

SCIENCE ON YOUR SEAT

Perspectives in Nutrition

INFANT FEEDINGS: THE FORGOTTEN PATIENT SAFETY RISK

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the importance of preparation accuracy (such as use of an appropriate scale for weighing powdered ingredients and precise calculation of recipes) and offered detailed advice on equipment and staffing needs.¹ Nonetheless, over 80 years later, many hospitals have yet

to implement such practices.

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In the modern era, the Pediatric Nutrition Practice Group (PNPG) of the Academy of

Nutrition and Dietetics (formerly the American Dietetic Association) brought this topic to the forefront with a series of four publications between 1991-2018 designed to outline best practices:²

- Anderson DM, Boyne LJ, eds. *Preparation of Formula for Infants: Guidelines for Health Care Facilities*. Chicago, IL: American Dietetic Association; 1991.
- Robbins ST, Beker L, eds. *Infant Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities*. Chicago, IL: American Dietetic Association; 2004.
- Robbins ST, Meyers R, eds. *Infant Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities*. 2nd ed. Chicago, IL: American Dietetic Association; 2011.
- Steele C, Collins EA, eds. *Infant and Pediatric Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities*. 3rd ed. Chicago, IL: Academy of Nutrition and Dietetics; 2019.

In addition, over the past two decades, other professional organizations have published recommendations on best practices while individual healthcare facilities have published original research on their own quality improvement initiatives regarding handling of infant feedings.²⁻¹⁴

To obtain 1.5 CPEU for Registered Dietitians or 1.0 CE credit for nurses, please read this article and follow the links to answer the knowledge check questions in their entirety.

After reading this article, the learner will be able to:

1. List the three primary concerns with handling of infant feedings in the hospital setting.
2. Describe current best practices and be able to locate resources available.
3. List the proper storage times and temperatures for human milk and formulas.
4. Create a basic HACCP plan for the handling of infant feedings.

Background

Many may consider centralized handling of infant feedings within the healthcare setting a novel and progressive approach. However, the use of a centralized room for the preparation of infant feedings is not a new concept. The 1936 textbook *Essentials of Pediatrics for Nurses* included an entire section on “The Hospital Milk Room,” which described the importance of having a location where infant feedings “can be prepared in a satisfactory manner” and indicated that the space should be a separate room with no other purpose or function.¹ The authors discussed the importance of using “clean” technique at all times and methods of preventing contamination.¹ Furthermore, the publication stressed

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Infant Feeding Handling Risks

The importance of proper handling of infant feedings within the healthcare setting is well-documented.²⁻¹⁴ Premature and hospitalized infants often have complex nutritional needs necessitating individualized feeding regimens that require the fortification of human milk or preparation of formula to modify the nutrient density.^{2,6,7,14,15} Primary concerns with the preparation, handling and administration of feedings include preparation errors, contamination, and misadministration (providing the wrong human milk or wrong formula to a patient)—all of which pose safety concerns and could result in serious adverse effects.²

Contamination of infant feedings may occur at any step of the process if aseptic technique is not diligently followed. Case reports of sepsis linked to improperly sanitized breast pump parts have been documented in the literature.¹⁶ Centralized formula preparation has been shown to decrease the presence of any microbial growth in facility-prepared powdered formulas from 43.7% to 4%.¹⁴ Hospitals using human milk bar code scanning have found that errors were more frequent than realized prior to use of such technology, with published data showing 110 to 598 wrong milk scans and from 254 to over 6,000 expired milk scans annually per facility.^{5,7,17}

Best Practices

Best practices to address these primary concerns include the use of:^{2-10,12-15}

- Centralized preparation of feedings in a designated location used for the sole purpose of human milk and formula preparation
- Use of technology to ensure accuracy of orders and recipes:
 - Systems that alert for inappropriate orders (such as alerting when a formula for a child over one year of age is ordered for an infant)
 - Systems that automatically calculate recipes based on the feeding order
- Use of bar code scanning technology to prevent misadministration at each point in the process, including use of systems to ensure that the correct:
 - Human milk, fortifiers, modulars and/or formulas are used during preparation



- Final prepared product is provided to the correct patient at time of feeding
- Human milk is discharged home with the correct patient

- Use of dedicated technicians for the purpose of preparation and distribution of infant feedings

Healthcare facilities that have adopted such practices have reported reduced patient safety risks, fewer errors, improved efficiency, and improved staff and family satisfaction.^{5-8,14,15}

Staff Competency

Facilities may differ as to which staff are tasked with preparing infant feedings, ranging from the bedside nurse to support staff to dedicated technicians.² Regardless of job title, all staff participating in feeding preparation should have annual competency validation to ensure proper technique. Required skills include:²

- Hand hygiene and aseptic technique
- Proper use of measuring equipment (such as gram scales, graduated cylinders and syringes)
- Determination of expiration dates/times of storage human milk, prepared feedings and products (formulas, fortifiers and modulars)

- Recipe calculation for fortified human milk or facility-prepared formulas (as appropriate)
- Use of bar code scanning system or other technologies in use (as appropriate)

Documentation of competency in these areas specific to feeding preparation should be maintained for appropriate staff and cannot be assumed by nature of their position.

Space Planning

A dedicated location used solely for the purpose of handling

human milk and formulas that is separate from patient care areas is considered a best practice and should be employed in all facilities.^{2,3} The Facility Guidelines Institute (FGI) provides guidelines for the design and construction of healthcare facilities.² These guidelines recommend that neonatal intensive care units (NICUs) have a separate feeding preparation room that supports the flow of materials to maintain an aseptic preparation space.² Many states have either adapted the FGI Guidelines or have their own regulations, which often include the following recommendations:²

- An area or room used exclusively for the preparation of infant feedings
- The area is separate from patient care (it may be adjacent to the NICU or elsewhere in the hospital)

- A refrigerator, work counter, storage facilities and hands-free handwashing station are required
- A separate cleanup area for washing and sanitizing is required if any reusable preparation equipment is used

The total square-footage dedicated to infant feeding preparation will depend on several factors, including number of patients being served, volume of feedings prepared, complexity of feeding orders and technologies employed (such as bar code scanning or use of a human milk analyzer). The size of the preparation room must account for the number of refrigerators and freezers (either in or adjacent to the preparation area) needed for both long-term storage of human milk as well as short-term storage of prepared feedings.²

Sanitation

Hand hygiene and attention to aseptic technique during infant-feeding preparation are crucial for patient safety. Although commonly used interchangeably, aseptic technique is not the same as sterile technique.² While sterile technique eliminates all microorganisms, aseptic technique aims to minimize the presence of pathogenic microorganisms and is typically the level of sanitation appropriate for infant feeding preparation.² Hand hygiene, proper sanitation of

work surfaces before and between each feeding preparation, and cleaning/disinfection of any reusable items are the aspects that reduce risk of transferring pathogens between patients.^{2,3}

Recently, the novel coronavirus has brought focus on sanitation and hand hygiene to the general public; however, other viruses could be transferred with poor handling techniques.¹⁹ Most hospitals do not routinely test for all potential viruses (including influenza and other respiratory viruses) and many hands may touch bottles that are being transported from home to the hospital; therefore, it is reasonable to make the assumption that the outside of any bottle could easily become contaminated.¹⁹ However, the use of chemical disinfectants to wipe down the outside of bottles has been noted as unnecessary and potentially unsafe by the Human Milk Banking Association of North America (HMBANA).²⁰ Bottles should instead be handled to prevent transfer of any potential microbes from the outside of the bottle to the contents.¹⁹

Use of the Hazard Analysis Critical Control Point (HACCP) system is beneficial in identifying critical control points (CCPs) where contamination may be introduced in the infant feeding preparation process.² These CCPs may then be monitored and a plan implemented to prevent contamination.² A multi-disciplinary

HACCP team is beneficial in designing the plan, monitoring methods, corrective actions and responsible individuals.²

Storage of Human Milk and Prepared Feedings

Proper storage times and temperatures are critical to reduce risk of microbial growth and promote patient safety.^{2,3} Recommendations within the healthcare setting are geared toward the preterm, ill, and/or immunocompromised infant and, therefore, tend to be more conservative than guidelines for the healthy infant at home.^{2,3,7,18} Storage guidelines are as follows:^{2,3,13,18}

Risk of microbial growth as well as potential changes to HM composition may occur over time.^{2,19,21} While the optimal length of time between preparation and feeding of fortified HM is unknown, the recommendation for a 24-hour maximum storage time after fortification (regardless of whether fresh HM or previously frozen, thawed HM is used) is supported by current research.^{2,3,19,21} With centralized handling, the maximum storage time must account for total time required for feeding preparation, transport to the patient/unit and storage time before feeding.²¹ In other words, the total time from when the first feeding is prepared to when it is finally consumed must fall within 24 hours.²¹

Feeding Type	Storage Conditions	Recommended Storage Time
Human Milk		
Fresh Human Milk (HM)	Room temperature (20°C–25°C, 68°F–77°F) Cooler with ice packs (15°C, 59°F) Refrigerator (≤4°C, ≤39°F)	≤4 hours 24 hours 48 hours*
Thawed HM	Refrigerator (≤4°C, ≤39°F)	24 hours
Thawed pasteurized donor HM (DHM)	Refrigerator (≤4°C, ≤39°F)	48 hours
Fortified HM or DHM (fresh or thawed)	Refrigerator (≤4°C, ≤39°F)	24 hours
Frozen HM	Freezer (home unit combined with refrigerator: <-18°C, <0°F) Freezer (≤-20°C, ≤-4°F) Freezer (-70°C to -80°C, -94°F to -112°F)	3–6 months 6–12 months 12 months +
Formula		
Facility-Prepared Formulas	Refrigerator (≤4.4°C, ≤40°F)	24 hours
Commercially Sterile Ready-to-Feed Formulas (after opening)	Refrigerator (≤4.4°C, ≤40°F)	24 hours

* While there has been discussion around longer storage times for fresh HM in the refrigerator, the recommended maximum of 48 hours is appropriate for most healthcare facilities to minimize risks.^{2,19} To adopt longer storage times, it would be important to ensure optimal handling and storage throughout the process, which would include practicing centralized handling in a dedicated space employing strict sanitation procedures as well as having the ability to evaluate that the milk was expressed under very clean conditions with thorough cleaning and sanitation of all pump kit parts.^{2,19} Based on recent research evaluating the antimicrobial capacity of HM against *Cronobacter sakazakii* (a bacterium associated with poor handling of both HM and infant formulas that may lead to potentially fatal neonatal infections), it would not be recommended to extend storage beyond 72 hours—even if the other conditions could be met.²²

Appropriate bedside hang time should also be monitored to prevent microbial growth. The maximum hang time for expressed HM or DHM (with or without fortifiers) and facility-prepared formulas should not exceed four hours.^{2,18} When using commercially sterile ready-to-feed formulas, the maximum hang time for neonates less than 30 days of age and any immunocompromised infant/child is four hours; this may be increased to eight hours for infants over 30 days of age and children who are not immunocompromised.^{2,18} However, a facility may opt for a standardized four-hour hang time for all products to prevent confusion and to account for the fact that any ill infant/child may be at greater risk of illness stemming from microbial growth in feedings.

Implementing Best Practices: Tools and Resources

Whether implementing a brand-new infant feeding handling program or improving on current processes, putting research and published recommendations into actual day-to-day practice can be daunting. However, the benefits to patient care make it well worth the effort! The key to success is tapping into existing tools and resources and knowing where to turn for information.

Overall Processes

Infant Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities (3rd ed.). Academy of Nutrition and Dietetics; 2019.²

- Considered by many clinicians and surveyors as the definitive resource for handling of infant and pediatric feedings
- Contains practical guidelines based on current research, scientific evidence and expert consensus
- Latest edition includes new chapters addressing the following infant feeding topics:
 - Getting Started
 - Lactoengineering
 - Donor Human Milk, Human Milk Products and Milk Sharing
 - Modularity and Other Additives

Steele C. Best Practices for Handling and Administration of Expressed Human Milk and Donor Human Milk for Hospitalized Preterm Infants. *Frontiers in Nutrition*. 2018;5:76. doi 10.3389/fnut.2018.00076.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6129589/pdf/fnut-05-00076.pdf>

Knowledge check!

Access this summary article from the link above and answer the following:

1. T/F. The use of a laminar flow hood results in a sterile finished product.
2. All feeding preparation and storage items should be free of _____ and _____.
3. T/F. Long nails and artificial nails have been associated with which microorganism?
4. Why are commercially sterile liquid fortifiers and additives preferred over powdered products? _____
5. What are the benefits of bar code scanning technology? _____

ASPEN Safe Practices for Enteral Nutrition Therapy (consensus recommendation). American Society for Parenteral and Enteral Nutrition; 2017.¹²

- Includes recommendations for best practices at each step of the process from initial patient assessment, feeding orders, product selection, preparation, labeling and administration
- Provides background, practice recommendations, rationale, topics for future research and references for each area addressed

ASPEN Enteral Nutrition Handbook (2nd ed.). American Society for Parenteral and Enteral Nutrition; 2019.¹⁸

- Includes recommendations for best practices at each step of the process from initial patient assessment, feeding orders, product selection, preparation, labeling and administration
- Provides a multi-disciplinary perspective on step-by-step techniques, monitoring patients, complications and home enteral nutrition

Space Planning

Facility Guidelines Institute (FGI). <https://fgiguidelines.org/>

Knowledge check!

Access the FGI guidelines via the link above. Under the “Guidelines” tab, select “Adoption of the FGI Guidelines.” Find your state on the map and see if it adopts the FGI guidelines officially or if your state has its own regulations.

Sanitation

Centers for Disease Control and Prevention. When and how to wash your hands. <https://www.cdc.gov/handwashing/when-how-handwashing.html>

Knowledge check!

Review the CDC handwashing guidelines from the link above and the “Read the Science Behind the Recommendations” link within the webpage and answer the following:

1. List the five steps for correct handwashing. _____
2. T/F: Hot water is necessary to eliminate pathogens during handwashing.

Association for Professionals in Infection Control and Epidemiology. Guide to hand hygiene programs for infection prevention. 2015. <http://www.apic.org/Professional-Practice/Implementation-guides#HandHygiene>

World Health Organization. WHO guidelines on hand hygiene in health care: a summary. http://apps.who.int/iris/bitstream/10665/70126/1/WHO_IER_PSP_2009.07_eng.pdf

Knowledge check!

Review the WHO guidelines from the link above and answer the following:

1. Find the poster on Hand Hygiene Technique with Soap and Water. How many steps are in the process after wetting your hands? _____
2. How long should the handwashing procedure take? _____

FDA Food Code 2017. U.S. Food and Drug Administration. <https://www.fda.gov/food/guidanceregulation/retailfood-protection/foodcode/ucm595139.htm>

Knowledge check!

Review the 2017 FDA Food Code. In the document Preface section, there are five major risk factors related to employee behaviors and preparation practices that contribute to foodborne illness. Which three of these five are most relevant to the preparation and handling of human milk and infant formula?

Hazard Analysis Critical Control Point (HACCP). U.S. Food and Drug Administration. <https://www.fda.gov/food/guidanceregulation/haccp/>

Knowledge check!

Review the HACCP guidelines from the link above and answer the following:

1. HACCP is a management system in which food safety is addressed through the analysis and control of _____, _____, and _____ hazards from raw material procurement through consumption of the finished product.
2. Name the seven HACCP Principles. _____
3. List the five Preliminary Tasks in the Development of a HACCP Plan. _____

Click here for an example of one hospital's HACCP plan for human milk. https://www.neomedinc.com/wp-content/uploads/2016/01/HBM_Risk_Factors_PIIS0196655311001672.pdf

Centers for Disease Control and Prevention. How to Keep Your Breast Pump Kit Clean: The Essentials. April 11, 2017. <https://www.cdc.gov/healthywater/hygiene/healthychildcare/infantfeeding/breastpump.html>

Knowledge check!

Review the CDC breast pump kit cleaning guidelines from the link above and answer the following:

1. Sanitizing the pump kit is especially important for which three infant populations? _____
2. List two methods of sanitizing breast pump kit parts. _____

Human Milk and Donor Milk

Academy of Breastfeeding Medicine (ABM) <https://www.bfmed.org/>

- All ABM Protocols may be found under “Resources” on their website
- Free podcasts on breastfeeding and lactation issues

Knowledge check!

Locate the ABM Protocols under the “Resources” tab on the ABM website (link above) and answer the following:

1. What is the protocol number for the ABM Protocol that provides an overview of human milk storage? _____
2. What population and setting are the focus of this protocol? _____

Human Milk Banking Association of North America (HMBANA) <https://www.hmbana.org/>

- Information on processing of donor human milk
- Resource tab includes links to other helpful sites

Knowledge check!

Use the link above to access the HMBANA website. Go to “Milk Processing and Safety” under the “Our Work” tab to answer the following:

1. What method of pasteurization is used in HMBANA milk banks? _____

Infant Feeding and Infant Formulas

American Academy of Pediatrics. Infant Food and Feeding. <https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/HALF-Implementation-Guide/Age-Specific-Content/Pages/Infant-Food-and-Feeding.aspx>

United States Department of Agriculture (USDA) National Agricultural Library. Infant Nutrition. <https://www.nal.usda.gov/fnic/infant-nutrition>

Knowledge check!

Access the USDA Infant Nutrition page using the link above and answer the following:

1. How to safely prepare formula with water. If a parent is concerned above the safety of the household tap water for home formula preparation, it may be boiled for a maximum of _____, then cooled to room temperature for a maximum of _____ before using.

U.S. Food and Drug Administration

- Infant Formula Regulations <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/InfantFormula/default.htm>
- Consumer Information <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048694.htm>

Quality Improvement Processes and Tools

American Society for Quality <http://asq.org>

- Failure Mode Effects Analysis (FMEA) <http://asq.org/learn-about-quality/process-analysis-tools/overview/fmea.html>
- Fishbone Diagram <http://asq.org/learn-about-quality/cause-analysis-tools/overview/fishbone.html>
- Plan-Do-Check-Act Cycle <http://asq.org/learn-about-quality/project-planning-tools/overview/pdca-cycle.html>
- Six Sigma Tools <http://asq.org/learn-about-quality/six-sigma/tools.html>

Knowledge check!

1. Use the link above to access FMEA information. When would an FMEA be useful with regards to human milk and infant formula handling? _____
2. Use the link above to access information about Fishbone Diagrams. When would a Fishbone Diagram be useful for a team designing an infant feeding preparation process? _____
3. Use the link above to access Plan-Do-Check-Act cycle information. Define each of the PDCA steps. _____

For Commission on Dietetic Registration (CDR) credentialed practitioners to receive a certification of completion, you must complete the four additional evaluation questions below.

Critical Thinking Evaluation Tool for Self-Study Programs

1. Did you find the education valuable? *If yes, what aspects of the education was valuable? If no, why not?* _____
2. Did you or will you change your practice(s) based on what you learned in the program? *If yes, what change do you intend to make? If no, why not?* _____
3. What barriers or limitations do you anticipate when trying to implement this new information into your practice? _____
- 4a. What are the strengths and limitations of the information presented? _____
- 4b. What are the identified gaps in the information provided? (Ex. outcomes that apply to a specific patient/client population; limited data in gender, age, other races, etc.) _____

This self-study activity has been approved for one contact hour by Kendra Schreiner, 18160 Cottonwood Rd., PMB 352, Sunriver, OR, an independent provider approved by the California Board of Registered Nursing, Provider #15828. Application to the CDR has been made for 1.0 CPEU credit for Registered Dietitians.

To receive credit and a certificate, go to: <https://clicktime.symantec.com/383wQuN15xTgRJNh7R2qfw-Z6H2?u=https%3A%2F%2Fwww.surveymonkey.com%2F%2F5NKKVJH> to complete the post-test and evaluation.

Allow 30 days for your certificate. Maintain a copy for your records.

Name: _____

License #: _____

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