Pasteurized Donor Milk

A Guidebook for Hospitals and Birth Centers served by Mid-Atlantic Mothers' Milk Bank

mid-atlantic mothers' milk bank

Revised August 2024

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Welcome to your regional nonprofit milk bank.

This organization exists for the babies and hospitals of Pennsylvania, West Virginia, New Jersey, Maryland, and Delaware. It was founded to give our littlest neighbors the best possible start through the provision of pasteurized human milk when mother's own milk is unavailable.

It is hard to believe that less than a decade ago the use of donor milk was a rarity in the Mid-Atlantic region. Today, it is the standard of care in all of the regional level III and IV NICUs and inpatient use is even expanding beyond the NICU setting. Coverage continues to evolve with many states now having laws requiring insurance coverage of pasteurized donor human milk for infants with certain medical circumstances.

Teamwork is key and successful nonprofit milk banking is a collaborative effort between the milk bank, hospitals, birth centers, community clinicians, maternal child health organizations, and the generous milk donors that make it all possible.

Please know that the communication lines are always open and that we greatly appreciate feedback and suggestions that help us improve care or make your job easier. Many of the policies and services that are outlined in this guidebook are a direct result of the requests of facilities in our region.

We hope that you find this guidebook to be helpful. Thank you for all that you do to serve babies and families. We are so glad that you have partnered with us.

The Staff and Board of Mid-Atlantic Mothers' Milk Bank

"With my first son, Auggie, I built up a freezer stash of milk in anticipation of my return to work. However, COVID quickly descended upon us, and we no longer had need for the frozen milk. We were fortunate to donate over 300 ounces to the milk bank in the spring of 2020. Skip ahead two years and our second son, Rory, was immediately admitted to the NICU after birth due to meconium aspiration. As he was unable to breastfeed while receiving respiratory support, we were offered donor milk. It was a radical, full circle moment as we embraced the generosity of the donors who shared their milk with our son. I pumped throughout his 30 day NICU stay and unintentionally built up another freezer stash. In the fall of 2022, Rory and I joyfully donated 460 ounces to share with babies in need, just like he had been a few months prior. We are so fortunate to be both donors and recipients of milk. Thank you to all the parents and babies who share this life saving gift!"

- Brittany, Milk Donor and Mom of Auggie and Rory

ABOUT MID-ATLANTIC MOTHERS' MILK BANK

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Instagram: "midatlanticmilkbank"
Twitter: "PAMilkBank"
TikTok: "@midatlanticmilkbank

Hospital Portal
Scroll to the bottom of the homepage of midatlanticmilkbank.org and click "Portal Login"
Password: theperfectfood
On the portal you will find PDFs of guidebooks and other documents along with the milk bank's current licenses and accreditation certificates.

Direct link to the Portal

ABOUT MID-ATLANTIC MOTHERS' MILK BANK- DEFINITIONS

Bridge Milk: Short term donor milk use, as an outpatient or inpatient, in the first two weeks of life while a mother works to establish a milk supply that meets all of their newborn's needs.

CICU: Cardiac Intensive Care Unit.

Depot: A community partner that collects raw milk for a milk bank. Donors who drop off milk to a depot have already been screened and approved by the milk bank. Depots may be hosted by a health system, pediatrics practice, lactation center, birth center, or another community organization.

Dispensary: A community partner that dispenses pasteurized donor human milk from to outpatients in the community. Dispensaries may be hosted by a health system, pediatrics practice, lactation center, birth center, or another community organization.

HMBANA: The Human Milk Banking Association of North America (hmbana.org). Accrediting body of the 33 non-profit milk banks across the United States and Canada. HMBANA accredited milk banks must strictly follow evidence-based guidelines for donor screening, milk testing, milk processing, and distribution and are frequently inspected.

Milk Bank: Human milk banks collect milk from donors and process, screen, store, and distribute donated milk to meet the specific needs of individuals for whom human milk is prescribed by licensed health care providers. The Pennsylvania Department of Health is responsible for licensing milk banks per the requirements of Act 7 of 2020.

Mother Baby Unit: Inpatient unit where mothers and healthy newborns are cared for following delivery until discharge. Also may be referred to as a level I NICU.

NEC: Necrotizing Enterocolitis. An inflammation of the intestines that primary affects infants. Significantly premature infants and those with certain congenital or acquired conditions are most at risk. NEC is a common emergency in the NICU setting and a major contributor to mortality and disability in the premature infant population.

NICU: Neonatal Intensive Care Unit. There are 4 levels of NICUs based on the severity of conditions they are able to treat. Level III and IV NICUs have the capability to care for critically ill infants and those born before 32 weeks gestation.

Pasteurization: A food manufacturing process involving the application of mild heat (under 100ºC) to inactivate pathogens and extend storage life.

PDHM: Pasteurized Donor Human Milk.

VLBW Infant: Very Low Birth Weight infant. Neonate born weighing 1500g (3.3 lbs.) or less. VLBW infants are at greater risk for the complications of prematurity.

ABOUT MID-ATLANTIC MOTHERS' MILK BANK- WHO THE MILK BANK SERVES

The mission of Mid-Atlantic Mothers' Milk Bank is to improve the health and survival of medically vulnerable infants and young children through the safe collection, pasteurization, and provision of donor milk.

Three Rivers Mothers' Milk Bank dba Mid-Atlantic Mothers' Milk Bank (MAMMB) is a 501(c)(3) nonprofit organization that provides hospitals, birth centers, and outpatients with pasteurized donor human milk (PDHM) from carefully screened volunteer donors. We are an independent nonprofit organization that is not affiliated with any health or university system. The self-defined focus area of MAMMB is Pennsylvania, West Virginia, Maryland, New Jersey, and Delaware.

Donor Milk in Various Settings

In the Neonatal, Cardiac, and Pediatric Intensive Care Units

Human milk optimizes the health and well-being of all infants but is absolutely essential for infants born prematurely and/or with congenital or acquired cardiac, gastro-intestinal, or other serious conditions. For these medically fragile infants, a human milk diet provides powerful, unparalleled protection against complications that can lead to longer hospital stays, multiple procedures, readmissions, life-long disability, or even death.

Unfortunately, up to 70% of mothers who have an infant in the neonatal intensive care unit (NICU) or cardiac intensive care unit (CICU) are unable to provide all of their baby's needs, at least initially, even with adequate lactation support and effort. The use of PDHM for medically necessary supplementation is associated with decreased risks of necrotizing enterocolitis (NEC), sepsis, bronchopulmonary dysplasia, and retinopathy of prematurity along with shorter hospital stays.

"I watched the clock go from 11:59pm to 12:00am, at that exact moment my water broke. Although the next few hours didn't go as planned, I had so much love and support around me. With an unexpected NICU stay, I am so grateful that my son was able to receive donor milk. I immediately knew I wanted to become a donor myself. Watching our journey come full circle made every minute worth it."

-Mid-Atlantic Milk Donor and Mother of a Recipient

ABOUT MID-ATLANTIC MOTHERS' MILK BANK- WHO THE MILK BANK SERVES

Bridge Milk in Both the Hospital and Outpatient Settings

Bridge milk refers to short term PDHM use as an outpatient or inpatient in the first two weeks of life as a mother works to establish a milk supply that meets all of their newborn's needs. In addition to promoting the development of a healthy microbiome and avoiding the risks of formula introduction, the use of PDHM for necessary supplementation in well babies is associated with higher rates of later maternal breastfeeding success.

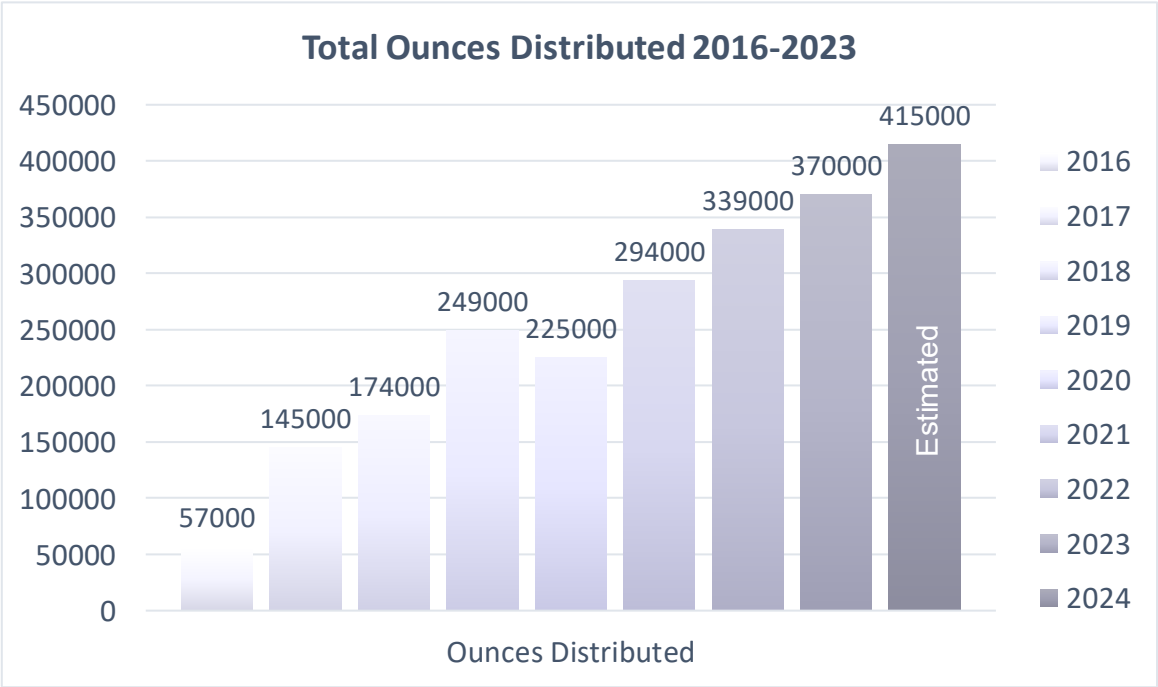
Most of the milk dispensed by a MAMMB Dispensary will be bridge milk. The use of bridge milk may be initiated as an outpatient or be a continuation of use that began in the hospital.

Outpatients with Medical Needs

PDHM may also be used by infants cared for at home with a variety of conditions. These are typically children with complex medical needs, often unable to thrive on other forms of nutrition. Common diagnoses include cardiac conditions, gastro-intestinal conditions, immune disorders, inborn errors of metabolism, formula intolerance, malabsorption disorders, post-surgical nutrition, renal disease, short bowel syndrome, failure to thrive, severe allergies, and organ transplantation. Outpatients with medical needs tend to be high volume users of PDHM and usually coordinate with MAMMB for shipments sent directly to their homes but families may utilize a local MAMMB Dispensary for a starter supply or an emergency need.

Discretionary Outpatient Use

Discretionary use describes a situation where an infant does not have a documented medical indication for PDHM but has limited or no access to maternal milk. Such circumstances include adoption, surrogacy, insufficient supply, maternal illness or death, and maternal medication. Bridge milk would also be classified as discretionary use.



ABOUT

Mid-Atlantic Mothers' Milk Bank (MAMMB) is a community-based nonprofit organization committed to bettering the lives and health outcomes of our region's smallest residents. In our ideal world, every baby would receive donated human milk if mother's own milk is not available. The reality is that there is a limited supply of this precious resource and that there are significant costs associated with the screening and processing necessary for the medically fragile infants that we serve. MAMMB relies on the generosity of volunteer milk donors and therefore cannot guarantee availability of milk. We developed this Distribution Policy in accordance with the guidelines of the Human Milk Banking Association of North America (HMBANA) to ensure that infants with the greatest medical need for donor milk are given priority.

Definitions, as defined by the Medical Advisory Board of MAMMB

Medical Need: A diagnosis or circumstance in which donor milk may provide a therapeutic benefit. Such conditions include, but are not limited to, malabsorption disorders, prematurity, short gut syndrome, congenital heart disease, renal disease, post-surgical nutrition, immunological deficiencies, failure to thrive, allergies, and formula intolerance. Most cases of documented medical need are covered by insurance. Those that are not are eligible for an income based discount through MAMMB's Sliding Scale Program.

Discretionary Outpatient Use: A situation in which an infant does not have a documented medical indication for human donor milk and has limited or no access to maternal milk. Such situations include adoption, maternal death, insufficient supply, maternal mastectomy, temporary discontinuation of breastfeeding due to medication, and bridge milk use. Discretionary use is unlikely to be covered by insurance and is not eligible for MAMMB's Sliding Scale Discount Program.

Formula Intolerance: Suboptimal growth and/or symptoms after documented trials of different formulas. MAMMB defines formula intolerance as continued issues after at least 3 documented formula trials including a hypoallergenic or amino acid based preparation.

Bridge Milk: Limited short-term donor milk fed to a healthy baby in the first two weeks of life as a mother works to increase her own milk supply.

Classification of Need

If a prescription for donor milk does not clearly fall under one of the above definitions, the Medical Advisory Board of MAMMB will review the information provided and determine whether the request is a medical need or discretionary use.

Order Fulfillments

MAMMB aims to provide facilities and ill outpatients in PA, WV, NJ, MD, DE with a reliable, ample supply of pasteurized donor milk. Orders are filled using the following guidelines: Milk distribution is prioritized as follows: 1) Level 3 and Level 4 Neonatal Intensive Care Units (NICUs) and Cardiac Intensive Care Units; 2) Lower Level NICUs; 3) Outpatients with Medical Needs; 4) Mother Baby Units; 5) Discretionary Use and Bridge Milk. To ensure that needs 1 through 4 are met, discretionary use orders may not be filled if the current inventory falls below the rolling average of critical use from the previous 6 weeks.

Review of Use

MAMMB's Medical Advisory Board reviews all outpatient prescriptions regularly.

ABOUT MID-ATLANTIC MOTHERS' MILK BANK- ACCREDITATION AND REGULATION

Federal and State Regulation

On a federal level, donor milk banking is classified as food production and as such, milk banks are required to follow food safety guidelines, register with the FDA, and are subject to unannounced inspection. Strict adherence to best practices in food handling, processing, and storage are critical for the safety of donor milk. Some states do regulate milk banks, adding additional requirements addressing donor screening and safety aspects specific to human milk. MAMMB holds licenses in Pennsylvania, Maryland, and New York. New Jersey has passed a law to regulate milk banks, but the state has not yet developed requirements. The remainder of states in MAMMB's service area do not have milk banking standards currently.

HMBANA Accreditation

MAMMB is accredited by the Human Milk Banking Association of North America (HMBANA, hmbana.org), the nonprofit organization that accredits non-profit milk banks across the United States and Canada. Accreditation requires frequent inspection and strict adherence to the HMBANA Standards which include guidelines for donor screening, milk storage, milk testing, pasteurization and the operation of depots and dispensaries. HMBANA's guidelines are a living document that evolves as evidence and technology advances.

Since its founding in 1985, HMBANA has been recognized as the leading expert in safe, ethical milk banking practices and its rigorous, evidence-based requirements are considered a gold standard across the world.

HUMAN MILK BANKING ASSOCIATION OF NORTH AMERICA

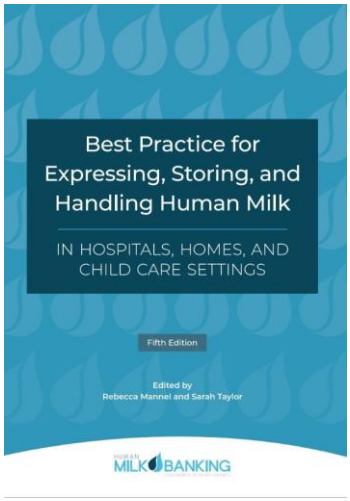
Mission: HMBANA advances the field of nonprofit milk banking through member accreditation, development of evidence-based best practices, and advocacy of breastfeeding and human lactation to ensure an ethically sourced and equitably distributed supply of donor human milk.

HMBANA Fast Facts:

- There are 33 HMBANA accredited milk banks across North America (30 in the United States and 3 in Canada). Each milk bank is a separately incorporated nonprofit organization with its own board of directors and governance.
- Collectively, HMBANA accredited milk banks *distribute over 10 million ounces of donor milk annually.*
- The vast majority of hospitals in North America rely on HMBANA accredited milk for a reliable supply of safe, ethically PDHM for their primary donor milk needs.
- Nearly all of the PDHM used by outpatients in North America is from HMBANA accredited milk banks.
- HMBANA strictly prohibits anyone from profiting from donor milk so only nonprofit milk banks are eligible for HMBANA accreditation.
- The compensation of donors is strictly prohibited by HMBANA due to safety and ethical concerns so all donors to the nonprofit milk bank network are non-remunerated volunteers.

DEVELOPING PROTOCOLS- RECOMMENDED RESOURCES

Safe practices are essential, and each hospital must develop its own evidence-based protocols for using and handling donor milk. Frozen or pasteurized human milk has decreased bacterial inhibitory factors and requires greater precautions. Mid-Atlantic Mothers' Milk Bank recommends the following resources:

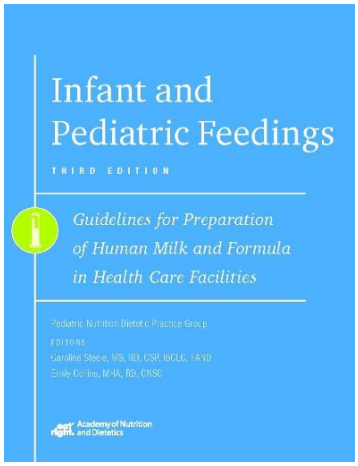


Best Practice for Expressing, Storing, and Handling Human Milk in Hospitals, Homes, and Child Care Settings 5th Edition

Human Milk Banking Association of North America

Edited by Rebecca Mannel, MPH, IBCLC, FILCA and Sarah Taylor, MD, MSCR

May be purchased at hmbana.org



Infant and Pediatric Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities Third Edition

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

May be purchased at: eatrightstore.org or amazon.com

This article is an excellent summary of best practices and a copy of it is provided on the following pages:

Steele C. Best Practices for Handling and Administration of Expressed Human Milk and Donor Human Milk for Hospitalized Preterm Infants. *Front Nutr*. 2018;5:76. Published 2018 Sep 3. doi:10.3389/fnut.2018.00076

frontiers in Nutrition

MINI REVIEW
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Best Practices for Handling and Administration of Expressed Human Milk and Donor Human Milk for Hospitalized Preterm Infants

*Caroline Steele**

Children's Hospital of Orange County, Orange, CA, United States

The importance of human milk for the preterm infant is well established (1–3). However, the feeding of human milk to preterm infants is typically much more complicated than the mere act of breastfeeding (3, 4). The limited oral feeding skills of many preterm infants often results in human milk being administered via an enteral feeding tube (4). In addition, fortification is commonly required to promote optimal growth and development—particularly in the smallest of preterm infants (2, 4, 5). Consequently, a mother's own milk must be pumped, labeled, transported to the hospital, stored, tracked for appropriate expiration dates and times, thawed (if previously frozen), fortified, and administered to the infant with care taken at each step of the process to avoid microbial contamination, misadministration (the wrong milk for the wrong patient), fortification errors, and waste (1–5). Furthermore, the use of pasteurized donor human milk (DHM) for preterm infants when a mother's own milk is not available has been endorsed by many organizations (1). Therefore, appropriate procurement, storage, thawing (if received frozen), fortification, labeling, and administration must occur with the same considerations of preventing contamination and fortification errors while ensuring the correctly prepared final product reaches the correct patient (1). Many professional organizations have published best practices to provide hospitals with guidelines for the safe and accurate handling and preparation of expressed human milk (EHM) and DHM feedings for preterm infants (1–5). These best practices emphasize the importance of preparation location, trained staff, proper identification of human milk to prevent misadministration, and strategies to prevent fortification errors (1–6). The purpose of this mini-review article is to summarize current published best practices for the handling of human milk for preterm infants within the hospital setting (1–6). Emphasis will focus on the use of aseptic technique with proper sanitation and holding times/temperatures to limit microbial growth; use of technology to prevent misadministration of human milk and fortification errors as well as for tracking of expiration dates/times and lot numbers; and workflow strategies to promote safety while improving efficiencies (1–7).

Keywords: human milk handling, infant feeding preparation, human milk bar code scanning, aseptic technique feeding preparation, safety and human milk

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INTRODUCTION

The importance of human milk for the preterm infant is well established (1–3). However, the feeding of human milk to preterm infants is typically much more complicated than the mere act of breastfeeding (3, 4). The limited oral feeding skills of many preterm infants often results in human milk being administered via an enteral feeding tube (4). In addition, fortification is commonly required to promote optimal growth and development—particularly in the smallest of preterm infants (2, 4, 5). Consequently, a mother's own milk must be pumped, labeled, transported to the hospital, stored, tracked for appropriate expiration dates and times, thawed (if previously frozen), fortified, and administered to the infant with care taken at each step of the process to avoid microbial contamination, misadministration (the wrong milk for the wrong patient), fortification errors, and waste (1–5).

Furthermore, the use of pasteurized donor human milk (DHM) for preterm infants when a mother's own milk is not available has been endorsed by many organizations including the World Health Organization (WHO), the Academy of Breastfeeding Medicine (ABM), the European Milk Bank Association, the Human Milk Banking Association of North America (HMBANA), the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN), the American Society for Parenteral and Enteral Nutrition (ASPEN), the United States Surgeon General, the Academy of Nutrition and Dietetics, and the American Academy of Pediatrics (AAP) (1). Therefore, appropriate procurement, storage, thawing (if received frozen), fortification, labeling, and administration must occur with the same considerations of preventing contamination and fortification errors while ensuring the correctly prepared final product reaches the correct patient (1).

Many professional organizations, including the Academy of Nutrition and Dietetics, ASPEN, the National Association of Neonatal Nurses (NANN), and HMBANA, have published best practices to provide hospitals with guidelines for the safe and accurate handling and preparation of expressed human milk (EHM) and DHM feedings for preterm infants (1–5). These best practices emphasize the importance of preparation location, trained staff, proper identification of human milk to prevent misadministration, and strategies to prevent fortification errors (1–6).

The purpose of this mini-review article is to summarize current published best practices for the handling of human milk for preterm infants within the hospital setting (1–6). Emphasis will focus on proper sanitation, use of technology for tracking and error prevention, and workflow strategies to promote safety while improving efficiencies (1–7).

LOCATION

For handling of human milk, fortifiers, and feeding systems, preparation location and practices that minimize microbial growth (such as adherence to good hand-hygiene practices and use of "no touch" preparation and administration techniques) are critical (1). A location dedicated for the purpose of handling human milk feedings that is separate from patient care areas reduces risk of contamination and is considered a best practice (1, 2, 8, 9). EHM or DHM feedings should not be prepared in *any* patient care area, including the patient's bedside, due to risk of contamination (1, 2, 5, 7, 9).

EQUIPMENT AND SUPPLIES

Sinks and Dishwashers

The preparation area should contain a handwashing sink with hands-free controls (1). Unless all preparation items are disposable, a three-compartment sink or commercial dishwasher is needed to ensure proper cleaning and sanitizing of all reusable items (1, 10, 11). The dishwasher should reach a wash temperature of 66°C (150°F) and a rinse temperature of 82°C (180°F) (10, 11).

Refrigerators and Freezers

Although not required, dedicated human milk refrigerators and freezers are preferred. Adequate space to store human milk while allowing for appropriate airflow is important to ensure proper temperatures. Refrigeration guidelines for the storage of human milk for healthy infants at home have been described (12). Within the health care setting, refrigerators for human milk storage must be able to maintain temperatures between 2–4°C (35–39°F); freezers must allow for temperatures at or below −20°C (−4°F) to long-term storage (1, 13). A reliable method of temperature monitoring is imperative to prevent loss and promote safety (1). Use of automated systems that alarm when temperatures exceed desired ranges may be beneficial. Location of refrigeration units in areas with limited access, may help prevent tampering and waste.

Laminar Flow Hoods

While laminar flow hoods provide an additional barrier against contaminants, they are typically used in the preparation of sterile products (including medications and processing/packaging of pasteurized donor human milk) (1, 14). However, use of a flow hood does not result in a sterile finished product when used during the preparation of non-sterile feedings (such as unpasteurized EHM and/or non-sterile fortifiers or additives) (1, 15). Furthermore, use of a flow hood should not be a replacement for good handing practices and aseptic technique.

Measuring/Mixing Devices and Storage Containers

All preparation and storage items should be made of stainless steel or food grade plastic that is free of bisphenol A (BPA) and Di(2-ethylhexyl) phthalate (DEHP) (11). Glass items (such as graduated cylinders or beakers) are not generally used for routine handling of human milk in the health care setting due to risk of exposure to glass particles should the glass crack or break (11).

Single-use, disposable items are often selected for human milk collection and feeding preparation due to their convenience and sanitation. Such items may be sterile or non-sterile as there is no evidence that use of non-sterile items results in

higher bacterial loads in collected human milk or prepared feedings (1, 16). If reusable items are selected, they must be cleaned and appropriately sanitized between uses to prevent cross contamination.

Human milk and other liquid ingredients should be measured using containers with precise graduations such as graduated cylinders, beakers, liquid measuring cups, or syringes (1). Powdered fortifiers and additives should be measured on a gram scale accurate to a tenth of a gram (1). Scales should undergo regular calibration to ensure accuracy and promote safety (1).

STAFFING AND STAFF HYGIENE

Use of dedicated staff for the handling and preparation of human milk feedings within the health care setting is considered a best practice and has been shown to reduce risk of misadministration errors (1–3, 5). Staff should be well trained in aseptic technique and demonstrate proper steps for handling human milk and fortifiers. Hand hygiene is critical in the handling of human milk to prevent introduction of exogenous microbial contamination (17, 18).

Use of disposable gowns and other personal protective items including a bonnet or hairnet and gloves are recommended (1). Artificial nails and long natural nails have been associated with a *Pseudomonas aeruginosa* outbreak in a neonatal intensive care unit (18, 19). Therefore, it is recommended that staff nails should be short, neatly groomed, and unpolished (17–21).

HUMAN MILK STORAGE

Stored milk should be rotated using first-in-first-out (FIFO) principles with the oldest milk being used first. Storage times and temperatures impact nutritional quality, biologically active components in human milk, and rate/incidence of microbial growth (12, 22–26). Within the acute care setting when human milk is used for immunocompromised patients, storage recommendations are more conservative than for the healthy infant at home (1, 12). Therefore, it is generally recommended (1, 13, 16, 22, 27):

TABLE 1 | Steps for human milk feeding preparation within the acute care setting (1, 13, 28–32).

Don personal protective items per facility policy (may include disposable gowns and bonnets/hairnets)
Perform hand hygiene upon entry into the preparation area, after sanitizing work surfaces, and between each individual patient feeding preparation
Sanitize work space using a facility-approved sanitizing solution appropriate for food contact surfaces upon entry, between each individual patient feeding preparation, and as required to support aseptic technique
Thaw milk if needed using water bath or commercial warmer
Perform a two-person double check of a minimum of two-patient identifiers or use bar code scanning technology to confirm that all bottles of human milk belong to the same patient before combining
Following hand hygiene, don gloves prior to initiating the actual preparation
Measure appropriate volume of human milk using measuring container with 1 mL graduations
Add fortifiers, if appropriate • Ensure accuracy with calculations and measurements to avoid over or under fortification • Consider systems such as a two-person double check or bar code scanning to confirm appropriate fortifier is used • Use pre-portioned fortifiers when available • If not pre-portioned, measure liquid fortifiers using graduated cylinders, beakers, liquid measuring cups, or syringes and weigh powders using a gram scale
Gently mix ingredients in clean disposable or cleaned and sanitized reusable container
Place finished product in a clean disposable or cleaned and sanitized reusable closed container • Prepare no more than 24-h volumes • Finished product may be unit dosed for individual feedings or in bulk volumes
Label each container Recommended components include: • Patient name • Identification number (such as medical record number) • Contents (human milk plus any fortifiers or additives) • Caloric density • Volume in container • Volume per feeding and frequency or rate of administration • Administration route • Expiration date and time • "For enteral use only" or "Not for intravenous use" • "Refrigerate until use"
Refrigerate final product until used
Perform a two-person double check of a minimum of two-patient identifiers or use bar code scanning technology to verify the feeding label against the patient armband to confirm correct identity prior to administration
Monitor time for prepared feedings at room temperature • Decant no more than 4-h volumes for continuous enteral feedings • For oral feeding, discard any milk remaining in the bottle 1 h after initiating feeding due to potential for bacterial contamination from oral flora that may colonize the milk remaining in the bottle

- Fresh milk be stored in the refrigerator (≤4°C or ≤39°F) for a maximum of 48 h
- Thawed unpasteurized milk be stored in the refrigerator (≤4°C or ≤39°F) for a maximum of 24 h
- Thawed pasteurized DHM be stored in the refrigerator (≤4°C or ≤39°F) for a maximum of 48 h
- Fortified milk be stored in the refrigerator (≤4°C or ≤39°F) for a maximum of 24 h
- Hang time for continuous feedings at room temperature for a maximum of 4 h
- Frozen human milk be stored in the freezer for 6–12 months at ≤−20°C (≤−4°F) or beyond 12 months at −70 to −80°C (−94 to −112°F).

PREPARATION AND ADMINISTRATION OF HUMAN MILK FEEDINGS IN THE HEALTH CARE SETTING

Handling of human milk and preparation of individual feedings within the health care setting requires strict adherence to guidelines to ensure the preservation of nutrients and bioactive compounds while reducing risk of harmful microbial growth (1). Fortification accuracy is imperative to prevent feeding intolerance and promote optimal health and growth. Steps for human milk feeding preparation within the acute care setting are outlined in **Table 1** (1, 13, 28–32).

Sterile liquid fortifiers and additives are preferred over powdered products (which are not sterile) to reduce the risk of microbial contamination; sterile options should be used for human milk fortification whenever possible (1, 13). At present, the optimal length of time between preparation and feeding of fortified human milk is unknown (13). Research has shown that over time, the osmolality of fortified human milk increases (by up to 4%) and the size of milk fat globules may become altered (possibly impacting fat digestion) (33). While shortening the storage time for fortified human milk may be advantageous, there is not enough published evidence to suggest a revision of the current recommendations for a maximum of 24 h (1, 13). Centralized fortification of human milk is a best practice and has been shown to improve patient safety (1–8, 13). However, centralized handling processes often preclude the ability to prepare each individual feeding immediately prior to use. Based on current evidence, the benefits of centralized handling appear to outweigh the risks of potential changes to human milk when feedings are prepared in advance (1–8, 13, 34, 35). Facilities may want to consider the shortest amount of time realistically feasible while still utilizing centralized handling processes. To this end, some organizations have opted to prepare 12-h volumes instead of 24-h volumes which also may be beneficial in more quickly implementing feeding order changes and preventing waste (1).

In addition to safe handling practices, processes must be in place to ensure safe administration of human milk and prevent inadvertent infusion via intravenous (IV) lines (1, 13). Enteral feeding misconnections, which may result in death, have been reported in the literature (36). The International Standards Organization (ISO) has set a standard for enteral devices to provide a female (administration set or syringe) to male (feeding tube) orientation known as ISO 80369-3 (37). Feeding connection sets with this unique configuration are known as ENFit® systems (1, 37). Adoption of ENFit® compatible connectors for all enteral infusions promotes patient safety by preventing enteral feedings from being accidentally connected to IV lines or other medical device ports (1, 13, 37).

USE OF BAR CODE SCANNING TECHNOLOGY TO IMPROVE SAFETY

Bar code scanning technology is commonly used in the health care setting to promote patient safety by reducing the risk of misadministration (providing the wrong product to the wrong patient) for processes such as medication, blood, and human milk administration (3–5). Bar code scanning is often used in lieu of a two-person double check to reduce risk of human error and confirmation bias which may occur when a manual check is used (3–5). Such systems have been shown to reduce errors and improve efficiencies (3–5). Scanning technology can assist with monitoring expiration dates and times. Human milk that is beyond its expiration is at greater risk for excessive microbial growth which could be particularly devastating in the critically ill neonate. Consequently, scanning systems may add a layer of patient safety by alerting the clinician if an attempt is made to use an expired feeding. Furthermore, some systems offer the ability to automate fortification calculations and scan fortifiers or additives to reduce risk of fortification errors (3–5). Automatically tracking lot numbers for pasteurized DHM and fortifiers or additives is more efficient than having staff track such information manually and provides a faster method of identifying exactly which patients received a particular product in the event of a product recall. Therefore, bar code scanning technology with human milk preparation and feeding is considered a best practice and is endorsed by many organizations (1–5).

SUMMARY

Human milk in the health care setting, particularly the neonatal intensive care unit, is often viewed as "medicine" or an adjunct therapy. Some of the most fragile patients are those premature or critically ill infants receiving human milk feedings. Therefore, every precaution must be taken with human milk handling to ensure safety. Aseptic technique with proper sanitation and holding times/temperatures to limit microbial growth; use of technology to prevent misadministration of human milk and fortification errors as well as for tracking of expiration dates/times and lot numbers; and workflow strategies to promote safety while improving efficiencies are worthy endeavors of all facilities (1–7).

AUTHOR CONTRIBUTIONS

The author confirms being the sole contributor of this work and approved it for publication.

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PENNSYLVANIA DEPARTMENT OF HEALTH
2019– PAHAN –468 – 12-06 - ADV
Preparation, Handling and Storage of Human Milk for Hospitalized Infants

DATE:	**12/06/19**
TO:	Health Alert Network
FROM:	Rachel Levine, MD, Secretary of Health
SUBJECT:	**Preparation, Handling and Storage of Human Milk for Hospitalized Infants**
DISTRIBUTION:	Statewide
LOCATION:	Statewide
STREET ADDRESS:	n/a
COUNTY:	n/a
MUNICIPALITY:	n/a
ZIP CODE:	n/a

This transmission is a "Health Advisory" provides important information for a specific incident or situation; may not require immediate action.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, INFECTION PREVENTION AND CONTROL, NURSING, PHARMACY, AND LABORATORY STAFF IN YOUR HOSPITAL
EMS COUNCILS: PLEASE DISTRIBUTE AS APPROPRIATE
FQHCs: PLEASE DISTRIBUTE AS APPROPRIATE
LOCAL HEALTH JURISDICTIONS: PLEASE DISTRIBUTE AS APPROPRIATE
PROFESSIONAL ORGANIZATIONS: PLEASE DISTRIBUTE TO YOUR MEMBERSHIP

Summary

- The Pennsylvania Department of Health is advising hospitals and healthcare facilities to review their procedures for preparation of human milk for infant feeding. Procedures should align with existing standards.
- Infants less than 3 months old or with immunocompromising conditions are at increased risk of harm from improperly prepared human milk compared to older and immunocompetent infants.
- Human milk preparation (mother's own milk or pasteurized donor human milk) is an aseptic process and proper cleaning and disinfection of feeding equipment is essential.
- Caregivers should be educated about proper preparation, storage and handling of human milk.
- Always report outbreaks or unusual clusters of illness to the Bureau of Epidemiology by calling 1-877-PA-HEALTH or your local health department.

The Pennsylvania Department of Health (PADOH) recognizes human milk as the ideal nutrition for infants. Human milk is associated with a decreased risk of many illnesses. For premature and sick infants, human milk may offer critical immune support. However, microorganisms can multiply rapidly in human milk. Severe illness has been documented in premature infants subsequent to feeding with human milk contaminated during expression or by using improperly cleaned and disinfected breast pumping parts, bottles, or equipment. Safe preparation, handling, and storage of human milk will prevent adverse outcomes associated with contamination.

PADOH is advising hospitals and healthcare facilities to closely review their infection prevention and control procedures for preparation, handling and storage of human milk for infant feeding. Policies and procedures should align with existing standards and be developed by an interdisciplinary group of infection preventionists, physicians, nurses, dieticians and lactation professionals. In a healthcare facility, human milk should *ideally* be prepared in a dedicated space by a trained milk preparation technician. Regular competency review and evaluation should occur.

Small amounts of bacterial contamination in water can lead to contamination of equipment used to prepare human milk for consumption. Premature and sick hospitalized infants are particularly vulnerable to these infections. Improperly cleaned equipment used to measure or prepare human milk will provide a reservoir for bacterial proliferation, with the potential for patient harm. This includes items such as bottle brushes, measuring cups or cylinders, and storage bins. For more information on reducing risk from water in healthcare settings, CDC resources are available at https://www.cdc.gov/hai/prevent/environment/water.html.

PADOH recommends review of the following resources to develop facility-specific infection prevention and control policies for preparation, handling and storage of human milk.

- Grota P, et al, eds. APIC Text Online. 2014. Available at https://text.apic.org/the-apic-text-online
- Jones, F. (2019). Best Practice for Expressing, Storing, and Handling Human Milk in Hospitals, Homes, and Child Care Settings. (4th edition). Human Milk Banking Association of North America, Fort Worth, TX.
- The Centers for Disease Control and Prevention (CDC) infant feeding hygiene guidelines available online at: https://www.cdc.gov/healthywater/hygiene/healthychildcare/infantfeeding.html

Although there are many aspects of infection prevention and control that should be considered for human milk preparation in a healthcare setting, the following are key recommendations:

- Wash hands with soap and water before handling human milk, feeding equipment, or breast pump equipment;
- Prepare human milk in an aseptic manner;
- Wash and sterilize all feeding equipment designed for multiple users per manufacturer's instruction;
- Wash and disinfect all feeding equipment designed for single users per manufacturer's instruction;
- Express and store human milk intended for hospitalized infants in sterile containers;
- Provide education to mothers and other caregivers about proper practices for milk expression and handling of human milk, especially for premature or sick infants, or healthy infants under 3 months old.

For educational resources for parents and caregivers, review CDC publications for infant feeding hygiene. Handouts for caregivers on human milk expression with a breast pump and human milk safety are available at https://www.cdc.gov/healthywater/hygiene/healthychildcare/infantfeeding/breastpump.html.

PADOH reminds you to always report outbreaks or unusual clusters of illness to the Bureau of Epidemiology by calling 1-877-PA-HEALTH or your local health department.

Categories of Health Alert messages:
Health Alert: conveys the highest level of importance; warrants immediate action or attention.
Health Advisory: provides important information for a specific incident or situation; may not require immediate action.
Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of December 6, 2019 but may be modified in the future.

DEVELOPING PROTOCOLS- STORAGE AND HANDLING HIGHLIGHTS

A number of safety measures are employed by MAMMB to ensure that donor milk is safe for the fragile infants that we serve. This special care must extend beyond the time that donor milk leaves our milk bank. Frozen or pasteurized human milk has decreased bacterial inhibitory factors and requires greater precautions. The following are some recommendations for your facility. This is not a complete list of the measures needed to ensure safety and is not a substitute for comprehensive resources such as those listed on pages 10-17 of this guidebook.

- There are nuances to food handling that are not always addressed with medical training. It is important that those handling donor milk (and all human milk) are trained in food handling and safety. Online courses are available, and the milk bank can help identify resources.
- Donor milk is food and will support bacterial growth. Single use measuring and mixing equipment is best. Sterilizing equipment between uses is also appropriate.
- Donor milk must be stored frozen until use. Freezer temperatures should be maintained at a temperature no higher than -20°C/-4°F.
- In the event of a power failure or other unexpected event, partially defrosted milk may be refrozen if ice crystals are still present.
- Frozen donor milk is best thawed in the refrigerator. Refrigerator temperatures should be maintained at a temperature no higher than 4°C/39°F.
- Bottles of donor milk can thaw slowly at room temperature or in a non-water warmer, but the bottles should be closely monitored and placed in the refrigerator while ice crystals are still present.
- Never microwave milk. This can cause superheated spots within the bottle and will degrade the bioactivity of the milk.
- Before use, completely thaw bottles until liquefied. Thawing just enough to pour off a single feed will result in uneven distribution of nutrients.
- Thawed milk must be refrigerated at all times and should be used within 48 hours (per HMBANA Best Practices). Adding anything to donor milk, including human milk derived and bovine derived fortifiers, alters storage time so it is not recommended to fortify donor milk until the time of feeding.
- Donor milk is not homogenized so fat will separate. Gently swirl thawed milk to distribute nutrients before feeding. Do not shake as this will trap air.
- Feeds for multiple infants may be poured from the same bottle.
- When using donor milk, the batch ID number of the bottle (located on the bottle label) must be documented in the infant's electronic health record. This is critical for tracking purposes.

Annual Human Milk Bank Operations Disclosure 2024

Each year, Mid-Atlantic Mothers' Milk Bank (MAMMB) provides the facilities that it serves with important information regarding its operational procedures.

Accreditation and Licensure

- MAMMB strictly follows the guidelines of and is accredited by the Human Milk Banking Association of North America (HMBANA). HMBANA provides evidence-based guidelines for the safe and ethical screening of donors, processing of milk, testing of milk, and distribution. MAMMB is regularly inspected by HMBANA to confirm adherence to the guidelines. The last routine HMBANA onsite inspection occurred in January 2024.
- MAMMB is licensed as a milk bank in the Commonwealth of Pennsylvania.
- MAMMB is licensed as a tissue bank in the states of Maryland and New York.
- MAMMB considers its general service area to be PA, WV, MD, NJ and DE. At this time, only PA, NY, and MD regulate milk banks.
- The federal government currently categorizes donor milk as food production. MAMMB is registered with the FDA as a food production facility and is subject to inspection. The last routine FDA inspection occurred in January 2024.
- 2 MAMMB staff members are certified Preventive Controls Qualified Individuals (PCQIs). The Preventive Controls for Human Food regulation (often referred to as FSMA) is a law enacted to ensure the safe preparation of food products for human consumption in the US in order to prevent food borne illnesses. Certification involves a week of training in the development and application of risk-based preventive controls.

HMBANA Requirements

- *Donors:* Donors are volunteers and are not compensated in any way. Donors are carefully screened in a process that includes: 1) an interview by phone or in person; 2) completion of a medical history questionnaire; 3) statements of health from the health care providers of the donor and her infant; and 4) blood screening which includes HIV, Hepatitis B and C, HTLV, and syphilis. HMBANA prohibits donor remuneration due to ethical and safety concerns.
- *Pasteurization*: The Holder Method of Pasteurization, a low temperature (62.5°C for 30 minutes) process, is used to inactivate pathogens while maintaining important bioactive components such as Secretory IgA and Human Milk Oligosaccharides (HMOs). MAMMB uses *Thermo Scientific* shaking water baths, and custom built pasteurizers.
- *Temperature Monitoring*: Freezers are maintained no higher than -20°C and refrigerators no higher than 4°C. All temperatures are monitored through *Digi SmartTemps*.
- *Post Pasteurization Bacterial Cultures*: Cultures are performed by the AHN Jefferson Hospital Microbiology Laboratory. Per HMBANA guidelines, milk batches that show any growth post-pasteurization are not distributed.
- *Maintenance of Records*: All information pertaining to distribution, milk testing, and donor screening are retained for every batch for a minimum of 10 years. This information can be provided within 6 hours of the receipt of the batch numbers in question and includes: de-identified screening information from every donor of the batch (including blood screening), post pasteurization bacterial cultures, drug testing results of the milk pool, and nutrient analysis of the batch. MAMMB performs a mock recall annually.

Operations Disclosure 2024 cont.

- *Medical Director:* MAMMB's volunteer Medical Director is Jennifer Zarit, MD, IBCLC, FAAP, NABBLM-C.
- *Medical Advisory Board*: The Medical Advisory Board includes members with expertise in a variety of areas including neonatology, pediatrics, obstetrics, pharmacology, and infectious diseases.

Additional Testing Done by MAMMB but Not Required by HMBANA or State Regulation

- *Drug Testing:* Each pool of milk is tested for a panel of common drugs including amphetamines, benzodiazepines, cocaine, cotinine, and THC using a microplate reader and ELISA kits from Neogen.
- *Macronutrient Analysis*: Each batch of donor milk is tested for protein, fat, and carbohydrate content using the Miris Human Milk Analyzer, the first and only FDA approved device for the measurement of human milk nutritional content.

Shipping

- Frozen pasteurized donor milk is shipped to hospitals, birth centers, and outpatients outside of the greater Pittsburgh area via FedEx or UPS priority overnight shipping.
- For added tracking, MAMMB uses PeriShip or Unishippers, perishable items logistics companies for FedEx or UPS, respectively.
- Dry ice is used to ensure that bottles arrive frozen.
- Frozen pasteurized donor milk is transported to facilities in the greater Pittsburgh area by the hospital's courier.

Distribution Policy

- MAMMB has a Distribution Policy in place that prioritizes NICUs and outpatients with medical needs in the unlikely event of a shortage. This distribution policy adheres to the recommendations of HMBANA.
- Per HMBANA guidelines, NICUs are provided with donor milk that has a minimum of 19.5 Kcal/oz and 0.7 g protein/dL. Donor milk that does not meet this minimum is distributed to outpatients only.

Depots and Dispensaries

- Through community partner hosts, MAMMB has a growing number of Depots and Dispensaries to provide greater convenience for donor families, increased access for recipient families, and to establish local visibility in the communities within its service area.
- Donor Depots house a secure freezer to collect milk from approved MAMMB donors.
- Dispensaries store and distribute small quantities of bottled, pasteurized, frozen donor milk to recipient families.
- Depots and Dispensaries are hosted by health systems, lactation centers, birth centers, physician's offices, and other maternal and child health related facilities. A site may be both a Depot and a Dispensary.
- For more information and a list of Depots and Dispensaries, visit the "Donor Milk in Your Neighborhood" section of midatlanticmilkbank.org.

Operations Disclosure 2024 cont.

Hospital Guidebook

This document is only a brief overview of key elements of MAMMB's operations. For more detailed information, please refer to MAMMB's "Pasteurized Donor Human Milk: A Guidebook for Hospitals and Birth Centers Served by Mid-Atlantic Mothers' Milk Bank" and midatlanticmilkbank.org.

Facility Portal

A copy of this letter, the hospital guidebook, and the most current certificates of the items listed below are available on the Facility Portal at midatlanticmilkbank.org. Scroll to the bottom of the home page and click "Portal Login" or use the QR code below. The Portal password is theperfectfood

Current HMBANA Accreditation
Current Pennsylvania License
Current Maryland License
Current New York License
FDA Facility Registration
PCQI Certificates
CLIA certificate of accreditation for AHN Jefferson Regional Medical Center

DEVELOPING PROTOCOLS- PROCESSING MATTERS

Processing Really Does Matter

One of the most important safety practices in donor milk banking is the heat processing of donated milk to inactivate pathogens. Any type of processing alters human milk, so it is imperative to choose a method that has the least impact on important components. All HMBANA milk banks use the Holder Method of Pasteurization (62.5°C for 30 minutes), a low temperature process that inactivates a broad spectrum of pathogens while retaining bioactivity. Nearly all published research regarding the efficacy of donor milk in preventing NICU complications was conducted using donor milk processed in this way.

Emerging evidence shows that heat sensitive components such as IgA (the main immunological factor in human milk) play an important role in the prevention of serious NICU complications. An increase of even 5°C during processing can increase degradation of components. It is for these reasons that HMBANA does not allow the high heat processing that creates a shelf stable product.

The following pages are excerpts from MAMMB's educational piece entitled "Processing Matters", which summarizes this research.

PDF of the full document

More Than Food

Human milk includes species specific bioavailable components that are just as important as the macronutrients critical to optimal newborn development. These components play major roles in disease protection and support of a healthy microbiome. When medically vulnerable infants don't have access to their mother's milk, the goal is to provide human milk that has been processed to eliminate pathogens while maximizing the retention of nutrients and unique bioactive factors. These bioactive components include, but are not limited to:

- Lactoferrin – A multifunctional protein that facilitates iron absorption and inhibits bacterial growth; present in quantities 100x greater than found in bovine milk.
- Lysozyme – An antibacterial protein that kills gram-positive and gram-negative bacteria; present in quantities 3000x greater than found in bovine milk.
- Immunoglobulins – Antibodies custom to pathogens in the maternal environment; one in particular, secretory immunoglobulin A (sIgA), is present in quantities 4000x greater than found in bovine milk, and constitutes 90% of the total immunoglobulins in human milk.
- Human Milk Oligosaccharides (HMOs) – HMOs are the third most abundant factor in human milk yet they are indigestible by infants. These short chain sugars serve many functions in the intestinal tract, including pathogen and toxin binding, enrichment of beneficial gut bifidobacterial, immune system support, and enhancement of the intestinal epithelial barrier function.
- Lysine– An amino acid that plays an important role in the production of carnitine which is necessary for converting fat into energy.

Overview of Milk Processing Methods

Holder Pasteurization and Vat Pasteurization for Frozen Human Milk

Globally, Holder pasteurization is widely used by milk banks to inactivate bacteria and viruses. In this low-heat method of processing, bottled milk is warmed to 62.5°C, held for 30 minutes, rapidly cooled, and then frozen until use. While there are no changes in the overall macronutrient profile of pasteurized human milk, retention of bioactive factors varies. Nonprofit milk banks accredited by the Human Milk Banking Association of North America (HMBANA) only use Holder pasteurization. Nearly all research regarding the efficacy of donor milk has used milk processed by Holder pasteurization. Vat pasteurization, used by some for-profit human milk derived product manufacturers, is a larger scale version Holder pasteurization.

Retort Processing for Shelf-Stable Human Milk

Retort processing, an older technology (canning), is currently being used by some for-profit corporations to produce a shelf-stable human milk product. Retort processing (shelf-stable human milk) uses high temperatures (115°C to 145°C) under pressure for several minutes to sterilize human milk. While this method is economical and allows for the efficient processing of large quantities of milk from hundreds of donors, emerging research suggests that retort processing significantly reduces several key bioactive components. To date, there is no data regarding clinical outcomes in the recipients of shelf stable donor milk.

All HMBANA accredited non-profit milk banks use the Holder Method of Pasteurization. This small batch, low temperature process ensures safety while retaining bioactivity.

Differences in Holder/Vat Pasteurization Versus Shelf Stable Human Milk (Retort)

Attributes	Meredith-Dennis (2017)[7]	Lima (2017)[8]	Lima (2018)[9]	Liang (2022)[10]
Types of Milk	Holder; shelf-stable	Raw; Holder; shelf-stable	Raw; Holder; shelf-stable	Raw (previously frozen), thawed and refrozen, thawed, homogenized and refrozen, Vat, Retort, Retort plus homogenization, Ultra High Temperature, Ultra High Temperature plus homogenization
Sample Size	N = 3 per milk type, each type received from a different milk bank	N = 36 total from the same pool 12 samples raw, 12 Holder, 12 shelf stable	N = 36 total from the same pool 12 samples raw, 12 Holder, 12 shelf stable	N=18 total samples of 7 different types from the same pool. The number of donors that contributed to the pool was not reported
Study Design	Cross-sectional (each milk type was from different donors and had a different pool size)	Cross-over (each milk type was from the same combined milk pool of 60 donors)	Cross-over (each milk type was from the same combined milk pool of 60 donors)	**Cross-over (each milk type was taken from the same pool)
Lactoferrin	*Higher in Holder vs shelf-stable	Not measured	Not measured	Vat retained 35% shelf stable (retort) retained 16%
Immunoglobulins	*Higher IgM and IgG in Holder vs shelf-stable	Holder retained 87% sIgA; shelf-stable retained 11% sIgA	Not measured	Vat slightly decreased IgA and IgM but not IgG
Lysozyme	*No difference between Holder vs. shelf-stable	Holder retained 54%; shelf-stable retained 0%	Not measured	No significant changes after any of the studied processing methods
HMO	*Higher in Holder vs shelf-stable	Not measured	Not measured	Not measured
Lysine	Not measured	Not measured	Raw= 0.85 mg/100 mL Holder=0.77 mg/100 mL shelf-stable=0.68 mg/100 m	Not measured
Thiamine	Not measured	Not measured	Raw= 0.24 mg/L Holder=0.26 mg/L shelf-stable=0.14 mg/L; p<0.01	Not measured
Bacteria Levels	Not measured	B. Cereus detected in 3 Holder samples; no bacteria detected in shelf-stable.	Not measured	Not measured
Other	Holder was higher in protein, fat, caseins (α, β, κ), α-1-antitrypsin, α -lactalbumin, and osteopontin, likely due to the fact that Holder milk was from preterm donors.	Not measured	Not measured	Growth Factors: No change in immunoreactivity of VEGF or TGFß2 with Vat Pasteurization. 95% reduction in VEGF and 92-99% reduction in TGFß2 in shelf stable (retort) samples.
Conclusions	Differences in processing, pooling of milk, and stage of lactation may contribute to differences in nutrient and bioactive composition, warranting further research.	Significant loss of bioactive proteins in shelf-stable milk compared to Holder. Holder requires post pasteurization testing for B. Cereus. HMBANA milk banks do not dispense milk with B. Cereus or other pathogens detected.	Macronutrient content is relatively unaffected by processing. Lysine and thiamine were significantly decreased in shelf stable milk but not by Holder. Thiamine losses are clinically significant and fortification may be necessary.	Overall, Vat pasteurization preserved more of the bioactive proteins compared with Ultra High Heat or Retort Sterilization. Therefore, human milk processors should consider the impact of processing methods on key bioactive proteins in human milk.

**This study was a cross-sectional study, so difference in composition may be attributed to different donors and different stages of lactation; therefore, the scale of differences was not assessed due to lack of control.*

*** This study was funded by a for-profit human milk derived products manufacturer*

There is a high loss of bioactive factors in shelf-stable human milk which may translate into different health outcomes in the medically fragile infant. More research is warranted before use of retort processed milk can be recommended for fragile infants. Several promising food science technologies are being investigated for use with human milk. These include high pressure processing, ultraviolet radiation, and high-temperature short-time processing. At this time, fundamental knowledge is lacking and extensive research is still required before using these processing methods with human milk. Meanwhile, non-profit milk banks, such as those within the Human Milk Banking Association of North America's network, continue to use Holder pasteurization for human milk.

DEVELOPING PROTOCOLS- BRIDGE MILK

Bridge Milk: *Short term donor milk use, as an outpatient or inpatient, in the first two weeks of life while a mother works to establish a milk supply that meets all of their newborn's needs.* This is the definition of bridge milk developed by the Medical Advisory Board of MAMMB.

An increasing number of hospitals served by MAMMB have extended donor milk use to beyond the NICU setting. Providing bridge milk for necessary supplementation has many benefits:

- Avoids the potential negative effects of early formula introduction such as increased risk of allergies, altered microbiome establishment, and disruption to the natural human milk feeding pattern
- Easily digestible
- Microbiome support
- Associated with higher rates of exclusive maternal breastfeeding at discharge and beyond
- Low cost patient satisfier

To date, there are no published best practices for the use of bridge milk. Based on our experience working with units who have implemented the use of donor milk and established best practices regarding supplementation in general, MAMMB encourages facilities to consider the following as they develop protocols:

Assent/Consent

Make sure that consenting procedures are not creating an obstacle to bridge milk use. Units have handled this in a number of ways including nurse or IBCLC rather than physician led consent, switching to assent, or even having prenatal education and consent in place.

Post Discharge Bridge Milk

Frequently, families will require the support of bridge milk post discharge. Usually, just a bottle or two is necessary until the mother can achieve exclusive breastfeeding. If your health system requires parents to pay for post discharge bridge milk, MAMMB has a simple process in place to allow parents to "borrow" bottles from the hospital's supply and pay the milk bank directly. The bottles are then replaced in the hospital's next order. Learn more about this process beginning on page 38. Families can also utilize a MAMMB Dispensary if one is located nearby.

DEVELOPING PROTOCOLS- BRIDGE MILK

A Bridge Not a Detour

Bridge milk can be a very effective support for breastfeeding but without evidence-based protocols in place, its impact can be lessened or at the extreme, even sabotage exclusive breastfeeding.

Lactation Support

Bridge milk must be paired with lactation support both in and out of the hospital. Ideally, latch and breastfeeding assessment is done prior to supplementation. Ideally, outpatient lactation services are in place at the time of discharge, or at the very least, parents should be given a list of local resources.

Appropriate Volumes

All supplementation, including bridge milk, must be given careful consideration. While bridge milk can be a very helpful breastfeeding support, it is a supplement and has the potential to inappropriately displace maternal milk if given in non-evidence based volumes. Resources such as the Academy of Breastfeeding Medicine's *Clinical Protocol #3: Supplementing Feedings in the Healthy Term Breastfed Neonate* are useful tools to develop your own unit's policies.

It is imperative that discharge volumes are individualized to the needs of each baby. Standard discharge amounts (for example, 5 bottles are automatically sent home with each family) are strongly discouraged. Due to its cost and/or the perception of being "liquid gold" parents may even be more inclined to use every ounce of donor milk to not be wasteful. This could potentially sabotage breastfeeding efforts.

Academy of Breastfeeding Medicine Protocol

A Precious Resource

Similar to blood and other donated biological products used in the healthcare setting, donor milk should be dispensed only when needed. There is a reliable and ample supply of pasteurized donor milk in our region, but it is a precious resource that is to be given only when necessary.

ORDERING DONOR MILK FOR THE INPATIENT SETTING- GETTING STARTED

Mid-Atlantic Mothers' Milk Bank works with the contracting and supply chain departments of each facility along with those staff members in the unit who are responsible for ordering donor milk to establish an account.

New Hospitals

MAMMB's self defined service area and priority is Pennsylvania, West Virginia, New Jersey, Maryland, and Delaware. Our organization believes that strong regional milk banks are the best way to meet the needs of families. We encourage facilities that have an in-state milk bank to utilize and support that nonprofit organization.

If your health system already has a contract with MAMMB and you are simply adding another hospital or unit please notify us as soon as possible.

Contracting

Email orders@midatlanticmilkbank.org to request the new hospital info containing MAMMB's template contract. The hospital may also provide its own vendor contract. In addition to contracting provisions regarding the agreement's term, compliance with relevant laws and regulations, confidentiality, warranties, etc., MAMMB asks that the following provisions are included in any services agreement:

Payment Terms

- Facility shall pay all undisputed invoices within 45 days after receiving an invoice from MAMMB.
- Failure to pay invoices within 45 days may result in delay in future shipments or requirements that future shipments be paid in advance.
- Payments received beyond 45 days after a facility's receipt of an invoice from MAMMB may be subject to a 3% interest charge.
- Payments made by credit card will be assessed a 4% convenience fee to cover the costs of credit card processing.

Ordering

Most facilities order expected volumes needed for one to two weeks. Orders are sent to orders@midatlanticmilkbank.org. Emailed orders are strongly suggested. Faxed orders may delay shipping until the next day.

- Orders received before noon will be shipped the same day with arrival the following day. If an order is received after 12pm on a Thursday will be shipped on the following Monday.

- Milk is shipped out Monday through Thursday. Both UPS and FedEx have modified overnight shipping for Saturdays and weekend service with both carriers is increasingly unreliable across MAMMB's entire service area. Friday shipping has been discontinued due to a consistent loss rate of over 50%, which wastes financial resources and most importantly, the milk generously donated.
- Orders that are to be delivered by courier are fulfilled Monday through Friday.
- Orders shall contain a correct and up-to-date purchase order number.
- The specific unit must be listed on the PO.

Shipping and Courier

- Facilities within the greater Pittsburgh area directly pay for their own couriers.
- For those outside of the greater Pittsburgh area, shipping fees will appear as an additional charge on the invoice and the exact cost from the shipping carrier will be applied. A commercial carrier designated by MAMMB is used.
- If your hospital has a preference between FedEx or UPS, please indicate this on the Account Set Up form.
- Tracking information will be included in invoices and can be used to obtain proof of delivery.
- MAMMB utilizes third party perishable item logistic companies for heightened shipping tracking/visibility and discounted shipping carrier rates.

Miscellaneous

- Families who receive pasteurized human donor milk should be aware of the risks and benefits of donor milk and formula. Facilities must develop their own protocols for assent or consent.
- MAMMB and the facility will comply with the guidelines of the Human Milk Banking Association of North America (HMBANA) for usage and storage of pasteurized donor human milk. MAMMB will maintain all applicable state licenses, as well as membership in, and accreditation and certification from, HMBANA.
- Both parties shall abide by guidelines stated in regarding storage and handling of donor milk. Refer to pages 10 to 18 of this Guidebook for specific recommendations and resources.
- Each facility is asked to complete the **Hospital Account Setup Form** which contains contact information and specific instructions for each hospital. It is **very important that this form is submitted in its entirety as it is necessary to communicate with facilities regarding important ordering, clinical updates, or substitutions when necessary.**

mid-atlantic mothers' milk bank

HOSPITAL ACCOUNT INFORMATION

Please complete and return via email (orders@midatlanticmilkbank.org) or Fax (412-281-4236)

HOSPITAL INFORMATION

Hospital Name _____

Hospital Unit: _____

Shipping Address_____

_____

UNIT INFORMATION

Name/Title of person ordering milk_____

Phone_____Fax_____

Email _____

Name/Title of person receiving the milk delivery_____

Phone_____Fax_____

Email _____

Medical Director _____

Phone_____Fax_____

Email _____

Nurse Manager _____

Phone_____Fax_____

Email _____

Mid-Atlantic Mother's Milk Bank sends periodic emails to units to give important updates, remind units to check their inventories before holidays, distribute the annual operations disclosure, etc. All clinical information updates will be sent to the Medical Director and Nurse Manager. Unless otherwise noted, ordering emails will be sent to the Nurse Manager and the person listed as ordering milk above.

mid-atlantic mothers' milk bank

HOSPITAL ACCOUNT INFORMATION

BILLING INFORMATION

Accounts Payable Contact_____

Phone_____Fax_____

Email _____

Billing Address _____

_____

Phone_____Fax_____

Billing Email:_____

Purchase Order Number Required? ☐ Yes | ☐ No If Yes, ☐ blanket PO | ☐ unique PO per order

Special Instructions_____

_____

SHIPPING AND DELIVERY INSTRUCTIONS

Orders are shipped overnight by FedEx or UPS.

Special Shipping Instructions: _____

_____

_____

Saturday Shipping Instructions:_____

For Orders to greater Pittsburgh area Hospitals

Courier Company Name_____

Courier Phone Number and Cost Center Code_____

Name (printed) _____

Signature_____Date_____

ORDERING DONOR MILK FOR THE INPATIENT SETTING- TYPES OF MILK

Mid-Atlantic Mothers' Milk Bank offers a variety of specialty milks to fit the needs of recipients. For your convenience, a color-coded round label is placed on the cap of each bottle to indicate milk type. Nothing is added to donor milk at MAMMB or at any other HMBANA accredited milk bank. Nutrient content is the result of naturally occurring variation.

Term Milk- NICU (purple, pink, or black): Milk that is produced from 37 weeks gestation and beyond. Available in 20kcal (19.5 to 21.4), 22kcal (21.5 to 23.4) and 24 kcal/oz (23.5 to 25.4).

Bridge Milk and Outpatient (light blue): Milk that is produced from 37 weeks gestation and beyond. Meets all HMBANA requirements including macronutrient content but is not nutritionally labelled. Milk sent to hospitals will be 20kcal (19.5 to 21.4) or above. QR code on the top cap leads to a page on MAMMB's website which contains information for recipient families including safe storage/handling instructions, resources for lactation support, donor milk education, payment, and how to order additional milk.

Defatted Milk (green): Term milk that is manually skimmed to reduce fat content to 1% or less. Appropriate for babies who have developed a chylothorax. The increased price for this milk is due to the extra time involved in the skimming process.

Cream (white): The byproduct of skimming. This is not a standardized product and as such each batch varies with an approximate range of 11% to 16% fat. Macronutrient content is available for each batch. The increased price for this milk is due to the additional costs of processing in smaller (50ml) bottles.

Preterm Milk (blue): The first 4 weeks of milk produced on or before 36 weeks gestation. The increased price for this milk is due to the additional costs of processing in smaller (50ml) bottles.

Colostrum (orange): Milk from the first 4 days post-partum. The increased price for this milk is due to the additional costs of processing in smaller (50ml) bottles.

Restricted Diet (yellow): Milk that is donated by donors that follow a restrictive diet such as low dairy or soy. MAMMB cannot control the diets of donors so content is not guaranteed. A low dairy or soy diet is defined as one that avoids dairy (milk, cheese, butter, ice cream, etc.) and/or soy (tofu, edamame, miso, etc.) but may include incidental ingestion from processed foods such as baked goods.

ORDERING DONOR MILK FOR THE INPATIENT SETTING- TYPES OF MILK

A Note About Preterm Milk and Colostrum

Per the preference of the facilities in our service area, MAMMB isolates both preterm milk and colostrum.

Pasteurized Preterm Milk: Milk from the first four weeks post-partum produced by a parent that delivered before 37 weeks gestation.

Pasteurized Colostrum: Milk produced in the first four days post-partum.

Supply

Premature babies are the most common recipients of donor milk because of their medical needs and the fact that up to 70% of their mothers are unable to meet their milk volume requirements, at least initially, even with adequate lactation support and effort. It is not surprising then that the supply of preterm donor milk is limited and unpredictable. In fact, it makes up less than 8% of the donated milk collected by MAMMB and is often the result of a donation after infant loss.

Use of a Limited Resource

MAMMB kindly requests that facilities develop preterm milk use policies that reserve preterm milk for babies who are at the most risk or who are not growing adequately with their present nutrition plan. Policies that reflect the scarcity of this precious resource ensure that there is more availability for recipients who are the most in need.

Hospitals Can Make a Big Difference in Enhancing the Supply of Preterm Milk

Hospitals are uniquely positioned to facilitate the donation of preterm milk when appropriate. The staff of MAMMB often hear stories of preterm milk being discarded by parents or units because of freezer space. Familiarizing yourself with the donation process and criteria (beginning on page 51) will help you to identify and assist parents who may be interested in donation.

ORDERING DONOR MILK FOR THE INPATIENT SETTING- PROCESSING FEES

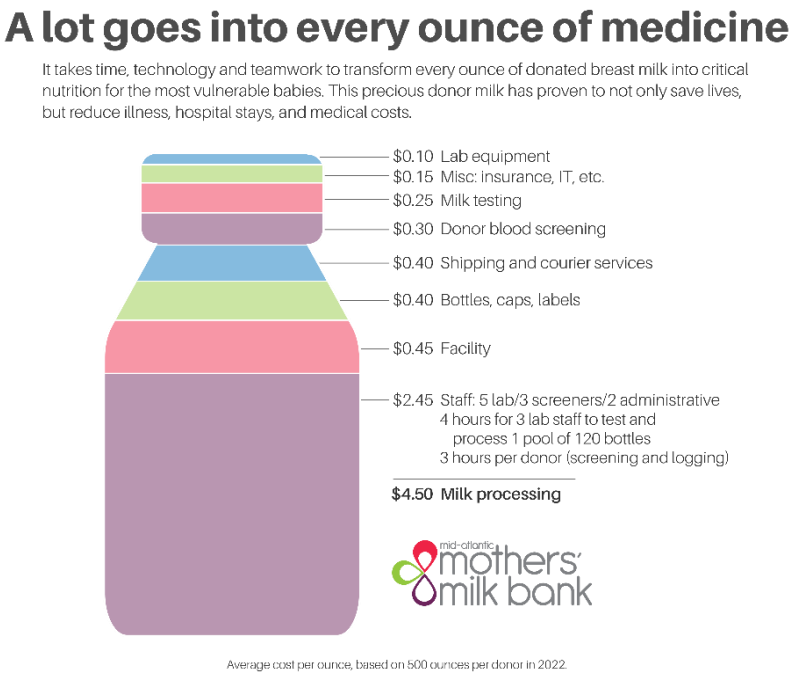
Donor milk itself is free because it is generously donated by volunteers. What is charged is a milk processing fee which pays for donor screening along with milk bottling, testing, and pasteurization. Fees do not include courier or shipping costs. Exact shipping costs from FedEx or UPS will be charged.

Type of Milk	Item Number	Ounce Price	Bottle Price
Term Milk 100ml Bottles			
NICU 20 kcal/oz	MAMMB100T20	$4.50	$15.00
NICU 22 kcal/oz	MAMMB100T22	$4.50	$15.00
NICU 24 kcal/oz	MAMMB100T24	$4.50	$15.00
Bridge Milk and Outpatient Unless otherwise noted, all milk sent to well baby units will be Bridge Milk	MAMMB100Bridge	$4.50	$15.00
Term Milk 200ml Bottles			
NICU 20 kcal/oz	MAMMB200T20	$4.50	$30.00
NICU 22 kcal/oz	MAMMB200T22	$4.50	$30.00
NICU 24 kcal/oz	MAMMB200T24	$4.50	$30.00
Bridge Milk and Outpatient Unless otherwise noted, all milk sent to well baby units will be Bridge Milk	MAMMB200Bridge	$4.50	$30.00
Defatted Milk 90ml Bottles For NICUs, CICUs, and Outpatients	MAMMB90DF	$5.10	$15.30
Preterm Milk 50ml Bottles For NICUs only	MAMMB50PT	$6.00	$10.00
Colostrum 50ml Bottles For NICUs only	MAMMB50Colostrum	$6.00	$10.00
Cream 50ml Bottles For NICUs only	MAMMB50C	$8.00	$13.33
Specialty/Restricted Diet			
Low Dairy/Soy/Other Donor Diet Restricted Diet 100ml Bottle	MAMMB100SD	$4.50	$15.00
Restricted Diet 200ml Bottle	MAMMB200SD	$4.50	$30.00

ORDERING DONOR MILK FOR THE INPATIENT SETTING- PROCESSING FEES

Breakdown of the Milk Processing Fee

The following breakdown is based on an average donation of 500 ounces per donor. Of note, MAMMB's fees are below the average for nonprofit milk banks in North America.



Availability of Types of Donor Milk

The Most Options

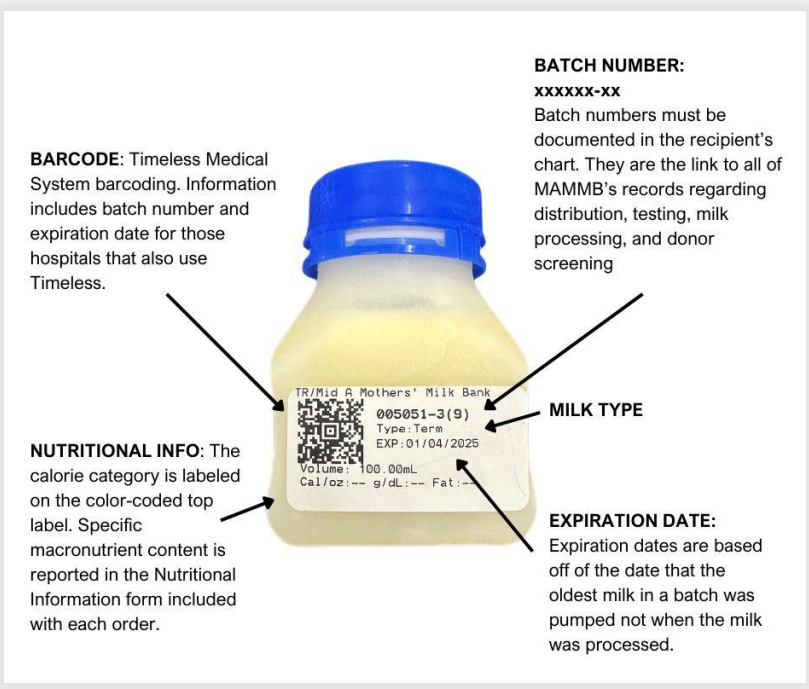
MAMMB offers more types of milk than any other nonprofit milk bank in the United States. HMBANA requires that the milk of multiple donors is pooled but does not require nutritional testing. MAMMB takes the extra step to quantify and report nutritional content, isolate milk with special attributes (preterm, colostrum, restricted diet), and skim milk to provide hospitals with more options in tailoring nutritional plans to the needs of each infant.

Overall Milk Supply and Availability

MAMMB strives to meet the needs of all facilities within its service region. *There is always milk in our freezers, but we cannot control the types of milk that are donated or the macronutrient content*. While separating milk into different categories is very useful, it also creates greater complexity.

Pasteurized donor human milk is a natural, not manufactured product. Nothing is ever added to manipulate the nutritional content. If a specific calorie type is not in stock, MAMMB staff will substitute the next closest type. If the bottle size requested is not available, another size will be substituted and the number of bottles sent will be equivalent to the volume of ml ordered. Be sure to communicate your substitution preferences to your buyer. Substitution preferences may be indicated on the order form.

ORDERING DONOR MILK FOR THE INPATIENT SETTING- MACRONUTRIENTS



Macronutrient Information

The Miris Human Milk Analyzer

MAMMB was one of the first milk banks in North America to begin utilizing the Miris Human Milk Analyzer, the first and only FDA approved medical device to measure the macronutrient content of human milk. Currently, less than half of the nonprofit milk banks in the United States have a Miris unit.

HMBANA Calorie Guidance

HMBANA does not require milk banks to measure the nutritional content of donor milk but does provide best practices for those milk banks that choose to do so. It is recommended that calorie content is reported by range as follows:

20 kcal/oz :19.5 to 21.4 kcal
22 kcal/oz: 21.5 to 23.4 kcal
24 kcal/oz: 23.5 to 25.4 kcal

MAMMB Calorie Content and Availability

The macronutrient content of human milk is quite variable and depends on many factors including lactation stage, time of day, and a number of maternal attributes. The milk of several donors is pooled to enhance immunological factor and HMO diversity as well as leveraging the individual macronutrient variability. The majority of milk donated to MAMMB is from the first three months of lactation. This milk tends to have higher caloric content, resulting in an average of 22 kcal/oz. Target pooling is not an exact science but we do utilize this method to provide the 20kcal and 24kcal categories, as possible.

ORDERING DONOR MILK FOR THE INPATIENT SETTING- MACRONUTRIENTS

True Protein

The Miris unit reports True Protein, which is crude protein minus non-protein nitrogen. The non-protein nitrogen value for human milk can be substantial and may result in over reporting if not accounted for. In the literature, mean values for mature human milk are 0.8 to 1.0 g/dL of True Protein. Milk that is below 0.7 g/dL is not distributed to NICUs.

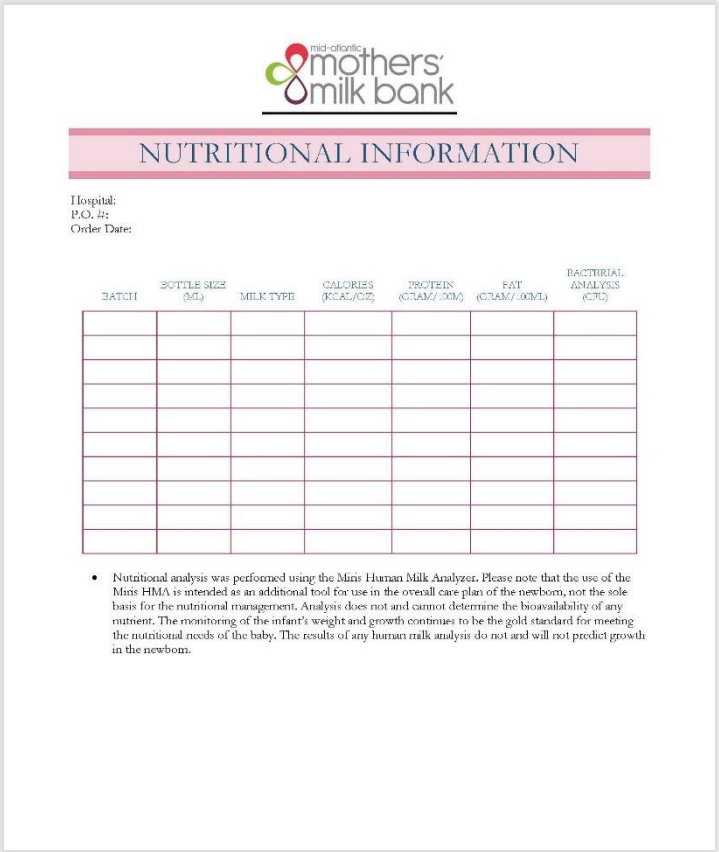
Macronutrient Considerations

Measuring macronutrient content enables MAMMB to ensure that NICUs are receiving milk that meets or exceeds established guidelines. While having the content quantified can provide useful information to your unit, please keep in mind the following:

- Human milk is a dynamic, complex, amazing tissue and its unique interaction with the human body along with many other factors affect growth. The focus must be on watching the infant, not the macronutrient numbers.
- Donor milk is not a homogenized, manufactured product so there is variation. It is best to use the calorie ranges listed on page 35 rather than the exact reported amount.
- MAMMB does not place macronutrient content information on bottles intended for bridge milk or outpatient use.

Nutritional Information Sheet

A Nutritional Information Sheet containing specific information about each batch is included with each order to intensive care units. The sheet lists calories, protein, fat, and confirmation of post pasteurization bacterial analysis.



mid-atlantic mothers' milk bank

NUTRITIONAL INFORMATION

Hospital:
P.O. #:
Order Date:

BATCH	BOTTLE SIZE (ML)	MILK TYPE	CALORIES (KCAL/OZ)	PROTEIN (GRAM/.00M)	FAT (GRAM/.00ML)	BACTERIAL ANALYSIS (CFU)

- Nutritional analysis was performed using the Miris Human Milk Analyzer. Please note that the use of the Miris HMA is intended as an additional tool for use in the overall care plan of the newborn, not the sole basis for the nutritional management. Analysis does not and cannot determine the bioavailability of any nutrient. The monitoring of the infant's weight and growth continues to be the gold standard for meeting the nutritional needs of the baby. The results of any human milk analysis do not and will not predict growth in the newborn.

mid-atlantic mothers' milk bank

HOSPITAL DONOR MILK ORDER

Orders must be received by noon for next day delivery

Facility:_____

Unit:_____

PO#:_____Date_____

Name and email of person(s) of person ordering:_____

_____

ITEM	DESCRIPTION	QUANTITY
MAMMB200T20	Term NICU, 200ml bottles 20 kcal/oz	
MAMMB200T22	Term NICU, 200ml bottles 22 kcal/oz	
MAMMB200T24	Term NICU, 200ml bottles 24 kcal/oz	
MAMMB100T20	Term NICU, 100ml bottles 20 kcal/oz	
MAMMB100T22	Term NICU, 100ml bottles 22 kcal/oz	
MAMMB100T24	Term NICU, 100ml bottles 24 kcal/oz	
MAMMB200Bridge	Bridge Milk, 200ml bottles	
MAMMB100Bridge	Bridge Milk, 100ml bottles	
MAMMB90DF	Defatted Milk, 90ml bottles	
MAMMB50PT	Preterm Milk, 50ml bottles	
MAMMB50Colostrum	Colostrum, 50ml bottles	
MAMMB50C	Cream, 50ml bottles	
MAMMB 200SD or MAMMB 100SD	Restricted Diet	Contact us at orders@midatlanticmilkbank.org before ordering

Special Instructions:_____

_____

Substitutions: Please indicate your preferences if a specific type of milk is unavailable. If the bottle size requested is not available another size will be substituted but the volume of milk ordered will be the same.

For preterm milk:

☐ Substitute term milk with the highest protein content in stock
☐ Contact me to consult before filling the order phone:_____

For calorie type:

☐ Substitute term milk with the next closest calorie category in stock
☐ Contact me to consult before filling the order phone:_____

EMAIL ORDERS to orders@midatlanticmilkbank.org (preferred) or FAX to 412-281-4236
PHONE: 412-281-4400

ORDERING DONOR MILK FOR THE INPATIENT SETTING- POST DISCHARGE BRIDGE MILK

For inpatients, MAMMB's donor milk processing fees are usually paid by hospitals and are part of the bundled payment (DRG) system. There are some specific scenarios where families pay the milk bank directly. For ease of use of families and to avoid hospitals needing to collect payment, MAMMB has an online payment system.

Bridge Milk at Discharge

Many hospitals in MAMMB's service area have extended donor milk use beyond the NICU including bridge milk for well babies. Some families will require a small amount of bridge milk post discharge until exclusive maternal breastfeeding can be achieved.

If bridge milk will be required after discharge, the hospital will need to supply the family with enough donor milk until they can purchase donor milk directly from MAMMB. Some health systems absorb the costs of post discharge milk and others have the family pay the fees to MAMMB using the bridge milk private pay procedure. See page 43-46 for additional information.

Bridge Milk Private Pay Procedure

1. **Payment:** Instruct the family to go midatlanticmilkbank.org and click "Recipients" in the top navigation bar. Scroll down and click "Order Milk". From there, the family clicks the **"**For Families Using Donor Milk Post-Discharge" which will enable them to fill out the Dispensary Form and pay for the bottles by credit card. A receipt is generated which can be shown to hospital staff. Payment information can also be found via the QR codes on the top cap label and the milk bank's information cards.
2. **Documentation:** The batch numbers of all bottles of donor milk taken home by the family must be documented in the baby's chart along with assent or consent per the procedures of the hospital.
3. **Education:** Families will need information about safe storage and handling of donor milk. MAMMB provides free Donor Milk Storage and Handling cards and this information can also be found on the milk bank's website. The QR on the top cap of bridge milk bottles leads to a page that contains the same instructions along with additional resources.
4. **Lactation Support:** It is important for lactation support to be paired with bridge milk. Hospitals are encouraged to ensure that mothers are discharged with lactation services in place or at a minimum, with a list of community resources.
5. **Replacement:** The family indicates which hospital they are being discharge from on the online Dispensary Form. The bottles taken home by the family will be replaced in the hospital's next donor milk order.

Label on the top cap of bridge milk bottles. The QR code leads to the "Donor Milk in Your Neighborhood" page of midatlanticmilkbank.org which contains safety storage and handling instructions, where to find lactation support, payment, patient education, and how to order additional milk.

ORDERING DONOR MILK FOR THE INPATIENT SETTING- POST DISCHARGE BRIDGE MILK

Purchasing Additional Bridge Milk Post Discharge

For hospitals that allow families to return to their facility for additional bottles of milk the same bridge milk private pay procedure can be used. Of note, MAMMB obtains consent for donor milk use for all outpatients and this form is signed online when the family fills out the Dispensary Order Form.

Families can also pickup milk at MAMMB or one of its dispensary hosts. For those families without a location nearby, donor milk can be shipped. Please be aware that milk is only shipped Monday through Thursday for next day delivery and that the family will incur shipping costs.

Infants That Have a Medical Need for Outpatient Milk and Will Require Use Beyond 2 Weeks

Outpatient use beyond 40 total ounces requires a prescription. Insurance often covers medically necessary donor milk. It is imperative to prepare the prescription and request insurance pre-authorization prior to discharge as soon it is determined that outpatient donor milk will be needed. The outpatient procedure is outlined beginning on page 40.

Inpatient Private Pay

If an infant does not meet a hospital's donor milk inclusion criteria and a family wishes to private pay for milk consumed as an inpatient, they may use the bridge milk private pay procedure described on page 38.

"Having premature twins in the NICU is no easy thing, but then bringing them home with eating difficulties and health issues makes it even harder. Our twins never were able to latch, so I quickly became an exclusive pumper. Even with pumping every 2-3 hours, I couldn't produce enough. We ended up discovering the boys had an allergy and developed enterocolitis from trying 9 different formulas. There were nights I sat at my pump and just cried wondering what I was going to feed them.

To the milk donors- YOU are rockstars. You donating your milk literally saved our twins from further hospitalizations. The twins went from 0% on their growth charts to 44 and 56% all thanks to your dedication. Thank you all for everything you have done for us."

-NICU Nurse and Mom of Donor Milk Recipients

ORDERING PASTEURIZED HUMAN MILK FOR OUTPATIENTS- PRESCRIBING AND INSURANCE

Approximately 20% of the donor milk collected and processed by MAMMB is distributed to outpatients. The vast majority of outpatient donor milk is used by infants with significant medical issues. Elective use (bridge milk, adoption, maternal illness/death, etc.) represent a very small portion of the milk bank's distribution.

Distribution Policy and Priority

Outpatient use is subject to availability. For more detailed information please review MAMMB's *Distribution Policy* found on page 8. The policy, which is compliance with HMBANA's standards, protects the supply for NICUs and ensures that priority is given to the sickest outpatients. Due to the generosity of donors and the help of clinicians, hospitals, and community organizations, MAMMB has been able to maintain a reliable supply to meet the needs of our service area.

Prescription

Outpatient donor milk requires a prescription. The only exception is limited use of no more than 40 total ounces (12 100ml bottles) per baby per lifetime. This maximum includes bridge milk that was taken home from the hospital post discharge. MAMMB's Prescription Form, which can be filled out online, is strongly preferred but other prescription forms are acceptable. A PDF of the prescription form can be found on page 47. All prescriptions must include the following information:

- Date of prescription
- Recipient child's name
- Recipient child's date of birth
- Amount of milk needed per day or week (oz or ml)
- Period of time donor milk is required in weeks or months (a new prescription is required after 6 months)
- Reason donor milk is needed and diagnosis code(s)

To fill out the prescription form or upload your own, visit midatlanticmilkbank.org. Click "Order" in the top navigation bar and then click "For Healthcare Provider Prescribing Outpatient Donor Milk".

Insurance Coverage

Donor milk required for a documented medical need is likely to be covered by insurance.

Pre-Authorization

Pre-Authorization, requested by the prescribing healthcare provider, is required by most Medicaid plans and commercial plans. To avoid gaps in coverage and significant costs to the family, **it is imperative that the request for pre-authorization is made prior to discharge and as soon as the need for outpatient donor milk is identified**. Please note that insurers will not allow the milk bank to request pre-authorization, it must be done by the prescriber. Once pre-authorization is obtained, please email orders@midatlanticmilkbank.org.

Letter of Medical Necessity Template

To facilitate the pre-authorization process for prescribers, MAMMB has an a fillable online Statement of Medical Necessity for Outpatient Donor Milk template (PDF on page 48). The template has a check the box and fill-in format that includes information required by most plans. It can be accessed at midatlanticmilkbank.org. Click "Order" in the top navigation bar and the click "For Healthcare Provider Prescribing Outpatient Donor Milk". Once completed, the form can be downloaded and printed. The form must be sent to the insurance plan not MAMMB to start the pre-authorization process.

Helpful Information

- Three Rivers Mothers' Milk Bank dba Mid-Atlantic Mothers' Milk Bank is a DME provider
- The HCPCS code for human breast milk processing, storage, and distribution is T2101
- The milk bank's NPI# is 1902267594. Please make sure that the milk bank's NPI – not the prescriber's NPI – is listed on the authorization as the supplying provider.

State Donor Milk Insurance Coverage Laws

Insurance coverage for donor milk is expanding and evolving with many states instituting coverage mandates. The provisions of these laws vary considerably. The following states within MAMMB's service area have passed legislation for coverage:

*Pennsylvania***:** Owen's Law became effective in Pennsylvania on January 20, 2024. This Medical Assistance mandate addresses both inpatient and outpatient donor milk for babies with specific medical circumstances. For inpatients, coverage remains under the All-Patient Refined Diagnosis Related Group payment to the hospital for the infant. The following outlines the provisions for outpatients:

> Outpatient infant PDHM is covered for an infant who is younger than twelve months of age based on the infant's corrected gestational age, who is receiving care in an outpatient setting and has any of the following health conditions:
>
> (1) A congenital or acquired gastrointestinal condition or other serious medical condition associated with long-term feeding or malabsorption complications.
> (2) Congenital heart disease requiring surgery in the first year of life.
> (3) Has had or will have an organ or bone marrow transplant or has an immunologic deficiency.
> (4) A history of sepsis.
> (5) Renal disease requiring dialysis in the first year of life.
> (6) Any other health condition for which the use of PDHM is medically necessary as determined by the Department.
>
> Pre-authorization is required for outpatient use.

*New Jersey***:** In January 2020, a donor milk coverage mandate for both Medical Assistance and commercial insurance was signed into law. Insurers must cover the costs if the infant is aged younger than 6 months, the milk comes from a milk bank that meets the quality guidelines of the Human Milk Banking Association of North America or is licensed by the New Jersey Department of Health, and it is prescribed to the infant by a physician. As of August 2024, the NJ Department of Health has not

developed milk bank regulatory standards or determined conditions that benefit from donor milk so the law has yet to be enforced. The specific language of Bill 3159:

“The criteria is as follows:

(b) the infant meets any of the following conditions:

(i) body weight below healthy levels, as determined by the licensed medical practitioner issuing the medical order for the infant
(ii) the infant has a congenital or acquired condition that places the infant at a high risk for development of necrotizing enterocolitis; or
(iii) the infant has a congenital or acquired condition that may benefit from the use of donor breast milk and human milk fortifiers, as determined by the Department of Health.”

Charitable Care

Sliding Scale Fee Discount Program

If an outpatient child with a documented medical need does not have insurance coverage for donor milk, the family may apply for MAMMB’s income based Sliding Scale Fee Discount Program which provides a 10-90% discount. An application, including income verification and proof of insurance denial is required**.** Recipients must reside in PA, WV, NJ, MD, or DE. Families can contact us at orders@midatlanticmilkbank.org or 412-281-4400 for more information.

Discount Program for Special Circumstances

MAMMB provides automatic discounts for two populations experiencing the following circumstances. Proof of insurance denial is required.

- Maternal Death, Cancer, or Serious Illness: 75% discount for 8 weeks
- Infant Exposure to HIV in utero: 75% discount for 6 weeks

The 75% discount is not income based but the program is available only to recipients in PA, WV, NJ, MD, and DE.

Instructions for Families

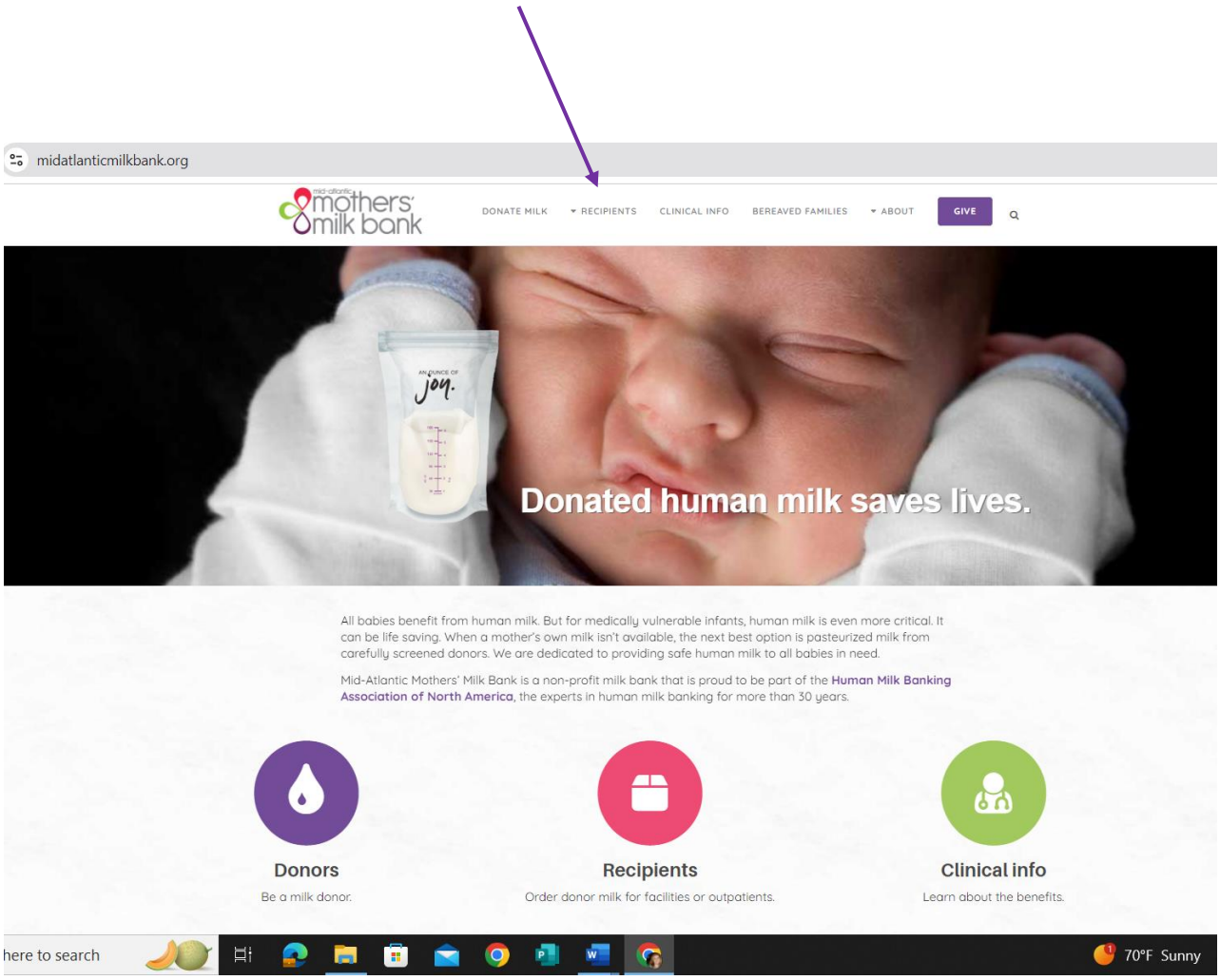
Outpatients requiring high volumes or use beyond two weeks must order milk directly from MAMMB. Please instruct families to visit midatlanticmilkbank.org for more information. Click “Order” in the top navigation bar and then click “For Families Needing Milk on an Outpatient Basis” for instructions. It is important that the family reaches out to us as soon as the need for outpatient milk is determined. Much of the registration, consent, payment, and paperwork can be done online or through email. If a family does not have internet access they may call 412-281-4400.

ORDERING PASTEURIZED HUMAN MILK FOR OUTPATIENTS

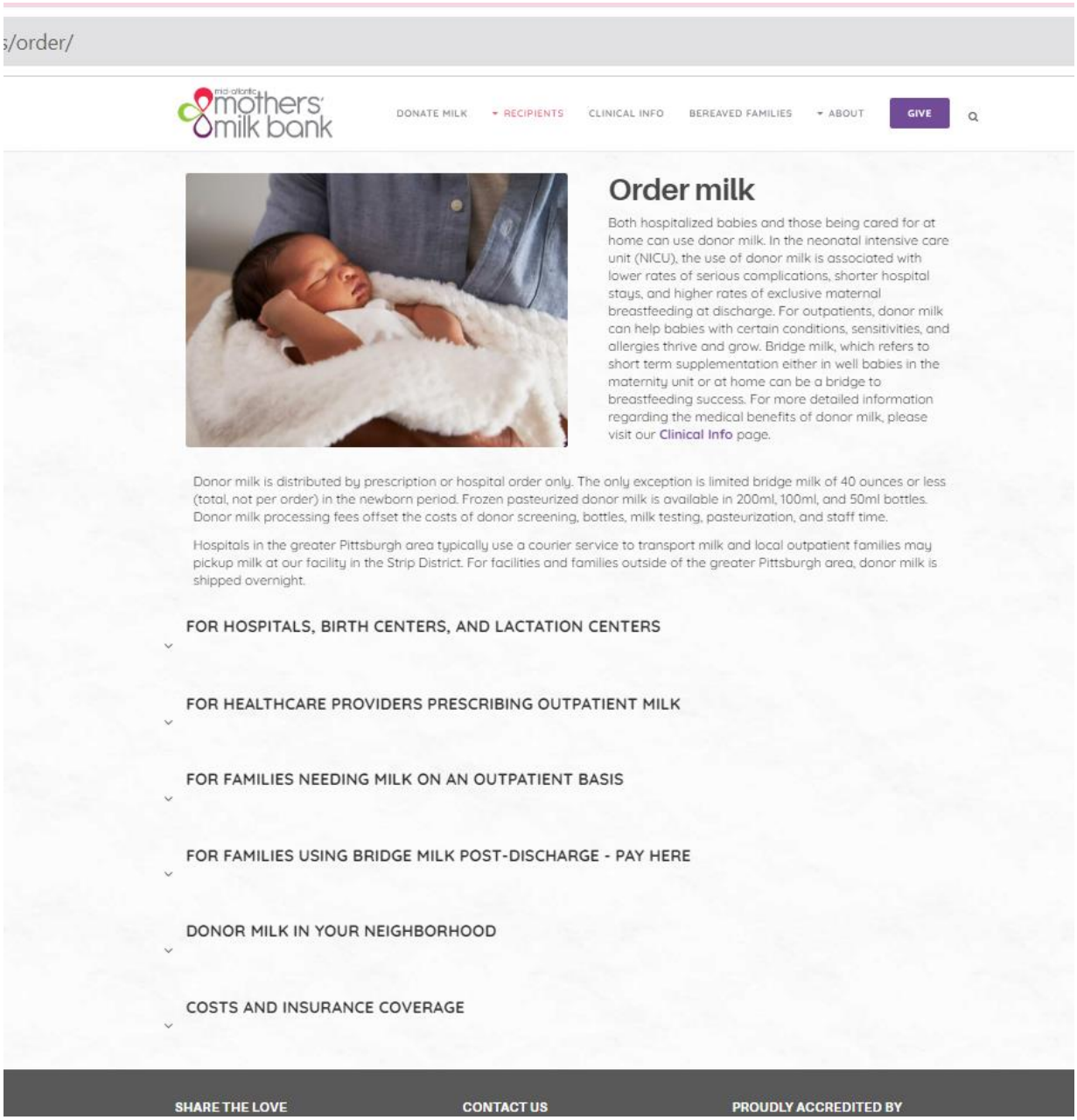
The following website instructions for midatlanticmilkbank.org apply to all families that use donor milk in the home setting.

From “RECIPIENTS”, click:

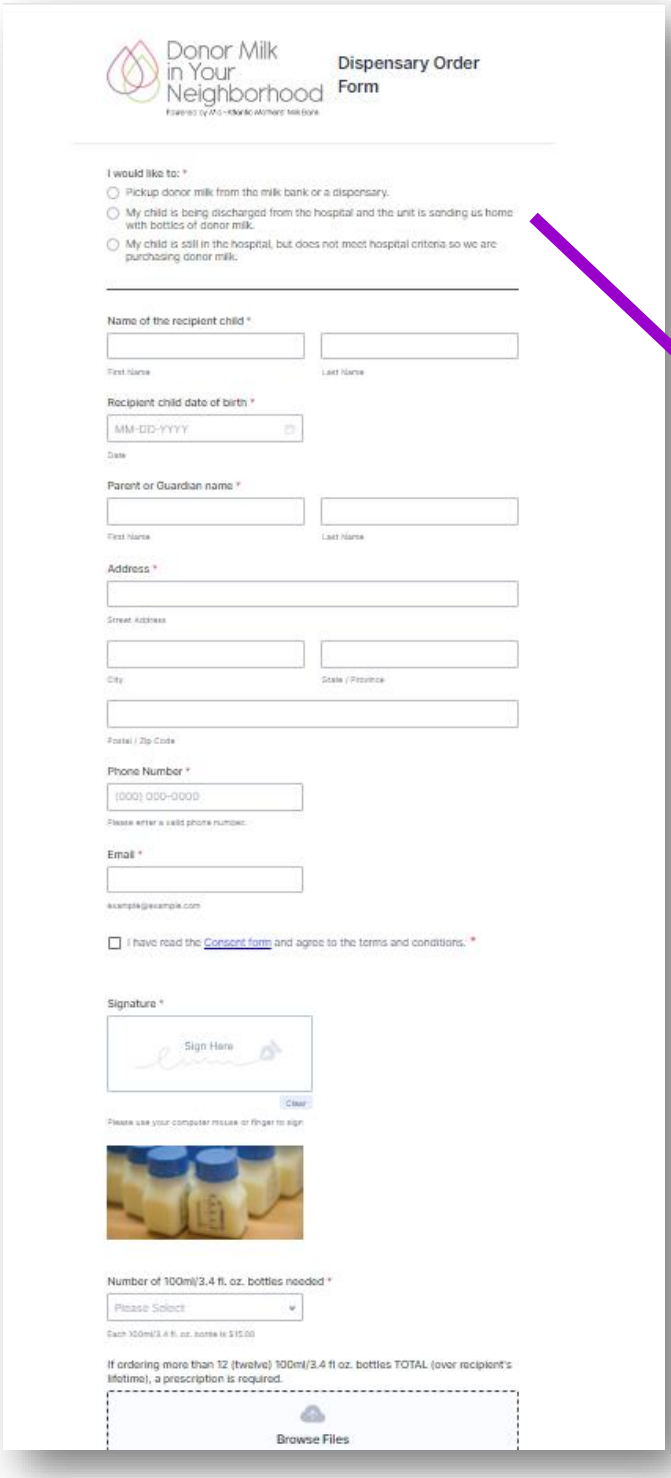
“MILK RECIPIENTS” for inpatient family education including the Meet Nico video
“ORDER MILK” for outpatient prescribing and insurance info
“DONOR MILK IN YOUR NEIGHBORHOOD” for info for outpatient families including those using post discharge bridge milk (handling instructions, paying for post discharge bridge milk, lactation support, etc)



ORDERING PASTEURIZED HUMAN MILK FOR OUTPATIENTS



ORDERING PASTEURIZED HUMAN MILK FOR OUTPATIENTS



Donor Milk in Your Neighborhood
Powered by Mid-Atlantic Mothers' Milk Bank

Dispensary Order Form

I would like to: *
- Pickup donor milk from the milk bank or a dispensary.
- My child is being discharged from the hospital and the unit is sending us home with bottles of donor milk.
- My child is still in the hospital, but does not meet hospital criteria so we are purchasing donor milk.

Name of the recipient child *
First Name | Last Name

Recipient child date of birth *
MM-DD-YYYY
Date

Parent or Guardian name *
First Name | Last Name

Address *
Street Address
City | State / Province
Postal / Zip Code

Phone Number *
(000) 000-0000
Please enter a valid phone number.

Email *
example@example.com

I have read the Consent form and agree to the terms and conditions. *

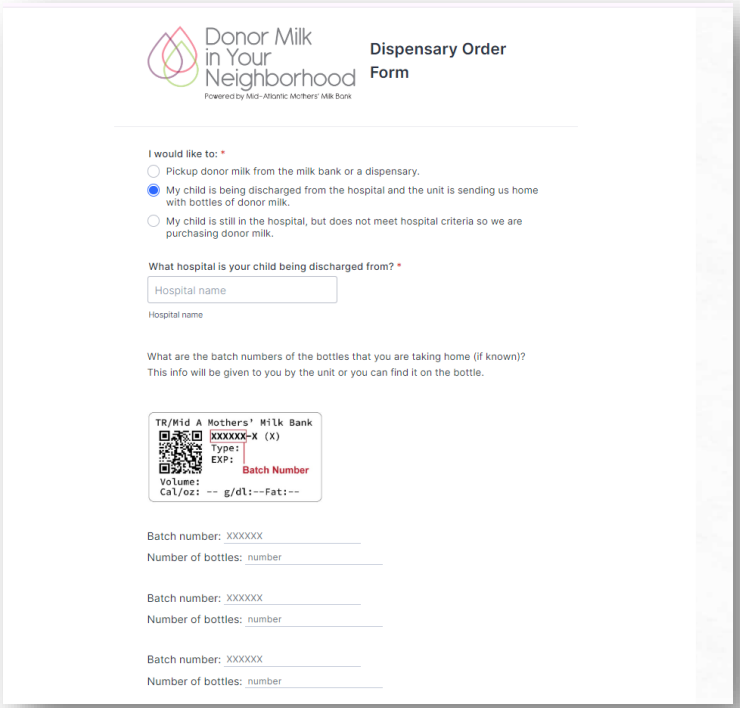
Signature *
Sign Here
Clear
Please use your computer mouse or finger to sign

Number of 100ml/3.4 fl. oz. bottles needed *
Please Select
Each 100ml/3.4 fl. oz. bottle is $15.00

If ordering more than 12 (twelve) 100ml/3.4 fl oz. bottles TOTAL (over recipient's lifetime), a prescription is required.

Browse Files

If a family chooses option #2 (my child is being discharged from the hospital and the unit is sending us home with bottles of donor milk) the window shown below opens. It is important for families to fill in the hospital and campus name. It is very helpful if the batch numbers are entered as well but if the parents do not have access to the bottles while completing the form they may omit the batch information. The batch numbers must always be recorded in the infant's hospital chart.



Donor Milk in Your Neighborhood
Powered by Mid-Atlantic Mothers' Milk Bank

Dispensary Order Form

I would like to: *
- Pickup donor milk from the milk bank or a dispensary.
- My child is being discharged from the hospital and the unit is sending us home with bottles of donor milk.
- My child is still in the hospital, but does not meet hospital criteria so we are purchasing donor milk.

What hospital is your child being discharged from? *
Hospital name
Hospital name

What are the batch numbers of the bottles that you are taking home (if known)?
This info will be given to you by the unit or you can find it on the bottle.

TR/Mid A Mothers' Milk Bank
XXXXXX-X (X)
Type:
EXP:
Batch Number
Volume:
Cal/oz: -- g/dl:--Fat:--

Batch number: XXXXXX
Number of bottles: number

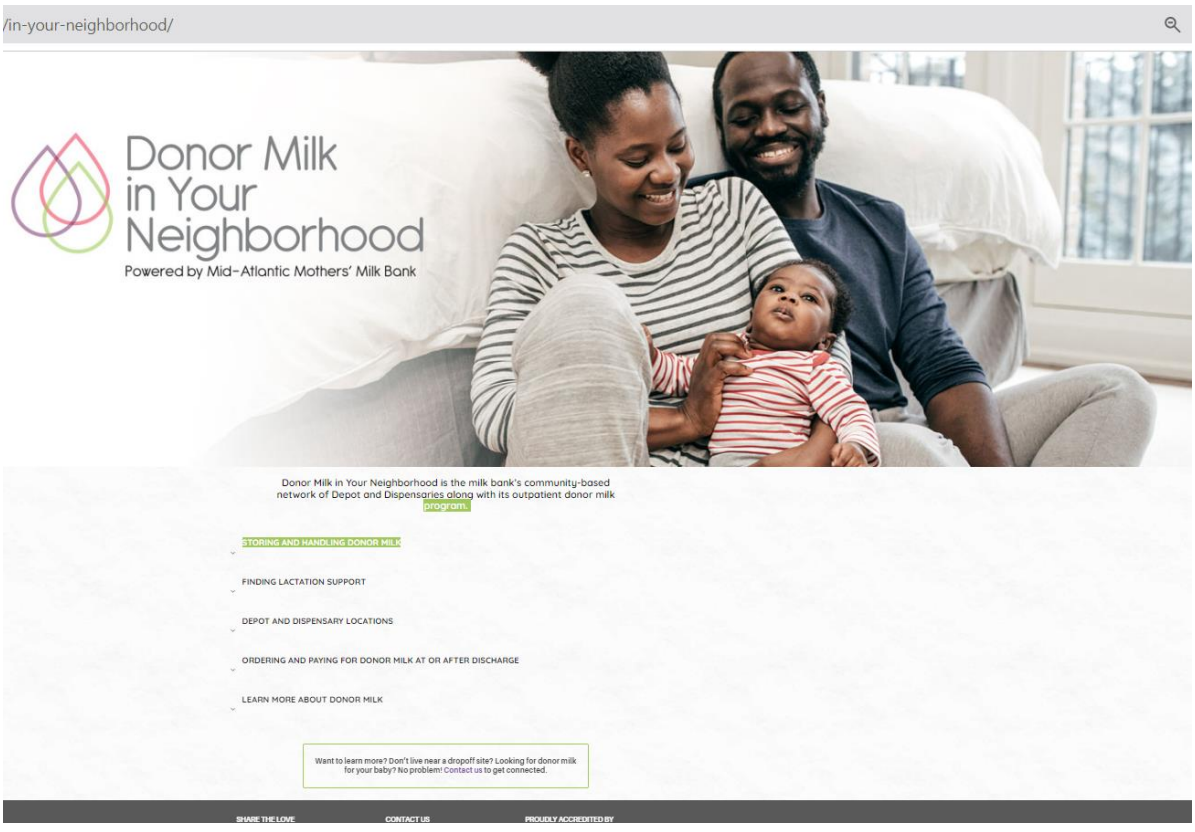
Batch number: XXXXXX
Number of bottles: number

Batch number: XXXXXX
Number of bottles: number

ORDERING PASTEURIZED HUMAN MILK FOR OUTPATIENTS- BRIDGE MILK

Bridge Milk and Outpatient Donor Milk Top Cap

The top cap of bottles of pasteurized donor milk for bridge milk or outpatient use have a label with a QR code that leads to important information including storage and handling instructions, payment/ordering, and where to find lactation help.



PRESCRIPTION FORM FOR PASTEURIZED HUMAN DONOR MILK

Child's Name:_____

DOB:_____ Today's Date:_____

Please provide _____ounces/day of pasteurized Donor Human Milk for: ____weeks ____months (up to 6)

Medical reason(s) donor human milk is required: _____

_____

Diagnosis codes: _____ _____ _____ _____ _____ _____ _____

If formula intolerance is a reason for the donor milk request, please list the formulas that have been trialed:

1) _____ 2)_____ 3) _____

Formula intolerance is defined by the milk bank as continued suboptimal growth and/or symptoms after 3 documented trials of formulas including a hypoallergenic or amino acid based formula.

Is this prescription for discretionary use of donor milk? ☐ Yes ☐ No

Discretionary use describes a situation in which an infant does not have a documented medical indication for human donor milk and has limited or no access to maternal milk. Such use may not be covered by insurance.

Has insurance pre-authorization been requested? ☐ Yes ☐ No

Authorization #:_____ Plan:_____

Medicaid and private insurance carriers may cover the cost of donor milk if there is a medical need. ***Plans require the prescribing physician to contact the insurer to obtain an authorization number.*** *Without insurance authorization, the donor milk processing fee ($29.33/200ml bottle) is the responsibility of the family. You may need the following info when contacting an insurer: Three Rivers dba Mid-Atlantic Mothers' Milk Bank is a DME provider. The code for human breast milk processing, storage, and distribution is T2101. The milk bank's NPI# is 1902267594.*

Mother's own milk is always the goal. Check here ☐ if mother needs assistance in finding lactation support.

Distribution Policy: Medical need describes a diagnosis or circumstance in which donor milk may provide a therapeutic benefit. Such conditions include, but are not limited to, malabsorption disorders, prematurity, short gut syndrome, congenital heart disease, renal disease, post-surgical nutrition, immunological deficiencies, failure to thrive, allergies, and formula intolerance. Mid-Atlantic Mothers' Milk Bank relies on the generosity of volunteer donors. In times of shortage, priority is given first to NICUs then outpatients with medical needs. Discretionary use orders will only be filled as supply permits. A full explanation of the milk bank's distribution policy is included in the outpatient packet and online.

Provider Name:_____

Practice/Hospital:_____

Address:_____

Phone:_____ Fax:_____

NPI:_____ Signature _____

PLEASE FAX PRESCRIPTION TO 412-281-4236

Questions? 412-281-4400 or orders@midatlanticmilkbank.org 3127 Penn Avenue Pittsburgh, PA 15201

STATEMENT OF MEDICAL NECESSITY FOR OUTPATIENT DONOR MILK

This form is provided as a tool to generate a statement of medical necessity to be used when seeking pre-authorization for donor milk coverage. Most plans require preauthorization which must be initiated by the prescriber. Submit the completed form to the insurance plan, not the milk bank.

Patient Name:_____ Patient Birth Date:_____

Insurance Plan:_____ Policy Holder:_____

ID Number:_____ Group/Group Number:_____

Birth Weight:_____ Current Weight:_____

I am requesting that insurance coverage be provided for pasteurized human donor milk for the above patient. This child is unable to thrive using commercially available formulas or has a documented medical condition that is known to benefit from pasteurized donor human milk.

Infant Diagnoses: list one or more

Common Infant ICD-10 Codes
☐ R62.51 Failure to thrive in child (0-17yrs)
☐ P07.30 Preterm newborn
☐ P07.20 Extreme immaturity of newborn, unspecified gestation
☐ P05.10 Newborn SGA, unspecified weight
☐ K90.9 Intestinal malabsorption, unspecified
☐ P77.9 Necrotizing enterocolitis in newborn
☐ Z91.011 Allergy to milk products
☐ Q79.3 Gastroschisis
☐ K52.22 Food protein induced enteropathy
☐ P27.1 Brochopulmonary dysplasia originating in perinatal period
☐ Q24.9 Congenital malformation of heart, unspecified
☐ J94.0 Chylous effusion
☐ P96.1 Neonatal withdrawal symptoms from maternal drugs of addiction
☐ G12.0 Spinal muscular atrophy, type I

Additional Codes
☐
☐
☐
☐
☐
☐
☐
☐
☐

Maternal Diagnoses: list one or more

Common Maternal ICD-10 Codes
☐ O92.3 Agalactia
☐ O92.4 Hypogalactia
☐ O92.5 Suppressed lactation
☐ O92.70 Other disorders of lactation

Common Maternal ICD-10 Codes
☐
☐
☐

Does the patient have one or more of the following conditions?

- ☐ A congenital or acquired gastrointestinal condition or other serious medical condition associated with long-term feeding or malabsorption complications?
- ☐ Congenital heart disease requiring surgery in the first year of life
- ☐ Has had or will have an organ or bone marrow transplant or has an immunodeficiency
- ☐ A history of sepsis
- ☐ Renal disease requiring dialysis in the first year of life

Formula Trials

Formula	Dates	Symptoms

Formula has not been trialed due to the following reasons:

_____

Clinical Information

Donor milk is the only appropriate form of nutrition for this child due to the following:

_____

_____

Improvements observed with donor milk and the ways it is helping this child:

_____

_____

Negative outcomes that could occur without the provision of donor milk for this child:

_____

_____

Describe the child's treatment plan regarding donor milk:

_____

_____

Additional clinical documentation attached:

☐ Growth Charts

☐ Tests

☐ Notes

☐ Other: _____

Pasteurized Donor Human Milk Requirements

Type of pasteurized human donor milk required:

☐ Term

☐ Defatted

☐ Restricted Diet (milk from donors with special diets- low dairy, low soy, etc.)

Anticipated amount required:

_____ ☐ oz ☐ ml per day for _____ ☐ weeks ☐ months

Provider Information

Provider Name:_____NPI#:_____

Email:_____

Phone:_____Fax:_____

Address:_____

City:_____State:_____Zip:_____

Signature:_____Date:_____

Pasteurized donor human milk to be provided by:

Mid-Atlantic Mothers' Milk Bank
3127 Penn Avenue Pittsburgh, PA 15201
P: 412-281-4400 / F: 412-281-4236
NPI#: 1902267594

Mid-Atlantic Mothers' Milk Bank is a nonprofit milk bank that provides hospitals and outpatients with pasteurized human milk from carefully screened, unpaid volunteer donors. The milk bank is accredited by the Human Milk Banking Association (HMBANA) and licensed in PA, MD, and NY.

Visit midatlanticmilkbank.org for more information.

MILK DONATION- DONORS

Nonprofit milk banks like MAMMB could not exist without the generosity of donors. They are our heroes!

Donors

Donors are simply healthy lactating parents who have more milk than their own babies need. They come from many different backgrounds including:

- Any mother with an abundance of milk who wants to help
- Mothers whose own baby or a family member received donor milk while hospitalized
- Healthcare workers who know the importance of donor milk
- Bereaved mothers
- Mothers who have no more room in their freezer
- Surrogates

A Volunteer Act of Generosity

Donors are never paid. HMBANA strictly prohibits the remuneration of milk donors due to safety and ethical considerations. The nonprofit uncompensated donor model provides a safe donor pool without introducing scenarios that could affect the wellbeing of recipients, donors, and the babies of donors. Donation does require time and work which is greatly appreciated by MAMMB. Staff strive to make donation a simple and rewarding experience. Donors are also acknowledged in many ways:

- A certificate of appreciation that lists the total number ounces donated
- A special “One for Me, One for the NICU” baby t-shirt
- A copy of the children’s book *An Ounce of Sharing* written by former MAMMB board member, Jan Mallak
- Social media posts and other public acknowledgements for those donors who share their stories
- As feasible, an email is sent to donors the first time that their milk is part of a distributed batch of milk.
- Flyers with recipient stories and words of gratitude are included in donor packets and boxes.

“I've had such a great experience being a milk donor during the first year of both of my children's lives. We are so happy to share milk with the babies that we refer to as our "friends" through the milk bank!”

-Alison, 2nd Time Milk Donor

MILK DONATION- BEREAVED DONORS

For parents who have experienced a perinatal loss, donation can be a meaningful and comforting experience. We believe that lactation is an important but often overlooked topic following loss. Feelings surrounding lactation vary tremendously among bereaved parents and all need to be acknowledged and supported. Clinical support for lactation following the death of an infant is essential.

The perinatal loss programming that MAMMB has developed aims to provide needed information, support parents in their lactation goals (regardless of their interest in donation), identify resources, and educate the medical community.

The Donation Process

All donors must complete the screening process, including bereaved donors. Some aspects of the process are modified for parents who have experienced loss. Screening can begin while the parents are still in the hospital and milk can be shipped from the NICU directly to MAMMB. Mothers can be directed to midatlanticmilkbank.org to learn more about the process and set up a screening interview.

MAMMB Resources for Bereaved Families

Breast Milk and Bereaved Parents

This booklet was written by the staff and Medical Advisory Board of MAMMB and addresses topics such as engorgement, discontinuation of lactation, and feelings about lactation. It includes quotes both from parents that did and did not have milk donation as part of their journey. These booklets are provided to facilities, practices, and organizations free of charge. The PDF version of the booklet can be found and printed copies can be ordered, free of charge, at midatlanticmilkbank.org.

Memorial Tree Mural

A central feature at our facility is the “Ashton’s Garden” mural which contains the Memorial Tree. The tree displays artist created ceramic leaves inscribed with the name and birth date of the baby of each bereaved donor.

MILK DONATION- BEREAVED DONORS

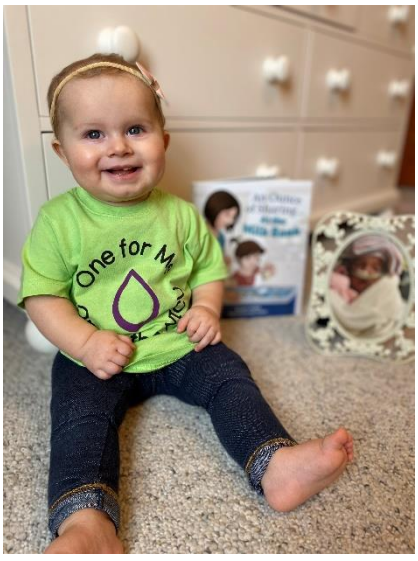
Resources on midatlanticmilkbank.org

Resource List

A list of web-based and local (PA, WV, NJ, MD, and DE) resources is maintained. The list is regularly updated.

Hand Expression Video

Breast massage and hand expression are important tools for the comfort of bereaved mothers. To provide a resource that is sensitive to the needs of mothers who have experienced loss, MAMMB collaborated with Breastfeeding Medicine of Northeast Ohio to develop the video "Breast Massage and Hand Expression Following Perinatal Loss". A link to the video is on midatlanticmilkbank.org. Feel free to share the film for educational purposes.



"Although this is my second time donating breastmilk to Mid-Atlantic Mothers Milk Bank, this experience was a little different. The first time I donated milk it was after the death of my daughter Eve. I donated her milk as a way of coping with the grief of losing my daughter but also it gave me comfort knowing that her life impacted others.

After having Eve's little sister, Gemma, I had more than enough milk to feed her and I knew immediately that I wanted to donate the extra milk. I realized that even though she is not with us, Eve was teaching her little sister about sharing and the importance of helping others when you can. I always say "Gemma wanted to share her milk just like her big sister did." And I love that although she will never meet her sister, one thing they will always have in common is that they both were able to help other babies who needed the gift of life saving milk."

-Milk Donor and Mother of Eve and Gemma

MILK DONATION- SCREENING

Donor screening is a critical part of making donated milk safe for recipients. Some medications, supplements, and health circumstances that are acceptable for feeding a mothers' own baby may not be compatible with donation due to the fragility of the population served by MAMMB.

The Screening Process

Screening is a straightforward but thorough process:

1. *Contact Form:* After clicking "Donate" at midatlanticmilkbank.org, potential donors can learn more about the process, answer prescreening questions and schedule an interview.
2. *Phone Interview:* During this 15-20 minute interview the mother is asked questions about medication/supplement use, risks for bloodborne pathogens, and relevant medical information. Education regarding milk collection and storage is provided and the potential donor can ask questions.
3. *Online Packet:* Potential donors complete an online packet which contains a more detailed health questionnaire, the consent to donate, authorization to contact healthcare providers, and detailed instructions for collection, cleaning, labeling, and storage.
4. *Blood Screening:* Donors are screened for HIV, HTLV, Hepatitis B and C, and syphilis.

All screening and shipping costs are paid for by the milk bank.

Why a Potential Donor May be Deferred or Ineligible

The following is a list of the most common reasons for deferment. There are several reasons why a donor may not be able to donate milk and the list below is not exhaustive. However, many medications and circumstances are acceptable. To ask if a particular medication or situation is compatible, please contact us at donate@midatlanticmilkbank.org.

- Antihypertensives
- Certain antidepressants. All SSRIs are acceptable.
- Mega-doses of vitamins E or A (20x RDA)
- Consumption of caffeinated drinks that exceeds 24 oz. per day
- Frequent consumption of alcohol. An occasional alcoholic beverage is permissible. Donors are advised to not share milk that was pumped within the 12 hours after consumption.
- Blood transfusion requires a 3 month deferment. Screening should begin three months after the date that the transfusion was received. Once screening is complete, stored milk pumped during the three month period can be donated.

MILK DONATION- SCREENING

Collection, Hygiene, and Labeling

- Any commercially available bottle or bag designed for breast milk storage is acceptable
- MAMMB provides bags to donors upon request
- Name and date pumped must be written on each bag or bottle
- Donors must thoroughly wash their hands and pump parts before each pumping session and sanitize their pump kits according to manufacturer's instructions daily
- Milk that has been stored frozen up to 8 months can be donated

Dropoff and Shipping

Once the donor is approved, there are several options:

- Dropoff to our facility in Pittsburgh
- Dropoff to a local depot (for a complete list visit midatlanticmilkbank.org)
- Shipping: an empty box, label, and instructions are sent to the donor along with a phone number to call to arrange for FedEx or UPS to pickup the packed box at the donor's home
- Shipped from a NICU: procedure similar to shipping from home

How to Begin the Screening Process

The best place to start is to refer the parent to midatlanticmilkbank.org. By clicking "Donate" they can learn more about the process and begin screening by answering prescreening questions and scheduling the phone interview. If a parent is unable to complete an online process they can contact the screening team at donate@midatlantgicmilkbank.org or 412-281-4400.

All About Donation

The downloadable PDF of the flyer on pages 56-57 is available on the hospital portal.

All About Milk Donation

It is important for unit staff to be informed about the milk donation process to adequately educate both recipient and donor families. Health systems are also uniquely positioned to raise awareness about donation.

Who are the Donors?

Milk donors are healthy lactating moms who simply have more milk than their own baby needs.

Mid-Atlantic Mothers' Milk Bank is a nonprofit organization and all of its donors are unpaid volunteers. The Human Milk Banking Association of North America (hmbana.org), the accrediting body of nonprofit milk banks in the United States and Canada, strictly prohibits the compensation of donors to prevent the introduction of safety and ethical issues.

How Can Units Help?

- Display milk bank educational materials.
- Educate mothers with over supplies of milk about the option of donation.
- Include donation information in your prenatal classes and discharge packets.
- Make sure that your team is knowledgeable about donation.
- Facilitate the process for your inpatient families.
- Host a milk bank depot for your community.
- Post about your unit's use of donor milk on the hospital's social media.
- Encourage recipient families to share their stories.

A thorough but straightforward screening process that is easy for donors.

Contact Form

5 minutes

By clicking "Donate" at midatlanticmilkbank.org, interested parents can learn about the process and fill out the contact form. They will be asked a few prescreening questions and can schedule the next step.

Phone Interview

15-20 minutes

The mother is asked about medication/supplement use, risk factors for bloodborne pathogens, and other health questions. Instructions for collection, labeling, and pumping hygiene are given and parents can ask questions.

Online Packet

15 minutes

The online packet includes a health questionnaire, consent form, authorization to contact healthcare providers, and written instructions for donors.

Blood Screening

varies

Donors are screened for HIV, Hepatitis B & C, HTLV, and syphilis. Mothers can go to Quest Diagnostics or Lab Corp. Alternatively, a kit from the Center for Organ Recovery and Education (CORE) can be sent for an in hospital blood draw.

mid-atlantic mothers' milk bank **Frequently Asked Questions**

Frequently Asked Questions About Milk Donation

Are there any costs for the milk donors?
All screening and shipping costs are paid by the milk bank. Breast milk storage bags are also provided, if needed.

What type of milk is accepted?
Milk can be stored in any commercially available bottle or bag that is specifically designed for human milk storage. Milk is accepted that has been frozen for up to 8 months. Each bag or bottle must be labeled with the name of the donor and the date that the milk was pumped. Due to the significant screening costs incurred by the milk bank, a minimum total donation of 150 ounces is required. This minimum is waived for bereaved parents.

How is raw donated milk transported to the milk bank?
Donors in the greater Pittsburgh area drop their milk off in person to the milk bank's lab. Outside of southwestern Pennsylvania, donors may drop off to a depot if one is located nearby or they can ship their milk. For those donors who choose shipping, insulated boxes and packing instructions are sent to their homes along with numbers to call to schedule a pickup by FedEx or UPS. Ice or dry ice is NOT needed to ship raw milk. An identical shipping process can be used to ship milk from a NICU to the milk bank.

What would prevent a mother from donating?
Medication and supplement use is one of the most common reasons for donor deferral. Fortunately, many prescription and OTC medications are compatible with donation, but there are a few that are not due to the fragility of the population of donor milk recipients. Of note, anti-hypertensives are not permitted. All SSRIs are allowable but other anti-depressants are not. Synthroid. insulin, and commonly given vaccines, including flu and COVID, are fine. Our screening team is always happy to answer questions and can be reached at donate@midatlanticmilkbank.org.

The mother of one of our patients has a large amount of extra milk. How do I proceed?
Direct the mother to midatlanticmilkbank.org and tell her to click the "Donate" button to learn more. Information cards with a QR code that lead to the website are available to units free of charge. It is recommended that a mother (not bereaved) have 50 ounces or more of stored milk that will not be needed by her own baby before initiating the screening process. Milk can be shipped or couriered directly from the NICU to the milk bank once the mother becomes an approved donor or the mother can drop off or ship milk from her home.

Tell me more about hosting a depot or dispensary.
Depots and Dispensaries are a great convenience for donor and recipient families, provide a visible community presence that raises awareness, decrease shipping costs and environmental impact for nonprofit milk banks, and send a clear message about the importance of breastfeeding and human milk to the community. They are a meaningful way for hospitals and outpatient practices to give back and increase access to donor milk. Depot hosts accept raw milk donations from local approved donors and store them in a dedicated freezer in a secure location. The collected milk is shipped monthly, or as needed, to the milk bank using insulated shipping containers and prepaid labels provided by the milk bank. Dispensaries store a small amount of processed donor milk from the milk bank for use by babies needing bridge milk post discharge or as a starter supply for ill outpatients who will be directly served by the milk bank. It is possible for a depot to also be a dispensary and store both raw and processed milk in the same freezer. A minimal amount of documentation is also required. To learn more, email info@midatlanticmilkbank.org

MILK DONATION- FACILITATING DONATION

Ideas to Promote Donation

MAMMB relies on the generosity of milk donors. Having a visible, engaged milk bank in a community also helps breastfeeding success rates. As a clinician and healthcare facility, you are uniquely able to reach mothers in both the prenatal and post-partum periods. There are many ways that you can help educate families and spread the word about donation. Here are a few ideas:

- Include Information About Donor Milk in Prenatal Breastfeeding Classes: Keep the message very simple. Parents just need to know that donation is an option and that if their baby requires donor milk, it is very safe. If donation is being considered, it is helpful for parents to visit midatlanticmilkbank.org to learn about the criteria and process as soon as possible.
- NICUs and Mother Baby Units**:** Make sure that your staff are knowledgeable about milk donation. MAMMB is happy to provide staff in-services or other educational programs. Display MAMMB posters.
- Make the donation process easier for NICU families: Parents often tell us that they discarded milk during their NICU stay due to space. For a variety of reasons, the NICU presents specific challenges for donors. The following assistance can make screening easier for families and expedite the process:

    - Statements of Health: These forms (one for the donor and one for the baby, unless bereaved) are required as part of the screening process. Promptly completing and returning these forms to the milk bank is very helpful.
    - Assist with Paperwork: Far from home, many parents do not have access to a computer or printer. Providing access to a computer or printing/faxing forms can be a great help for the donor.
    - Bloodwork*:* MAMMB contracts with Quest Diagnostics, LabCorp and CORE. Leaving the hospital for a blood draw can be challenging for NICU parents. Establishing a protocol to have the blood drawn at the hospital can be a great help.
    - Storing and Shipping Milk: Being willing to store milk until the screening process is near completion relieves stress for parents. If your staff is willing to pack the milk, MAMMB can provide the box coolers and make arrangement for shipment (paid for by MAMMB).

- Post-Partum Info Packets: Include MAMMB Donation Info Cards.
- Pediatricians, Obstetricians, and Midwives: Encourage practices affiliated with your health system to be familiar with milk donation and display posters and brochures in their offices.
- Social Media and Newsletters: Highlight how donor milk is used in your facility in a social media post or feature.

MILK DONATION- DEPOST AND DISPENSARIES

Depots and Dispensaries

Donation Depots (drop-off points for donated raw milk) and Dispensaries (sites where processed milk may be purchased or picked up) are hosted by hospitals, health systems, practices, or lactation centers. They serve as a convenience for donors, enhance access for recipient families, and increase the milk bank's visibility in the community. Hosting a Depot and/or Dispensary is a great way to give back to the community and promote breastfeeding and milk donation while letting new people interact with your facility. For a complete list of Depots and Dispensaries visit midatlanticmilkbank.org.

Hosting a Donation Depot

Donation Depots provide a way for MAMMB approved donors to drop off their milk donation right in their community. Gathering the donations of several donors together in one shipment to MAMMB's lab also decreases shipping costs and environmental impact. Basic Depot requirements include:

- Maintain a freezer in a secure area of the facility.
- Accept and store donations from approved MAMMB donors.
- Maintain logs of freezer temperatures, donations received, and shipments to MAMMB.
- Pack boxes with donations and arrange for FedEx or UPS pickup. MAMMB sends cooler boxes to the depot and pays for all costs associated with shipping.

Hosting a Dispensary

Dispensaries enable recipient families to quickly and conveniently purchase small quantities of donor milk locally. Typically, dispensaries are used for bridge milk in the early post-partum period and for starter supplies for outpatients with medical needs. Outpatients who are donor milk dependent require large volumes and are best served by ordering directly through MAMMB. Basic Dispensary requirements include:

- Maintain a freezer in a secure area of the facility.
- Accept and store bottles of pasteurized donor milk from MAMMB.
- Manage necessary forms (very minimal).
- Maintain logs of freezer temperatures and milk distributed.
- There is no need to handle financial transactions. Donor milk is distributed by a consignment model with families paying MAMMB directly through MAMMB's website.

Depot and Dispensary Handbook

Each Depot and/or Dispensary is given a copy of the of a handbook that explains every procedure in detail along with necessary forms. These documents and the Depot information flyer found on page 60 are also available as PDFs on a password protected page of midatlanticmilkbank.org.

If you are interested in hosting a Depot and/or Dispensary, please contact us at info@midatlanticmilkbank.org

HOST A DONOR MILK DEPOT

Facilitate Donation
and Increase Access to Donor Milk

WHAT ARE MILK DEPOTS?

A Donor Milk Depot is a site that collects milk from local approved donors for a milk bank. The Depot maintains a freezer in a secured area and ships milk to the milk bank using prepaid shipping containers or the milk is picked up by a milk bank courier.

WHO CAN BE A HOST?

A wide variety of facilities can be Depot hosts including health systems, community practices, birth centers, government offices, and universities. Locations need to be easily accessible with adequate parking for families who are transporting coolers of milk and are often accompanied by their children.

Depots are welcome in any area of our self defined service region of Pennsylvania, West Virginia, New Jersey, Maryland, and Delaware.

BENEFITS BOTH THE COMMUNITY & FACILITY

A strong network of depots across a nonprofit milk bank's service area greatly benefits a region. Raising milk banking awareness creates a culture where families know that pasteurized donor human milk is safe and evidence based if their child needs it, and that donation is easy if they have more milk than their own baby will use. By serving your community as a Depot host, you will be:

- Increasing the visibility of Mid-Atlantic Mothers' Milk Bank in your area
- Providing a convenience appreciated by families
- Reducing the costs and environmental impact of overnight shipping from individual households
- Increasing the donor milk supply available to medically fragile infants
- Increasing traffic to your facility, making young families aware of your services and even generating some fun social media posts
- Sending a clear message about the importance of breastfeeding and human milk

mid-atlantic mothers' milk bank

Mid-Atlantic Mothers' Milk Bank is a nonprofit milk bank accredited by the Human Milk Banking Association of North America (hmbana.org). The organization distributes over 35,000 ounces of tested and pasteurized donor human milk to 70 hospital units and dozens of outpatients each month across PA, WV, NJ, MD, and DE.

FAQ?

Who are the Donors and how are they screened?
Donors are simply healthy mothers who have more milk than their own baby needs. They are unpaid volunteers who undergo a thorough screening process including blood testing. They are our heroes! Only approved donors drop off to a Depot. Each donor is screened for medication/supplement use, blood borne pathogens, medical history, and lifestyle. The process includes:

- Interview: A short (15-20 min) phone interview with a MAMMB screener
- Completion of a detailed application packet via an online fillable form
- One page statement of health form from the healthcare provider
- Blood Screening: includes HIV, HTLV, syphilis, and Hepatitis B & C

What type of freezer is needed?
Milk is stored in dedicated freezers used for donor milk purposes only. A residential type of freezer is sufficient. Freezer temperature is held no higher than -18°C (-4°F). The freezer must be locked or be housed in a secure area..

What else is required?
There is a small amount of documentation required. Simple logs of freezer temperatures, donor dropoffs, and shipments are maintained. Training, full instructions, and necessary supplies are provided.

How many families can I expect?
Depots can expect 2-12 drop-offs per month depending on the population density of the area. Depots can decide when and how families drop-off milk.

How is milk transported to the milk bank?
Collected milk is sent to the milk bank monthly, or sooner if the freezer is full. For those Depots within 90 minutes away from Mid-Atlantic Mothers' Milk Bank, milk bank staff may pickup. Otherwise, insulated boxes and packing instructions are sent to the Depot along with numbers to call to schedule a pickup by FedEx or UPS. Ice or dry ice *is not needed* to ship raw milk. All shipping and transportation costs are paid for by the milk bank.

What is a Donor Milk Dispensary?
Dispensaries are sites where processed donor milk may be purchased or picked up. Some Depots also serve as Dispensaries. The Dispensaries enable recipient families to quickly and conveniently obtain small quantities of donor milk locally. Typically, Dispensaries are used for bridge milk in the early postpartum period and for starter supplies for outpatients with medical needs. There is no need for the sites to handle transactions. Mid-Atlantic operates its Dispensaries by a consignment model with families paying the milk bank directly through its website.

INTERESTED IN LEARNING MORE?
CONTACT US AT INFO@MIDATLANTICMILKBANK.ORG

DONOR MILK PROCESSING AND TESTING- PROCESSING

Testing and pasteurizing donated milk are also critical safety procedures. MAMMB strictly follows HMBANA, state, and federal guidelines for safe milk processing and food handling. Drug testing and macronutrient analysis are two examples of additional measures that MAMMB takes beyond accreditation and licensure requirements.

Milk Processing

Mixing and Bottling

The milk of 4-8 donors is thawed, combined, and thoroughly mixed. Pooling the milk of multiple donors evens out nutritional variations, increases the diversity of immunological factors, and dilutes the attributes of any single donor. The pooled milk is then poured into BPA free bottles with tamper resistant caps.

The bottled milk is then pasteurized in water baths using specialized equipment. All HMBANA accredited milk banks must use the Holder Method of Pasteurization which holds the milk at 62.5°C for 30 minutes. The efficacy of this method in inactivating a wide variety of bacteria and viruses is well established. Many of the bioactive components of milk, including secretory IgA, are very heat sensitive. Utilizing this low temperature method retains many of these important components which help to protect babies.

For more information about processing methods refer to the document Processing Matters on MAMMB's website and page 22 of this Guidebook.

DONOR MILK PROCESSING AND TESTING- TESTING

Milk Testing

The milk itself undergoes various testing:

Bacteriological Culturing: After pasteurization, a random bottle from each batch of milk is sent to an independent CLIA certified laboratory for bacterial culturing.

Macronutrient Analysis: The Miris Human Milk Analyzer, the first and only FDA approved medical device for measuring the macronutrient content of human milk is used to quantify the calorie, protein, fat, and carbohydrate content. To date, macronutrient analysis is not required by HMBANA.

These units are designed and approved for both in hospital bedside and milk bank use. If your hospital is interested in analyzing maternal milk at your facility MAMMB staff are happy to answer questions and share our experiences with analysis.

Drug Testing: Each pool of milk is tested for a panel of 7 common drugs of abuse including opiates and THC. Drug testing is not required by HMBANA.

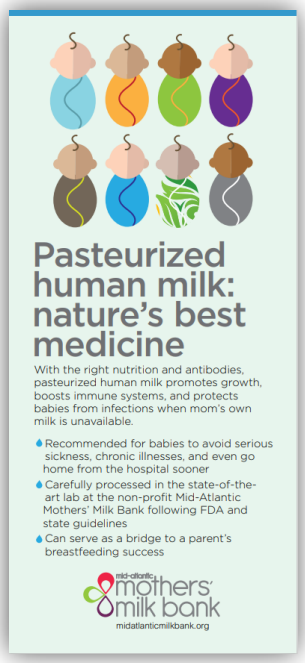
"Khaleesia was born with many complications. She ended up having a stroke and needing a feeding tube. I pumped milk for the first year of her life. However, my supply started to run out. We tried numerous formulas and nothing worked. She would get so sick. I thank God every day for the milk bank. We ended up using donor breastmilk for a few months until we could finally transition her to a blended diet that worked for her. The staff was wonderful. I can't thank everyone including the donors enough! Khaleesia would not be where she is today without each and every one of you!"

-Mom of outpatient recipient, Khaleesia

FAMILY AND CLINICIAN EDUCATION MATERIALS

Family Educational Materials

MAMMB provides educational materials to hospitals, practices, and community organizations free of charge. To request materials, and to view PDF versions of materials, click “Educational Materials” on the homepage of midatlanticmilkbank.org. All cards and booklets are available in both English and Spanish.



Inpatient Recipient Family Information Cards

Provides a basic and brief overview of donor milk and MAMMB. For NICU, mother/baby unit, and outpatient use. Available in English and Spanish.

Inpatient Recipient Family Information Stickers

1.5 X 2 inch stickers. QR code leads to inpatient information on midatlanticmilkbank.org including the Meet Nico video.

“Meet Nico” Video

2.5 minute recipient family facing animated video available in 7 languages- English, Spanish, Arabic, Chinese, Haitian Creole, Nepali, and Russian. Explains why donor milk is used, milk testing, pasteurization, and donor screening. Access on midatlanticmilkbank.org and via QR codes on various materials. Co-branding possible for health systems.

Outpatient Recipient Family Information Cards

Basic and brief overview of using donor milk in the outpatient setting. For community use.

Safe Use of Donor Milk Cards

Outlines safe donor milk storage and handling practices in the home setting. For outpatient use only. Used by dispensaries and units that send patients home with donor milk at discharge.

Donor Information Cards

Information about how to become a milk donor.

Bereavement Brochures

Booklet that contains information about lactation after loss. Topics include discontinuing lactation, engorgement, and comfort measures.

FAMILY AND CLINICIAN EDUCATION MATERIALS

Inpatient Wall Cling

11 X 17 inch wipeable, repositionable wall cling. QR code leads to inpatient information on midatlanticmilkbank.org including the Meet Nico video.

Clinician and Student Education

MAMMB believes clinicians can best inform and care for both recipient and donor families when they have an understanding of how milk banking works. To meet the educational needs of the facilities that it serves, MAMMB provides in-person and virtual in-services and presentations at no cost. To schedule an in-service or a tour of the milk bank's facility in Pittsburgh contact us at info@midatlanticmilkbank.org.

RESEARCH

HUMAN MILK
Science Institute & Biobank

Housed within MAMMB, the non-profit Human Milk Institute and Biobank (HMSIB) aims to make the study of human milk more accessible for researchers through the provision of samples and serves as the research arm of the milk bank.

Information for Researchers

Participants: HMSIB upholds rigorous standards of consent and research ethics. All participants undergo a process approved by the Institutional Review Board (IRB) before contributing to the biobank, ensuring that their participation is informed and voluntary. This process not only safeguards the rights and welfare of the donors but also upholds the integrity and reliability of the data and samples housed within the institute.

Samples: Freshly pumped and previously frozen samples are available. HMSIB also offers cellular pellet, supernatant, and fat along with pooled and/or pasteurized human milk sample. All samples are stored at -80 degrees Celsius.

Data: Milk samples may be paired with an extensive array of de-identified maternal and infant data points, providing researchers with a comprehensive dataset for analysis and exploration.

Customization: HMSIB provides customized solutions, offering tailored sample provision, data management, and participant engagement. Samples can be adjusted to various sizes and formats. Data is organized according to researchers' specifications, ensuring compatibility with their analytical needs. As part of the consenting process, approved follow-up questionnaires can be sent to participants.

Approval: Sample requests are reviewed by HMSIB staff. Samples will not be provided for research that relates to the development of a human milk substitute (i.e. infant formula). A material transfer agreement is required. HMSIB is approved through Advarra IRB.

Learn more at humanmilksamples.org