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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 colleagues[23] 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 colleagues[24] 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 al[44] 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 guidelines[60] 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 Bjork[59] 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 10^3 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 al[35] 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 al[83] 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

• 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"
	• 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:
	  ○ 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.
[a]Date-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

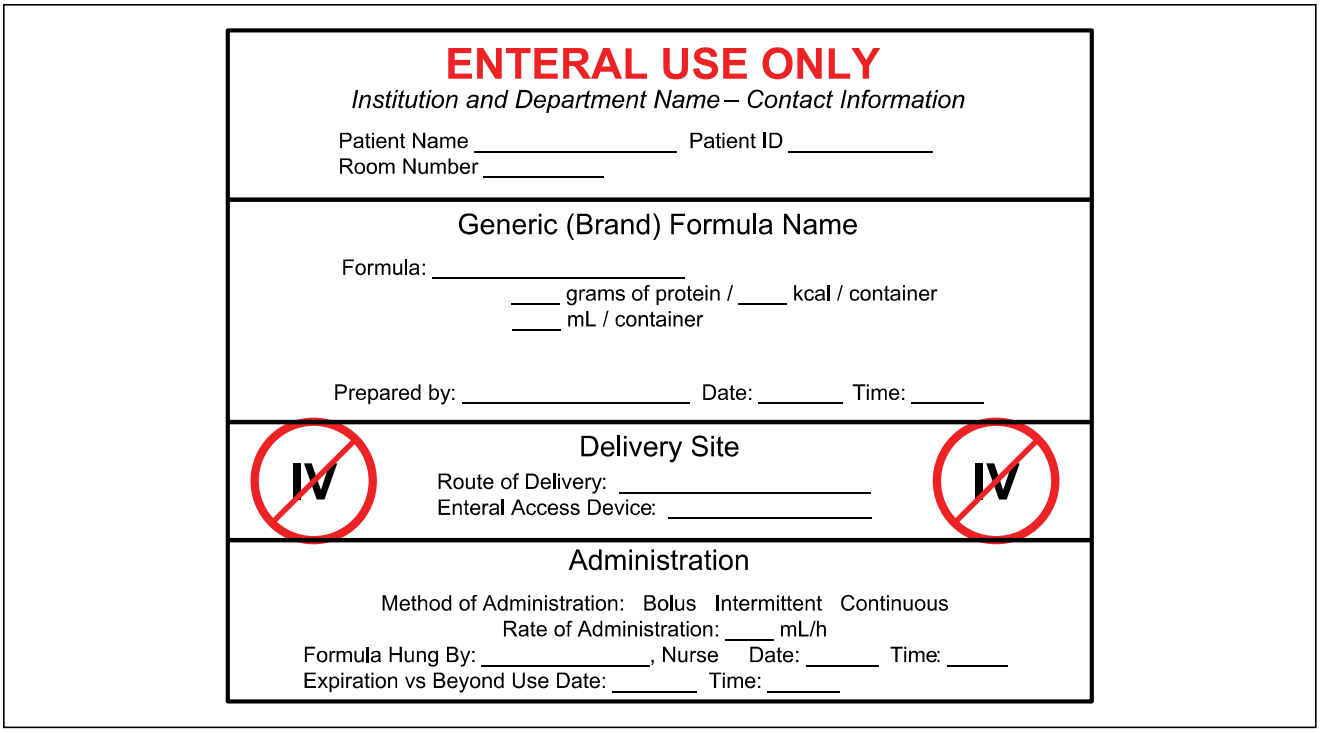

Figure 5. Standard enteral nutrition (EN) label template (adult patient). ID, identification; IV, intravenous. Adapted from Bankhead R, Boullata J, Brantley S, et al. Enteral nutrition practice recommendations. *JPEN J Parenter Enteral Nutr*. 2009;33(2):122-167.

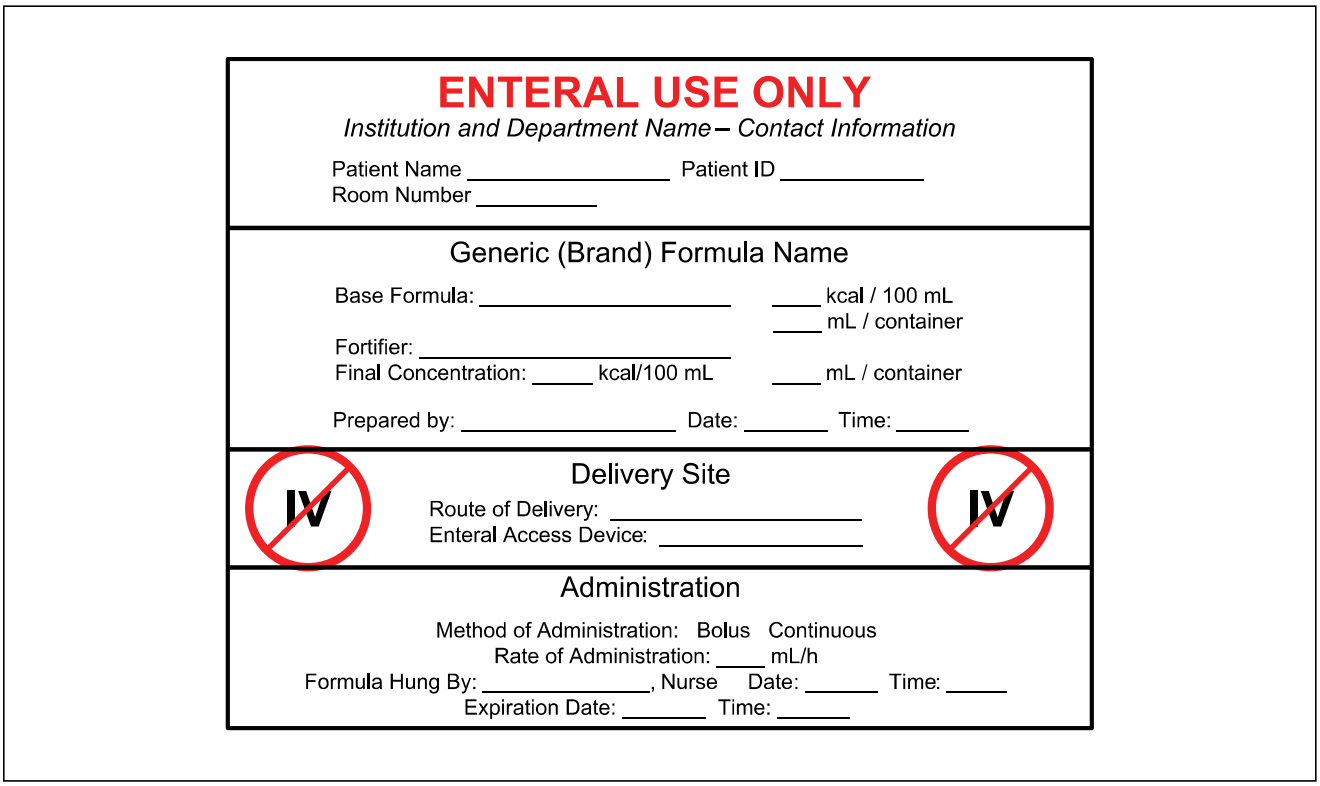

Figure 6. Standard enteral nutrition label template (neonatal or pediatric patient). ID, identification; IV, intravenous. Adapted from Bankhead R, Boullata J, Brantley S, et al. Enteral nutrition practice recommendations. *JPEN J Parenter Enteral Nutr*. 2009;33(2):122-167.

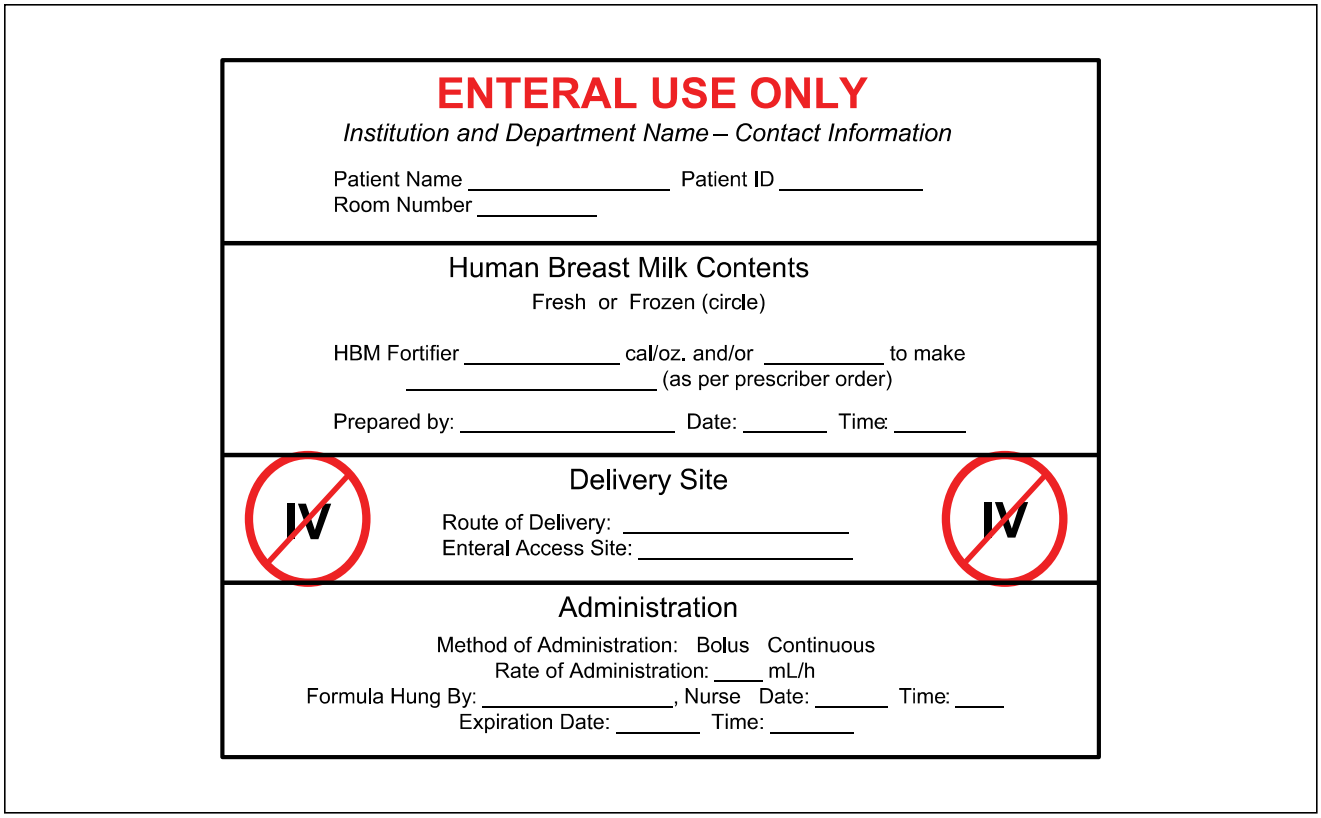

Figure 7. Standard human breast milk label template (infant patient). HBM, human breast milk; ID, identification; IV, intravenous. Adapted from Bankhead R, Boullata J, Brantley S, et al. Enteral nutrition practice recommendations. *JPEN J Parenter Enteral Nutr*. 2009;33(2):122-167.

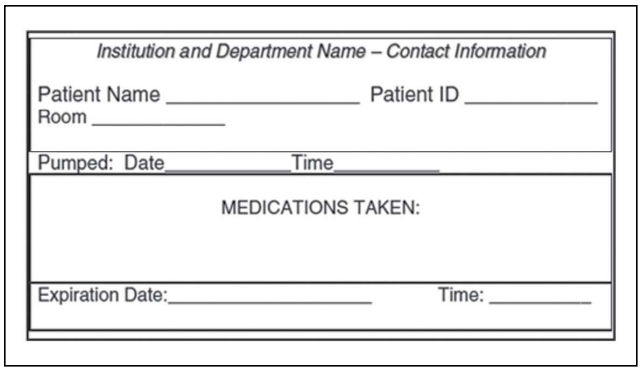

Figure 8. Human breast milk storage label. ID, identification. Reprinted from Bankhead R, Boullata J, Brantley S, et al. Enteral nutrition practice recommendations. *JPEN J Parenter Enteral Nutr*. 2009;33(2):122-167.

- 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 misconnections, 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.