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Implementation of an Enteral Nutrition and Medication Administration System Utilizing Oral Syringes in the NICU

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Abstract

NICU patients are at particularly high risk of harm and even death from medical error. In one NICU, a process change was undertaken to minimize the risk of errors resulting in the intravenous (IV) administration of enteral formulas and oral medications. In addition, a double-check system for medication doses was introduced to reduce the likelihood of medication errors. The previous practice was to deliver enteral formulas via syringe pump using IV syringes and tubing and to dispense medications in bulk bottles, drawing up patient-specific doses at the bedside. Converting to oral syringe delivery of medications and enteral formulas utilizing enteral-only tubing eliminated the necessity for Luer-Lok IV tubing and syringes, thereby reducing the potential for wrong-route error. Converting from dispensing medications in bulk to a unit-dose system permitted establishment of a double-check system in which doses are first checked by a pharmacist and then checked by the nurse before they are administered. This article describes the planning, implementation, and postimplementation process required to make this change in practice a success.

Unit-dose packaging of medications has been the standard of care in acute hospital care for many years. Whereas standard adult doses are easily purchased in unit-dose packaging or can be repackaged before they are dispensed, patient-specific oral pediatric doses must be drawn up immediately before use. Many hospitals utilize oral syringes for this purpose to minimize the risk of wrong-route administration. Although this works well for oral dosing, most orogastric, nasogastric, and nasojejunal tubes have Luer-Lok tips that prevent the use of oral syringes. This has been a barrier to the use of oral syringes in the NICU because administration of most enteral medications and nutrition in the NICU is through one of these tubes.

In 2004, we began discussing conversion to an enteral-only system for nutrition and oral medication administration. At the time, our process was to use large intravenous (IV) syringes (20 ml, 30 ml, or 60 ml) to administer enteral nutrition in a specific amount over a specified length of time via a syringe pump. This required the use of Luer-Lok-tipped enteral tubes, Luer-Lok-tipped microbore extension tubing, and syringe pumps. Liquid oral medications were dispensed from the pharmacy in 1-, 2-, or 3-ounce bottles. Patient-specific doses were drawn into small IV syringes by the nurse at the bedside immediately before administration.

The stimulus for our conversion to an enteral-only system was reports from other institutions of wrong-route administration of medications and formula, although wrong-route errors are not the most common error made.[1] But administering an enteral medication or formula parenterally could have devastating consequences. The Institute for Safe Medication Practice has stated that "having [the] pharmacy prepare doses in oral syringes is safer than drawing up medications extemporaneously on nursing units by placing oral liquids into parenteral syringes."[2] The Joint Commission on Accreditation of Healthcare Organizations also requires that "medications [be] dispensed in the most ready-to-administer forms available from the manufacturer or if feasible, in unit-doses that have been repackaged by the pharmacy or licensed repackager" (p. 187).[3] With these driving forces, we felt that converting to an oral syringe system would prevent medication and nutrition

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TABLE 1 ■ Comparison of Existing and Proposed Medication and Nutrition Administration Systems

Existing System	Proposed System	Advantage of Proposed over Existing
IV syringe	Oral syringe	IV and oral systems would no longer interconnect, preventing wrong-route errors.
Medications drawn up by nurse	Medications drawn up in pharmacy	Double-check system: Dosage would be drawn up and checked in the pharmacy, then rechecked by the nurse before administration.
Bulk bottles dispensed	Oral syringes dispensed	Risk of contamination and expiration of product would be reduced.

errors by stopping wrong-route administration, establishing a double-check system, and providing fresher medications to the patient with less risk of contamination (Table 1).

PLANNING

A work group of key individuals from the pharmacy, nursing, and information systems was formed to evaluate converting to an enteral-only system, to identify barriers, and to design creative solutions.

In evaluating this process change, our first barrier was equipment. Only one company manufactures an enteral feeding tube in neonatal sizes with an oral syringe tip, and no compatible extension tubing is available. Also, no syringe pump is engineered to recognize oral syringes.

We worked with the enteral tube supplier, Specialty Medical Products (Woodstock, Georgia), to have an extension tube manufactured to our specifications. The company was willing to provide us with the product, and after about six months, we had a working prototype. None of the syringe pump manufacturers could comply with our request for addition of oral syringes to their programming, but we found that selecting one of the IV syringe settings produced acceptably low error in formula administration time. For instance, a feeding programmed to be delivered over 30 minutes would be complete in 27 minutes. The team felt that this was a minimal amount of error in nutrition and proceeded to use this work-around solution.

We identified a formulary of 24 medications that we use routinely in the NICU, as listed in the sidebar, and that we would begin dispensing in oral syringes. Of these, 6 medications are dosed in standard amounts and could be dispensed from the automated dispensing machine. The other 18 medications would need to be drawn up daily in the pharmacy in patient-specific weight-based doses. Our current pharmacy computer system does not support oral syringes, so special computer programming for dispensing sizes, labeling, and billing was necessary before the pharmacy could proceed. Using the functionality of Crystal Reports Writer (IPS-Sendero, Atlanta), we were able to accomplish this within our institution.

COST ANALYSIS

Establishing an exact cost comparison of the existing and proposed systems was difficult. We knew that dispensing medications in bulk was wasteful and that large quantities of medications were being disposed of after each patient's discharge. Using patient averages for a two-week medication regimen, we calculated that we would save between $10 and $15 per patient-day. With an average daily census of 22, that translated into per-day savings of $220–$330.

The new system would increase our supply costs because we were adding oral syringes, but it would also decrease them because the enteral tubing was less expensive than the Luer-Lok tubing we were using under the existing system. Labor costs were not included in the analysis because no additional personnel would be necessary in either the pharmacy or the nursing staff. We estimated a reduction in net equipment cost of $13.20 per day.

Considering all of these factors, our estimated net cost savings were calculated to be $138.70–$255.20 per day. This projected to annual cost savings of $50,625–$93,148.

IMPLEMENTATION

Once the equipment and computer problems were worked out, we educated the staff on this new process. The nursing staff received training on the new labeling, the proper use of the new syringes and tubing, the syringe pump work-around solution, and the process for receiving and double-checking medications on cart fill. The pharmacy staff received training in ordering,

Oral Syringe NICU Formulary

Items in Automated Dispensing Machine	
Cholecalciferol (Calciferol)	400 units/0.05 ml
Fatty acids (MCT oil)	0.25 ml
Folic acid	50 µg/ml
Multivitamin (Adeks) drops	0.5 ml
Multivitamin (Poly-Vi-Sol) with iron	0.5 ml
Tocopherol (Aquasol E)	15 units/0.3 ml
Items from Pharmacy	
Aminophylline	3 mg/ml
Caffeine citrate	20 mg/ml
Captopril	1 mg/ml
Chlorothiazide (Diuril) suspension	50 mg/ml
Digoxin	50 µg/ml
Ferrous sulfate	25 mg/ml
Fluconazole (Diflucan)	10 mg/ml
Furosemide (Lasix)	10 mg/ml
Hydralazine (Apresoline)	1 mg/ml
Hydrochlorothiazide/spironolactone (Aldactazide) suspension	1 mg/ml
Lansoprazole (Prevacid)	3 mg/ml
Levothyroxine (Synthroid)	10 µg/ml
Metoclopramide (Reglan)	0.1 mg/ml
Propranolol (Inderal)	4 mg/ml
Ranitidine (Zantac)	15 mg/ml
Sodium chloride 23.4%	4 meq/ml
Ursodiol (Actigall)	60 mg/ml
Zidovudine	10 mg/ml

the change, we feel that we have taken a giant step in reducing our risk of medication and enteral administration errors in the NICU.

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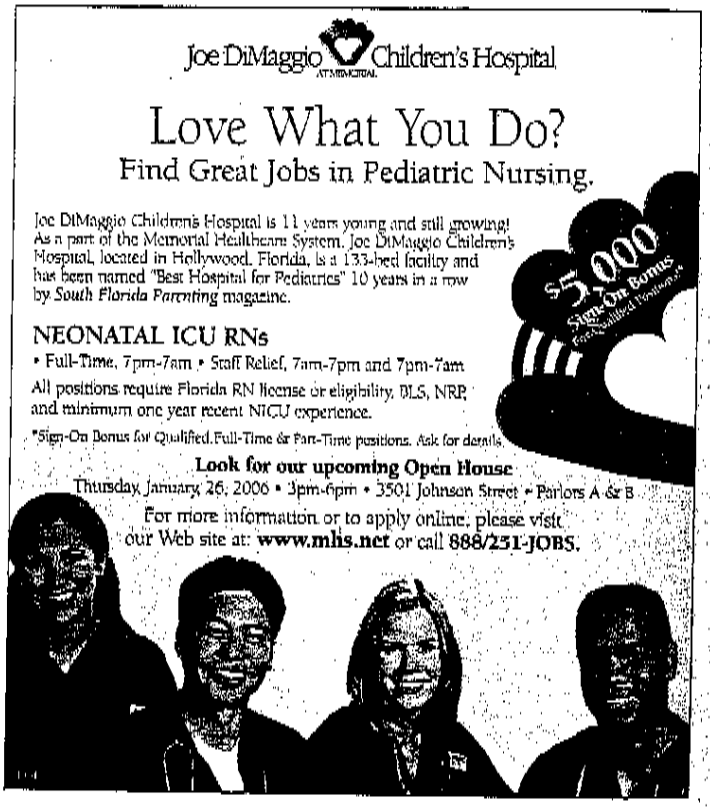

TABLE 2 ■ Issues Identified on Implementation of New Process and Steps Taken to Resolve Them

Issue	Detail	Resolution
Multiple medications given when the infant's stomach is empty	Some patients may have medication intolerance because multiple medications are pushed into the stomach before feeding is started. MCT, Fer-In-Sol, and Poly-Vi-Sol are of particular concern.	Separate medications into different feedings to avoid giving several medications at once. RN writes desired administration times on orders before faxing them to pharmacy.
Duplicate doses of same medication	When a dose is changed, the old syringes are left in the bin, and the new medications are added, resulting in the existence of two different doses for the same patient.	When a new dose is added to the bin, the nurse removes all old doses of that medication and sends them back to the pharmacy for destruction. A pharmacy tech uses the return labels to verify that discontinued doses are returned to the pharmacy.
Phenobarbital is not dispensed in an oral syringe	Because of narcotic control, phenobarbital must be dispensed in a 5 ml cup from the automated dispensing machine.	The RN will need to remove 5 ml cup, draw up dose in an oral syringe, and record waste. 1 ml and 3 ml oral syringes are available.
Can't see color of gastric residual	Because of the amber color of the syringes, bilious or bloody residual may be missed.	Squirt a small amount of the gastric content onto a 4x4 to check color, Central supply will replace 3 ml syringes with clear oral syringes for gastric checks once amber syringes are used up.
Extension tubing takes 2 ml	Old IV microbore extension tubing took only 1 ml; new tubing takes 2 ml.	Hook up tubing and prime through; push syringe volume to exact feeding volume (no overfill).
Labels for self-zip plastic bags	Cart-fill labels print without a header label, so no label is available to place on the outside of self-zip plastic bags for each medication.	Information technology has revised the report to print header labels.
Availability of Luer-Lok orogastric (OG) tube for surfactant administration	The only OG tubes available are in the resuscitation bags. There are cases when a resuscitation bag would have to be opened for this purpose only.	Surfactant kits with Luer-Lok OG tubes are now stocked in the supply room for immediate use.
Medications needed as required (prn) not available	Patient is on PRN acetaminophen; the medication is not in drawer and not in automated dispensing machine.	Acetaminophen and simethicone drops were added to the automated dispensing machine, drawn into oral syringes. The RN is to carefully administer only the prescribed dose.
1 ml oral syringes not available on unit	Phenobarbital and some rarely used medications will need to be drawn up on the unit. 1 ml oral syringes need to be available.	1 ml oral syringes were provided in a bin in the medication room.
We keep running out of Poly-Vi-Sol	Automated dispensing machine levels of Poly-Vi-Sol are not high enough to accommodate use.	Automated dispensing machine is restocked three times a day. A list of out-of-stock medications prints every 2 hours and should be refilled ASAP. If something is needed, the pharmacy should be able to restock when called (missing medications are treated as ASAP and filled within 1 hour of the pharmacy's being notified).

labeling, and dispensing; proper technique with oral syringes; and the double-check process with oral syringes.

After training, we implemented the new process. As with any new process, some unexpected problems occurred. During the first week, we continuously compiled a list of issues and resolved all critical ones immediately. At the end of the first week, we pulled together key individuals from the pharmacy, nursing, and information systems to review and resolve the issues that had been identified (Table 2).

CONCLUSION

Although no system is perfect, our interdisciplinary approach to planning and the creative problem solving of talented individuals created a system that met our goals and that works well in this institution. With no wrong-route errors and very few wrong-dose errors reported under the old system, we have no data to support our claim of quality and safety improvement. However, looking at errors that have been reported in the literature and reviewing our own processes before and after

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Case Report of Inadvertent Administration of Enteral Formula Through the Intravenous Route

Brian Wood, Paula Creekmore, Glen Green, Kathy Huddleston and Mike Dubik

Infants in neonatal intensive care units often receive formula and intravenous nutrition simultaneously. Infusion pumps are used to deliver each type of nutrition, so the potential for inadvertent delivery of enteral feeding by the intravenous route exists. The purpose of this report is to alert clinicians of this possibility by presenting details of a case in which enteral feedings were inadvertently delivered intravenously. Strategies for managing and preventing such occurrences are discussed.

This patient was a 25 week gestational age female with a birthweight of 860 grams. On day 53 of life, she weighed 1350 grams and was on nasal CPAP with an FiO_2 of 25%. She had been on full enteral feedings but because of apneic episodes, she was made NPO and was started on peripheral parenteral nutrition, including intralipids. When enteral feedings were reinitiated, by continuous infusion, they were inadvertently administered through the infant's peripheral intravenous line. Over 3 hours, the patient received 9 mls of Similac Special Care 24 calorie/fluid ounce infant formula through the IV. A literature review revealed no reports of similar events in the pediatric age group. The formula company (Ross Laboratories) had no clinical recommendations for treatment, nor were they aware of any reports of an infant formula having been given intravenously.

Following the intravenous administration of formula the infant rapidly deteriorated. She became hypotensive and apneic. She required intubation and mechanical ventilation. A total of 100 mls/kg of blood products were administered, dopamine and dobutamine infusions were started. Four hours after the event, human intravenous immune globulin (IVIgG) was given because of her low white cell count. (See Table 1). A persistent metabolic acidosis ensued, requiring repeated doses of sodium bicarbonate. Poor perfusion persisted and over several hours multiple cutaneous necrotic areas developed. Despite adequate ventilation, achieving oxygenation remained difficult, requiring 100% oxygen for over seventy-two hours.

Because of continued hemodynamic instability, a double volume exchange transfusion was performed (15 hours after incident). A dramatic change was observed immediately following the exchange transfusion: her arterial blood pressure increased, her metabolic acidosis resolved, and her peripheral perfusion improved. Hemodialysis was entertained but was not pursued because of the clinical improvement following the exchange transfusion. The benefits were short-lived, however, and by day three, she was again hemodynamically unstable. A cranial sector scan (CSS) on the day of the incident revealed no hemorrhage. However, on the second day following the event, clinical seizure activity was noted and treatment with phenobarbital was initiated. Follow-up CSS and MRI demonstrated the loss of gray and white matter and periventricular leukomalacia.

Table 1 Laboratory Values

Laboratory Values	4 hours	3 days	2 weeks
White Blood Count	1.6	16.3	18.8
Red Blood Count	3.35	5.76	5.07
Hemoglobin	10.0	17.1	14.0
Hematocrit	29.0	49.9	40.6
Platelet Count	17000	42000	50000
SGOT	1623	689	193
SGPT	526	604	97
Triglycerides	—	413	182
Serum Creatinine	0.7	2.0	0.4
BUN	7	55	14
Total/Direct Bilirubin	.9/.7	7.2/6.7	3.4/2.7

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Cultures from the formula were negative; however, blood cultures were positive for Group D enterococcus. Although initial metabolic lab results were abnormal, liver and renal function improved slowly. (See Table 1) The patient was extubated 3 weeks after the incident, yet continued to require oxygen for several months. Neurological sequalae accounted for the greatest morbidity in this case. After two months, the infant had poor head control, poor truncal tone, right-sided weakness, and jittery movements. Her suck/swallow coordination was poor and she required placement of a gastronomy tube.

An extensive search found similar case reports in the adult literature.[1,2] Several articles propose that the similarity in the appearance of intravenous intralipid preparations and enteral formulas has led to the confusion.[3,4,5,6] Morbidity has been associated with septicemia, high osmolarity, and micro emboli.[1,2,7] Particular to this pediatric case, cutaneous and central nervous system infarctions were significant complications not previously described.

Particular to this pediatric case, cutaneous and central nervous system infarctions were significant complications not previously described.

The exchange transfusion was performed as a therapy of last resort, and may have been life-saving for this infant. It seems reasonable that early treatment and repeated exchange transfusions might minimize the extent of injury.

The inadvertent administration of enteral feedings via a parenteral route can be avoided and the risk minimized if certain precautions are employed. We now use an adaptor for all enteral feedings which will not interface with standard IV tubing. Other suggestions include adding color to the formula.[6]

This case illustrates the seriousness of this iatrogenic complication and describes the effectiveness of an exchange transfusion. Different treatment modalities need to be discussed and other options explored. Efforts must center on the prevention of inadvertent intravenous administration of enteral feedings to avoid this catastrophic event. ■

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In summary, the cost for start-up supplies came to under $100, primarily for new developmental forms. Volunteers have provided many different resources. Parental education and multi-disciplinary practice is documented on the nursing record. Developmental care has been implemented and is truly a multi-disciplinary practice at Palomar Medical Center on a minimal budget. ■

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Infant Feedings:

Guidelines for Preparation of Formula and Breastmilk in Health Care Facilities

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Dietetic
Association

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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 cleanliness.
- 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

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).

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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.

	Hang Time at Room Temperature* (Hours)		Frequency of Tubing Change (Hours)		Frequency of Feeding Reservoir Change (Hours)	
Nutrition Source	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 ≤45°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

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 ±5% for neonates, ±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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