Infant Feeding Best Practices: Tracking, Engineering, and Paying for It All!

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Objectives

• List 2 methods of ensuring proper identification of breastmilk at each step of the process.

• List the nutritional information that may be obtained when analyzing breastmilk with Near Infrared or Mid-Infrared Spectrometers.

• List 3 resources to assist with funding for healthcare projects such as breastmilk tracking and analyzing.

• HOWEVER—Regardless of your area of practice, this may provide ideas on process change & implementation!

Historical Perspective—Concerns Regarding Contamination

• 2000: TJC began looking for evidence of the use of HACCP Guidelines for handling of pediatric formulas and breastmilk

• 2002: New FDA/CDC recommendations
  − Cronobacter spp infections/fatalities in hospitalized infants fed powdered formulas
  − NICU Salmonella outbreaks traced to contaminated formula powder
  − Emphasis on preterm & immunocompromised patients

• 2004: Revised ADA guidelines

• 2010: ASPEN peds nutrition support guidelines

• 2011: Updated ADA guidelines

Concerns with Powdered Formulas & Breastmilk Additives

• Not sterile upon manufacture

• Up to 10^4 cfu/gram of acceptable (FDA)

• May include pathogenic organisms

• Improper handling can promote growth of these organisms & introduce new ones

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Results of Recommendations

• Increased attention on proper handling

• Greater variety of sterile products
  - Pasteurized donor breastmilk & breastmilk products
  - Sterile, liquid human milk fortifiers (HMF)

• Practices continue to vary
  - Increased numbers of breastmilk & formula prep rooms
  - Many facilities without a breastmilk & formula prep area

Location, Location, Location…

• Separate room strongly recommended
  - Separate from patient care areas
  - Prep area apart from storage & anteroom
  - Used solely for feeding prep

• Preparation should not be done bedside
  - Separate breastmilk & formula prep area designated
    - Section of the food production area
    - Galley on a patient care floor
    - Dedicated space in the nursery
  - Space must support aseptic technique

Regulatory Standards

• 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. The patient’s room number or physical location is not used as an identifier.

Resources for the Nuts & Bolts of Feeding Preparation

• Standards for Specialized Nutrition Support: Hospitalized Pediatric Patients (ASPEN)

• Infant Feedings: Guidelines for Preparation of Formula and Breastmilk in Health Care Facilities (ADA)
State Department of Health Surveyors

- State of California example
- States Requiring a Tissue Bank License
  - California, Maryland, and New York
  - Director and Personnel listed including CVs
  - Patient consent or information forms

State Building Codes

- Example: Office of Statewide Health Planning & Development
- Proposed changes to CA Building Code (Title 24, Part 2)
  - Must have a separate room for preparing infant formula.
    - Must include refrigerator, work counter, storage facilities, hand-washing station, and separate cleanup area for washing & sanitizing.
  - No direct access from the formula prep room to any pt care room.
  - Formula prep room should be located in or adjacent to NICU (may be at another location as approved).
  - When only commercial ready to use infant formula is used, omission of separate cleanup & preparation rooms shall be permitted.
    - Still must be handled in an appropriate room containing a work counter, hand-washing station, and storage facilities.

New Areas of Focus

- Breastmilk Misadministration
- Formula Misadministration
- Customization of Breastmilk (fine tuning nutrition rx)

Consequences of a Feeding Administration Error

- Breastmilk Administration Errors
  - Medical/infectious disease concerns
  - Economic concerns
    - Bodily fluid exposures may be a reportable event
    - May be viewed as a HIPAA breach
    - With each error scrutiny increases
    - Fines of $25,000 or more per incident are possible
    - Blood work-up costs for each party (donor & recipient) are >$500
- Formula Administration Errors
  - Allergic reactions
  - Medical complications (such as chylothorax, s/p NEC, or metabolic disorders)
  - Economic consequences of medical complications

oshpd.ca.gov (search formula preparation)
Rationale for Greater Nutritional Customization

- Greater emphasis on breastmilk use
- More complex medical cases
- Smaller and younger premature infants
- Greater emphasis on precision of calculations and specific product availability

Implementing Change in Infant Feeding Preparation

- Assemble the correct people
- Understand the regulations
- Understand market trends (What are other similar facilities doing?)
- What are the risks/consequences of doing nothing?
- What are the benefits of change?
- What is the cost of making the change? What resources are available?

Making the Case for Process Change

- Multi-disciplinary team (reps from each inpatient nursing unit, Clinical Nutrition & Lactation, Quality, and Transport)
- Year-long review of every step of the breastmilk handling process including collection, storage, transport, administration, and discharge.
- Identified all potential failure points.
- Failure points scored for severity, occurrence, and detectability to obtain a Risk Priority Number (RPN) for each failure point.

Failure Mode Effects & Analysis (FMEA) Process
FMEA Results

- 282 potential failure points
- RPN scores ranged from 1-810
- Root causes were identified for each of the 85 failure points with an RPN score of 160 or higher.
- Results identified the need for process redesign for all steps of breastmilk handling within the organization.

Identified Areas of Concern

- Risk for breastmilk administration errors
  - Unclear and cumbersome process for the bedside nurse
  - Inadequate double check at key points in the process
  - Human error/confirmation bias
- Risk of breastmilk contamination due to space constraints for preparation

Evaluation of Potential Failure Points

- NICU alone administers over 10,000 feedings per month
- NICU RN may handle breastmilk 12x per shift
  - Risk of confirmation bias & reduced sensitivity to the potential risk
- Handling breastmilk bedside due to space constraints
  - Research has indicated the contamination of infant feedings are increased exponentially when feedings are mixed, drawn up, or measured at the patient bedside.
- Of the top 85 potential failure points, 55% were unlikely to be detected.
  - 16% “Almost Impossible” to detect
  - 33% “Remote” chance of being detected
  - 6% “Very Slight” chance of being detected

PI Team

- Representatives from each inpatient nursing unit, Clinical Nutrition & Lactation, and Quality
- Tasked with the following goals/objectives:
  - Redesign breastmilk handling process based on FMEA identified failure points & underlying root causes.
  - Provide adequate storage for breastmilk
  - Meet the Academy of Nutrition & Dietetics and the Human Milk Banking Association of North America (HMBANA) guidelines
  - Support hospital’s strategic plan within the pillars of Excellence & Infrastructure
The centralized handling of breastmilk (and formulas) has become the industry standard in children’s hospitals with many having changed to this process over a decade ago.

Review of standards from TJC, state dept of health, and state construction/planning department.

Audits at many facilities have found issues where there is not centralized handling of breastmilk including:
- incorrect labeling
- incorrect expiration dates/times
- introduction of bacteria & other microbes

Analysis of Other Facilities and Regulations

Preventing Breastmilk Misadministration Phase I: Centralized Breastmilk Handling & Preparation

Process Redesign
- Registered Dietetic Technicians (DTRs) to prepare all breastmilk, unit dose, and distribute to nursing units.
- Double check of name & MRN on every bottle
  - At 5 steps during the process between collection, preparation, distribution, & administration (compared to 1 step)
  - At 3 steps at the time of discharge (compared to 1 step)
- Initials required at each double check for auditing purposes
- Redesign alone would directly address 63 of the 85 (74%) prioritized failure points.

Nutrition Lab
- Repurposed Formula Room to accommodate both centralized breastmilk & formula preparation hospital-wide.
- Received approval from state department of health to proceed.
- Comprehensive additional training provided to DTRs.
Preventing Breastmilk Misadministration Phase II: Breastmilk Bar Coding

Benefits of Breastmilk Bar Coding

- Address 12 of the remaining 22 Potential Risk Factors not addressed by the re-design.
- Eliminate need for extra staffing to perform the double check.
- Automate all calculations of volume & additives.
- Automate labeling.
- Provide a real time inventory to all staff in the EMR.

Grant proposal submitted focusing on safety aspects.

Received funding for the purchase of a breastmilk bar coding system and implementation costs.

Breastmilk Bar Code System
Printing Labels

- Mothers label milk using the provided bar code labels.
- Date and time milk is pumped is handwritten in.
- Mothers drop off milk with nursing unit where it is stored in the fridge or freezer for the Nutrition Lab to collect and check in.

Receiving Milk

Receiving Milk, Cont’d.

Preparation
Preparation—Scanning

Feeding Orders Import Directly from EMR

Bedside Scanning/Feeding
Stats (November 12-March 26)

- 24,016 individual bottles of breastmilk received
  - Average of 178 per day

- 24,619 individual breastmilk feedings prepared
  - Average of 182 per day

Outcomes

<table>
<thead>
<tr>
<th>Reported Wrong Milk to Pt</th>
<th>Reported Labeling Errors</th>
<th>Reported Storage Errors (Milk in wrong bin)</th>
<th>Reported Administered Expired Breastmilk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior to Process Change</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>May 2010-Dec 2012</td>
<td>3</td>
<td>16</td>
<td>26</td>
</tr>
<tr>
<td>Bedside Prep</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manual Double Check</td>
<td></td>
<td></td>
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</tbody>
</table>

| PI Phase I                |                          |                                             |                                          |
| Jan 9-Nov 11, 2013       | 0                        | 4                                           | 3                                        |
| Centralized Prep          |                          |                                             |                                          |
| Manual Double Check       |                          |                                             |                                          |

| PI Phase II               |                          |                                             |                                          |
| Nov 12, 2013-present     | 0                        | 1                                           | 4                                        |
| Centralized Prep          |                          |                                             |                                          |
| Bar Code Scanning         |                          |                                             |                                          |
| 48 near misses            |                          |                                             |                                          |
| 99 near misses            |                          |                                             |                                          |

| POTENTIAL ERRORS AVAIDED PER YEAR | 130 | 268 |

Preventing Formula Misadministration Phase III: Formula Bar Coding—Future Plans

Formula Bar Code System

- Same system as breastmilk tracking that can be used to track formulas.

- Analysis of potential effects of receiving the wrong formula.

- Seeking funding.
Breastmilk Analyzers

- Currently 2 types commonly used in the U.S. with breastmilk:
  - Calais (mid-infrared)
  - Spectra Star (near-infrared)
- No specific information on comparing mid-IR to NIR with regards to breastmilk, but articles from the food industry indicate comparable results.
- Technology widely used in the food, pharmaceutical, & chemical industries (including the dairy industry)
- Assess total Cal/oz and macronutrient distribution (protein, CHO, fat)
- Not to be confused with Creamatocrits which assess Cal/oz and fat content

Process

- 2-5 mL sample from 24 hour pooled volume of breastmilk
- Warm sample to body temperature
- Sample is homogenized
- Sample placed on glass window
- Infrared beam analyzes the sample and compares to known reference standards
  - Variance for CHO, pro, & fat is minimal (+/- 0.1-0.2%)
- Track trends
Obtaining the Breastmilk Analyzer

- Obtained grant funding for purchase of near-infrared breastmilk analyzer
- Investigational Device Exemption (IDE) Obtained
  - IRB determination of NSR
  - IRB approval and informed consent
- IRB Approval for Protocol Obtained

Breastmilk Analyzer

- **Who?**
  - ELBW patients receiving breastmilk or donor milk
  - Breastmilk fed infants with growth failure or at risk for growth failure
  - Breastmilk fed infants requiring manipulation of macronutrients due to medical dx (such as metabolic disorders or chylothorax)
- **Goal**
  - Initiate fortification from known baseline
  - Prevent growth failure (no need to wait for growth parameters to indicate inadequate nutrient intake)
  - Increase use of breastmilk with certain medical dx
- **Guardrails**
  - Limiting fortification regardless of data

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**Breastmilk Analysis**

Bag of [ ]

To find out the calories and other nutrients in your milk, we need to have all the milk you pump in a 24 hour time period.

**Instructions:**
1. Pump and label your milk as usual.
2. Place all bottles of pump milk from Sunday 7:00 am through Monday 7:00 am in this bag.
3. Do NOT freeze the bottles placed in this bag.
4. Store bag in the refrigerator until you bring it to the hospital.
5. Bring the bag to the hospital Monday and give it to your nurse.
   - If you are unable to come to the hospital on Monday, put the bag in the freezer so that the milk is not wasted.

**CHOC STATE**
Please place this bag in the REFRIGERATOR for pick up by the NUTRITION Lab.
Do NOT freeze.

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**Grants & Funding**
Typical Components of a Grant Proposal
(BUT follow guidelines ☺☺ ☺☺)

- Proposal Summary
- Introduction of the Organization Seeking Funding
- Problem Statement (or Needs Assessment)
- Project Objectives
- Project Methods or Design
- Project Evaluation
- Future Funding
- Project Budget
- Appendices

Ten Tips for Successfully Obtaining Grant Funding

1. Obtain guidelines, annual reports, & other pertinent info from the foundation BEFORE sending a proposal (check the organization’s website).
2. Stay local (especially for operating or program costs)
   - National foundations are more likely to fund capital expenses of programs that can be replicated nationally.
3. See if anyone in your organization knows the trustees.
   One call can help put your proposal on top of the pile.
4. Collect anecdotes & pt testimonies that may be helpful.
5. Plan ahead so that you don’t need to use Express Mail to meet the deadline. This can signal that your organization is a poor steward of funds.

Ten Tips, cont’d.

6. Most grants will specify what to send. Don’t send more than requested.
7. Once awarded, send progress reports even if they aren’t requested. Keep in touch with your funding sources.
8. Be sure to follow all specifications outlined in the call for proposals.
9. Before mailing your proposal, call the foundation to be sure you have current contact information.
10. Many groups use a “Common Grant Application,” developed by groups of grant makers to ensure that all applicants provide the same information. Check individual foundation guidelines to see if this tool is used.

Words of Wisdom from Successful Grant Awardees

- It is their money, follow their rules.
- Work with your facility grants officer for guidance.
- Review & ask others to review—you’ll make fewer mistakes.
- Remember who your target audience is.
- Use charts, graphs, tables, and pictures.
- Tell a good story—make your need compelling.
- Most grants want to know about the diverse population. Look for what makes your target population in need.
- Answer the question!
- Consider what your organization will do “in kind.”
5 Common Grant Proposal Mistakes to Avoid

1. Taking more about problems than solutions
   - Show that you are familiar with the issue, but focus on what you are going to do about the problem or need.

2. Addressing specific problems with general solutions
   - A successful proposal provides a clear picture of what your organization will do to address the issue.
   - Provide specific details about the actions you will take.

3. Using buzzwords and jargon
   - Avoid vague claims, trendy language, & obscure terms.
   - Keep in mind the reviewer may not be familiar with healthcare.

4. Budgets that don’t make sense
   - A surprising number of proposals arrive with math errors.

5. Repeating exact phrases from the funder’s guidelines
   - Do not cut and paste!
   - Instead tell how and why your proposal fits their guidelines.

Areas of Focus for Proposals

- Equipment
- Staff Training
- Specific tools or educational items for patient use
- Things that focus on patient safety

Examples:
- Pediatric RD Residency
- Gluten Free/Allergen Free Station
- Breastmilk Analyzer
- Breastmilk & Formula Bar Coding
- Breastfeeding Scales/Carts
- Breast Pumps
- Formula Mixing Cups/Spoons
- Educational Materials for Metabolic Disorders

Seeking Funding

- Employee Giving Funds
- Local Charitable Foundations
- Formula, Drug, or Other Healthcare Companies
- Businesses with Ties to the Community
  - Big box stores
  - Grocery stores
  - Manufacturing industries with local operations

Other Considerations

- Get IRB approval for any project!
  - Don’t keep good work from being published by not obtaining proper approval.
  - Publishing & recognition can help gain internal support for future projects as well as help support grant funding.

- Narrow your focus
  - Will help show more clear outcomes and assist with internal and external support.
Summary—Catch the Wave of the Future

- Hot topics:
  - Breastmilk & formula misadministration
  - Breastmilk engineering/customization

- Objectively look at current processes and assess for potential failure points.
  - Target efforts on those potential failure points.
  - Consider short term as well as long term solutions.
  - Begin planning for separate space/staffing. Will likely be required in the future.
  - Evaluate technology options such as bar coding.

- Make your case!
  - Presenting suggestions within your organization
  - Seeking grant funding
  - Research & publishing

Thank you!