



Understanding the Current Guidelines for Preparing Pediatric and Newborn Feedings in Health Facilities

Presented by
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ANNENBERG CENTER FOR HEALTH SCIENCES
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Mead Johnson Nutrition.

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Faculty Disclosures

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Employee

Timeless Medical Systems

Speakers Bureau

Mead Johnson Nutrition, Medela

Topics limited to safe handling of human milk & formula in the healthcare setting

Faculty have documented that this presentation will not involve discussion of unapproved or off-label, experimental, or investigational use.



Learning Objectives



Recognize the risks associated with mishandling and misadministration of human milk and formula



Review current guidelines for the safe preparation of human milk and formula feeding




Identify at least 1 best practice for implementation within your unit or hospital



OVERVIEW



Outline risks associated with HM & formula handling in the NICU setting



Summarize current standards and best practices



Describe how centralized handling and bar code scanning reduce errors



PRIMARY CONCERNS WITH INFANT FEEDINGS

Contamination

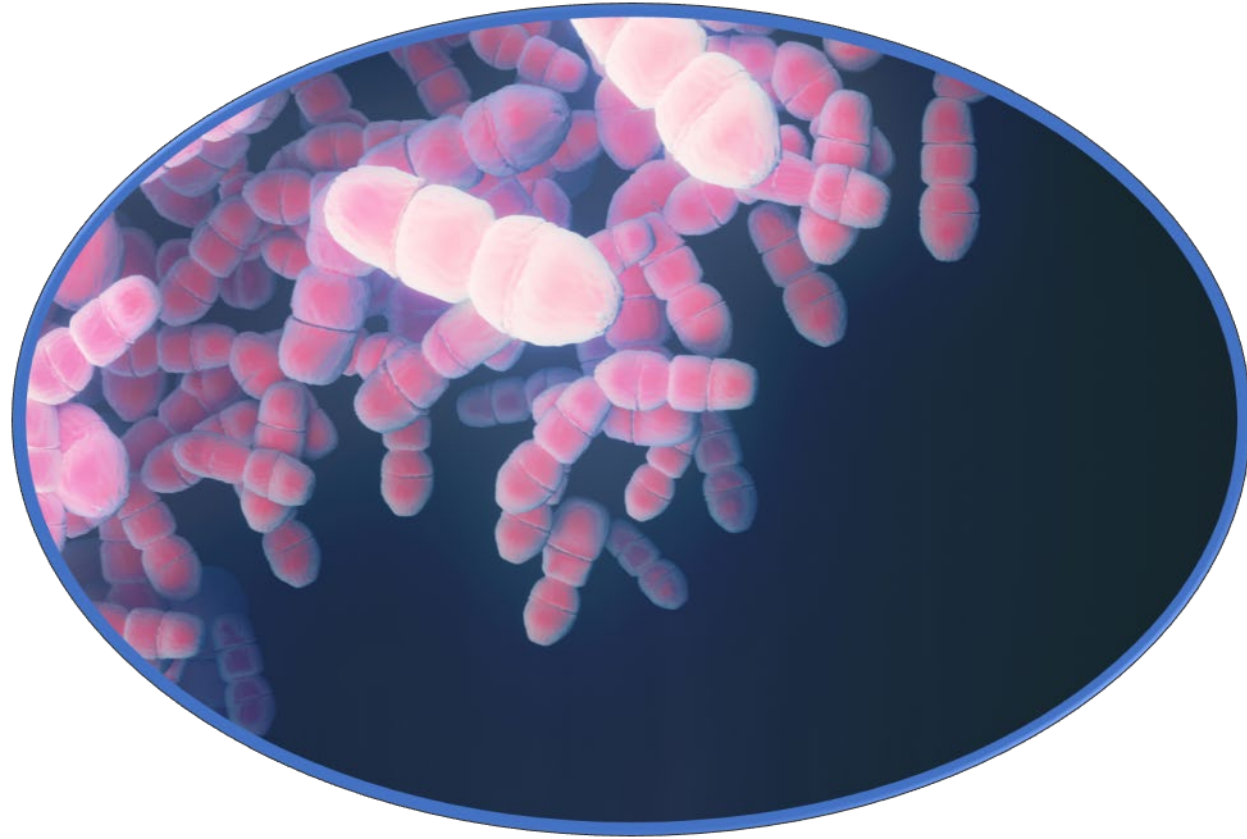


**Preparation
Accuracy**



Misadministration

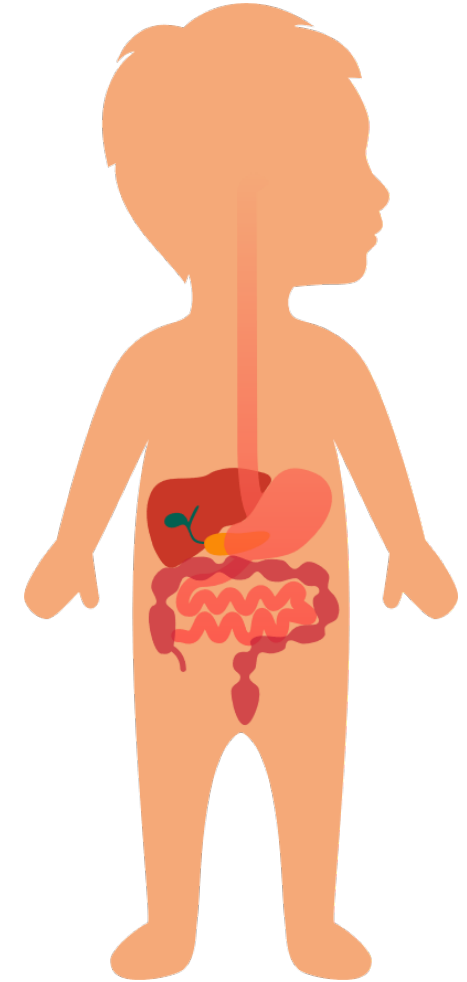




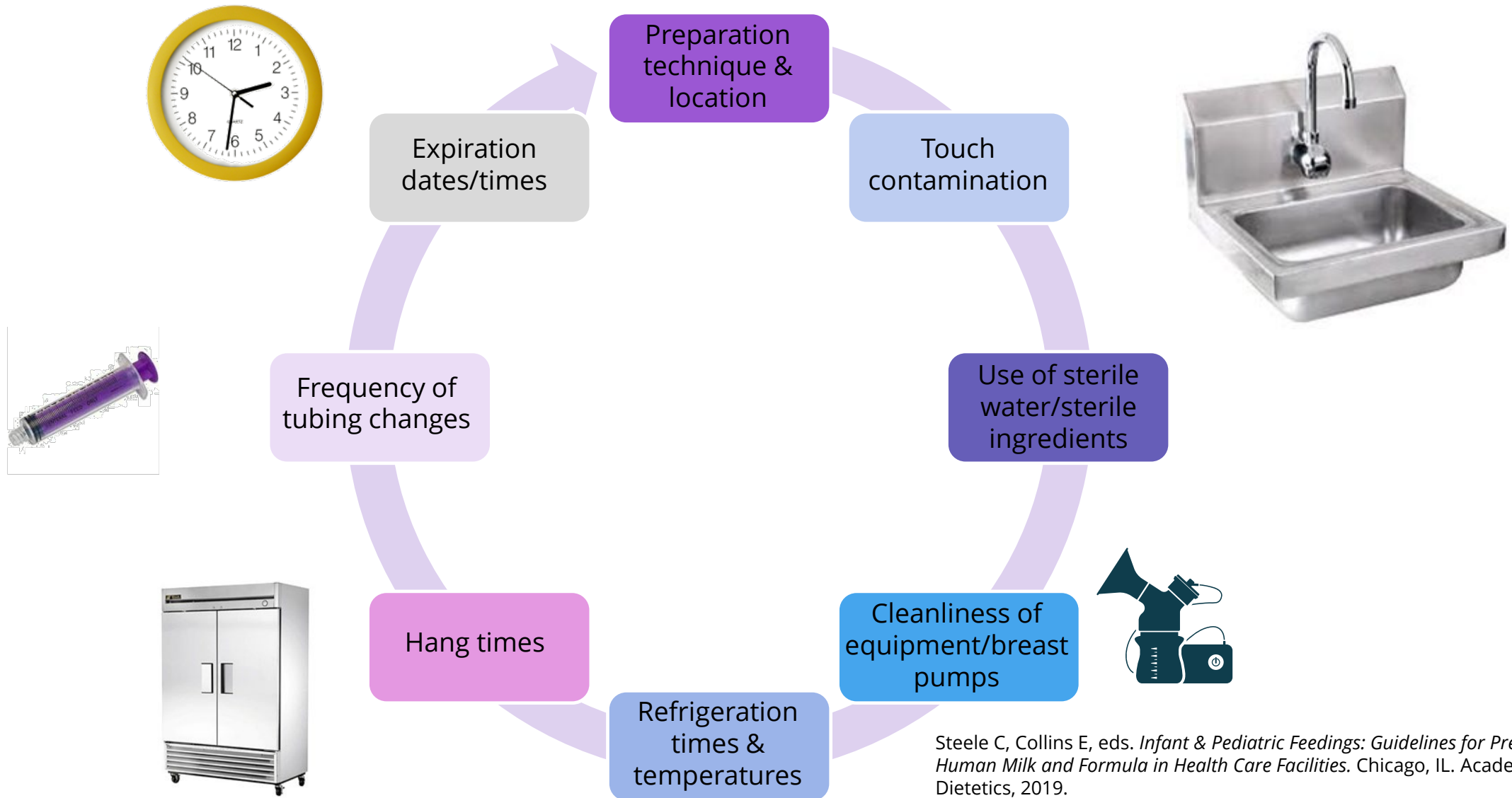
CONTAMINATION

CONSEQUENCES OF INFANT FEEDING CONTAMINATION

- “Feeding Intolerance”
- GI Illness
 - $\geq 10^5$ CFU/mL associated with GI distress and diarrhea
 - Gastroenteritis or NEC
- Systemic Disease
 - Organisms invade beyond mucosal barrier
 - Sepsis

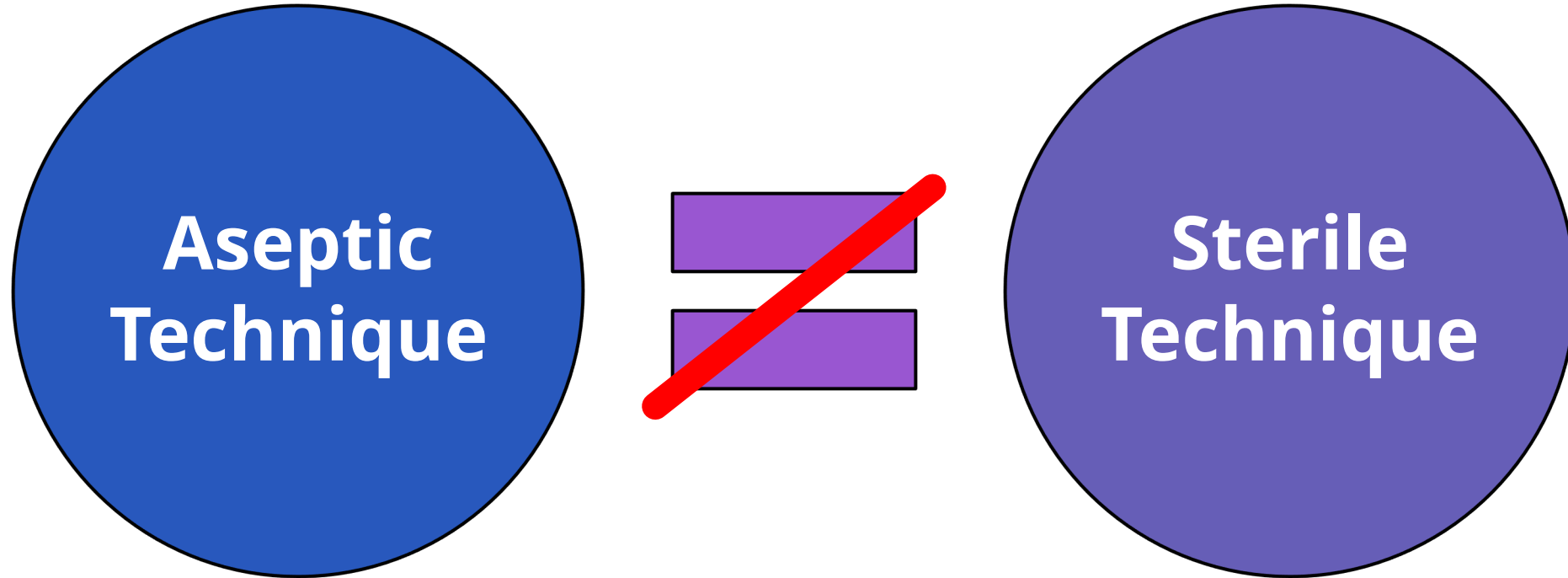


CONTAMINATION: INFLUENCING FACTORS



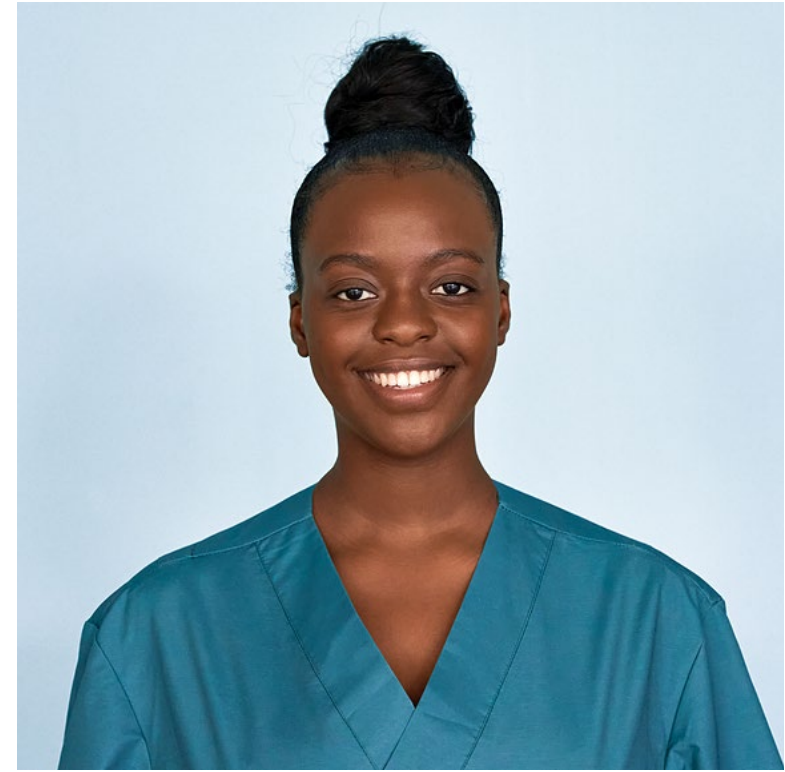
Steele C, Collins E, eds. *Infant & Pediatric Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities*. Chicago, IL. Academy of Nutrition & Dietetics, 2019.

STERILE TECHNIQUE VS ASEPTIC TECHNIQUE



- Minimizes presence of pathogenic microorganisms.
- For feeding prep, refers to good hand hygiene, use of “no-touch” technique, and meticulous attention to details that minimize microbial exposure and growth.

- Designed to destroy all microbes.
- Commonly used in healthcare, particularly for surgery and other medical procedures.



PREPARATION ACCURACY

INFANT FEEDING ACCURACY

So many things to monitor...

Accuracy of recipe

Accuracy of order
(cross check for provider error)

Correct quantities
(HM, fortifiers, modulars)
are used

Tracking in case of a recall

Correct fortifier/
formula used



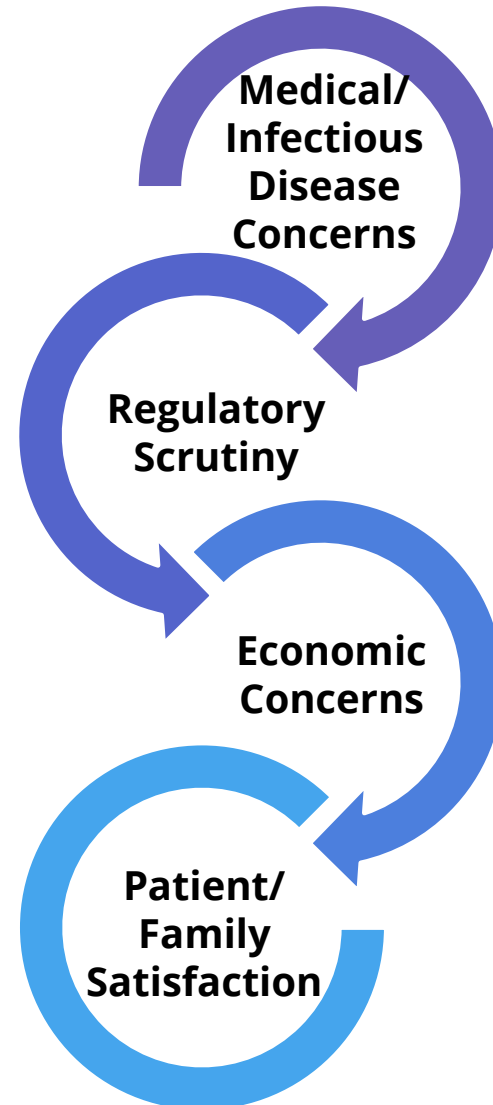


HUMAN MILK AND FORMULA MISADMINISTRATION

MISADMINISTRATION CONSEQUENCES

- Bodily fluid exposures may be reportable events
- May be viewed as HIPAA (Health Insurance Portability and Accountability Act) breach

- Loss of confidence in medical care
- “What other errors are they making?”



HM

- Hepatitis C, HIV
- Exposure to drugs/meds

Formulas and Fortifiers

- Allergic reactions
- GI intolerance
- Metabolic complications

- HIPAA fines of \$25,000+ possible
- Blood workup costs >\$500
- Cost of medical complications



REGULATIONS & GUIDELINES

THE JOINT COMMISSION (TJC)

PC.02.02.03

.01 Responsible for the safe & accurate provision of food & nutrition products

.06 Prepares products using proper sanitation, temperature, light, moisture, ventilation, and security

NPSG.01.01.01

Minimum of 2 patient identifiers for human milk administration

EC.01.01.01.11

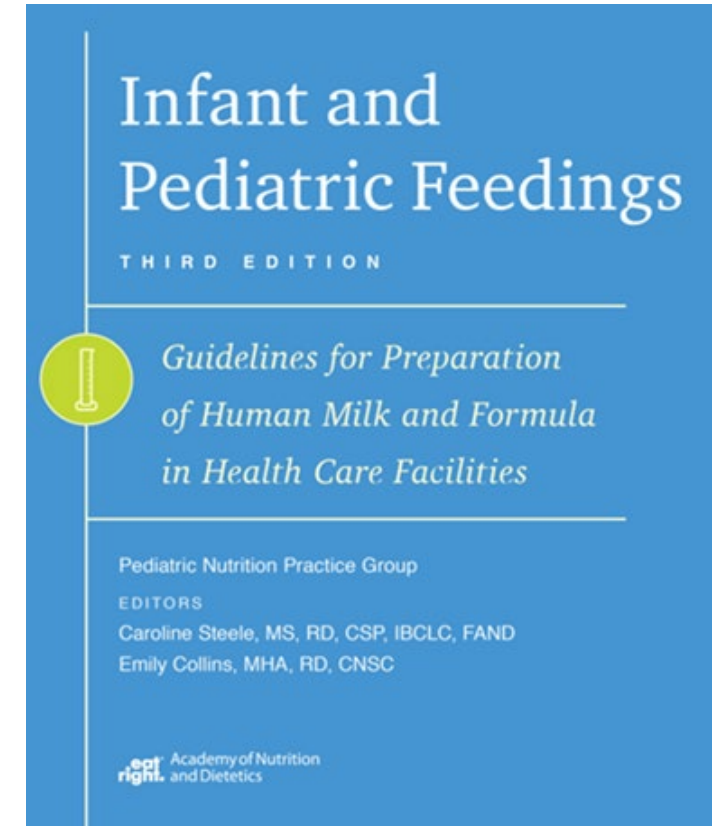
Responds to product notices and recalls

IC.01.05.01

All hospital components functions are integrated into infection prevention and control activities

BEST PRACTICES

- Academy of Nutrition & Dietetics^[1]
- Human Milk Banking Association of North America (HMBANA)^[2]
- American Society for Enteral & Parenteral Nutrition (ASPEN)^[3]
- National Association of Neonatal Nurses (NANN)^[4]
- Human Milk in Feeding Premature Infants: Consensus Statement^[5]



1. Steele C, Collins E, eds. *Infant & Pediatric Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities*. Chicago, IL. Academy of Nutrition & Dietetics, 2019.
2. Jones F. *Best Practice for Expressing, Storing, and Handling Human Milk in Hospitals, Homes, and Child Care Settings*. Fort Worth, TX. Human Milk Banking Association of North America, 2019.
3. Boullata J, et al. *JPEN*. 2017;41(1):15-103.
4. NANN Position Statement #3065, April 2015.
5. Moro GE, et al. *JPGN*. 2015;61(1):S1-S19.

INTERNATIONAL CONSENSUS STATEMENT

- 11 authors representing the US, UK, Italy, France, Turkey, Netherlands, and Sweden
- Presented 16 May 2015
- Published in Sept 2015 supplement to *Journal of Pediatric Gastroenterology and Nutrition*
- Purpose: Come to agreement on best practices with regard to human milk and donor milk for preterm infants worldwide



XII. Human Milk in Feeding Premature Infants: Consensus Statement

Guido E. Moro, Sertac Arslanoglu, Enrico Bertino, Luigi Corvaglia, Rosario Montiroso, Jean-Charles Picaud, Staffan Polberger, Richard J. Schanler, Caroline Steel, Johannes van Goudoever, and Ekhard E. Ziegler

CENTRALIZED HUMAN MILK HANDLING

The utilization of quality improvement measures with regards to safe handling of HM in NICUs is becoming a common practice in many centers (26).

The following recommendations are suggested to reduce the risk of HM errors and infant feeding contamination within the hospital setting:

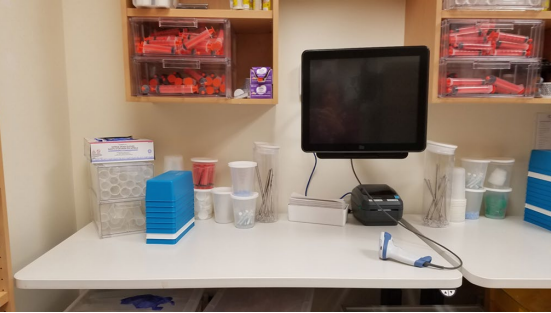
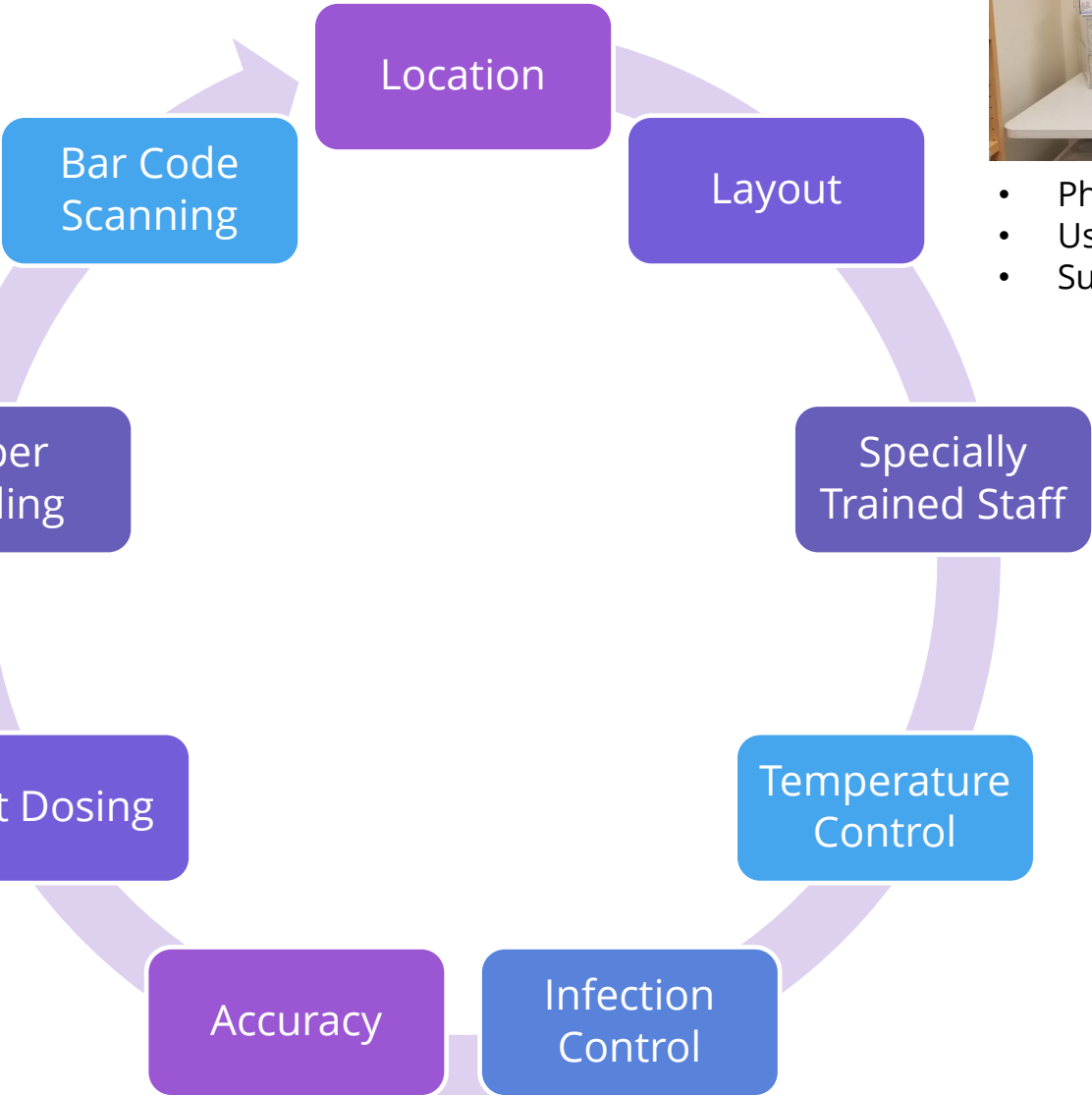
- Centralized preparation of HM should be performed in a dedicated space designed to support aseptic techniques in every NICU.
- Presence of a dedicated and trained staff for the preparation of HM in this specific space is desirable.
- Technology (i.e. bar code scanning) to reduce risk of preparation and administration errors and for traceability of HM is highly suggested.

BEST PRACTICES: US NEWS & WORLD REPORT BEST HOSPITALS

- 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
 - Room requires restricted access and healthy personnel with no other activity occurring in the room
- Does your NICU program have a specific risk-reduction program that includes processes designed to reduce breast milk errors?
 - Bar code system for correct ID
 - Dedicated breast milk technician who prepares milk for proper identification & distribution



BEST PRACTICES



- Physically separated from direct care areas
- Used solely for purpose of HM/formula prep
- Supports aseptic technique

6103724 NICU 205-01 Sample, Inpatient
Breastmilk, 24 Cal/oz. Fortified with HMF.
NGT, 18 mL q 3 hours. Start 11/26/14 10:43:00

Expiration Date/Time: _____
FOR ENTERAL USE ONLY



BEST PRACTICES: LOCATION, LOCATION, LOCATION

- Separate room away 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
- All food preparation (including HM and formula) should follow the FDA Food Code



BEST PRACTICES: LAYOUT

- 2010 Facilities Guidelines Institute (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”



BEST PRACTICES: LAYOUT



BEST PRACTICES: LAYOUT

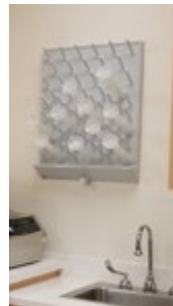
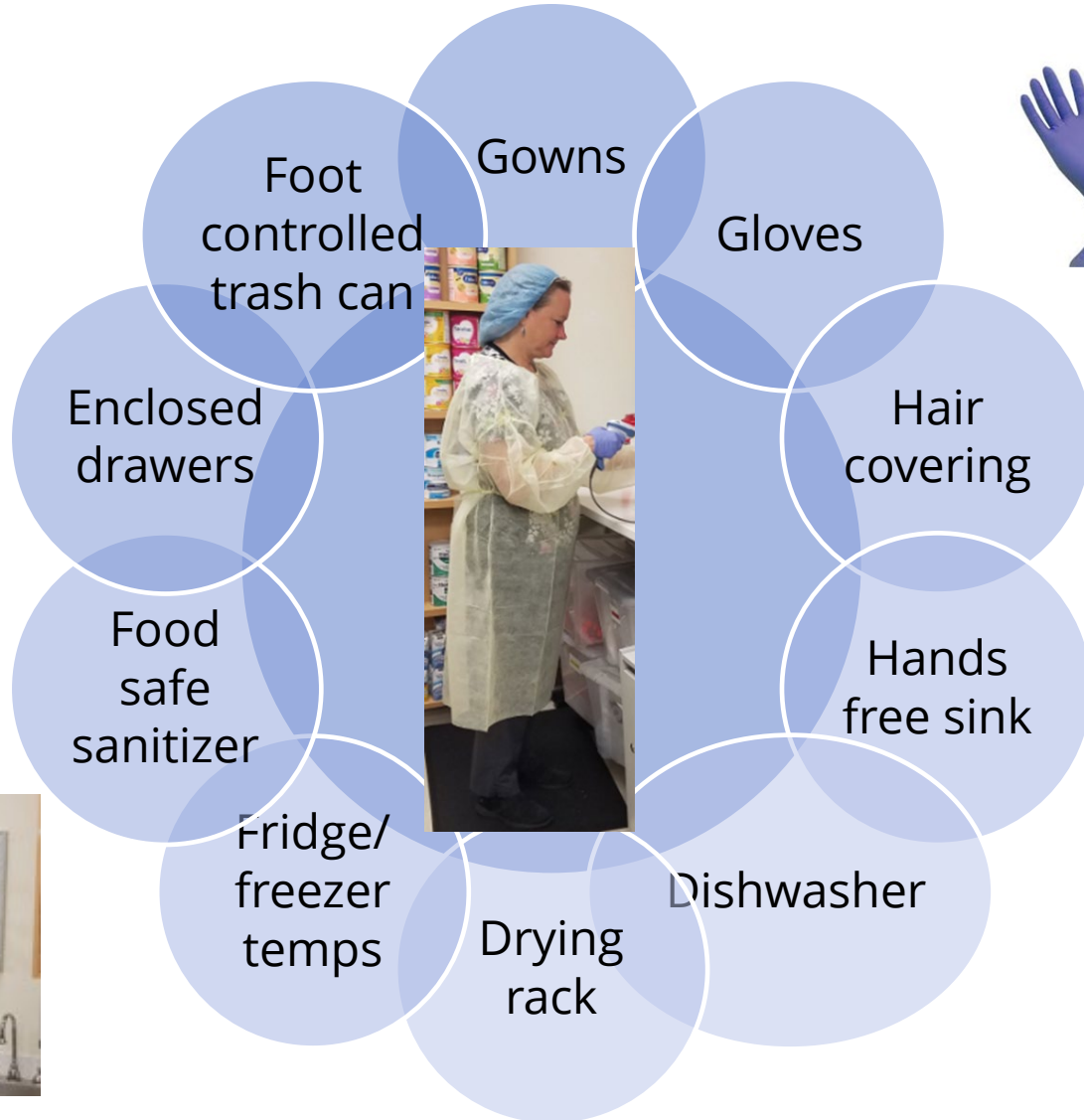
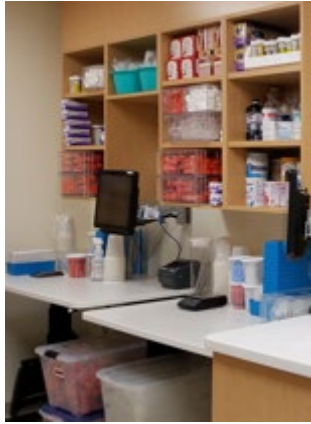


BEST PRACTICES: TEMPERATURE CONTROL

- Laboratory/pharmacy grade refrigerators & freezers
 - ✓ Single vs double door
 - ✓ Temperature monitoring system
 - ✓ Back up (generator) powder
 - ✓ After-hours correct action plans
- Bins
 - ✓ Tall or covered bins
 - ✓ Long, narrow to optimize storage
- Consider heat/noise



BEST PRACTICES: INFECTION CONTROL



BEST PRACTICES: INFECTION CONTROL

1. Wash Hands before starting any part of the process



2. Sanitize workspace with food grade sanitizing wipes



3. Wash Hands



4. Put on gloves



5. Prepare feeding



6. Remove dirty gloves



7. Sanitize workspace with sanitizing wipes



8. Wash Hands



9. Repeat steps 4-8 for each individual feeding

BEST PRACTICES: ACCURACY (ORDERS AND CALCULATIONS)

- Appropriateness of orders
 - ✓ Tech training
 - ✓ Provider alert

- Calculation of additives
 - ✓ Manual processes
 - ✓ Automated processes

DISCERN ALERT

The formula you have selected is not intended for children under 12 months of age. Please confirm this is the desired formula for this patient before proceeding



BEST PRACTICES: ACCURACY (MEASUREMENTS)

- Gram scales for powders
 - ✓ Regular calibration
 - ✓ Validation of weights
- Syringes or graduated cylinders for liquids



1. Steele C, Collins E, eds. *Infant & Pediatric Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities*. Chicago, IL. Academy of Nutrition & Dietetics, 2019.
2. Boullata J, et al. *JPEN*. 2017;41(1):15-103.

ACCURACY: PROCEDURES & TRACKING FOR RECALLS

- Manufacturers must remove all formula determined to present a risk to health
- Procedures to identify & remove pasteurized DHM, HM-derived fortifiers, & formulas/fortifiers in event of a recall
- Procedures should include:
 - Ability to identify recalled product based on lot number
 - Notification of appropriate staff
 - System for reporting, follow-up documentation, retention of records
- Examples: Scanning, paper logs, EHR documentation



Steele C, Collins E, eds. *Infant & Pediatric Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities*. Chicago, IL. Academy of Nutrition & Dietetics, 2019.

Boullata J, et al. *JPEN*. 2017;41(1):15-103.

<https://www.federalregister.gov/documents/2014/07/15/2014-16476/current-good-manufacturing-practices-quality-control-procedures-quality-factors-notification>

US Food and Drug Administration. Code of federal regulations (CFR) title 21 CFR sections 106-107.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?>

BEST PRACTICES: UNIT DOSING & PROPER LABELING

UNIT DOSING

- Reduces risk of contamination
- Reduces risk of misadministration
- Ensures feedings cool more quickly to refrigerator temperature



PROPER LABELING

- Patient name & MRN or ID
- Contents & caloric density
- Volume & frequency or rate
- Route of administration
- Expiration date/time
- “For enteral use only”
- “Keep refrigerated until used”

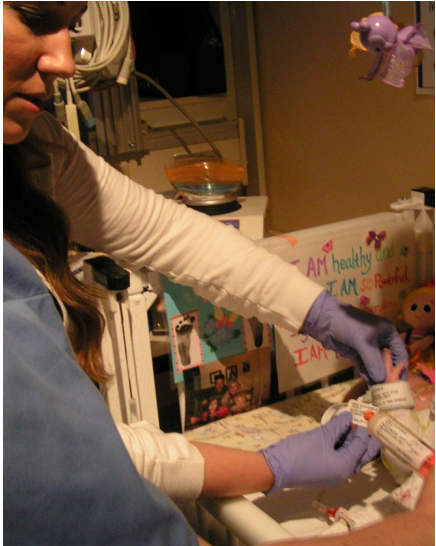
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BEST PRACTICES: ID VERIFICATION

Patient identification for HM should be confirmed:

- When combining bottles (such as for fortification)
- When relabeling
- Prior to feeding
- At discharge



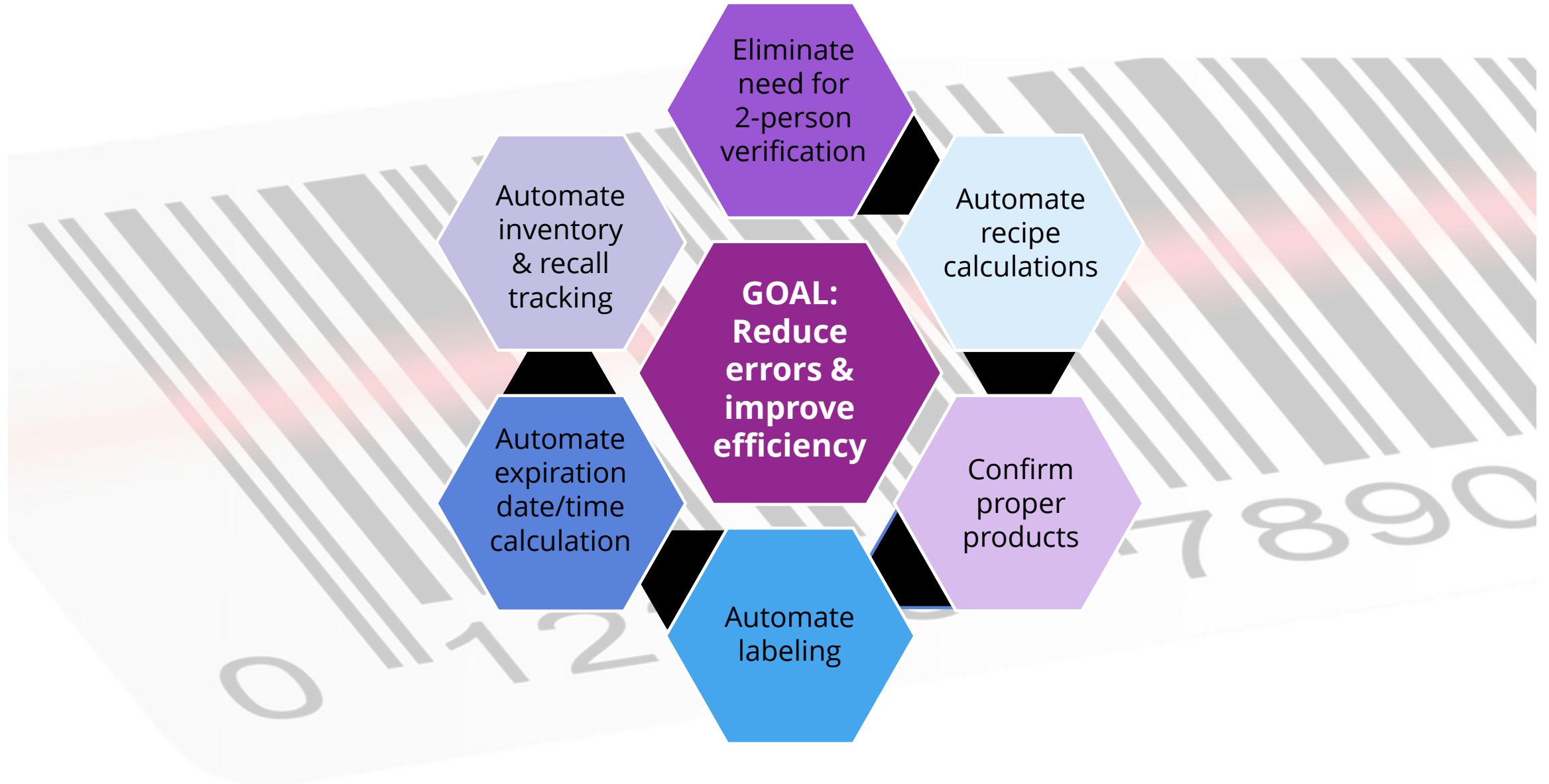
2-person verification check
of 2 recognized patient
identifiers

Bar code
scanning



Correct formulas/fortifiers should be confirmed
prior to preparation (if applicable) and feeding

CONSIDERATIONS FOR A BAR CODE SCANNING SYSTEM

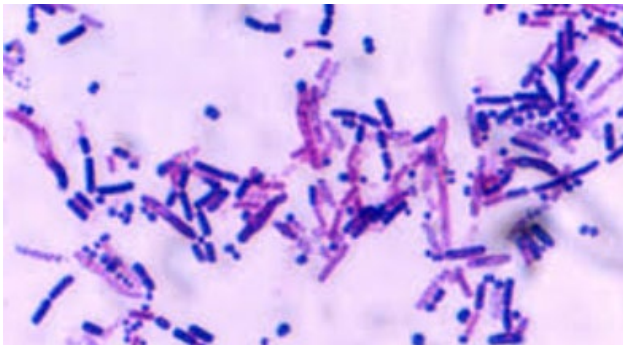




PUBLISHED OUTCOMES

RESEARCH: CONTAMINATION OF INFANT FEEDINGS

- Contamination of bedside vs centralized prep
- 2 phases (526 samples)
- Bedside prep 24x more likely to show contamination ($P < 0.001$)



Presence of Any Microbial Growth

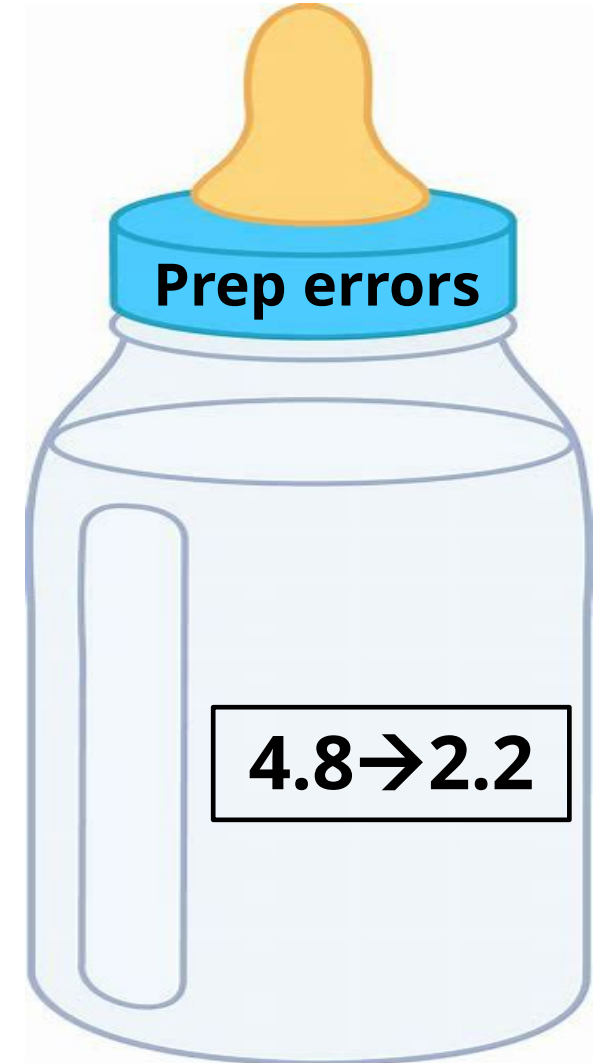
	Powdered Formulas	Sterile Liquid Formulas
Bedside Prep	43.7%	6.3%
Centralized Prep	4%	0%

RESEARCH: REDUCTION OF HM ERRORS IN NICU

- 6-year analysis of incorrect scans (near misses) in 114 bed NICU feeding >6,000 HM feedings monthly
- Bar code scanning implemented
- Based on high numbers of incorrect scans, additional interventions implemented
 - ✓ Hardware at each bedside
 - ✓ Centralized HM handling
 - ✓ Dedicated technicians



NEAR MISS SCANS PER 1,000 BOTTLES DECLINED:



RESEARCH: REDUCTION OF HM/FORMULA ERRORS

- 7-year analysis of incorrect scans (near misses) in 105 bed NICU feeding >10,000 HM feedings monthly and receiving 120,000–143,000 oz HM annually
- Centralized HM handling with dedicated staff implemented followed by bar code scanning 1 year later
- Data tracked for:
 - ✓ Wrong patient for HM/DHM (preparation, feeding, d/c)
 - ✓ Expired HM/DHM (preparation, feeding)
 - ✓ Wrong fortifier, formula, or ingredients at time of prep



7-YEAR DATA FOR WRONG PATIENT (HM/DHM)

Avg 175/year
or almost
once every
other day!

3

Reported incidents in the
2.5 years prior to
centralized prep &
scanning

ZERO

Reported incidents after
implementing centralized
prep with dedicated staff
(no bar code scanning)

1,226

Incorrect HM/DHM scans
(near misses) during the 7
years of centralized prep
with dedicated staff and
bar code scanning

7-YEAR DATA FOR EXPIRED HM/DHM

Avg 300/year
or almost
once daily!

ZERO

Reported incidents in the
2.5 years prior to
centralized prep &
scanning

ZERO

Reported incidents after
implementing centralized
prep with dedicated staff
(no bar code scanning)

2,103

Expired milk scans (near
misses) during the 7 years
of centralized prep with
dedicated staff and bar
code scanning

2.5-YEAR DATA FOR WRONG INGREDIENTS USED IN PREPARATION



ZERO

Reported incidents in the 2.5 years prior to centralized prep & scanning

ZERO

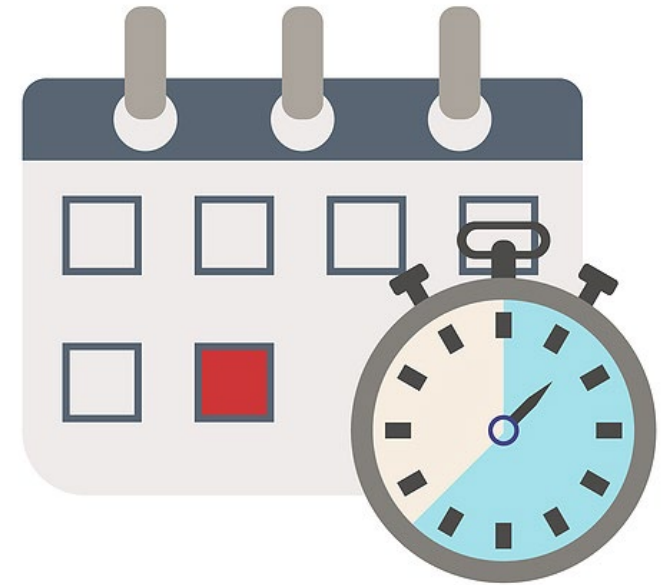
Reported incidents after implementing centralized prep with dedicated staff (no bar code scanning)

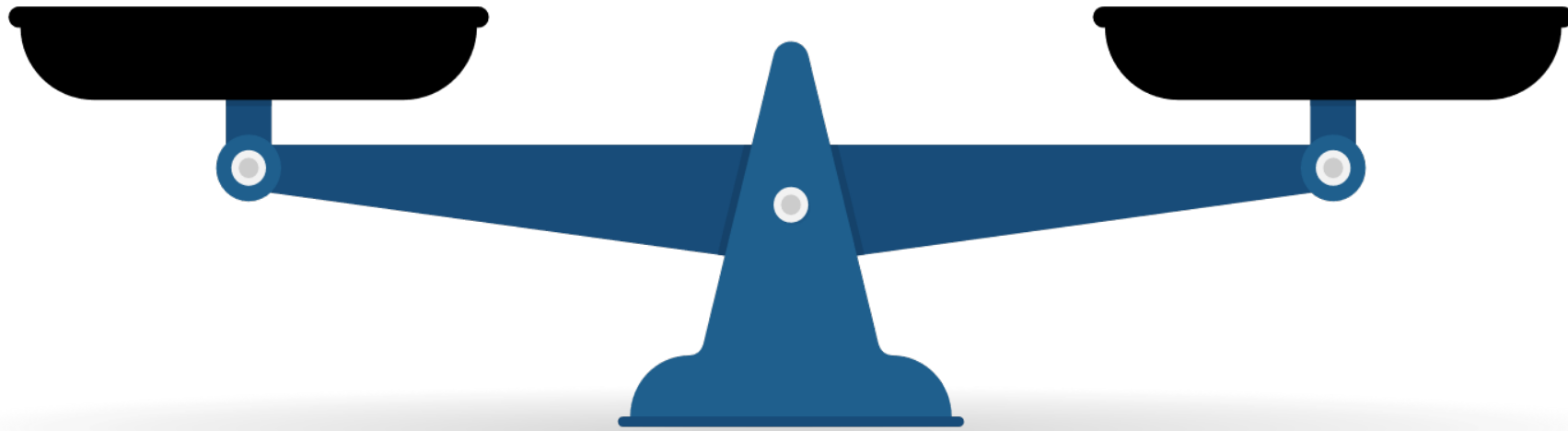
480

Incorrect product scans (near misses) during the 2.5 years of centralized prep with dedicated staff and bar code scanning

RESEARCH: TIME SAVINGS THROUGH BAR CODE SCANNING

- Time study using centralized preparation with dedicated technicians implementing HM/DHM bar code scanning
- 24-day time study conducted at 3 timepoints
 - Before scanning implementation
 - 3 weeks after scanning implementation
 - 3 months after implementation
- 1,405 prep room staff time hours saved
- 963 bedside RN hours saved per year based on 30 HM babies/yr
 - 263 hours per year for the 2-person HM verification
 - 700 hours per year in charting time





IMPLEMENTING BEST PRACTICES: GETTING STARTED

ASSEMBLE THE CORRECT PEOPLE

- Form PI or project team
- Consider key stakeholders
 - ✓ Bedside Nurses
 - ✓ Nurse Educators
 - ✓ Clinical Nurse Specialists
 - ✓ Management
 - ✓ Dietitians
 - ✓ Lactation
 - ✓ Milk Lab Technicians
 - ✓ Other Clinical or Ancillary Staff
- Champions



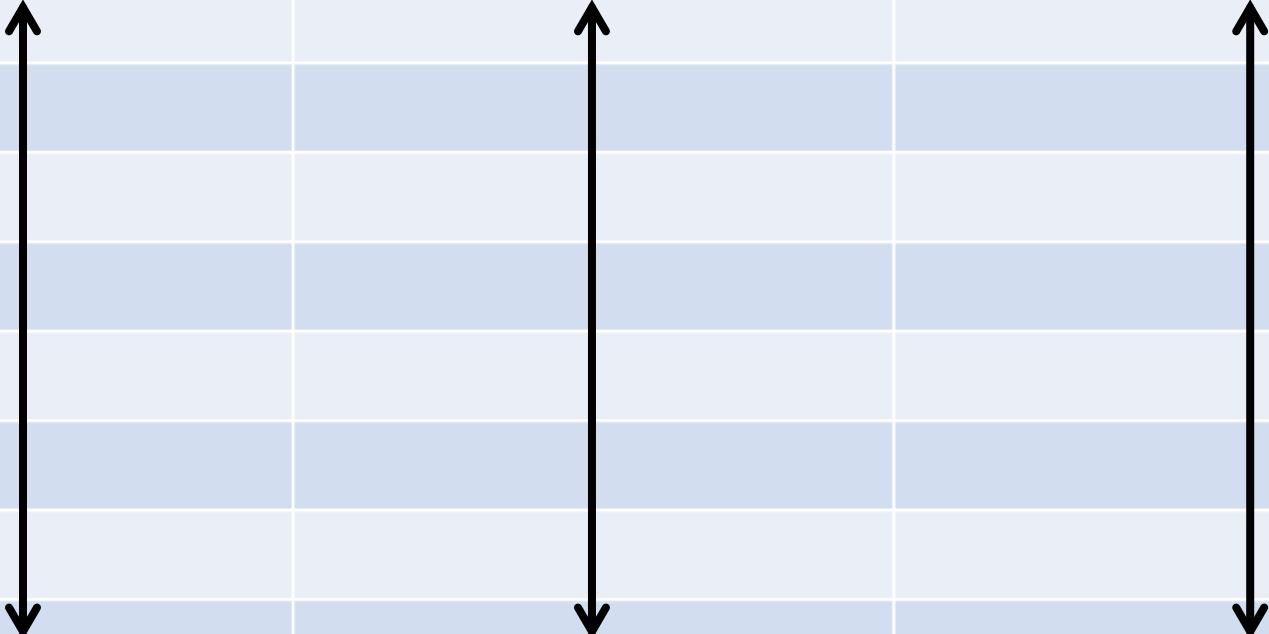
FAILURE MODE & EFFECTS ANALYSIS (FMEA) PROCESS

- Complete review of every step of a process
- Goal to identify all potential failure points
- Failure points are then scored for severity, occurrence, and detectability to obtain a Risk Priority Number (RPN) for each failure point



RISK PRIORITY NUMBER (RPN) SCORING

	Severity	Likely Occurrence	Detection
1	No effect	Almost never	Almost certain
2			
3			
4			
5			
6			
7			
8			
9			
10	Hazardous	Failure almost certain	Almost impossible



RPN = Severity Score x Occurrence Score x Detection Score

FROM FMEA TO IMPLEMENTATION

- Consider potential solutions
 - Start with unedited brainstorming
 - Choose the most appropriate solution(s)
- Determine next steps:
 - Is equipment needed? Is permission from any regulatory body needed?
 - Is staff training required? Do policies need to be revised?
 - Does the change impact a department not represented on the team?
 - What is the timeline for implementation?
- Identify owners for different parts of the project
- Determine the goals of the project and desired outcomes (metrics to be used)



SET A PROJECT PLAN

- Evaluate workflow
- Outline implementation steps
- Determine timeline for implementation
- Assign responsibility for project steps
- Track and report progress





FINAL THOUGHTS

RECOMMENDATIONS FOR THE HOSPITAL MILK ROOM (1936)

- Location where infant feedings “can be prepared in a satisfactory manner”
- Separate room with no other function
- “Clean” technique at all times and methods of preventing contamination
- Preparation accuracy
 - Scales for weighing powders
 - Precise recipes
- Detailed advice on equipment and staffing needs



Jeans PC, Rand W. Infant Nutrition. Artificial Feeding. In: *Essentials of Pediatrics for Nurses*. 2nd edition. Philadelphia: J.B. Lippincott Company; 1936:180-185.

KEY TAKEAWAYS

- Regulatory standards reference the proper handling of food and nutrition products for all patients
- 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

