies and procedures to determine whether systems are suboptimal or break down, and use system improvement methods to address problems.
7. Encourage use of electronic connectivity between enteral pump and the intake portion of the EHR to document EN volume infused.

Rationale

Many stakeholders are involved in ensuring that adequate feeding volumes are infused, including the patient/family, direct care staff, and those who oversee specific aspects or the overall management of the patient course, from recovery to healing and maintenance. Daily care staff are responsible to account for EN infusion volume over a specific period. If the infusion rate is multiplied by the number of hours infused, there is a risk that periods when feeding was held may be inadvertently omitted from the intake record. Feeding pump infusion volume may also be an unreliable measure. Volume-based ordering has been recommended over rate-based ordering for more accurate EN delivery.^{39,48,83} Sometimes, staff or patients themselves question why 100 mL of EN remains after an overnight infusion when the total volume should have infused. However, when the less-than-optimal infusion volume is not noticed, nutrition deficits can accrue. Professionals who oversee the broad aspects of EN delivery volume use records of daily feeding volumes to assess the overall EN delivery trend and its effects. They may be responsible for establishing and updating the nutrition plan based on trends and outcomes. Delivery and calculation of EN formula may be more accurate when volumes can be ordered in specific amounts, such as 2 cartons/cans/cups of feeding 3 times per day or one 1000-mL container per night. Similarly, if water intake is ordered in specific amounts and accountability for it is built into the EHR, such as via the medication administration record, delivery may be more reliable and accurate. Also, when water is described in terms of household measurements, such as a cup of water, the patient, family, and staff might more easily equate feeding to meals.

Enteral feeding pump inaccuracy contributes to the discrepancy between ordered and delivered formula volume. Feeding pumps may either overdeliver or underdeliver prescribed volume within the prescribed timeframe.^{84–86} Deficits of 0.5%–21% have been observed.^{84,85} The set rate on the

pump does not always correlate with the amount of formula delivered, and this discrepancy may be responsible for up to 81% of cases where the patient does not receive the prescribed amount of formula.⁷⁶ Advances in enteral feeding pump technology may improve accuracy.

Double-checks and assessments for accuracy of delivered amounts such as comparing formula amount and time hung with amount remaining at the end of a time period compared to expected delivered amount can help detect inaccuracies of EN delivery.

Topics for Future Research

- Comparison of gastric vs small bowel feedings on clinical outcomes in patients requiring prone positioning
- The advantages and disadvantages of holding enteral feedings for surgical procedures and for what duration prior to the procedure
- Incidence of overt or microaspiration in patients fed via the bolus method
- Jejunal feeding transition from continuous to intermittent or bolus method for patient convenience
- Feasibility of transferring enteral volume data directly from enteral feeding pump to the EHR

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