Centralized Model of Human Milk Preparation and Storage in a State-of-the-Art Human Milk Lab

Lisbeth Gabrielski, MSN, RN, IBCLC, and Rachelle Lessen, MS, RD, IBCLC, LDN

Abstract: Strategies to ensure safe handling and administration of human milk for sick, hospitalized infants are necessary to avoid compromising the integrity of the milk and to prevent administration to the wrong patient. A centralized system of storing and preparing human milk in a milk lab that incorporates multiple verification points using a bar-coding system ensures that the right milk is prepared, delivered, and administered to the right patient, at the right time, and with the right additives. A team of skilled technicians dedicated to handling and preparing human milk, and a system of careful temperature control of refrigerators, freezers, water baths, and warmers, ensures the safety and quality of the milk. Nurses spend less time away from the bedside and more time in patient care when the milk is stored and prepared in a milk lab and delivered ready-to-feed to the bedside. Patient and staff satisfaction are high when a centralized system of storing and preparing human milk is implemented in the hospital setting.

Keywords: centralized human milk handling and storage; misadministration of human milk; preparation of human milk; bar coding human milk

H uman milk is recommended for all infants but is particularly valued for its immunological properties for hospitalized sick and preterm infants.1-4 Exclusive human milk feeding is associated with a reduced risk of necrotizing enterocolitis, respiratory tract infections, gastrointestinal infections, sepsis, and sudden infant death syndrome.5,6 Human milk has also been shown to improve cognitive outcomes especially for preterm and low-birth-weight infants.7,8 Fortification of human milk may be necessary to meet the caloric, protein, vitamin, and mineral requirements of premature and medically fragile infants.

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infants receiving the wrong milk. Mismangement of human milk could place infants at risk for infections, cause stress among families, and create mistrust in the organization caring for their infant.

Centralized handling of human milk is an important strategy to provide optimal quality care to patients and to assure safety in storage, preparation, and distribution of human milk for hospitalized infants. Limited information on a centralized model for storing and preparing human milk was available to guide this process. However, information on formula preparation rooms was easily accessed.

**Description of the Milk Lab Project**

This article describes an innovative model for designing and constructing a centralized environment for storing and preparing human milk for mothers of high-risk neonates in the newly opened 60 bed Neonatal Intensive Care Unit (NICU) at The Children’s Hospital in Aurora, Colorado. The Human Milk Lab opened in October 2007 and is staffed by a team of dedicated milk technicians (MTs) who work closely with the NICU nurses, registered dietitians (RDs), and other health care providers.

There were two main goals for the Human Milk Lab. The first goal was to standardize the storage, preparation, and administration of human milk in order to improve the safety and quality. The second goal was to decrease nurses’ time away from the patient’s bedside and to increase their time with direct care activities.

**Project Development**

The previous model of decentralized human milk storage and preparation in the NICU was evaluated and concerns were identified. Nurses cared for their patients in large open bay rooms with human milk refrigerators and freezers stationed in each room. Open forums were held for the NICU staff to discuss their concerns about handling and storage of human milk. Timing studies were conducted to demonstrate the significant time taken away from patient care to retrieve, thaw, prepare, and return milk to refrigerators for later use. It was evident that the nurses felt it was an overwhelming task to store, thaw, and prepare human milk and that the risk of error was high. An efficient workflow necessitated nurses staying with their patient as much as possible with all equipment, medications, and feedings at or near the bedside. The storage and preparation of human milk was identified as a function that was not specific to a nurse’s scope of practice and, if delegated to assistive personnel, could provide increased time devoted to activities specific to the practice of nursing. Nurses identified many concerns and possible solutions. They felt that having more legible labels and someone other than themselves to store and keep all the milk organized and in the correct bins would be beneficial. Also important for patient care was reducing the number of steps away from the bedside when retrieving and returning milk.

Although mothers had their own storage bins that were organized twice daily by the unit clinical technician, these were often in disarray and milk containers were found in the wrong bin. Milk containers were not always labeled or were labeled incorrectly, including using labels from the delivery hospital, or not having the date or time of milk expression on the label. The milk thawing and warming procedure was inconsistent and a small systematic evaluation pilot demonstrated that 77% of the time milk was outside the recommended temperature range of 96°F to 99°F prior to administration (Figure 1). The area where the milk was prepared was not consistently controlled to assure aseptic preparation. Milk that required additives was not routinely checked by a second RN and the recipe for preparing the milk was not identified on the container. There were frequent interruptions while the nurse prepared the milk for feedings. Timing studies demonstrated that nurses left the bedside an average of 20 times during a 12-hour shift retrieving and returning human milk to and from the refrigerators and freezers, thawing and warming the milk, and finding another nurse to verify the patient name and medical record number.

In 2001, there were 3 human milk misadministrations where infants mistakenly received human milk from someone other than their own mother with no adverse outcomes. The costs of an actual human milk exposure at this hospital were significant and included staff’s time and expenses, laboratory fees, health care team consultations with families, review of related laboratory values, investigation of the errors, documentation, medical treatment, review of risk analysis, and quality assurance audits. In addition, the possible costs of litigation could be significant. However, loss of public confidence in an organization’s ability to provide safe care is immeasurable. These issues and the proposed solutions led to the development of a centralized model for the Milk Lab and an action plan was developed to address the concerns (Table 1).

**Project Groundwork**

The ground breaking for a new pediatric facility in 2003 provided the opportunity to design a state-of-the-art Human Milk Lab to support the safe storage and preparation of human milk. The design and square footage of the NICU guided the model for expressed human milk storage, preparation, and delivery. Further insight for the Milk Lab proposal came from visiting the Mother’s Own Milk Bank at Texas Children’s Hospital in Houston, Texas, the Milk Preparation Room at Northside Hospital in Atlanta, Georgia, and the Mothers’ Milk Bank, Presbyterian St. Luke’s Medical Center in Denver, Colorado, member of the Human Milk Banking Association of North America. The Clinical Manager of the Lactation Department coordinated the transition committee meetings and attended the monthly design meetings with the architects and engineers. Together they developed a room design and workspace that would support the functionality of the Human Milk Lab space (Figure 2). Attention to adequate cooling for the many refrigerators and freezer units, air flow, security, and easy accessibility for parents to drop off milk and pick up supplies were priority.
concerns. The core participants of the transition committee were the lactation team members who met every 2 to 4 weeks. Additional transition committee participants included representatives from medicine, nursing, pharmacy, nutrition, information services, infection control/epidemiology, and materials management who attended meetings when the project work required their expertise. Separate meetings were held with these disciplines as issues arose.

**Figure 1.**

Temperatures of a random sample of neonatal intensive care unit (NICU) feedings prior to administration before the implementation of the milk lab and standardization of warming.

**Table 1.**

Action Plan to Establish a Milk Lab With Bar Coding

- Implement human milk bar coding/verification with Palm Pilot
- Transition human milk orders from originating in the pharmacy order set to the human milk lab
- Develop new job description, hire and train milk technician personnel
- Develop new procedures for storing, preparing, and scanning human milk
- Implement Penguin Nutritional Warmers for thawing/warming human milk at appropriate temperatures
- Develop a charge description master for milk preps and additives
- Develop quality assurance audits to verify scanning compliance
- Establish the lactation support service as its own department

has 300 square feet, including 80 square feet for supplies. The room is located in a secure area with access only to appropriate hospital staff with limited traffic, has a clean air supply, and is constructed with floors, walls, and ceilings that can be maintained in a sanitary condition. There is one centralized location at the NICU entrance that allows easy access for parents to drop off or pick up milk, obtain containers and labels, pick up or return breast pumps, and to receive updates on their milk inventory (Figure 3). The Milk Lab is staffed by MTs who come from a variety of educational backgrounds, some of whom have graduate education. This newly created position requires a skill set that includes exceptional communication, customer service, math skills, and the ability to work in a fast-paced environment. Staffing in the Milk Lab is driven by inpatient census and the number of enteral feedings.

Approximately 80% of all infants younger than 1 month admitted to the critical care units (NICU and cardiac intensive care) receive human milk feedings. This percentage has steadily increased since the move to the new hospital. Lactating mothers are routinely seen by a lactation team member for an initial assessment and a lactation plan and education are documented. If a lactation team member, bedside nurse or Clinical Nursing Assistant is unavailable to assist with initial milk expression, parents can also receive assistance from the MTs with pumping and equipment.

In this centralized model, the MTs retrieve current feeding orders from Epic, the electronic medical record that manages all patient records electronically. MTs round with the nurses and RDs to anticipate order changes and interruption in enteral feedings. Morning meetings or team huddles are held daily involving MTs and lactation team members to review pertinent information on the patients and mothers that affect the feeding orders. Any procedures or tests that may interrupt feedings are taken into consideration. The method of feeding is reviewed with consideration as to how the nurses prefer the feedings.

**Major Components, Functionality, and Key Participants**

The Human Milk Lab is located adjacent to the entrance of the NICU and is open 7 days a week from 7:00 AM to 8:30 PM. It

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be delivered. Feedings are drawn up in syringes for small volume bolus feeds or bottles for larger feedings that are delivered by enteral feeding pumps. Nurses who are caring for patients who are orally feeding may request a bottle of milk to be used for oral feedings, when infants are not directly feeding at breast. When fortification is ordered, calculations are double checked by the MTs to ensure that the type and amount of fortifier is correct for the total volume of milk. Human milk feedings are prepared using electronic scales (Top Loading Balance, Rite Weight, Inc., Duluth, GA) to carefully measure the milk volume for 8-, 12-, or 24-hour aliquots and are drawn up into individual syringes and bottles (Figure 4). Care is taken to use colostrum for the initial feedings and then use fresh human milk if available. The feedings are identified with Epic-generated labels, which include the patient name, medical record number, barcode, feeding order, recipe, calories/ounce, additives, volume, feeding frequency, and expiration date and time. Feedings are kept refrigerated until they are delivered to the bedside where they are stored in private room refrigerators or designated refrigerators in the medication rooms (Figure 5).

The Human Milk Lab is the centralized communication center for the department and integrates a variety of essential job responsibilities of the Milk Lab team that supports the bedside nurse in their daily work processes (Table 2). These activities support the nurses and families and have demonstrated high levels of employee and family satisfaction. The Milk Lab, along with bar code scanning, was the second highest satisfier for NICU nurses in a post move survey, only surpassed by the large single patient rooms. The customer service surveys from families reveal consistently high scores for excellence in care by the Milk Lab staff.

**Analysis of Operations**

The Human Milk Lab stores and prepares all human milk for the NICU and all human milk feedings with additives for all other inpatient units. Verifying human milk through bar coding by specially trained MTs has been implemented in the Human Milk Lab for the preparation procedure and at the bedside for verifying by nurses before feeding in NICU. Monthly random audits are done to evaluate the compliance to human milk verification prior to administration, which compares a 24-hour period of feedings with the scanner database. Variances are identified for feeding verification prior to administration and the patient’s nurse contacted and the incident reviewed. If for some reason the scanner was not used to verify the feeding, the nurses use
Thermo Scientific Precision water baths (Thermo Fisher Scientific Inc, Waltham, MA) are used to slowly thaw larger containers of milk to a cool liquid state by maintaining water temperature between 35°C and 45°C. Penguin Nutritional Warmers are used in all inpatient units to warm and thaw human milk and warm refrigerated formula.

Maximizing Safety and Quality of Human Milk

Refrigerator and freezer temperatures are carefully monitored through CheckPoint (TempSys, Inc, San Francisco, CA) a wireless monitor system (Figure 6). This system is centrally located in the main power plant, which provides a continuous automatic electronic temperature recording and notification for variances or alerts that exceed minimum or maximum set limits. When an alert occurs, a call is placed to the department responsible for the equipment. If the refrigerator unit is faulty or has a mechanical problem and the temperature cannot be brought back into range, the contents are moved. Penguin Nutritional Warmers (Creche Innovations, Overland Park, KS) with disposable thermal liners are used to thaw variable volumes of frozen milk with customized selection for type of container while carefully controlling temperatures. Thermo Scientific Precision water baths (Thermo Fisher Scientific Inc, Waltham, MA) are used to slowly thaw larger containers of milk to a cool liquid state by maintaining water temperature between 35°C and 45°C. Penguin Nutritional Warmers are used in all inpatient units to warm and thaw human milk and warm refrigerated formula.

Maximizing Quality Care and Patient Safety

The Milk Lab and the feeding preparation area are in a separate location away from busy, hectic patient care areas with a separate area for storage of supplies and equipment. Safety is ensured when the workflow supports aseptic technique in milk preparation.
Errors are minimized when milk is prepared and verified throughout the process with 2 patient identifiers by a dedicated staff of MTs with extensive training. All milk that is dropped off is treated with isolation precautions by putting the milk containers in sealable bags to minimize risk of contamination. Recipe formulations for all orders are maintained in the electronic medical record and all new orders are verified for accuracy by a registered dietitian. Nurses dedicate time to verifying and administering feeds instead of preparing and retrieving feedings, minimizing time away from their patients. Preterm and term pasteurized donor milk is properly maintained and stored in the Human Milk Lab for patients who do not have their mother’s own milk available and are ordered to receive donor milk.

Cost/Benefit Analysis

The creation of a new model to support quality assurance for handling and preparation for human milk was done at considerable cost. The development of the physical space with sufficient cooling and ventilation, the modifications to provide optimal infection control for the walls, floors and counters, and the specialized equipment, including commercial freezers, refrigerators, pasteurizer, dishwasher, and drier, were some of the variables that needed to be considered.

The implementation of human milk bar coding was by far the most time consuming. The costs related to this project included the hardware, NICU Tracer Scanners (Phillips Medical Ventures, Pittsburgh, PA), thermal printers and labels, information services support, including the build to store the application and data on the server, and the build of audits to compare the database of scans with the feedings administered in Epic. The potential nursing salary cost savings with a bar-coding verification system was determined using the salary of 2 nurses, the factor of 2 minutes per feeding to manually verify human milk in the NICU, and the number of feedings administered per year. The cost of human milk verification using 2 nurses, 2 minutes per feeding was $173,740.00. Bar-coding verification is a one-person check and could potentially decrease that cost by half.

Labor costs included providing sufficient staffing to support the operations of the Human Milk Lab for 13.5 hours per day (7:00 AM to 8:30 PM). The time period between 7:00 PM and 8:30 PM provides the opportunity for the night nurses to review their patients’ feedings and contact the MTs with any concerns or changes before closing. All charge and resource NICU nurses have keys to access the Human Milk Lab when there is a need for storing frozen or retrieving additional milk. A notebook provides a method of documenting any milk transactions that have occurred during the night shift.

Organizational Impact and Risk Assessment

The advantage of preparing human milk with additives in a centralized model versus at a patient bedside has been demonstrated to reduce human milk errors in The Children’s Hospital NICU over the past 3 years. This state-of-the-art Human Milk Lab has been used as a model by other NICUs nationwide. The centralized model incorporates multiple scans during the storage, preparation and administration process to ensure the right patient receives the right milk. The NICU Tracer scanner has two applications: one for the preparation process in the Human Milk Lab and one for the nurses prior to the administration of the feeding. All container labels and bin labels have the same bar code that is on the patient and parent ID bands which is generated from the Epic system. Verification with scanning occurs eight times with the current process, always comparing the container label with either the order label or parent/patient ID band (Figure 7).

Since implementation of human milk bar coding in the fall of 2007 there have been 219,554 human milk feedings administered in the NICU. With the exception of one human milk misadministration in 2009 that resulted from a nurse who failed to follow the bar-coding procedure, there were no misadministration events. The scanning process in the NICU is a primary factor in preventing milk exposures through the strict storage, preparation, and administration process. During this same time period all non-NICU units manually verified (no scanning) 137,921 feedings with 3 human milk misadministrations. Fortunately, none of these misadministrations resulted in any adverse outcome for these patients. This represents a 3-fold increase in misadministration when human milk was not verified by bar coding and scanning (Figure 8).

Discussion

Careful review of practices used in institutions that care for infants and young children who receive maternal human milk will guide necessary changes to assure best practice. Patient safety is compromised whenever human milk is handled or stored improperly or not prepared or administered correctly. Attention should be given to those non-NICU units that are less familiar with
Figure 7.
Human milk verification process.

Incorporating this knowledge into a centralized approach may require multiple mixing, several times per day for each patient. Staff and family satisfaction also need to be considered when reviewing systems and planning for the future. A shift away from nurses storing and preparing human milk will result in cost savings to support expenditures for centralized milk handling.

Limitations in resources, particularly space and financial constraints, may limit the extent to which an institution will be able to enact necessary improvements. Discussions with key stakeholders, including hospital administrators, medical directors, nursing, infection control, nutrition, and lactation will allow for creative solutions to provide optimal conditions for human milk preparation and storage. After the initial implementation of the Milk Lab, it took approximately 18 months to refine workflow to support optimal operational processes. Further expansion of the Milk Lab service to prepare all orders for human milk with additives was then rolled out to all inpatient units to provide a consistent standard of care.

Conclusion

In summary, the design, construction, and implementation of a state-of-the-art Human Milk Lab with a centralized model
of storage and preparation of human milk, and the integration of bar coding and scanning, represent a significant change in practice for nurses that support high-quality nursing care, safe infant feeding, and enhanced family-centered care. The Milk Lab achieved the original goals of standardizing the storage, preparation and administration of human milk to improve milk safety and quality, as well as decreasing nurses’ times away from the patient’s bedside resulting in increased time in direct care activities. Errors in preparation and milk fortification are avoided when milk is carefully mixed in a Milk Lab by a team of dedicated MTs and not by bedside nurses who are frequently interrupted with other patient care responsibilities. Significant safety measures have been incorporated into this new model supported by verifying at multiple points of contact through bar coding and scanning to ensure the right patient gets the right feeding at the right time. Human milk offers significant protection and improves health outcomes for the sickest and most vulnerable hospitalized infants. Yet unless proper handling, storage, preparation, and administration of human milk are ensured, these same infants may be at risk. At The Children’s Hospital in Colorado, administrators and staff are dedicated to ensuring that safe human milk remains the number one feeding of choice for all mothers and infants.

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