It is hard to believe that nutrition— one of the most basic components of medical care—can be a potential hazard for the home tube feeding patient. While choosing the right formulation to support the patient’s nutritional requirements is important, the method of administration must be given equal consideration.

Preventing an enteral tube feeding from becoming contaminated is as important as preventing an open wound from becoming infected. Just as an infected wound can be the source of sepsis, a contaminated tube feeding can be the source of clinical infection (McGee & Kim, 1997). The FDA, CDC and ADA have developed guidelines to minimize the potential for contamination of formulas, especially those that are reconstituted from powder. These recommendations were generated following an incident involving the bacterium Enterobacter sakazakii, which has been associated with powdered infant formulas in rare but serious cases of infection, primarily in neonatal intensive care units. Powdered formulas are heat-treated during processing, but unlike liquid formula products, they are not subjected to high temperatures for sufficient time to make the final packaged product commercially sterile (Taylor, 2002).

Increased infection risk arises from multiplication of any potentially pathogenic bacteria in reconstituted formulas (regardless of whether they were originally powder or liquid) if they are kept at room or warmer temperatures for prolonged periods of time (International Association of Infant Food Manufacturers, 2004). In April 2001, a premature infant who received a powdered formula became septic after 11 days, and cultures of the cerebrospinal fluid revealed growth of E. sakazakii. The infant ultimately died nine days later. A follow-up study identified the presence of 10 E. sakazakii infections or colonizations out of 49 infants screened. A cohort study of these 49 infants found only one common risk factor related to all 10 infections, which was the use of a specific powdered infant formula product. As a result, the CDC (2001) published the following recommendations:

1) Formula products should be selected based on nutritional needs; alternatives to powdered forms should be chosen when possible.
2) Trained personnel should prepare powdered formula under aseptic technique in a designated preparation room.
3) Manufacturer’s instructions should be followed; product should be refrigerated immediately and discarded if not used within 24-hours after preparation.
4) The administration or “hang” time for continuous enteral feeding should not exceed four hours.
5) Written healthcare facility guidelines should be available in the event of a manufacturer product recall, including notification of healthcare providers, a system for reporting and follow-up on specific formula products used and retention of recall records.

In our own home, we would never pour a glass of milk, drink half the contents, leave it at room temperature, wait eight hours, pour more milk into the same glass and continue drinking. Yet, in the home care setting, it is not unheard of to pour a can of tube feeding formula into a feeding container, administer half the contents, and eight hours later, refill the half empty feeding container with another can of formula. This scenario is complicated further when bacteria encountered from touching the top on an unwashed can is transferred to the opening of the feeding container. In addition, the extra handling required to reconstitute powdered formula or mix in a nutritional additive may worsen the situation. These steps may be performed routinely without thinking of the implications to the patient.

Most healthcare providers are accustomed to the traditional “open” tube feeding system. This term describes the use of cans of liquid ready-to-use formula or reconstituted powders decanted into an empty feeding container.
and administered over eight to 12 hours. When the feeding container is empty, it may be discarded and replaced with a new container, or, typically, it is refilled with more formula and tube feeding administration is continued. In some instances, the feeding container and pump set are rinsed with tap water before additional formula is added. This series of events may be repeated two to three times daily.

Enteral formulas, similar to other foods, provide an excellent medium for bacterial growth. Recognizing this risk, most open tube feeding systems are limited to a short recommended hang time, usually from four to 12 hours, as a precaution against bacterial growth (see Table 1).

### Recommended Formula Hang Times

<table>
<thead>
<tr>
<th>Formula</th>
<th>Recommended Hang Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Powder, reconstituted</td>
<td>4 hours max</td>
</tr>
<tr>
<td>Ready-to-use, open system</td>
<td>4 – 12 hours</td>
</tr>
<tr>
<td>Ready-to-use, closed system</td>
<td>48 hours</td>
</tr>
</tbody>
</table>

Table 1

“Closed” system tube feedings offer an alternative for the tube feeding patient. Commercially sterile, prefilled, non-air-dependent, ready-to-hang bags provide a 24-hour or larger volume of formula. The closed system container is spiked with the administration set and hung until empty. The combination of a commercially sterile formula with reduced formula handling and preparation can help maximize patient safety and simplify administration. The potential for increased safety of a closed system is reflected in its recommended hang time, usually 24 to 48 hours.

### Causes of Tube Feeding Contamination

Studies have documented that, by the time a feeding is completed, anywhere from 5 percent to 100 percent of open tube feeding systems are contaminated and consequently, the patients receiving these tube feedings may be at risk for developing some sort of infection (McGee & Kim, 1997 and Carlson, 2005). The incidence and degree of bacterial contamination is directly related to the amount of handling and manipulation required to prepare the tube feeding (Wagner et al., 1994 and Kohn & Keithley, 1989). The following preparation steps are the most typical sources of contamination:

- Poor handwashing technique
- Reconstituting a powdered formula in a blender
- Diluting a ready-to-use formula
- Filling, emptying and refilling the feeding container
- Adding additional nutrients or medications to formula
- Spiking and re-spiking the feeding container
- Rinsing a previously used feeding container and administration set before refilling and reusing.

### Frequency of Tube Feeding Contamination

Food safety issues need to be applied to enteral tube feedings. Levels of contamination exceeding 20,000 colony forming units/mL (104 cfu/mL), the USDA limit for pasteurized milk and the Centers for Disease Control standards for food-borne disease, are frequently found in enteral feeds (Kohn-Keeth et al., 1996 and Anderson et al., 1984 and Fason, 1987). Blenders are a significant source of this contamination. Water used to dilute or reconstitute formula may contain gram-negative organisms. Touch contamination can occur while pouring formula into the blender or a feeding container, or because of careless handling during setup.

A hospital-based study of the microbial concentration of open versus closed tube feeding systems revealed that, on initial cultures drawn during pharmacy preparation, 100 percent of reconstituted powdered tube feeding formulas and 30 percent of liquid ready-to-use formulas were contaminated to some degree during their preparation. On final culture, drawn from the remaining volume in the bag, significant contamination (that exceeding 104 cfu/mL) was found in 83 percent of the powdered formulas and 60 percent of the liquid formulas. The closed system tube feeding was free of bacteria at tube feeding initiation and only 2 percent of the closed system bags had bacterial growth at the end of a 48-hour hang time (Wagner et al., 1994) (see Chart 1). This hang time is well in excess of that typically used in the acute or chronic care setting. The authors concluded that non-air-dependent closed delivery containers may be safely administered for up to 48 hours, and they are associated with labor savings and reduced contamination.

Microorganisms isolated from contaminated tube feedings are rarely implicated in outbreaks of disease in healthy individuals, but many are opportunistic pathogens in seriously ill or immunocompromised patients. These may include oncology and HIV patients, those on immunosuppressive treatments, patients with reduced gastric acid secretion and the frail elderly (Paauw et al., 1984). Other under-appreciated factors in assessing the risk for formula contamination...
are the economic, social and psychological status of the patient and caregiver. The risk of tube feeding contamination and its complications are even greater if the environment is unclean, unstable or if the patient or caregiver is mentally challenged.

Complications of Tube Feeding Contamination

The clinical significance of formula contamination should not be underestimated. Diarrhea and aspiration are the most frequently cited complications (Kohn-Keeth et al., 1996). The incidence and frequency of formula contamination has generated a growing body of research indentifying contaminated formulas as the cause of bacteremia, septicemia, pneumonia and infectious enterocolitis (Anderton et al., 1986 and Casewell & Phillips, 1978). The financial costs for treating these complications are variable and difficult to measure, but depending on the severity of the infection, may include admission to the hospital, antimicrobial treatment of the infection and management of any related complications.

Reducing the Risk of Formula Contamination

Most formula contamination occurs as a result of careless or haphazard handling during preparation and administration. As more tube feeding patients are managed at home, it becomes necessary to provide education to the patient and his or her caregiver regarding the use of aseptic technique. As healthcare providers begin to understand the impact of formula contamination on patient outcomes, implementing some very basic infection-control guidelines can dramatically reduce the risk of contamination (Moe, 1991).

If using an open system:
- Wash hands thoroughly with soap and water to prevent touch contamination.
- Gather all supplies in a clean area.
- Check the expiration date and discard outdated formula.
- Rinse the top of the can before opening, or wash the blender before reconstituting a powdered formula.
- Inspect the empty feeding container for damage before filling.
- Avoid touching the mouth of the feeding container while filling.
- Fill the container with only the amount of formula that will be administered within the allowable hang time.
- Refrigerate unused formula according to the manufacturer’s recommendations.
- Utilize administration sets with Y-ports to minimize the number of times the set is disconnected from the feeding tube.
- Cap disconnected sets and feeding tubes.
- Note the date and time the feeding container is hung.
- Change the feeding container and administration set based on the guidelines provided by the manufacturer.
- Assess tube site for signs of infection.

If using a closed system:
- Wash hands thoroughly with soap and water to prevent touch contamination.
- Gather all supplies in a clean area.
- Check the expiration date and discard outdated formula.
- Inspect the feeding container for damage before use.
- Avoid touching the spike port when spiking the closed system container.
- Utilize administration sets with Y-ports to minimize the number of times the set is disconnected from the feeding tube.
- Cap disconnected sets and feeding tubes.
- Note the date and time the closed system container is hung.
- Adhere to the hang time guidelines provided by the manufacturer.
- Assess tube site for signs of infection.

Assessing Formula Contamination Risk Factors

There are many issues that need to be addressed when assessing a home care patient’s risk for tube feeding contamination.

The home care setting is radically different from that of a hospital setting. It becomes the clinician’s responsibility, as a patient advocate, to identify concerns.
and potential risks for formula contamination for their patients. Identifying these concerns and risks, along with intervention from other healthcare members, can help patients achieve their nutritional goals.

The questions provided in Table 2 may serve as a resource in assessing a patient's risk for tube feeding formula contamination and in determining the appropriate tube feeding system for a home care patient. Other factors that should be addressed include the patient’s financial resources, mental capacity and psychological state.

Summary

Enteral tube feedings are a critical component of medical treatment and recovery. High quality nutrition provides all the necessary elements for good health. That same high quality nutrition may also be a source of contamination. As more seriously ill adult and pediatric patients continue to dominate the home care setting, the risk and consequences of infection become more of a healthcare issue than previously considered. The risks of bacterial contamination of tube feeding can take on many forms. Identifying potentially hazardous sanitation practices provides the platform for improving basic infection-control procedures. Careful assessment of the home care setting as well as the patient and caregiver capabilities provides critical information for selecting the most appropriate tube feeding system.

<table>
<thead>
<tr>
<th>Tube Feeding Contamination Risk Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the patient independent in their activities of daily living?</td>
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<tr>
<td>2. Does the patient have a reliable caregiver?</td>
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<tr>
<td>3. Is a language barrier affecting education and training?</td>
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<td>4. Does the patient have electricity?</td>
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<tr>
<td>5. Does the patient have running water?</td>
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<tr>
<td>6. Does the patient have refrigeration?</td>
</tr>
<tr>
<td>7. Does the patient have access to a telephone?</td>
</tr>
<tr>
<td>8. Does the patient have proper storage for formula and supplies?</td>
</tr>
<tr>
<td>9. If using a powdered formula, is a blender available for mixing?</td>
</tr>
<tr>
<td>10. Is the patient/caregiver able to demonstrate proper cleaning of the blender?</td>
</tr>
<tr>
<td>11. Does the patient have any open wounds or drainage?</td>
</tr>
<tr>
<td>12. Does the patient have pets or animals?</td>
</tr>
<tr>
<td>13. Does the patient’s living environment have an infestation of insects or rodents?</td>
</tr>
<tr>
<td>14. Is the patient/caregiver able to follow the instructions for the tube feeding regimen?</td>
</tr>
<tr>
<td>15. Is the patient/caregiver able to physically prepare and administer the tube feeding?</td>
</tr>
<tr>
<td>16. Is the patient/caregiver able to demonstrate basic aseptic technique?</td>
</tr>
</tbody>
</table>

Table 2

References

LEARNING GOAL

To provide participants with an awareness of enteral tube feeding contamination and how to minimize the occurrence.

LEARNING OBJECTIVES

At the end of this program, the reader will be able to:
1. Define two types of enteral tube feeding systems.
2. Discuss the prevalence of bacterial contamination in tube feeding systems.
3. List three practices that can contribute to tube feeding formula contamination.
4. Describe the potential complications associated with a contaminated tube feeding.
5. Identify patients who are at risk for developing complications from receiving a contaminated tube feeding.
6. Describe three basic infection control practices for use with home tube feeding systems.
7. State the benefits of using the closed system method when administering tube feeding.
8. Assess factors that may promote the risk of tube feeding contamination in the home care setting.

SELF-ASSESSMENT QUESTIONS

In the Quiz Answers section on the next page, circle the correct answer for each question. To obtain two (2.0) contact hours toward CE credit, the passing score is 100%. Return your Self-Assessment Quiz to Coram via email, fax or mail. See the next page for details on how to return to your quiz. Please allow approximately seven days to process your test and receive your certificate upon achieving a passing score.

1. An open system:
   a. Uses pre-filled formula that can hang without risk of contamination for a 24-hour period
   b. Uses non-air-dependent, sterile, ready-to-hang bags
   c. Uses pre-filled formula that is spiked with an administration set
   d. Uses cans of ready-to-use formula that are put into an empty feeding container

2. One hospital-based study referenced in this article noted that:
   a. 80 percent of reconstituted powdered formulas were contaminated to some degree during their preparation
   b. 20 percent of liquid ready-to-use formulas were contaminated to some degree during their preparation
   c. 100 percent of reconstituted powdered formulas were contaminated to some degree during their preparation
   d. 100 percent of liquid ready-to-use formulas were contaminated to some degree during their preparation

3. When preparing/administering the tube feeding formula, the following will promote tube feeding contamination:
   a. Filling a feeding container with formula from a can
   b. Washing hands with soap and water
   c. Diluting formula
   d. Spiking a closed system container of tube feeding formula

4. Receiving contaminated tube feeding is most likely to cause:
   a. A bowel obstruction
   b. A deep vein thrombosis
   c. Bacteremia
   d. Macular degeneration

5. Which of the following patients are at lowest risk for developing infection complications associated with tube feedings:
   a. Patients with sleep apnea
   b. Patients who are HIV positive
   c. Transplant patients
   d. Elderly patients

6. To decrease risk of tube feeding contamination while administering tube feedings at home, caregivers should always:
   a. Wash hands after pouring tube feeding formula into a feeding bag
   b. Rinse the top of the can before pouring the tube feeding into the bag
   c. Refrigerate unopened cans of formula
   d. Top off formula to ensure feeding bag doesn’t run out

7. Which of the following is a benefit of using a closed system:
   a. It is less costly than using an open system
   b. There is a decreased risk of contamination
   c. It provides the ability to deliver additional protein to the feeding
   d. It is a high-tech method of formula delivery

8. What are the time limits for the hang time when using an open system?
   a. 4–12 hour hang time
   b. 48 hour hang time
   c. 24 hour hang time
   d. 16–20 hour hang time

9. When using an open system, what should one do to decrease the risk of contaminating the tube feeding?
   a. Take down formula that has been hanging in a feeding bag after 36 hours
   b. Fill the container with only the amount of formula that will be administered within the allowable hang time
   c. Add an antibacterial agent to the tube feeding bag
   d. Change out feeding bags every 48 hours

10. The following question BEST addresses assessing a patient’s risk for tube feeding contamination in the home setting:
    a. Does the patient have an attic?
    b. Does the patient have internet access?
    c. Does the patient have two refrigerators?
    d. Does the patient have proper storage for formula and supplies?
The Role of Infection Control in Home Enteral Tube Feeding

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