

Infant Feedings:

Guidelines for Preparation of Formula and Breastmilk in Health Care Facilities

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Delivery and Bedside Management of Infant Feedings

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At the bedside, careful handling of formula continues to be extremely important. The nursing staff, primarily, are responsible for ensuring that proper handling techniques are used once the formula has been delivered to the patient care unit and is safely refrigerated. Written policies are necessary to ensure that safe and appropriate procedures for product handling and delivery are in place and monitored.

Storage on Patient Unit

All formulas and expressed breastmilk (as well as feeding additives and supplies, if possible) should be stored on the patient unit in a secured area or in one with limited access, to avoid possible tampering or contamination. Temperatures in refrigerators must be suitable for safe food handling and should be used for patient food only, not medications or employee items. Ready-to-feed formulas, feeding supplies, and any additives not requiring refrigeration should be stored on clean, dry, covered shelves or in cabinets with protection from any environmental contaminants—eg, water splashes, dust, or cleaning supplies. Any items taken into an individual patient room should not be returned to the storage area or used for other patients.

Prepared formulas, thawed or fresh expressed breastmilk, and any additives requiring refrigeration must be stored in patient unit refrigerators. Ideally, expressed breastmilk and formula should be in separate refrigerators, but if this is not possible, expressed breastmilk must be stored in an individual bin labeled for a patient and on the lower shelves, to avoid any possibility of leakage onto prepared formula containers. If prepared items are to be stored on shelves attached to the inner door space, temperatures should be monitored to ensure that the refrigeration unit is maintaining a safe temperature.

A freezer needs to be available for frozen expressed breastmilk. Separate bins or sealable plastic bags need to be provided, to separate the expressed breastmilk for individual infants. For additional guidelines for storage, see Chapter 5, Expressed Breastmilk.

To avoid cross-contamination, other foods should not be stored in the patient unit refrigerators or freezers designed for prepared formula and expressed breastmilk storage, if at all possible. Frequent opening of unit refrigerators and freezers may result in temperatures that are unsafe for food or infant feeding storage.

Bottle Preparation

When preparing individual units for nipple or tube feeding, the following should be considered:

- Formulas should be handled on a clean, dry, disinfected surface. This same area may not be used for potentially infectious wastes—eg, weighing soiled diapers.

- Use hand hygiene before handling formulas, bottles, or other feeding devices.
- Bulk containers must be checked for the patient's name, identification number, and the expiration date. The formula label information should be checked to make sure it matches the current formula order. If there is any discrepancy, the formula room staff or a dietitian should be contacted for the appropriate formula.
- When pouring specially prepared formulas from a bulk container, remove the formula from the refrigerator immediately before pouring and return as quickly as possible to the refrigerator. Container and lid integrity should be evaluated for clearliness.
- For bottle or tube feedings, a graduated feeder should be used for feedings of 60 mL or less, and a standard single-use bottle with ounce or milliliter markings should be used for larger amounts.
- After pouring in the desired amount, cover immediately with the appropriate cap or nipple, leaving the protective covering intact until ready to feed. Formula should never be poured back into the bulk container once it has been poured into another container. It should be discarded.
- In the event that feedings are poured for more than one infant or that the container will be set down before delivery to the patient's bedside, the individual container should be labeled with the patient's name, identification number, full formula name and any additives, time poured, and date.
- All bottles, nipples, and graduated feeders should be used only once. Home bottles should not be permitted, except for special feeding purposes (eg, Haberman feeders).
- If using a specialty bottle or nipple that is not disposable and is meant to be reused, the feeding unit should be washed in warm, soapy water in the unit, rinsed well, and sterilized at least daily.

Warming

Although formula is traditionally warmed before feeding, bringing the formula to a warm temperature will promote accelerated bacterial growth. Formula that is to be tube fed via continuous drip does not usually need to be warmed, because it will assume room or body temperature as it travels through the tube. Warming of formula for full-term infants before feeding may not be necessary (1-4). Warming bolus feedings for preterm infants is needed, and older infants may show preference for warmed feedings. Acceptable methods for warming infant formula or breastmilk include electric warming units, warm water baths, and warm running water. The water should not reach the level of the nipple ring, and the lid should not be submersed in the water. Warm water baths should be cleaned and replaced with fresh water on a regular basis, according to institutional policy and any time contamination occurs. If formula is warmed, the process should take less than 15 minutes. Formula should not be stored in formula warmers, because extended warming time has been associated with bacterial growth (5,6).

Microwave ovens should *never* be used to warm infant formulas, because of the danger of overheating and the creation of hot spots. Feeding an infant overheated formula can burn the infant and the caregiver (7-10). When microwaved, the bottle may remain cool while the formula inside is heated, and it is easy to overheat the formula unintentionally (11). Overheating also causes vitamin loss.

Label Verification

Before feeding infant formula, the appropriate nursing personnel must verify the label for the correct patient name and identification number. The current formula order should be verified with the formula name on the label, including kilocalories per ounce and all additives. If feeding a ready-to-feed formula, the seal should pop when the bottle is opened. The expiration date should also be checked for both prepared and ready-to-feed formulas.

Bottle Feeding

The appropriate designated personnel or family member/caregiver should wash hands or use an approved hand hygiene method before feeding an infant (12). The nipple cover should be removed only

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after all preparations for feeding are made, immediately before inserting the nipple into the infant's mouth.

All formula for infants should be shaken before feeding. This will not only distribute heat if the formula has been warmed but will ensure that all components of the formula are in suspension. Before placing the nipple in the infant's mouth, the temperature of the formula should be checked by testing a few drops of formula on the inside of the feeder's wrist to confirm formula is near body temperature.

Prepared formula units that are removed from the refrigerator should be used immediately. For intermittent feedings, ready-to-feed individual bottles should be opened just before use. When feedings are decanted into another container, remaining formula may be refrigerated; this formula should be labeled with expiration date of 24 hours from time of opening. For continuous feeds, see Table 6.1.

A policy for administering medications in infant formula should be developed. In general, it is suggested that medications not be added to formula. If medication is added to formula or expressed breastmilk, special precautions and aseptic technique are necessary. The addition of any medication to a formula for infants should be done by properly trained personnel, in compliance with facility guidelines for medication administration. The medication must be compatible with the formula (14). With certain medications, consideration should also be taken for changes in osmolar load. Depending on the medication, addition to a small aliquot of formula may ensure that a complete and maximally effective dose is administered to the patient.

Tube Feeding

The guidelines for this section are based on best evidence currently available and on consensus of experienced practitioners in the field. Manufacturers' recommendations for product use should also be considered.

The following steps should be taken when administering tube feeding:

- Use hand hygiene before handling formulas or administration systems. Using clean, disposable gloves may be beneficial (12,15,16).
- Assemble feeding system on a clean, dry, disinfected surface (not on the patient's bed or top of incubator). Avoid touching any portion of the feeding system that will come into contact with formula (eg, tubing ends, syringe tips, or feeding ports).
- Keep formula refrigerated until ready to use. Use good hand hygiene and aseptic technique when filling, refilling, or changing feeding containers (12,17).
- Hang time of prepared formula and breastmilk should be limited to a maximum of 4 hours (18,19) or less,* with the expiration time clearly marked on the feeding container. If the feeding is interrupted or held or the feeding volume is reduced, there will be formula left in the feeding container beyond the hang-time limit. The entire setup must be replaced with a new supply of formula or breastmilk every 4 hours.
- Hang time of decanted, ready-to-feed formulas is suggested to be 8 hours. Longer hang times may be permitted for immune-sufficient patients. However, shorter hang times are appropriate for immune-compromised infants, newborns, or premature infants. If commercial closed systems become available and are shown to sufficiently decrease risk of bacterial growth, longer hang times may be considered.
- Flush the tube with sterile water or air after intermittent feeds and any medication additions.
- Feeding bags, containers, and tubing should be replaced every new hang time (19-22) (see Table 6.1). When a new feeding container is hung, the expiration time should be clearly marked.
- Allow the feeding containers to empty completely before adding additional formula. Rinsing the bag or tubing between feeds has not been proven to decrease microbial contamination (23).

*One manufacturer of Human Milk Fortifier recommends a hang time of 2 hours for fortified human milk (see Table 6.1).

Table 6.1

Bedside Hang-Time Practices for Infant Formulas

These guidelines are developed for pediatric formulas in the absence of any commercially sterile, ready-to-hang closed systems.

Nutrition Source	Hang Time at Room Temperature* (Hours)		Frequency of Tubing Change (Hours)		Frequency of Feeding Reservoir Change (Hours)	
	Neonates/Immuno-compromised Infants	Infants/Peds: Nonimmuno-compromised Infants	Neonates/Immuno-compromised Infants	Infants/Peds: Nonimmuno-compromised Infants	Neonates/Immuno-compromised Infants	Infants/Peds: Nonimmuno-compromised Infants
Sterile, ready-to-feed	4	8	4	8	4	8
Powdered formulas, concentrated liquid formulas, and nonsterile additives [†]	4 ^{††}	4 ^{††}	4	4	4	4
Expressed breastmilk, including with sterile liquid additives	4	4	4	4	4	4
Expressed breastmilk with added powdered fortifiers	2-4 ^{††}	4	2-4	4	2-4	4

*Hang times should be reduced by any additional time periods that feedings are not at a safe temperature. The time it takes for prepared formulas to reach $\leq 45^{\circ}\text{F}$, transport times that are not controlled for a chilled environment, the time it takes to warm feedings, and any additional times that feedings are not refrigerated should be accounted for as part of the described hang time. In addition, any break in aseptic technique or manipulation of the formulas, such as for the addition of medications, tap water, or modules, should reduce hang time.

[†]Do not use for a preterm or immunocompromised infant unless a sterile liquid alternative is not available and the attending physician has considered the risk/benefit factors for the individual patient.

^{††}One manufacturer recommends a 2-hour hang time for powdered formulas and any powdered additives, including human milk fortifier, when these products are used with neonates and immune-compromised pediatric patients. Powdered formulas are not recommended for this population unless a sterile liquid form is not available. Other manufacturers may have different recommendations. Always check with manufacturers for current recommendations.

Feeding Administration Systems

A number of different options exist for feeding administration systems for intermittent or continuous feedings. For gravity feeding, a gravity feeding set with screw top/drip chamber that can be attached to

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a graduated feeder or baby bottle is an option. Drip chambers were associated with prevention of retrograde bacterial contamination in one study (24). Retrograde contamination occurs when bacteria residing in the patient ascend the feeding tube and results in formula contamination (25,26). An open syringe connected to the feeding tube may also be used for intermittent feeding. Open systems should not be used to deliver enteral feeds unless it is by immediate bolus feeding, with the caregiver holding the open apparatus throughout the feed.

The Food and Drug Administration (FDA) has issued a safety assessment of a plasticizer, di(2-ethylhexyl) phthalate (DEHP) sometimes used in feeding tubes or feeding administration sets (27). The FDA recommends that products containing DEHP be avoided for male infants when devices that do not contain DEHP are available. This recommendation comes from animal models in which DEHP exposure has been associated with liver toxicity and testicular atrophy.

Pumps may be used to deliver an intermittent or continuous feeding. Types of pumps used for neonates and infants include syringe, enteral, and intravenous pumps. A syringe pump is used to deliver small amounts accurately. A typical syringe pump, such as the Auto Syringe AS50 Infusion Pump (Baxter Healthcare Corp, Deerfield, IL 60015), accepts a 1- to 60-mL syringe and can be set for a flow rate of 0.01 to 438 mL/h. Exhibit 6.1 lists recommended features for enteral feeding pumps for use with neonates and infants. Intravenous pumps are often used because of their accuracy at low infusion rates (28). Some intravenous pumps can be set for rates in 0.1-mL increments. Caution must be exercised when intravenous pumps are used for enteral feeding, because the pump should be used only for enteral delivery and not accidentally connected to an intravenous line (29). Unique tubing for enteral feedings—eg, one with a unique color and connector designed for feeding tubing—is *strongly* suggested. Systems with stopcocks should be avoided, because they may degrade in the presence of medium-chain-triglyceride (MCT) oil additives.

Exhibit 6.1

Recommended Features for Enteral Feeding Pumps for Use With Neonates and Infants

- Flow rate in 1-mL increments
- Flow rate accuracy of $\pm 5\%$ for neonates, $\pm 10\%$ for older infants
- Alarm for no flow or occlusion at a low pressure, ie, 12 to 20 psi
- Automatic antifree flow or bolus protection
- Lock-out feature that prevents changing settings
- Interlocking connectors to prevent accidental pull-apart

Features that may not be appropriate for this age group:

- Automatic tube flushing
- Some pumps state that pediatric patients need to be at a specific rate—ie, 25 mL/h or more—before the pump is appropriate to use; check the manufacturer's information
- Systems that can use intravenous tubing or have stopcocks

Continuous feeding regimens are associated with nutrient delivery problems for human milk and with added MCT oil (28). When breastmilk is continuously infused, large amounts of fat may be lost, with separation and layering of fat in the delivery system (30). The adherence of fat to feeding tubing and syringes results in a significant loss of protein as well (31,32). Tilting the delivery system so that the exit point of the feedings is elevated minimizes the loss of fat (33). MCT oil that is added to a formula or breastmilk may separate and/or adhere to the feeding system, with the risk of a fat bolus at the end of the infusion period (34,35).

The pump housing should be disinfected before initial use for a patient with facility-approved antimicrobial spray (nonbleach containing) or 70% isopropyl alcohol. Spills should be wiped off with warm water and a mild dishwashing detergent as they occur and on a regular basis. If there has been exposure to HIV or hepatitis, the pump should be disinfected with a 10% concentration of 5.25% sodium hypochlorite (household bleach). With exposure to tuberculosis, the pump housing should be thoroughly cleaned using a 70% concentration of isopropyl alcohol (36).

Feeding Additives at the Bedside

Whenever possible, additives such as nutrient modules, concentrated liquid formula, and formula powders should be added to formula in the formula preparation room, using aseptic technique. The Enteral Nutrition Council (now the International Formula Council) has cited the addition of substances to formulas at the point of use as a significant source of contamination, because the substances themselves may contain microorganisms (37). Powdered formulas and most additives are not sterile products. The addition of modules may significantly increase the risk of bacterial contamination (38,39).

If addition of additives in the formula room is not possible, dry additives may be measured in the formula preparation room and placed in a clean, food-grade, closed container (40). The container (ie, plastic cup with lid, syringe, and zippered plastic bag) should be labeled with the additive, the volume of formula (or expressed breastmilk) it is to be combined with to make the ordered formula, and the expiration date. If designed for a specific patient, the patient's name, identification number, and room number also need to be on the label. Nursing will then be responsible for adding the appropriate amount of formula or breastmilk and for shaking well before feeding. For liquids, the ingredient (ie, formula concentrate or fat module) may be measured in the formula room in a sterile or oral syringe for the designated amount and placed in zippered bags with mixing instructions and patient information labels. Formula concentrate requires refrigeration until it is used.

If an additive is a vitamin, mineral, or electrolyte, it should comply with facility guidelines for medication administration. Additives such as commercial thickeners and rice cereal may be added by nursing at the bedside. Smaller labeled containers for the individual patient, with a sterilized measuring spoon in a zippered plastic bag, may be more effective at limiting microbial contamination and providing an accurately measured amount.

Colorants should not be added to an infant feeding for detection of aspiration or for any other reason. There is little evidence to support the sensitivity and specificity of colorants as a method of detecting aspiration of tube feedings (41-45). Systemic absorption of enterally administered FD&C blue No. 1 may occur due to enhanced gut permeability in patients who become septic. The coal tar in the dye has been associated with multiple deaths, including that of a 12-month-old infant (46-48). When taken from multiple use containers, colorants may also become contaminated and have been associated with outbreaks of *Pseudomonas aeruginosa* respiratory infections (49).

Parent Demonstrations for Mixing

A policy should be developed to establish how parent education on formula preparation is handled. When demonstrations for mixing formula are included, guidelines should be developed for handling that procedure at each facility. If the patient is in a separate room, a designated clean area within the room may be an acceptable area for the parents to demonstrate mixing techniques. Other options include a separate clean room or the formula room (during a nonmixing period), following the same procedures for cleanliness and using separate product. Any opened, unused product should be sent home with the parent or discarded, not put back into the formula room stock.

Mixing Equipment

Any measuring devices, mixing equipment, or other utensils or devices used for formula preparation outside the formula preparation room should be sterilized before coming into contact with infant formula or additives to the formula. Measuring spoons should be sterilized and placed in resealable plastic bags. Any mixing equipment needs to be sterilized after each use and covered with plastic wrap. Can openers need to be cleaned after each use and the piercing end wiped with an alcohol wipe just before use.

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