Human Milk and Formula Handling: Best Practices for Healthcare Facilities

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Objectives
- Outline primary risks associated with human milk and formula handling within the hospital setting.
- Summarize regulatory standards and recommendations related to human milk and formula handling within the hospital setting.
- Describe how centralized handling and bar code scanning technology can reduce risk of preparation/fortification errors and misadministration.

Is the handling of infant feedings a concern?

“In an era of sophisticated technology in medicine, safe feeding of infants may be presumed to be a relatively mundane function of a modern hospital. In fact, when subjected to close scrutiny, this is an area that has often been fraught with practices more typical of a home kitchen than a facility providing state-of-the-art medical nutrition therapy.”


Primary Concerns
- Contamination
- Accuracy of preparation
- Misadministration

Barriers to Practice Change
- Viewed as “just food”
- Sterile alternatives not always available
- Need for specialized neonatal regimens
- Cost
- Limited acknowledgement of problems
  - Feeding the wrong breastmilk
  - Errors in feeding orders/formula prep
  - Contamination of equipment/supplies
  - Poor handling bedside (ie, hang times, changing of bags/tubing, etc.)
Contamination

Factors Influencing Microbial Growth
- Preparation technique and location
- Touch contamination
- Cleanliness of equipment
- Refrigeration times and temperatures
- Hang times
- Frequency of tubing changes
- Expiration dates/times

Consequences of Contamination
- GI Illness
  - ≥10³ CFU/mL associated with GI issues
  - Ingestion of live organisms or preformed toxin produced by organisms multiplying
  - Gastroenteritis or NEC
- Systemic Disease
  - Organisms invade beyond mucosal barrier

Contamination of Infant Feedings Study
- Primary Objective
  - Compare incidence of contamination between feedings prepared “bedside” vs. centralized prep
  - Limited to formulas due to variables in handling of breastmilk by the mother that could not be controlled for that might influence results
- Study Design:
  - 2 phases/526 formula samples
  - Each sample divided into 2 portions
    - First portion cultured immediately
    - Second at end of hangtime

Contamination Study Results
- Powdered formulas
  - Bedside prep: 43.7% with microbial growth
  - Centralized prep: 4% with microbial growth
- Sterile liquid products
  - Bedside handling: 6.3% with microbial growth
  - Centralized handling: 0% microbial growth
- Largest contributing factor was bedside prep
  - 24x more likely to show contamination (p <0.001)
- Second factor was use of powdered formulas
  - 14x more likely to be contaminated (p <0.001)

Infant Feeding Misadministration
Misadministration Consequences

- Medical/infectious disease concerns
  - Breastmilk
    - Hepatitis C
    - HIV
    - Exposure to drugs/medications
  - Formula:
    - Allergic, GI, or metabolic complications
- Economic concerns
  - Bodily fluid exposures may be a reportable event
  - May be viewed as a HIPAA breach (Fines of $25,000 or more per incident are possible)
  - Blood work-up costs for each party (donor & recipient) are >$500
  - Costs of any medical complications
- Regulatory scrutiny increases with each event

Consequences-Patient/Family Satisfaction

- Child Hospital Consumer Assessment of Healthcare Providers & Systems (HCAHPS)
  - Objective & meaningful comparisons among hospitals on topics important to consumers
  - Public reporting creates incentives to improve quality
  - Public reporting enhances public accountability in healthcare by increasing transparency
  - Parent perception of feeding misadministration is more significant than true medical risk
    - “What other errors are they making?”

Regulations & Guidelines

- 2000: TJC began looking for evidence of the use of HACCP Guidelines for handling of formula and breastmilk
- 2002: New FDA/CDC recommendations
  - Cronobacter spp infections/fatalities in hospitalized infants fed powdered formulas
  - Salmonella outbreaks in NICU’s traced to contaminated formula powder
  - Emphasis on preterm & immunocompromised patients
- 2004-2011: Guidelines published
  - American Dietetic Association (now the Academy of Nutrition & Dietetics)
  - American Society for Parenteral & Enteral Nutrition (ASPEN)
  - Human Milk Banking Association of North American (HMBANA)

Results of Recommendations

- Increased attention on proper handling
- Greater variety of sterile products
  - Banked breastmilk & breastmilk products
  - Sterile, liquid HMF
- Practices continue to vary
  - Increased numbers of prep rooms
  - Many facilities without adequate feeding preparation areas

TJC

- PC.02.02.03
  - .01 The hospital assigns responsibility for the safe and accurate provision of food and nutrition products.
  - .06 The hospital prepares food and nutrition products using proper sanitation, temperature, light, moisture, ventilation, and security.
- IC.01.05.01
  - All hospital components and functions are integrated into infection prevention and control activities.
- NPSG.01.01.01
  - Use at least two patient identifiers when providing treatments or procedures.
- Hospitals throughout the country (including CHOC) have reported breastmilk storage temperatures as a primary focus of TJC in 2014.
Best Practices

- American Dietetic Association Guidelines (now Academy of Nutrition & Dietetics)
- Human Milk Banking Association of North America (HMBANA)
- American Society for Enteral & Parenteral Nutrition (ASPEN)
- National Association of Neonatal Nurses (NANN)
  - "NICUs should consider development of a human milk management center to optimize milk, ensure its safety, and minimize wastage."

Physical Facilities
- Accessible and securely located
- Separated from patient care areas
- Designated for human milk
- Refrigeration/Temp Control
- Specially Trained Staff
- Infection Control
- Quality Assurance
- Unit Dosing
- Proper Labeling
- Bar Code Scanning

US News & World Report Questions

- Does your hospital offer a dedicated area within the facility but away from the bedside for milk and formula preparation? To answer "Yes" this area must meet both of the following criteria:
  - Infant feeding prep room using the aseptic technique
  - The room requires restricted access and healthy personnel with no other activity occurring in the room

- Does your NICU program offer the following?
  - NICU specific risk reduction program that includes processes designed to reduce breast milk errors

US News NICU Questions, cont’d.

- If yes to above, which of the following elements does your NICU specific risk reduction program include?
  - Individual breastmilk warmers at each bedside
  - Bar code system for correct breastmilk identification
  - Dedicated breastmilk technician who prepares milk for proper identification & distribution

- Does your NICU program track the breastmilk administration error rate? If yes, please report the number of breastmilk administration errors, breastfeeding patient days, and the breastmilk administration error rate (percentage) for the last calendar year.

International Consensus Statement

- 11 authors representing the US, UK, Italy, France, Turkey, Netherlands, & Sweden
- Presented 16 May 2015
- Published in Sept 2015 supplement to J of Pediatric Gastroenterology & Nutrition

- Purpose: Come to agreement on best practices with regards to human milk and donor milk for preterm infants worldwide

Other Agency Endorsements

- Agency for Healthcare Research & Quality (AHRQ)
- Institute for Safe Medication Practices (ISMP)
- National Patient Safety Foundation (NPSF)
- Healthcare Information and Management Systems Society (HIMSS)

Facilities Guidelines Institute Recommendations

- 2010 FGI Guidelines for the Design and Construction of Hospitals and Outpatient facilities included the recommendation for a separate neonatal intensive care unit (NICU) feeding preparation room.

- 2014 FGI guidelines, recommendations were updated to ensure the preparation area provided a “flow of materials from clean to soiled to maintain aseptic preparation space”
Many states have similar requirements regarding pediatric feeding preparation as part of their hospital construction regulations or licensing requirements.

The majority of states specifically addressing infant feeding and formula preparation recommend:
- Use of an area or room used exclusively for the preparation of infant feedings
- May be adjacent to the NICU or located elsewhere in the hospital, but that is separate from patient care areas
- Most indicate that a refrigerator, work counter, storage facilities, hand-washing station, and separate cleanup area for washing and sanitizing are required

Building code requires separate area for prep away from pt care areas.

Must include refrigerator, work counter, storage facilities, hand-washing station, and separate cleanup area for washing & sanitizing.

CDPH Dietitian Surveyors use Academy of Nutrition & Dietetics guidelines as the standard in absence of state regulations.

Sterile RTF formula shall be approved by the facility
- Adequate supply of sterile disposable ready-to-use bottles available
- Formulas shall be stored in enclosed cabinets
- Expiration date shall be checked on each bottle prior to feeding
- P&Ps shall be developed in conjunction with Infection Control Committee
- If the facility has a breastmilk bank, the policies and procedures shall be submitted to and approved by the AR Dept of Health and hospital infection control committee.

DoD NICU Space Planning Criteria
- Infant Feeding Prep Room with Breastmilk & Formula Storage
- Space for prep/storage of formula and HM additives away from bedside with layout to provide for flow of clean to soiled
- OK, OR, GA, TX:
  - Where infant formula is prepared on-site, direct access from the formula prep room to any nursery room is prohibited.
  - Room may be located near nursery or other appropriate location.
  - Must include facilities for washing and sterilizing supplies,

MI (R 325.1056):
- Separate formula prep room reserved for this purpose only
- Hand washing sink and double compartment sink

NJ (Article 115 Formula Preparation Facilities):
- Produced under sanitary conditions using aseptic technique
- Separate room with no other activities occurring in the room

MN (MS s 144.55; 144.56):
- Formula room shall be provided in the nursery or nutrition dept where adequate supervision can be provided
- Must be used exclusively for prep of formulas
- 2 compartment sink for cleaning; hand washing sink; sterilization equipment

Our Journey at CHOC Children’s
**Failure Mode Effects & Analysis (FMEA)**

- Initiated as a result of 3 errors occurring in a short time period
- Complete review of every step of a process
  - Collection
  - Storage
  - Transport
  - Administration
  - Discharge
- Identified all potential failure points.
- Failure points scored for severity, occurrence, and detectability to obtain a Risk Priority Number (RPN)

**Risk Priority Number (RPN) Scoring**

<table>
<thead>
<tr>
<th>Severity</th>
<th>Likelihood</th>
<th>Detectability</th>
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</thead>
<tbody>
<tr>
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<td>3</td>
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<tr>
<td>8</td>
<td></td>
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<tr>
<td>9</td>
<td>Hazardous</td>
<td>Failure almost certain</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\[ \text{RPN} = \text{Severity Score} \times \text{Occurrence Score} \times \text{Detection Score} \]

**Breastmilk FMEA Results**

- 282 potential failure points
- RPN ranged from 1-810
- Root causes were identified for each of the 85 failure points with an RPN score of 160 or higher

**Evaluation of Potential Failure Points**

- Identified the top failure points to assess further
- Determined root causes for each top failure point
- Used root causes to determine course of action

**Sample Root Causes**

**Evaluation of FMEA Potential Failure Points**

- NICU alone administers over 10,000 feedings per month
  - RN may handle breastmilk 12x per shift
  - Risk of confirmation bias & reduced sensitivity
- Results identified need for process redesign
  - Unclear and cumbersome process for the bedside nurse
  - Inadequate double check at key points
  - Human error/confirmation bias
  - Contamination risk due to space constraints
- Consequences of not taking action
  - Patient harm
  - Regulatory citations
  - Financial impact
  - Family satisfaction
Implementing Best Practices

Primary Considerations

- Location
- Sanitation
- Equipment
- Accuracy
- ID Verification
- Storage

Location

- Separate room separate from patient care areas
  - Support aseptic technique
  - Conform to all other standards for handling patient food/nutrition
- In no other unit would the employee responsible for diapering, IV placement, etc. be responsible for preparing meals
Sanitation/Infection Prevention

- Gowns
- Gloves
- Hair covering
- Food safe sanitizer
  - Use before & after each prep
  - Refilled daily
- Dishwasher
- Hands free sink
- Foot controlled trash can
- Refrigeration temps (TJC)

Accuracy

- Transcription INTERFACE of orders from EMR
- Detailed labeling
- Calculation of additives
- Determination of expiration dates/times
- Gram scales for powders
  - Regular calibration
- Syringes or graduated cylinders for liquids

Verifying ID for Breastmilk

- ID should be confirmed
  - When combining bottles (such as for fortification)
  - When relabeling
  - Prior to feeding
  - At discharge
- Minimum of a 2 person double check of 2 recognized patient identifiers (use TJC standards)
  - Example: Full name and MRN
  - 1 person can be the parent
- Bar code scanning

Benefits of Bar Code Scanning Systems

- Eliminate extra staffing for double check during preparation, feeding, and discharge
- Automate volume and additive calculations
- Automate labeling
- Provide real-time inventory to all staff via the EMR

Outcomes at CHOC Children’s

<table>
<thead>
<tr>
<th></th>
<th>Wrong Baby’s Milk</th>
<th>Wrong labels on bottles when milk dropped off</th>
<th>Expired Breastmilk</th>
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<tbody>
<tr>
<td>Prior to Changes</td>
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<td>16</td>
<td>0</td>
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<tr>
<td>FY 2013 (Phase I)</td>
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<td>FY 2014 (Phase II)</td>
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Breastmilk Errors

- **Wrong Baby’s Milk**
- **Wrong labels on bottles when milk dropped off**
- **Expired Breastmilk**
Nutrition Lab Time Savings

<table>
<thead>
<tr>
<th>Updating Orders</th>
<th>Receiving/Storing</th>
<th>Thawing</th>
<th>Preparation</th>
<th>Total Time</th>
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<tbody>
<tr>
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<td>0.46</td>
<td>0.46</td>
<td>3.9</td>
<td>6.19</td>
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<tr>
<td>0.68</td>
<td>0.46</td>
<td>0.46</td>
<td>3.9</td>
<td>6.19</td>
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<tr>
<td>0.51</td>
<td>0.46</td>
<td>0.46</td>
<td>3.9</td>
<td>6.19</td>
</tr>
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<td>3.9</td>
<td>6.19</td>
</tr>
</tbody>
</table>

Published Results

**Breast Milk Bar Code Scanning Results in Time Savings and Staff Efficiency**

<table>
<thead>
<tr>
<th>Time Spent Prior to Scanning</th>
<th>Time Spent 3 Weeks Post Implementation</th>
<th>Time Spent 3 Months Post Implementation</th>
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<tbody>
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<td>1.2</td>
<td>0.46</td>
<td>0.46</td>
</tr>
<tr>
<td>0.68</td>
<td>0.46</td>
<td>0.46</td>
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Other Outcomes

- Improved nursing staff satisfaction
  - Better use of nursing time for other duties
- Improved family satisfaction
- Recognition from:
  - California Dept of Health
  - TJC
  - HIMSS

Ongoing Monitoring

<table>
<thead>
<tr>
<th></th>
<th>Wrong Baby's Milk</th>
<th>Wrong labels on bottles when milk dropped off</th>
<th>Expired Breastmilk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Wrong milk actually fed</td>
<td>Wrong milk scanned (near misses)</td>
<td>Expired milk actually fed</td>
</tr>
<tr>
<td>Prior to Changes</td>
<td>3</td>
<td>---</td>
<td>16</td>
</tr>
<tr>
<td>PI Phase I</td>
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<tr>
<td>FY 2014</td>
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<tr>
<td>FY 2015</td>
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<tr>
<td>FY 2016</td>
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<td>182</td>
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Ongoing Monitoring & Follow Up

- Reconvened Breastmilk Handling PI Team
  - Both errors were exposures & HIPAA issues
- Conducted root cause analysis of errors
  - Storage and label integrity issue
  - Bedside inconsistencies for time of scanning
  - Scanning at discharge
  - Multiples
- Updated process & provided education to bedside staff
  - Recognized the need for ongoing monitoring and education
  - Easy to become too comfortable

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Providing Ongoing Feedback

- Quarterly tracking of all near misses (and errors)
- Sharing that information with all bedside staff
  - Frequency of near misses was eye opening to bedside staff
  - Helps staff understand that these are not rare occurrences & to be diligent
- Regular reinforcement of the process

Summary

- Regulatory standards reference the proper handling of food and nutrition products for all patients
  - Includes breastmilk and formulas
- Centralized handling & bar code scanning are considered best practices by numerous professional and quality organizations
- Research has shown improved outcomes and time savings associated with centralized handling & bar code scanning
- Family and staff satisfaction have been tied to implementing such processes