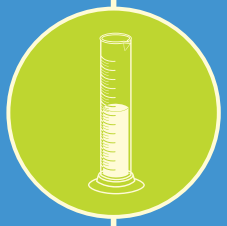
Infant and Pediatric Feedings

THIRD EDITION



Guidelines for Preparation of Human Milk and Formula in Health Care Facilities

Pediatric Nutrition Dietetic Practice Group

EDITORS

Caroline Steele, MS, RD, CSP, IBCLC, FAND

Emily Collins, MHA, RD, CNSC

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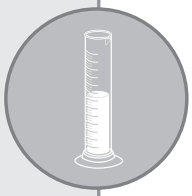

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FOREWORD

THE SAGE WORDS "Let food be thy medicine and medicine be thy food," often attributed to Hippocrates, come to mind as I review the contents of this new edition. The editors have kept the emphasis on safety and standardized processes for handling human milk (HM) and formula—truly both food and medicine—as they are provided to hospitalized infants and children. Interwoven within this standardized theme is the recognition of current trends toward personalized medicine, which place a premium on individualized approaches. This is especially evident with new chapters on lactoengineering, blenderized tube feeding, and modulars and additives (including probiotics).

Apparent in this new edition is the expanded content related to handling HM. Neonatal intensive care units have undergone a transformation in their use of human milk for very-low-birth-weight (VLBW) infants (those born weighing less than 1,500 g). With the strong evidence for reductions in morbidity and mortality related to prevention of sepsis and necrotizing enterocolitis associated with the use of HM compared with formula, the support from health care facilities for mothers to express their own milk has improved. Concurrently, the use of pasteurized donor human milk (DHM) has also dramatically increased, with the goal of providing many of the benefits of HM when the mother's own milk is not available. These trends, coupled with the need for routine fortification for VLBW infants, highlight an exponential increase in processes that must be anticipated and accommodated: correct labeling, storage, preparation, and administration of expressed milk ("right milk, right patient"); hygienic handling of both expressed HM and pasteurized DHM during feedings; and proper fortification (including the potential use of lactoengineering techniques). New products and milk components are rapidly emerging to best meet the needs of VLBW infants, needs that themselves vary because of differences in degree of prematurity, health status, and nonnutritional exposures. There is every reason to believe that this diverse array of options will continue to increase, and health care facilities would do well to develop policies and procedures that are both standardized and modifiable. The new chapters in this edition provide an excellent reference, whether for starting a new unit or for upgrading an established infant/pediatric feeding preparation operation.

Another trend is the move toward "natural" feeding in nutrition support through the use of blenderized foods for tube feedings. Both newly available commercial products and home-prepared concoctions are increasingly being sought after and used by families. The putative benefits of "real food" over traditional enteral formulas may be met with skepticism. However, as we learn more about the literally thousands of bioactive compounds (such as phytochemicals), the kernel of truth in such claims becomes increasingly plausible. This brings enormous potential complexity to formula preparation and warrants the new chapter addressing this topic. Whether health care facilities can sustain the effort and cost associated with safely providing such combinations for enterally fed patients remains to be seen, and this certainly warrants further examination.

Besides addressing these emerging trends, the third edition of this invaluable book contains useful details for traditional formula feeding in the health care setting. The guidelines emphasize meticulous care and adherence to standard operating procedures at every step. As the authors have commendably taken on several new trends, including the advance toward personalized feeding, the call for evidence-based practice could not be more relevant.

The foreword in the second edition of this book noted that recommendations are only as good as their implementation. This is no less true today. By recognizing that the quality of the feedings provided in a health care setting is a vital medicine, this book appropriately highlights the rigorous methods with which it should be prepared, handled, and provided to patients. In our current environment of health care choice with patients and families as consumers, expectations for adherence to best practices are not only reasonable but also imperative.

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PREFACE

IT MAY SEEM UNUSUAL that a reference book can be so endeared to so many, but this is one such case. Friends and colleagues have reported anxiously awaiting the third edition of *Infant and Pediatric Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities.* However, this latest edition would not have been possible without the work that preceded it and the tireless efforts of the original concept visionaries. The third edition is actually the fourth publication in a series on this topic published by the Pediatric Nutrition Practice Group (PNPG) of the Academy of Nutrition and Dietetics (formerly the American Dietetic Association).

The first publication in this series was *Preparation of Formula for Infants: Guidelines for Health Care Facilities*. That 1991 publication was the result of a project codirected by Diane M. Anderson and Linda J. Boyne, which was supported in part by MCJ 176020 from the Maternal and Child Health Services Block Grant Program (Title V, Social Security Act), Health Resources and Services Administration, Department of Health and Human Services. The manual was the first of its kind and the result of collaboration between the PNPG and many multidisciplinary professional organizations.

In 2004, the PNPG published the first edition of *Infant Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities*. Editors Sandra T. Robbins and Leila Beker led a group of clinically experienced authors in expanding the original concept from the 1991 publication to include the handling of human milk. The first edition was supported in part by grant funding from the Maternal and Child Health Bureau (grant 5 T79 MC 00023-03), Health Resources and Services Administration, and Cincinnati Children's Hospital.

Editors Sandra T. Robbins and Robin Meyers directed the publication of the second edition in 2011, which expanded further on the topics previously covered and provided

guidance on new areas such as the handling of pasteurized donor human milk, the use of sterile liquids over powdered formulas, and recommendations for probiotic-containing formulas. Commonly referred to as simply "the green book," the second edition has been widely cited as the definitive authority on human milk and formula handling within the health care setting and has been used by both clinicians and surveyors alike.

In 2015, Sandra T. Robbins, Liesje Carney (then–PNPG publications chair), and Nancy Nevin-Folino began discussions that initiated work on this third edition. Their persistence and conviction that this continue to be a relevant publication led to this successful project.

As editors of this 2018 third edition, we are grateful for the hard work and dedication of all the authors and reviewers, without whom this publication would not have been possible. We are exceptionally indebted to Sandra T. Robbins and Robin Meyers (current authors and previous editors), as well as Leila Beker and Diane M. Anderson (full manuscript reviewers for this edition and previous editors) for their support and guidance. It is an honor to be part of a project with such a distinguished history and rich background of collaboration. Our gratitude goes out to the authors, reviewers, and advisors of the previous publications in this series who have led this project to where it is today. We also thank our families and our employers, whose support allowed us to dedicate countless hours to ensuring that this publication's history of excellence continued into this edition.

Caroline Steele, MS, RD, CSP, IBCLC, FAND
Emily A. Collins, MHA, RD, CNSC
Editors

OVERVIEW OF THE THIRD EDITION

Caroline Steele, MS, RD, CSP, IBCLC, FAND

The purpose of this publication is to provide guidance for the handling of human milk (HM) and formulas in the health care setting to improve patient safety. Following is a list of serious problems related to the mishandling of infant/pediatric feedings:

- Contamination of feedings (foodborne illness)
- Preparation errors (incorrect quantities of modulars, additives, or product concentration)
- Misadministration of feedings (providing the wrong HM or formula to a patient)

With few exceptions, HM is the preferred feeding for infants, including those who are premature and hospitalized. Centralized handling of HM and formulas in a designated preparation space is considered a best practice and is supported by the literature.[1] Recommendations in this publication focus on such a model; however, options for the noncentralized handling of infant and pediatric feedings are discussed *should there be no alternative option* (refer to Section III: Considerations for Noncentralized Handling of Human Milk and Infant/Pediatric Formulas in Health Care Facilities).

This edition was prepared from 2016 through 2018 through a review of the literature by pediatric registered dietitian nutritionists and International Board Certified Lactation Consultants. Individuals from a variety of disciplines and clinical settings and from the industry have provided guidance and review for individual chapters.

ORGANIZATION OF THIS PUBLICATION

The goal of this publication is to provide facilities with guidelines to ensure that infants and children receiving HM and formulas in the health care setting are receiving feedings prepared in the safest manner possible. This edition is divided into three sections.

- **Section I** provides a summary of the guidelines from each chapter.
- **Section II** encompasses the individual chapters.
    - Each chapter provides detailed guidance on a specific aspect of infant and pediatric feeding preparation, with emphasis for health care facilities.
    - Sample tools or resources are provided in many chapters to assist facilities in developing their own processes or policies and procedures.
    - Handling of HM and formulas at home may differ from best practices for the ill, hospitalized infant or child; therefore, Chapter 11 does include information about discharge education.
- **Section III** examines considerations for handling of HM and formulas in health care facilities without formal centralized preparation and handling operations.

NEW IN THE THIRD EDITION

In the 7 years since the second edition was published, the literature has significantly increased surrounding the use of HM and donor human milk products, handling of infant and pediatric feedings, and quality assurance initiatives to improve patient safety in this area. With this expansion of scope, the title of this edition was updated to reflect the focus on both infant and pediatric feedings. Each chapter has been updated to include new information in each of these areas, and new chapters have been added to either expand on previously included topics or address new topics. New chapters include the following:

- **Getting Started (Chapter 1):** This chapter was designed to provide details on how to initiate and systematically implement process changes for HM and formula handling
- **Lactoengineering (Chapter 6):** This chapter was removed from the expressed HM handling chapter in the second edition and expanded to a full chapter to include details regarding HM analysis and processing of HM to change the composition
- **Donor Human Milk, Human Milk Products, and Milk Sharing (Chapter 7):** This chapter was carved out of the expressed HM handling chapter in the second

edition and expanded to include details about newer products available as well as information on risks and recommendations for informal milk sharing

- **Blenderized Tube Feeding (Chapter 9):** This chapter was added to address the growing trend of using blenderized real foods for enteral feedings within the pediatric health care setting
- **Modulars and Other Additives (Chapter 10):** This chapter was removed from the formula preparation chapter in the second edition and expanded to its own chapter to include greater detail regarding available products

APPLICATION OF THE CONTENT

The content in this edition should not be considered regulations. These recommendations are best-practice guidelines based on the research and scientific evidence available at the time of publication. In the absence of pediatric studies, information from the adult literature and expert consensus are included. Redundancy within this edition was intentional to emphasize important points. The goal of this publication is to provide facilities with guidelines to ensure that infants and children receiving HM and formula in the health care setting are receiving feedings prepared in the safest manner possible.

REFERENCE

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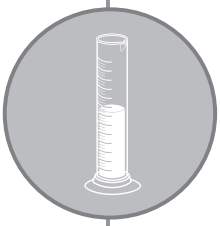
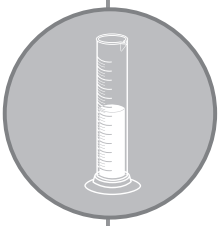


SECTION I

General Guidelines for Human Milk and Formula Preparation



SECTION II

GETTING STARTED

1

Caroline Steele, MS, RD, CSP, IBCLC, FAND, and Emily A. Collins, MHA, RD, CNSC

INTRODUCTION

Any change in health care practice requires careful planning and analysis. Evaluation of human milk (HM) and formula handling within the health care setting can be an overwhelming task and leave those responsible unsure of where to start. Before making any recommendations or changes, it is critical to evaluate the current state in order to identify opportunities for improvement. Ensuring that the proper individuals are assembled to both correctly analyze the current state and to determine the best practices for the future is of paramount importance.

ANALYSIS OF CURRENT STATE

When considering practice changes, first outline in detail the entire current state, including staff involvement and cost. It is also imperative to compile data on current error rates and patient safety concerns to determine opportunities for improvement and the appropriate course of action.

The team evaluating HM and formula handling should include individuals from various areas of the facility who have firsthand knowledge of the current processes and current problems or challenges. Frontline staff, as well as those in supervisory roles, should be included, as each brings a unique perspective and knowledge to the process. The following disciplines could be included as team members:

- bedside registered nurse
- registered dietitian nutritionist (RDN)
- nutrition and dietetics technician, registered
- nurse manager
- nurse educator
- clinical nurse specialist

- clinical nutrition manager/director
- risk manager
- infection prevention staff
- information technology staff
- foodservice or pharmacy staff (if appropriate based on preparation location)
- physician champion
- executive champion
- materials management staff

One method to evaluate the current state is a failure mode and effects analysis (FMEA), which uses a stepwise approach to identify all potential failure points within a process. An FMEA evaluates failures of existing processes or potential failures in processes being designed or modified.[1] By using a detailed outline of the current process, all potential failure points for each step are identified and may be scored in relation to severity, occurrence, and detectability to determine an overall risk priority number (RPN). Table 1.1 outlines RPN scoring.[2] Based on the RPN score, root causes can then be identified for the most critical potential failure points. Refer to Figure 1.1 on page 45 for an example of a completed FMEA form evaluating HM handling.

TABLE 1.1 Risk Priority Number[a] Scoring[2]

POINT VALUE	SEVERITY	LIKELY OCCURRENCE	DETECTION
1	No effect on patient or service.	Almost never. Failure unlikely.	Almost certain with current controls.
2	Very slight effect on patient or service.	Remote.	Very high likelihood with current controls.
3	Slight effect. Error does not reach patient.	Very few failures likely.	High likelihood with current controls.
4	Minor effect. Error reaches patient but does not cause harm/require attention.	Slight. Few failures in service.	Moderately high likelihood with current controls.
5	Moderate effect. Patient not harmed but requires attention.	Low. Occasional number of failures.	Medium likelihood with current controls.
6	Significant effect.	Moderate number of failures.	Low likelihood with current controls.
7	Major effect.	Moderately high number of failures.	Slight likelihood with current controls.
8	Extreme effect.	High number of failures.	Very slight likelihood with current controls.
9	Serious effect. Potential hazardous effect.	Very high number of failures.	Remote likelihood with current controls.
10	Hazardous effect. Safety related.	Failure almost certain.	Almost impossible with current controls.

[a]Risk priority number = severity point value × occurrence point value × detection point value

EXTERNAL CONSIDERATIONS AND BEST PRACTICES

In addition to an internal evaluation, external factors must also be considered. Most crucial are regulatory considerations. However, benchmarking against other facilities and incorporation of published best practices are important as well.

Regulatory Considerations

In 2000, The Joint Commission (TJC) suggested the use of the Hazard Analysis Critical Control Point (HACCP) guidelines for enteral feedings, at which time many facilities began using these guidelines specifically for the preparation of HM and formula feedings.[3] In addition, these four TJC standards may be applied to the handling of HM and formulas within the health care setting[4]:

- Provision of Care .02.02.03.01: The hospital assigns responsibility for the safe and accurate provision of food and nutrition products.
- Provision of Care .02.02.03.06: The hospital prepares food and nutrition products using proper sanitation, temperature, light, moisture, ventilation, and security.
- Infection Control .01.05.01: All hospital components and functions are integrated into infection prevention and control activities.
- National Patient Safety Goal .01.01.01: Use at least two patient identifiers when providing treatments or procedures. (This is potentially relevant as it relates to ensuring that two patient identifiers are used prior to HM administration. Although HM feeding is not a procedure, it does involve the administration of a bodily fluid.)

All states have regulations that require health care facilities to store, prepare, and distribute foods under sanitary conditions. These same criteria should apply to HM and formula because these are the primary foods for some hospitalized infants and children. The 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. In the 2014 FGI guidelines, recommendations were updated to ensure that the preparation area provided a "flow of materials from clean to soiled to maintain aseptic preparation space."[5] 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 the use of an area or room used exclusively for the preparation of infant feedings that may be adjacent to the NICU or located elsewhere within the facility but that is separate from patient care areas.[6-16] Most indicate that a refrigerator, work counter, storage facilities, handwashing station, and separate cleanup area for washing and sanitizing are required.[6-16]

Benchmarking Against Other Facilities

When proposing a change in practice, it is important for a facility to know how its current practice compares with those of other facilities in the region or other similar facilities nationwide. For example, a freestanding children's hospital may want to know the practices of other freestanding children's hospitals, whereas an adult hospital with a small level II NICU may want to understand the practices of other level II NICUs. These data can be obtained through listserv inquiries or networking through professional organizations such as the Pediatric Nutrition Practice Group of the Academy of Nutrition and Dietetics.

An informal survey of hospital RDNs on the Pedi-RD and Children's Hospital Association Clinical Nutrition Management listserves in 2016 found that, of the 37 respondents, 28 (75%) had a dedicated preparation room and 26 (70%) had dedicated staff for HM handling (unpublished data).

Published Best Practices

Many professional organizations, including the Academy of Nutrition and Dietetics, the American Society for Parenteral and Enteral Nutrition (ASPEN), the National Association of Neonatal Nurses, and the Human Milk Banking Association of North America (HMBANA), have published best practices surrounding the handling of HM and formula within the health care setting. These best practices emphasize the importance of preparation location, specialty trained staff, and proper identification of HM to prevent misadministration.[17-21]

In addition to meeting regulatory standards, many health care facilities seek the recognition of providing expert care by applying for various designations or awards. One example is the *US News and World Report* Best Hospitals rankings, which evaluate health care facilities on individual specialty areas considering many factors, including patient safety. For the first time in 2015, the application for recognition for neonatology services asked questions specifically about the handling and administration of HM (refer to Box 1.1).[22]

The addition of these questions highlights the recognition of the importance of HM handling for patient safety.

BOX 1.1 *US News and Wold Report* Best Hospitals Nutrition and Lactation Questions[22]

Does your hospital/neonatal intensive care unit (NICU) offer a dedicated area within the facility but away from the bedside for milk and formula preparation? To answer "Yes" then this area must meet both of the following criteria:

- Infant feeding preparation room using the aseptic (clean, "no-touch") technique;
- The room requires restricted access and healthy personnel, with no other activity occurring in the room.

Does your NICU program offter the following for nutrition and breastfeeding?

- NICU-dedicated lactation specialists who have the International Board Certified Lactation Consultant (IBCLC) certification or the Breastfeeding Counselor Certification (CBC)
- Cohort of NICU registered nurses specifically trained in lactation counseling
- NICU specific Breast Milk committee
- Process to rent breast pumps to families
- NICU specific risk reduction program that includes processes designed to reduce breast milk errors
- Donor breast milk program with written institution-specific criteria for the initiation and discontinuation of donor breast milk

Which of the following elements does your NICU specific risk reduction program include?

- Bar coding system, such as bedside scanning, for correct breast milk identification
- Dedicated breast milk technician who prepares milk for proper identification and distribution

Does your NICU program track the breast milk administration error rate (eg, wrong breast milk given to patient)? If yes, please report the number of breast milk administration errors, the breast milk feeding patient days in infants admitted at < 7 days of age and discharged home at <120 days, and the breast milk administration error rate for the last calendar year.

DETERMINATION OF RISKS

Whether an FMEA or other evaluation approach is used, the results of the current state analysis (including all potential failure points) can then be used to determine risks. When evaluating risk, it is important to consider the risks of doing nothing. Regarding HM and formula preparation and administration, the risks of not implementing best practices could include the following:

- Patient harm from receiving the wrong HM, the wrong formula or HM fortification, or contaminated feedings
- Regulatory citations for HM misadministration, including scenarios that are considered Health Insurance Portability and Accountability Act (HIPAA) breaches
- Financial impact, including:
    - fines for citations, cost of laboratory workup required following HM misadministration, cost of medical complications resulting from misadministration, or loss of revenue if families seek care elsewhere after an event
    - labor cost for staff time following up on a misadministration error, such as time spent explaining the issue and course of action to the family and time spent conducting a risk–cause analysis to determine why the error occurred. This would include time spent by the physician, RDN, risk manager, infection prevention specialist, nurse manager/director, nutrition manager/director, and others
- Loss of family satisfaction or confidence in the health care team
- Liability/family compensation for errors

DETERMINATION OF NEXT STEPS

Next steps may be determined after critically comparing current processes with best practices, evaluating error rates within the current system, and identifying potential failure points. The identified risks with the highest RPN score (those most common and/or least likely to be detected) should be priorities. Root causes of these risks will drive the practice changes. Involvement of the entire multidisciplinary team, including frontline staff, is critical to ensure that all aspects are considered when developing new processes and solutions to current problems. It is also critical to involve an executive champion throughout the process to ensure that he or she understands the depth of the current problem, best practices, and rationale for proposed solutions. Furthermore, the executive champion may serve as a liaison between departments as well as offer insight into potential barriers for making the change (such as competing priorities, financial resources, space, or lack of understanding of the need). The executive champion may also offer insight on how to best present the information when seeking senior leadership approval (such as communication style preferences or usual proposal format for the facility).

A plan proposed for practice change should start with an overall summary of the problem (including potential risks and root causes), regulatory requirements and best practices, and an overview of the competitive market. Additionally, the proposed plan should do the following:

- Explain how the plan addresses the potential risks identified. Consider including the percentage of risks addressed by each phase of change.
- Discuss options for potential risks not addressed by the plan.

- Outline the costs for making the change. Costs should include operating costs (such as supplies and staff), capital costs (such as equipment and major software licenses), and construction costs. Costs should also be identified as ongoing vs one-time costs.
- Outline the impact of doing nothing (refer to the Determination of Risks section of this chapter).
- Discuss any potential for revenue or cost savings associated with the change.
- Specify if the plan could be implemented in phases.
- Outline those within the organization who would be involved with making the change and who would be the owner of the project.

Refer to Figure 1.2 for a sample template for an HM and formula handling proposal.

PREPARATION OF THE OPERATIONAL PLAN

Once analysis of the current state is complete, creating a written plan of how to operationalize changes will help move the project from the analysis stage to the action stage. This written operational plan is of paramount importance for stakeholders as a tool for consideration of all relevant details and may be used as a reference for senior leadership, regulatory bodies, and, most importantly, the person(s) responsible for executing change. The creation of an operational plan is important no matter the breadth of the

FIGURE 1.2 Human Milk and Formula Handling Proposal Template

FACILITY NAME | **PREPARED BY**

HUMAN MILK AND FORMULA HANDLING PROPOSAL | **DATE**

EXECUTIVE SUMMARY
- 1 page or less overview of the problem and proposed solutions

OVERVIEW OF THE PROBLEM
- Frequency of reported errors or reason the process is being reviewed
- Summary of results from failure mode and effects analysis (FMEA) or other process analysis
- Potential failure points
- Root causes
- Barriers

REVIEW OF REGULATORY REQUIREMENTS AND REPORTED BEST PRACTICES
- The Joint Commission (TJC) and/or state requirements
- Review of the literature
- Review of recommendations from professional organizations and survey groups (such as those providing additional certifications or awards)

MARKET COMPARISON
- Review practices of other similar facilities or facilities that are geographically close (or both)

RECOMMENDATIONS
- Specific changes to be made, such as a change in preparation location, a change in staff, a change in workflow, etc

COSTS
- Initial costs (construction, equipment, supplies, training, etc)
- One-time costs
- Operating costs (staffing, supplies, software licensing fees, etc)
- Consider comparing annual costs of making the change vs the potential costs of having an error

change, whether it be expanding the current scope of services within the same space or opening a new operation in an existing or new space. In hopes of providing the most detail, operational planning for a new operation will be discussed. Operational plan considerations may include the following:

- Home department of the operation and space to be utilized
- Necessary workflow changes for the operation's overall scope
- Workload volume (number of patients and scope of service)
- Operational hours and schedule
- Number of full-time equivalents (FTEs) for operations
- Supplies and equipment needed
- Project cost (inclusive of all considerations such as equipment, staff, and supplies)
- Staff training required
- Funding sources
- Regulatory approval process

Refer to Figure 1.3 on page 32 for an operational plan template.

Early in the process, it is important to identify the workgroups necessary to develop the operational plan and work toward the final goal. Regularly scheduled meetings are encouraged to ensure continued progress of the group.

Department Oversight and Space

A feeding preparation operation affects many areas of a health care facility, and each institution may have a slightly different way of overseeing such an operation. For a new operation, identification of the home department is an important first step. Common examples of the home department include nutrition services, pharmacy, lactation services, nursing, or the NICU. Next, examination of the physical space to be used is important in conceptualizing the operation's services and workflow. Following is a list of physical space considerations:

- Size and function of preparation space
    - determination if space allows for all HM to be stored in the preparation space or if additional storage will be located elsewhere
    - determination if HM will be dropped off at the location or moved to a separate designated area
- Location characteristics
    - physical location within the building
    - proximity to patient unit(s)
    - adjacent rooms/corridors
    - access (including use of key/keypad/badge access security)
    - proximity to storage space outside of operation for HM, formula, fortifiers, supplies, and equipment
- Physical characteristics and size of the space
    - anteroom
    - preparation area
    - storage within room
    - plumbing, electrical, and technology needs

FIGURE 1.3 Operational Plan Template

FACILITY NAME

OPERATIONAL PLAN FOR FEEDING PREP ROOM PROJECT

PROCESS OWNER(S)

EXECUTIVE SPONSOR(S)

DATE PLAN APPROVED BY OPERATIONAL PLANNING TEAM

BACKGROUND INFORMATION

Describe the physical space of the new operation related to this service/process (include equipment storage, etc):

List/describe the elements of the new operation's design that necessitate change to the way this service/department currently operates, which will need to be considered as the operational plan is developed:

Identify any ongoing process or quality improvement activities that should be considered during this operational plan's development:

OPERATIONAL PLAN

General service delivery plan

Staff flow

How will staff come into and go out of this new space to provide service?

Patient flow (as applicable)

How will patients come into and go out of this department's space?

Other service delivery details for consideration

Hours of operation

Current operation

Future operation

Staffing plan to accomplish daily department operations

Patient/family education plan

Supply and equipment plan

Procurement, storage, etc

SCOPE OF SERVICE

Plan of delivery services to adult patients (if applicable)

Plan for patients requiring care outside the operation's geographical scope (requests for products for outpatients in clinic, pediatric research patients, etc)

Identify departments [✓] where you will *receive* or *deliver* service:

DEPARTMENT (examples for consideration)	RECEIVE	DELIVER
Inpatient Acute Care Unit A	☑	☑
Emergency Department	☐	☑
Environmental Services	☑	☐
Infection Prevention	☑	☐
Pathology	☑	☐
Pharmacy	☑	☑
Post-Anesthesia Care Unit	☐	☑
Ronald McDonald House within a facility	☑	☑

ADDITIONAL CONSIDERATIONS

Regulation/compliance/accreditation

Other plan components/issues

Communication and documentation

- What groups/meetings were convened to develop this plan? Indicate membership and meeting dates.
- Are there other groups (operational planning workgroups or task forces, units, suppliers, customers, etc) with whom this plan should be shared prior to approval by the Operational Planning Committee? If yes, identify them.

Are there existing Scope of Service Agreements regarding service provision related to this operational plan? Are there new agreements that need to be developed? If yes, note them here.

Are there any existing policies and procedures that will need to be changed or created in conjunction with the changes recommended? If yes, note them here.

Pilot/early implementation: Can any elements of this new operational plan be implemented in the current operational area? If so, what is the plan (time frame, order of steps) for doing so?

Workflow

Outlining the workflow is a critical step in operational planning. Operational routines will drive staffing needs. It may be helpful to identify the following in the workflow section of the operational plan:

- Current state, including:
  - preparation volumes
  - operational routines
    - daily tasks, as well as those tasks performed on a less frequent basis (eg, weekly, monthly, or quarterly)
    - time studies for entire workflow and individual tasks
  - reliance on other departments as part of daily routines (eg, coordination with pharmacy services for the addition of electrolytes to formulas)
  - delivery routes and patterns (eg, delivering feedings to central unit refrigerators vs individual patient rooms)
  - staffing needs
- Future state, including:
  - anticipated volumes/growth
  - determination of new services or locations, such as:
    - addition of HM handling, storage, and preparation
    - addition of donor human milk (DHM) capabilities
    - lactoengineering services (refer to Chapter 6)
    - addition of formula preparation or processing of ready-to-feed infant or enteral feeding orders
    - change in preparation or delivery frequency
    - change in delivery locations (eg, to additional patient care units or to individual patient rooms instead of centralized unit refrigerators)
    - change from bulk preparation to unit-dosed feedings
    - addition of new technology such as bar code scanning
  - new or continued reliance on other departments as part of daily routines (eg, coordination with pharmacy services for the addition of electrolytes to formulas)
  - predicted operational routines based on existing routines that will continue as well as newly identified services
  - predicted staffing needs based on predicted operational routines

Operational Hours

A complete review of the workflow allows for a better estimate of operational hours necessary to meet the operation's goals and projected volumes. Operational hours are dependent on the availability of FTE support (budgeted FTEs and the ability to fill necessary positions) and facility-specific goals and needs. Hours of service should be based on the time required to perform operational routines. Optimal schedules for internal customers based on typical feeding times, handling of urgent requests, nursing routines, bedside rounding times, and parent routines (if delivering to in-room refrigerators) should also be taken into consideration. A cost–benefit analysis of various operating hours may be used to highlight advantages and disadvantages of different proposed hours of operation. Clearly defined after-hours processes are critical to ensure the safe and accurate provision of feedings if the operation is not 24 hours per day.

Equipment and Supplies

Equipment planning will be most accurate if completed after the workflow and operational hours are determined. Considerations for equipment and supply planning include the following:

- Required volumes and inventory levels of all required supplies
- Source of supplies (internal or external), including:
  - updates to current purchasing agreements as necessary (such as modifying delivery location or financially responsible department)
  - need for new external vendors (including contract and delivery plans)
- Plan for equipment and supplies necessary on first day of operations

Budget

Cost estimation is a critical component of operational planning. Certain decisions may be based strictly on cost, and other decisions may be based on service or quality goals. It is important to formally ensure that cost projections are considered for the following (as needed):

- Renovation to space
- New equipment and supplies
- New technology-related equipment (computers, printers, bar coding/inventory systems)
- Projected FTE cost
- Training and optional certifications

If a new department will become responsible for infant and pediatric feeding preparation, it is important to ensure that budgets are transitioned to align with the appropriate cost centers.

Funding Sources

In conjunction with budgeting, both short-term and long-term funding sources should be identified. Following is a list of potential funding sources to explore:

- Home department operating budget
- Facility general funds
- Project funds (if moving into a new hospital, for instance)
- Capital equipment funds
- Grant funding
- Philanthropy

Regulatory Approval Process

The operational plan should also address regulatory approvals required prior to initiating service. Many states have certain requirements for new construction and hospital licensing. Refer to state and local regulations as well as facility-specific guidelines for details. In addition, some states require licensing for the handling and distribution of pasteurized DHM (refer to Chapter 7).

Senior Leadership Engagement

As previously noted, having an executive champion involved throughout the process is ideal. Collaboration with the executive champion will help identify the best timing and strategies for introducing plans to facility senior leadership and operational committees. The executive champion can provide insight into potential space, budget, and FTE opportunities and limitations. The operational plan will provide a high-level overview of the project for discussions with senior leadership.

PROJECT IMPLEMENTATION

Status Reports

Once the project is approved, a status report may be used as an organization and planning tool for tracking major milestones. Each status report will be institution specific; however, it will generally cover similar milestones when preparing to move, expand, or open a new operation. A status report serves as a concise communication tool between the project manager and key stakeholders (including senior leadership). It may be sent out on a regular basis (perhaps with increasing frequency as the project is nearing completion) to provide a clear depiction of the project timeline, assist the team in identifying the timing of key activities, and promote preplanning for unexpected events. Refer to Figure 1.4 on page 36 for an example of a status report.

Policies and Procedures

Creating an inventory of the facility's policies and procedures (P&Ps) for the current state will help identify necessary changes and new policies needed based on the operational plan. The current state analysis exercise should not be limited to the home department but instead should utilize a team of individuals with diverse knowledge bases and perspectives to identify necessary changes and new P&Ps needed. Many other departments may have P&Ps that relate to the operation's work. For instance, pharmacy may have a P&P on adding electrolytes to formulas, or nursing may have a P&P regarding storage or preparing to send HM home at time of discharge.

Once existing P&Ps are identified and revised or new P&Ps are created as needed, team members from each relevant area should help to identify the appropriate pathways for approval. Following approval, information distribution and corresponding staff education are important. In conjunction with distribution of new information, there should be removal of outdated information from patient care units, intranet resources, and parent education portals/handouts.

Scope of Service Documents

P&P updates often occur concomitantly with scope of service discussions. The scope of service discussion presents an opportunity for areas to work together on how to best meet the operational goals and builds interdepartmental collaboration by investing mutual time toward a shared goal. This exercise is especially important should the operation assume responsibility for a duty previously handled by another area (such as transitioning the storage and preparation of HM from nursing to a centralized preparation room). Leadership from each impacted area should meet to solidify service details prior to the

FIGURE 1.4 Sample Project Status Report

TITLE OF PROJECT/OPERATION

Project Name:

Project Manager:

Executive Director/Project Manager:

Status Report Period Ending (Date):

PROJECT DESCRIPTION

The scope of this project includes…

OVERALL PROJECT STATUS—CHECK ONE:

☐ Green (on schedule, within budget, within scope, no major issues)

☐ Yellow (on schedule, within budget, within scope, but there are issues that may become significant)

☐ Red (major issues that require management attention are present; may also change date and impact budget. See issues below.)

POTENTIAL RISKS THAT REQUIRE MANAGEMENT ATTENTION:

Items completed since last report (from period ending xx/xx/xx):

Ongoing items for the next reporting period:

Issues that require business decision:

Items planned but not completed in the last reporting period:

Items planned to be completed in the next reporting period (period ending xx/xx/xx):

KEY MILESTONES REPORTING Milestone Description	Estimated Completion Date*	Actual Completion Date
Define operational concept and funding potential	18 months	
Senior leadership approval of feeding plan operation concept	18 months	
Complete high-level job description of manager of operation	12–18 months	
Administrator/project manager overseeing operation to assemble oversight team (registered dietitian nutritionist [RDN] and associated leadership, nurse manager/educator, physician champion, executive champion)	12–18 months	
Obtain staffing approval for manager of operation from human resources	12–18 months	
Complete training plan for manager of operation	12–18 months	
Post position and complete interviews for manager of operation	12–18 months	
Hire RDN manager of operation	12–18 months	
Identify/request capital equipment needed	12–18 months	
Operation manager to begin benchmarking	10–12 months	
Operation manager to begin analysis of current state	10–12 months	
Submit first draft of operational plan	10–12 months	
Identify operation-specific technology needs (such as outlets, telephone or facsimile lines, and computer internet ports)	8–10 months	
Complete order for small equipment	8–10 months	
Complete final draft of operational plan	9 months	
Complete work process/flowcharts	9 months	
Complete plan for operational workflow schedule	9 months	
Identification/begin setup of inventory system (database, bar code system)	9 months	
Scope of service completed with applicable disciplines: nursing, lactation, environmental services, materials management, pharmacy services	8 months	
Completion of new and revised policies and procedures	7 months	
Assess order changes/additions to electronic medical record	6 months	
Complete inventory of products needed for opening (increase stock, etc)	6 months	
Complete training curriculum and plan for operational setup	5 months	
Complete job descriptions for operational workforce	5 months	
Set up key and/or security access to operational space	4 months	
Post positions for operational staffing	4 months	
Complete training manual for operational staffing	4 months	
Offer positions to new hires for operational duties	3–4 months	
Complete move day plan and order equipment needed for move day	3 months	
Complete feeding operation education for medical staff, nursing staff, and ancillary staff	3 months	
Complete emergency and security plan	3 months	
Finalize applicable regulatory approval	3 months	
Begin training of newly hired operational staff	3 months	
Set up and stock new operational area; inventory equipment that will be moved into space	3 months	
Complete test of equipment, technology, and phones	2 months	
Complete operational staff orientation and training and operational trial	1 month	
If applicable, move frozen human milk to new centralized operational space	1 day prior	
Move into new operational space	Move day	

** Dates listed above note suggested estimated time of completion prior to opening of new operation.*

operation opening. Keeping a written record of the discussion may be helpful for future reference. Refer to Figures 1.5 and 1.6 (see pages 38 and 39) for examples of scope of service discussion documents.

Scope of service discussion may involve leadership from the following disciplines:

- Clinical nutrition (RDN team)
- Foodservice operations
- Nursing
- Lactation
- Pharmacy
- Environmental services
- Materials management (if the institution has a centralized procurement department that will be ordering for the operation) or individuals who will be responsible for product and supply ordering (if procurement is decentralized)

EDUCATION

Education for both internal and external stakeholders is important for transitioning to a new operation or with any change in services. Thorough education relieves concerns about upcoming changes and allows for relationship building among all parties involved. Ample time for education is key to the success of a new or expanding operation, as it ensures that all stakeholders are alert to changes ahead of time. Education sessions that highlight details relevant to each audience will be the most successful and have the greatest impact to individual groups.

Internal stakeholders will have long-term interactions with the new operation; therefore, educational details for this group should be different from educational details for external customers. The scope of service discussion documents are useful to ascertain what is most applicable to share and will help when customizing education/training presentations for each group. Securing scope of service agreements as a foundation of operational standards is an efficient and consistent way to share new details and agreements for interdepartmental collaboration. Creating and providing educational resources for each area serves as a future reference.

Education for external stakeholders is also important to carefully examine. External stakeholders consist of the institution's patients, parents, and families. Education for medical providers external to the institution, such as prenatal providers, may also be needed. It is important to identify routes for sharing information, such as electronic education systems, printed handouts, and posted information. Finalizing these details prior to launching education efforts will help effectively and efficiently tailor the message to best meet patient, parent, and family learning needs.

MOVE DAY AND OPENING DAY PLAN

Creation of a move day plan helps outline what work must be done as operations prepare to transition or open, whether opening a new operational space within the same facility or moving to a new operational space in a new facility. Awareness of the target move/opening date will help with planning; allowing at least 3 months to identify and finalize details is recommended. Input for and review of this plan from all areas, including senior leadership and operational team members, will help to ensure that all relevant details

FIGURE 1.5 Sample Scope of Service Agreement

Topic title	
Revised date(s) of this document	Document dates of meetings
Members involved in agreement	Example: Feeding operation leadership, LC leadership
Topic discussion	
Discussion history	List decisions from past meetings with associated date for reference in future discussions.
Resolution options	Example: Activities that the Feeding Preparation Room will perform vs the LC team
Status	
Final decision	

LC = lactation consultant

are covered. The plan should outline activities that must occur in order to provide service at the new location while continuing current service until the time of changeover, such as the delivery of supplies or transport of HM to the new location. It should also address the types and timing of services planned for the move day. This could include the timing of first-service provision from the new location and plans for handling time-sensitive feeding needs on the move day.

Premove Considerations

Following is a list of considerations to discuss prior to moving:

- Information technology and telecommunications needs
- Preordering and stocking of supplies
- Planning and implementing practice scenarios (day-in-the-life training) for new operational activities, including:
    - practice with feeding preparation (including sanitizing steps, use of gram scales/graduated cylinders, drawing up feedings into syringes, use of computer programs or bar code technology, and other steps)
    - wayfinding for delivery routes
    - identification of all storage and delivery locations
- Safe transport of refrigerated and frozen HM from the old location to the new location, including:
    - inventory tracking
    - maintaining integrity of labeling and storage procedures to keep individual patients' HM separate
    - maintaining frozen state of stored HM during transport
    - maintaining timely availability of HM both before and after the move

Refer to the Project Status Report form in Figure 1.4 on page 36 for further considerations.

FIGURE 1.6 Sample Completed Scope of Service Agreement

Topic title	Scope of Service Discussion: LCs and Feeding Preparation Room Operation
Revised date(s) of this document	5/16; 5/18 (revised with feedback from 5/16 meeting); 6/14 (revised with feedback from 6/7 meeting); 7/1 (revised with feedback from 6/22 meeting)
Members involved in agreement	LCs, NICU nurse manager, feeding operation manager
Topic discussion	To foster open communication on operational details (and their relation to LCs) for the feeding operation (insert name here) regarding: HM logistics, ideal methods to track HM, HM handling at discharge, other lactation-related questions The end goal is to have a finalized scope of service agreement between the feeding operation and LCs to provide optimal flow of HM and related products in and out of the feeding operation with optimal safety.
Discussion history	4/26: Discussed best avenue for approaching LCs at breastfeeding committee meeting. 5/4: Feeding operation manager emailed LC representative to meet on 5/16 to discuss initial scope of service agreements. 5/16: Meeting to discuss topic (feeding operation manager, RN representatives, and LCs) 6/7: Met with LCs for further feedback on document. LCs shared their knowledge on HM handling. Ideas for handling HM in feeding operation were discussed. 6/22: NICU Manager (manager of LCs) and feeding operation manager met to review this document.
Resolution options	Activities that feeding operation will do vs the LC team: Feeding preparation team will be responsible for the following: Storing HM (labeling, tracking, etc) Preparing HM per electronic medical record orders twice daily Delivering to patient's bedside refrigerator For HM dropped for storage in feeding operation, signify using colored dot sticker to identify the first week of HM pumped; will aid in sequential usage. Provide HM storage guidelines when parent/delegate picks up HM from feeding operation prior to discharge to serve as reference. Triage questions regarding HM pumping, safety of expressed HM (discoloration, blood in milk, etc), and breastfeeding to education handouts available, patient RN, or page LC depending on concern/question of parent. Inventory and assist with packing extra stored HM at time of discharge. Personnel not involved in HM and formula preparation will not be permitted into the area. LCs will continue current activities/responsibilities as follows: Assist with any questions regarding use of HM pump and related equipment or any other frontline breastfeeding questions/ concerns of family (also RN responsibility). Work with mother/medical team if concerns on maternal medication use. Help families with questions on obtaining donor HM, if necessary. Assist with HM donation (for instance, should an infant pass away, work with mom to donate milk). If shipping milk to nearest milk bank, work on coordinating the donations/shipping.
Status	Suggest establishing an ongoing meeting (quarterly) once new feeding operation opens to address concerns that may arise.
Final decision	The above information was agreed upon by NICU nurse manager and feeding operation manager on 6/22. Feeding operation manager will continue to work with the LCs to confirm plans to optimize service delivery, such as a staff algorithm on when to page the RN, LC, or other personnel for parental questions and concerns that may arise. Document will be posted to a location that allows easy access for reference for both LC and feeding operation team. This was communicated to NICU nurse manager and she was in agreement.

LC = lactation consultant | NICU = neonatal intensive care unit | HM = human milk | RN = registered nurse

Considerations for Move Day

There are many considerations for the move day, including:

- Timing patient move (if a patient move is involved)
- Expected duration of the move
- Timing of equipment move (if items are to be moved from the old location)
- Timing and process of product move
    - Consider the need to empty products from refrigerators or freezers before moving vs moving units with products inside.
    - Survey special equipment required (such as cooler bags to maintain proper temperatures for transport of HM or prepared formulas from unit to unit or from bedside to the new operational feeding room).
- Team members available for the move (additional staff may be helpful to sustain normal operations during the move)
- Elevator or route accessibility (most applicable if moving into a new building)
- Level of service to be provided on the move day (fully operational vs limited services, such as larger premade batches of formula vs unit-dosed feedings)
- Supply needs for nursing teams to account for moving logistics (such as additional cans of enteral feeds, extra labels for moms to label HM if not automated, and other supplies)
- Contingency plans to account for unanticipated events or delays (such as vendors not delivering products in a timely manner to the new location)
- Anticipated time frame for the new feeding preparation location to be fully operational

Postmove Considerations

Depending on the extent of the move and the scope of the operations, postmove activities may occur the day after the move or at a later time. Postmove considerations include:

- timing of resuming premove ("normal") staffing levels (particularly if additional staff were used during the move process) and
- necessary follow-up in the old location (such as removal of equipment no longer needed or terminal cleaning following the move).

ONGOING MONITORING AND SHARING OF BEST PRACTICES

Ongoing monitoring is important for determining the effectiveness of any practice change. It is critical to obtain baseline metrics before implementing change in order to accurately measure improvements. An organization trying to make quick changes to show improvement and prevent errors typically proceeds without first gathering baseline data. This scenario not only makes it very difficult to determine the best course of action but also makes it challenging to determine the effectiveness of the intervention.

The method, frequency, and party responsible for gathering ongoing data to compare with baseline metrics must be determined. Some examples of metrics for HM and formula handling might include the following:

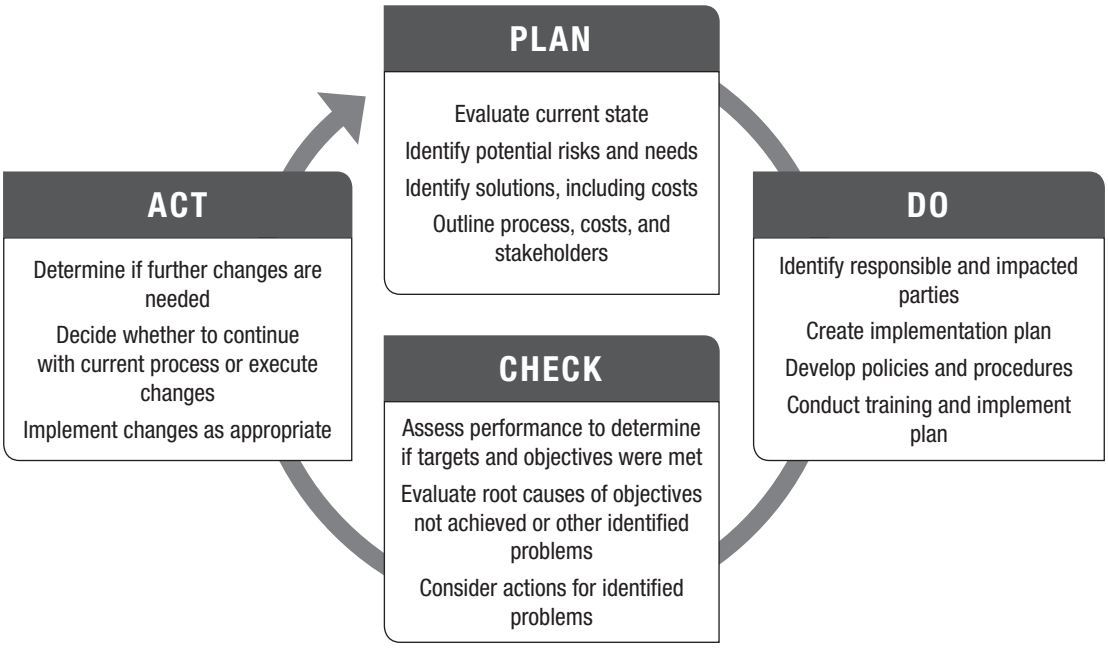
- Time spent for feeding preparation (may include breakdown by specific tasks such as inventorying products, checking orders, thawing HM, preparing formula, and other tasks)

- Labor costs for feeding preparation, including:
  - identification of nursing time and cost savings if feeding preparation technicians are implemented
  - identification of technician time savings if technologies are implemented
- Reported HM administration errors and near misses
- Reported formula administration errors and near misses
- Feeding order errors within the electronic health record (EHR)
- Formula, fortifier, and modular usage and waste
- Formula, fortifier, and modular costs
- HM waste
- DHM usage and waste
- DHM cost
- Staff satisfaction
- Patient/family satisfaction
- Process compliance (such as documenting a two-person verification or bar code scanning of HM at the designated steps; documenting lot numbers for formulas, fortifiers, modulars, and DHM; or proper sanitation for the preparation area)
- Timeliness and accuracy of preparation and delivery
- Changes in clinical outcomes (such as infection rates or growth associated with preparation accuracy)

Consult the hospital institutional review board (IRB) *before* doing any data collection to allow for publishing outcomes.

Ongoing monitoring may be more frequent at the beginning of the process change (such as daily or weekly) and become less frequent (such as monthly or quarterly) as a process becomes more established. The PDCA Model (Plan-Do-Check-Act) offers a method of continuous monitoring and ongoing opportunities for improvement that may be used any time a new process is implemented. Figure 1.7 shows the steps of the PDCA model.[23]

FIGURE 1.7 Plan-Do-Check-Act Model Template[23]



It is important to continue monitoring, even when a process becomes well established. Turnover may result in new staff who lack training or receive incorrect training on the process from peers. Increasing workloads may lead experienced staff to skip steps in an effort to save time. Ongoing monitoring is the only way to ensure that the process continues to be effective and to identify new barriers or challenges that may pose new potential risks. For example:

- An increase in NICU census may change the way the feeding preparation process works or may make the location too small to follow the procedures implemented.
- A large influx of new staff may result in failure to scan HM or perform a two-person verification at the identified process steps and could increase risk of administration errors.
- A new EHR could change the way formula orders are entered by providers or received by those responsible for preparing feedings.

As new challenges and risks are identified, the multidisciplinary team can reconvene for an FMEA or another risk evaluation process and propose solutions.

Using the ongoing monitoring data to provide feedback to frontline staff also helps ensure compliance to processes and identifies gaps in knowledge or new potential failure points. Carefully planned systems often give staff a false sense of security that errors cannot happen. Providing the following feedback is an important way to ensure ongoing diligence:

- Giving feedback to specific individuals who have not followed the process helps prevent ongoing errors due to knowledge gaps. This might include a staff member who is not familiar with the steps to properly sanitize the formula preparation space.
- Providing regular metrics to all staff helps remind everyone of the importance of following the current process. This might include publishing the frequency of the wrong HM being scanned for the wrong patient in nursing unit newsletters to help emphasize the importance of not skipping this step in the process to help prevent errors.
- Recognizing or awarding staff who correctly follow all steps in the process can encourage all staff in their performance and emphasizes the necessity of compliance with every step of the process.

Data collection allows for reporting back on improvements, such as improving patient safety by having fewer errors or showing cost savings through streamlining a process. These data may be reported regularly through facility committees such as:

- quality and patient safety
- pharmacy and therapeutics
- survey readiness
- medical staff
- department heads
- individual clinical or nursing units
- senior leadership

Finally, publishing outcome data is worthy of consideration. Many facilities are looking for data to determine the best methods of handling HM and formulas within the

health care setting. Published data of both failures and successes support process changes and can help guide others in their practices. As noted, be sure the facility's IRB has been consulted and consider seeking permission from the leadership team prior to publishing. Health care facilities should be proud of their ability to identify an issue and implement an effective solution to improve care and efficiency.

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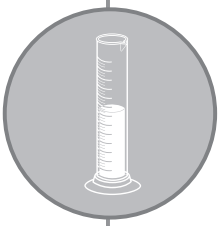
FIGURE 1.1 Sample Human Milk Failure Mode and Effects Analysis

PROCESS	FAILURE MODE	SEVERITY	OCCURRENCE	DETECTABILITY	RPN SCORE	ROOT CAUSES	PERSON RESPONSIBLE	COMPLETION DATE
Administration	Breastmilk double check not performed at bedside immediately prior to administration	9	9	10	810	Staff availability Ambiguity regarding the double-check process Accessibility of armband due to positioning, swaddling, or isolation precautions Perceived as unnecessary due to familiarity with patient Habit		
Administration	Breastmilk double check incomplete	9	9	10	810	Staff availability Ambiguity regarding the double-check process Accessibility of armband due to positioning, swaddling, or isolation precautions Perceived as unnecessary due to familiarity with patient Habit		
Administration	Inconsistency in what is being checked on the armband	9	9	10	810	Unclear understanding of the policy Staff member only checks what is convenient to view on armband		
Administration	Once fortified, will relabel with date/time of fortification and will use date/time of fortification, not thaw date/time	9	9	10	810	Unclear understanding of importance of expiration date More than one expiration date if fresh then fortified Multiple dates potentially on label (thaw date, expiration date, mix date) Complicated process Not enough room to write on label Not the practice to formulate expiration date (normal nursing practice is to document what they are doing) Not the way it was taught Adds one more step to process Belief that there is no need to label because most of the time registered nurse feeds what he or she has prepared (rather than passing a feeding on to the next shift)		
Administration	No double check to confirm that correct bottles were thawed for patient	9	10	9	810	Not addressed in policy Too much repetition in checking Cumbersome process Multiple babies (2–3) = multiple checks Staff not taught		
Administration	No double check that thawed bottles are correctly labeled	9	10	9	810	Not addressed in policy Too much repetition in checking Cumbersome process Multiple babies (2–3) = multiple checks Staff not taught		

FIGURE 1.1 Sample Human Milk Failure Mode and Effects Analysis (continued)

PROCESS	FAILURE MODE	SEVERITY	OCCURRENCE	DETECTABILITY	RPN SCORE	ROOT CAUSES	PERSON RESPONSIBLE	COMPLETION DATE
Collection	Labels may be given to mother by anyone	9	9	9	729	Staff availability Not defined in policy Lack of awareness of importance of process Lack of parent awareness to double check and who to ask for labels		
Collection	Labels are not consistently checked against mother's armband before labels are given out	9	9	9	729	General lack of awareness of importance Staff availability No accountability Lack of parent awareness of risk		
Administration	Failure to double check labels when breastmilk thawed to mix	9	8	10	720	Not addressed in policy Too much repetition in checking Cumbersome process Multiple babies (2–3) = multiple checks Staff not taught		
Administration	Failure to double check labels when making separate aliquots	9	8	10	720	Not addressed in policy Too much repetition in checking Cumbersome process Multiple babies (2–3) = multiple checks Staff not taught Complex process More steps Not required Not policy		
Administration	Failure to double check labels when transferring milk from one container to another	9	8	10	720	Not outlined in the official policy Takes too much time Staffing (too busy) Staff not taught Too complex Adding an additional step		
Administration	Failure to double check labels from warmer to patient	9	8	10	720	Not addressed in policy Too much repetition in checking Cumbersome process Multiple babies (2–3) = multiple checks Staff not taught Complex process More steps Not required Not policy		

RPN = Risk Priority Number



SECTION III

Considerations for Noncentralized Handling of Human Milk and Infant/ Pediatric Formulas in Health Care Facilities

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"We depended on the compilation of research and best practices presented in the last edition of this book to build a state-of-the-art formula room and to shape our operations. Infant and Pediatric Feedings helped us develop common language and agreed upon practices with our partners in the NICU, in the medical residency program, and on the night shift. Our patients are far safer, our techs are highly respected, and all our patient care teams are practicing safe feeding protocols."

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- lactoengineering techniques and current research;
- use of blenderized (real food) tube feedings within the hospital setting; and
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