Patient Safety & Quality Improvement Journal
http://psj.mums.ac.ir
PSQI

Human Milk Banks: A Narrative Review

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ARTICLEINFO

Article type:
Original article

***Article History*:**
Received:.03-Aug-2019
Accepted: 15-Mar-2020

Keywords:
Breast Feeding, Infant Formula, Milk Banks, Low Birth Weight, Very Low Birth Weight.

ABSTRACT

Introduction:
Not all mothers can provide sufficient milk, and infants admitted to a neonatal ward are less likely to be exclusively breastfed. Current recommendations are for the use of mother's own milk (MOM), and pasteurized donor human milk (PDHM) is the next best choice. The present article was prepared as a tool to study the optimal organization of Human milk banks (HMB) and to contribute to the diffusion of the culture and promotion of breastfeeding and summarize current best practices for the handling of PDHM.

Materials and Methods:
PubMed, Embase and Cochrane were searched using the search term combination "human milk banks" OR "pasteurized donor human milk".

Results:
HMB are responsible for human milk (HM) promotion, collection, processing, protection, quality control, distribution and support. The quality of expressed HM is the result of adequate hygienic-sanitary conditions, from expression to administration, and the evaluation of nutritional, immunological, chemical, and microbiological characteristics. It is essential a multidisciplinary team to support an HMB.

Conclusion:
In settings where donor HM supplies are limited, prioritization of infants by medical status is key. The manner in how investments in human milk feeding are applied should be targeted. The purchase cost of PDHM should be compared with the purchase costs of other nutrition interventions routinely used in care for critically ill neonates.

► ***Please cite this paper as:***
Vale JS, Miranda J, Nunes JS, Veiga M. Human Milk Banks: A Narrative Review. Journal of Patient Safety and Quality Improvement. 2020; 8(1):45-52. Doi: 10.22038/psj.2020.42356.1239

Introduction

Not all mothers can provide sufficient milk, and infants admitted to a neonatal ward are less likely to be exclusively breastfed. Current recommendations are for the use of mother's own milk (MOM), and pasteurized donor human milk (PDHM) is the next best choice. Considerable global variation exists in the storage, handling, fortification and feeding of PDHM (1). There are multiple avenues for compromising the nutritional and bioactive components of HM. It is pumped, transferred among containers, stored, warmed, fortified, and fed via infusion. So, HM is easily contaminated during these processes and can serve as an excellent medium for bacterial growth.

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The present article serves as a tool to study Human Milk Banks (HMB) in a narrative review, aiming to explore the existing literature, by describing its organization, management and procedures, and to determine the optimal requirements to establish a new HMB.

Also, this manuscript aims to contribute to the diffusion of the culture and promotion of breastfeeding and summarize current best practices for human milk handling within the hospital setting.

Materials and Methods

A search of literature was conducted to identify papers regarding Milk Banks and the handling of HM and PDHM. The authors identified sources (abstracts and full text articles) from the PubMed, Cochrane and Embase databases from 2000 to December 2018. Full texts published during 2019, referring to abstracts presented prior to December 2018 were also identified and analyzed. The search was narrowed to articles written in English.

The search strategy adopted the MeSH terms search combination Human Milk Banks" OR "pasteurized donor human milk". All titles were checked for describing Milk Banks and the handling of HM and PDHM.

Abstracts and then full texts were reviewed to select systematic reviews, meta-analyses, longitudinal, prospective and retrospective studies, and literature reviews.

Meta-analyses and systematic reviews on the topics were preferred. Besides, the reference lists of the identified studies were manually reviewed to identify complementary publications. During the screening step, studies were also excluded through an abstract assessment, followed by the full text if necessary. Articles were excluded for not being a full-length article and being duplicate study. Errata and commentary were also excluded.

Results

The search returned 181 records. After applying the inclusion criteria 19 articles were selected for the synthesis of this paper. The results section in this narrative review was organized in subtopics to obtain a more pleaded narration. The subtopics in order are: costs, workflow, pasteurization and other decontamination methods, and fortification.

Costs

Hospital administrators argue the expense of parental DHM as an enteral feeding option.

Edwards and Spatz reported that during one fiscal year(2), a large pediatric hospital spent U.S.$155,000 to purchase parental DHM from an HMBANA milk bank, while more than $18.4 million was spent on total parenteral nutrition in the neonatal intensive care unit (NICU)(2).

A systematic review aimed at evaluating the cost of DHM, the cost of treating necrotizing enterocolitis (NEC), and the cost-effectiveness of exclusive DHM versus formula milk feeding to reduce the short-term health and treatment costs of NEC, concluding that it is likely that DHM provides short-term cost savings by reducing NEC incidence(3).

A study by Trang et al. aimed to determine the cost-effectiveness of supplemental DHM versus pre-term formula for very low birth weight (VLBW) infants from a societal perspective to 18 months' corrected age, concluded that in a high mothers milk use setting, total costs did not differ, although post-discharge costs were lower in the DHM group(4). Eight estimates of the cost of DHM were reported across seven studies (3). The authors noted that improvements in how the milk banking service was organized could reduce labor and material costs.

HMBANA milk banks charge U.S $4.00 to U.S.$5.00 per ounce for parental DHM (2).Using a purchase cost of U.S.$4.50 per ounce and trophic feeds at a rate of 5 ml every 3 hours or 40 ml per day, the cost for 1 day of parental DHM would equal U.S.$6.00 per day for one infant (2).

The start-up and maintenance of an HMB is a costly project, which not all neonatal units can take on. Satellite Centers are centers that distribute pasteurized milk from an HMB. According to a Spanish study, Satellite Centers tend to be a more efficient alternative solution, saving 88,852 euros in equipment and 24,572 euros per year in maintenance (5).

Workflow

There are 500 HMBs operating in over 37 countries worldwide(6).

A multidisciplinary team needs to support an HMB function and success. Personnel must include a Neonatologist, Neonatology Specialist Professional Nurse, Infant Feeding Specialist, Infection Control Specialist Nurse, Dedicated HMB Coordinator, laboratory technician, Lactation advisor, and a Psychologist (7).

A MOM must be pumped, labeled, transported to the hospital, stored, tracked for expiration dates, thawed, fortified, and administered to the infant. Each step of the process must avoid microbial contamination, fortification errors, and waste. Best practices must emphasize preparation location, staff training, proper identification of human milk, and fortification errors prevention(8).

DHM recipients must be identified based on their clinical and nutritional status and access to the preferred infant feed. According to literature entry criteria include infants that present with necrotizing enterocolitis who do not have access to their own mothers' milk; preterm and VLBW infants who do not have access to their MOM; preterm or full-term infants who do not have access to their MOM; mother unable to express her own milk; mother absent due to health or other circumstances; mother receiving contraindicated medication; mother unable to produce/express sufficient milk/colostrum in the first few days(9).

There are evidence-based guidelines for donor screening. The specific panel of blood tests required is HIV 1 and 2 antibodies, Human T cell Lymphotropic Virus I and II antibodies, Hepatitis B surface antigen and core antibody, Hepatitis C antibody, Syphilis and CMV antibody. The CMV seropositivity is not a contraindication for milk donation, as DHM undergoes pasteurization(10).

Results should be given to the donor in person, whether positive or negative(11). Exclusion criteria include: history of smoking, nicotine use, cannabis, cocaine or other drugs of abuse; donors who take very high quantities of substances containing xanthine (coffee, tea, cola, or cacao), strong alcoholic drinks equal to or greater than 30–40 cc, or about 100cc of wine, or 200 cc of beer; potential donors who had unprotected sexual intercourses within the 6-12 months preceding the milk donation, with unknown partners or with partners: who used drugs of abuse, who received blood transfusions or blood products, who are HBV, HCV, HIV positive, who are affected by venereal diseases; donors who had piercing, tattooing if not performed with a throw away single use instrument, within the 6-12 months preceding milk donation; donors who traveled to the endemic zones for tropical diseases within the 3 months preceding the milk donation; donors who received blood transfusions, blood products, or organ transplants within the 6-12 months preceding milk donation; donors who received cornea or dura mater transplants and who use human pituitary-derived growth hormone are excluded permanently because of the risk of Creutzfeld-Jacob disease; those who have a history of post-surgery sepsis or an infant with sepsis following delivery; is not willing to undergo a blood test; total vegetarian and not taking Vitamin B supplementation; has had measles, mumps and rubella vaccine in the past month; has a local breast disease; currently receiving cytotoxic medication or other including herbal medication that is contra-indicated during breastfeeding; younger than the 18 years or mentally ill (9,10). Potential donors are required to attend a follow-up appointment to receive the results of the blood test and to receive a hospital grade breast pump and collection kit (thermally disinfected polypropylene bottles, collection instructions, and donor ID labels). Donors who continue to donate for more than 3 months from the date of the initial blood test are required to consent to a repeat blood test. Milk collected during this period is quarantined until the results are known(11). Informed consent must be obtained from the mother or legal guardian for DHM provision(9).

The preparation area should contain a hand-washing sink with hands-free controls. A three-compartment sink or commercial dishwasher is needed to ensure proper cleaning and sanitizing of all reusable items. The dishwasher should reach a wash temperature of 66ºC and a rinse temperature of 82ºC(8). Laminar flow hoods provide an additional barrier against

contaminants, however, the use of a flow hood does not result in a sterile finished product when used during the preparation of non-sterile feedings(8).

Dedicated human milk refrigerators and freezers with recording thermometers and temperature-sensitive acoustic and visual alarms are preferred(8,10). Refrigerators must be able to maintain temperatures between 2ºC–4ºC and freezers must allow for temperatures at or below −20ºC(8).

It is generally recommended that fresh milk is stored in the refrigerator (≤4ºC) for a maximum of 48h; thawed unpasteurized milk is stored in the refrigerator (≤4ºC) for a maximum of 24h; thawed pasteurized DHM is stored in the refrigerator (≤4ºC) for a maximum of 48h; fortified milk is stored in the refrigerator (≤4ºC) for a maximum of 24h; hang time for continuous feedings at room temperature for a maximum of 4h; frozen human milk is stored in the freezer for 6–12 months at ≤−20ºC, or beyond 12 months at −70ºC to −80ºC (8,11). According to the 2018 Human Milk Bank Association of North America guidelines, frozen pasteurized DHM expires 1 year after the earliest pumping date of milk within the pool(12). The transportation of milk collected at home should be carried out in such a way that the milk arrives at the HMB in a frozen state and the Milk Bank itself should be responsible for the milk collection and transportation(10). Any milk that has partially thawed can only be accepted if more than 50% of the milk volume has remained frozen, and the surface temperature of the bottle remains ≤0ºC (11). Maternal milk collected at home runs the risk of contamination, loss in its physicochemical stability and biological activity. Thus, it is very important that following its expression, the milk is handled and stored appropriately. The donor must always write, on each bottle, her name and the collection date. HMB should be informed when the donor takes any kind of medicine(10). A variety of methods are in use for decontaminating home breast pump milk related items. These methods have been compiled by the Working Group of Healthcare Infection Society and the Infection Prevention Society (13). After every single collection of milk, always in a sterile container, the milk container must be sealed and cooled immediately under running water. Immediate refrigeration followed by freezing within a period no longer than 24 hours (when further additions to the collected milk will be performed) is the preferred method of storage(10). The mother should be given a donor number.

Pasteurized DHM containers should be labeled for the identification of the Bank and the donor, the date of collection and the date of pasteurization. Bar code scanning technology can assist with monitoring expiration dates and times, tracking lot numbers for pasteurized DHM, fortifiers or additives, and identifying exactly which patients received a particular product in the event of a product recall(8). Each bottle donated is given a unique specimen ID (USID). The Batch Record consists of, a record of the USID that are pooled to make up the batch, a record of the time and temperature of pasteurization, and a record of the microbiological screening results. Once pasteurized, each bottle of pasteurized product is given a USID that is recorded on the product label, Batch Record and Product Database(11). Frozen milk, either fresh or pasteurized, should be thawed by defrosting the milk slowly in the refrigerator for a maximum period of 24h, defrosting the milk rapidly in a water bath at a temperature not exceeding 37ºC, or under running lukewarm water. Thawing products in an orbital incubator removes the potential hazard of product contamination due to water entering through the screw cap(11). All preparation and storage items should be made of stainless steel or food-grade plastic that is free of bisphenol-A and di(2-Ethylhexyl) phthalate. Single-use, disposable items are often selected for human milk collection and feeding preparation due to their convenience and sanitation(8,10).

Hand hygiene is critical in the handling of human milk to prevent the introduction of exogenous microbial contamination. Use of disposable gowns, and other personal protective items including a bonnet or hairnet and gloves are recommended.8 All the material that has been in contact with the milk, should be washed with hot water and

soap, and rinsed thoroughly after use. In HMBs where glass bottles are used, a bottle sterilizer with thermo-disinfection is recommended(10). DHM is examined bacteriologically both before and after pasteurization. The Bank's microbiological standards are based on literature(11).

A summary of how to train and explain all this process to mothers and the general HMB workflow not described in this text is laced in Table 1 and 2 respectively.All preparation and storage items should be made of stainless steel or food-grade plastic that is free of bisphenol-A and di(2-Ethylhexyl) phthalate. Single-use, disposable items are often selected for human milk collection and feeding preparation due to their convenience and sanitation(8,10).

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Table 1: Steps to mother's education and training

▪ Explain the procedure to the mother
▪ Breast, Areolar zone, nipples and hands should be cleansed
▪ Stimulate the oxytocin reflex, massage with a warm clean facecloth
▪ Hold a wide opening sterilized container near her breast, under the nipple and areola.
▪ Her thumb should be on her breast, above the nipple and areola with her first finger on the breast below the nipple and areola, opposite the thumb in a 'C' shape. Press her thumb and finger gently towards the chest wall and then she presses the thumb and her first finger together, compressing the milk duct between them and then releases. She then repeats the press and release action.
▪ It is also possible to use manual breast pumps
▪ Don personal protective items per facility policy (may include disposable gowns and bonnets/hairnets)
▪ Perform hand hygiene and sanitize work space between each individual patient feeding preparation

Table 2: Steps to milk storage preparation

▪ Thaw milk if needed using water bath or commercial warmer
▪ Perform a double check of a minimum of two-patient identifiers or use bar code scanning technology
▪ Measure appropriate volume of human milk
▪ Add fortifiers, if appropriate
▪ Ensure accuracy with calculations and measurements to avoid over or under fortification
▪ Double check or bar code scanning to confirm appropriate fortifier is used
▪ Label each container
▪ 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
▪ 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
▪ For oral feeding, discard any milk remaining in the bottle 1h after initiating feeding due to potential for bacterial contamination from oral flora that may colonize the milk remaining in the bottle

Pasteurization and other decontamination methods

International best practice requires that DHM must be pasteurized (heated to 62.5ºC for 30 min) before being fed to recipients (11,12). Heat treatment must be carried out on fresh or defrosted milk in sterile and tightly closed feeding bottles. It is necessary to keep the data regarding the heat treatment cycle. A control bottle should contain an immersion thermometer to register milk temperature during the pasteurization process, and about 25% of

the milk volume must be below the measuring point of the temperature probe. There is evidence that temperatures lower than 62.5ºC can effectively destroy bacterial and viral contamination in human milk. For example, evidence indicates that most viruses are destroyed at a temperature between 55ºC and 60ºC (14). Nevertheless, the thermo-sensitivity of these viruses has not been reported. An alternative simple option would be to optimize the conventional pasteurization technique, so the treated milk is free of infectious elements, and yet retains a maximum amount of biological components. The advantage of this approach is that it would be unnecessary to replace the pasteurization equipment currently available in most HMB. The most evaluated method is high-temperature short-time treatment, which involves heating milk at 72ºC for 15 seconds. This procedure induces a drastic reduction in the bacterial count and CMV infectivity (14). However, although better preservation of several components like immunoglobulin A (IgA) and lactoferrin has been described, bile salt-stimulated lipase activity is almost eliminated. Pascalization or high-pressure processing, in comparison with pasteurization, may increase IgA retention, lysozyme and other cytokines. However, the data lacks the effects of high pressure on bacterial spores, viruses or fungi in human milk (14).

Preliminary reports indicate that UV irradiation can achieve a reduction of 5-log10 in bacteria exogenously added to human milk without affecting the lipase activity, and unalter the concentrations of lactoferrin, lysozyme and IgA. Also, according to a recent report, UV-C irradiation inactivates CMV in human milk under the right conditions(14). These are all techniques commonly used in the food industry, but apart from pasteurization, there are no specific devices designed to manage the low volumes of milk processed in a milk bank.

Fortification

There may be relevant differences in the stage of lactation for which DHM replaces OMM. Mature DHM frequently replaces OMM colostrum and transitional milk. In this context, it must be highlighted that the concentrations of many milk bioactive compounds decline during lactation, as the infant matures.Feeding preterm infants with DHM obtained from mothers of much older infants has been considered a major gap in lactation and neonatology knowledge. DHM needs fortification with protein, energy, vitamins, minerals and has a lower protein content concerning milk produced during early lactation(15).Recent recommended dietary intakes have been revised. Up to 4.2g of protein and 135 kcal/kg per day is recommended for very preterm infants. Additional supplements are needed for current commercial fortifiers to achieve these dietary intakes and reduce the incidence of ex-uterine growth failure(16). Two fortification strategies - adjustable fortification and target fortification - optimize macronutrient intake and improve growth. Adjustable fortification uses blood urea nitrogen levels to adjust fortifier strength. Target fortification analyzes breast milk and fortifies macronutrients individually to achieve targeted intake (17–19). Centralized handling processes of human milk fortification is a best practice and has been shown to improve patient safety. However, these often preclude the ability to prepare each feeding immediately before use. The benefits of centralized handling appear to outweigh the risks of potential changes to human milk when feedings are prepared in advance. Facilities may want to consider the shortest amount of time feasible while still utilizing centralized handling processes. Some organizations have opted to prepare 12h volumes instead of 24h volumes which also may be beneficial in more quickly implementing feeding order changes and preventing waste(8).

Discussion

Evidence shows that breastfeeding has many health and economic benefits for young children and their mothers. The usability of DHM has been reported in countries where human milk banks have been established, and new human milk banks are being established every year to make donor human milk accessible.

Human milk banks rely on breastfeeding mothers to supply a steady stream of

donated human milk, which can save high-risk newborns and reduce medical costs. Therefore, different measures should be adopted to strongly support breastfeeding and increase breastfeeding rates. By first evaluating barriers to full feeding with MOM, we encourage healthcare workers to systematically consider the appropriateness of DHM. International guidelines for handling DHM and PDHM should be followed for best practice and patient safety. The cost of operating a human milk bank represents a large expenditure. However, HMB with mature administration systems are more cost-effective. In consideration of the argument that PDHM is too expensive and thus that its use must be restricted or limited, the purchase cost of PDHM must be compared with the purchase costs of other nutrition interventions routinely used in care for critically ill neonates. PDHM should be evaluated according to the clinical results, costs and savings of morbidity associated hospital stays, mortality and long-term costs. Despite a huge number of research efforts, current treatment of DHM is still unsatisfactory in terms of retention of bioactive components which are believed to mediate the beneficial clinical effects of HM in preterm infants. For this reason, current research is directed towards the identification of novel pasteurization methods which would be capable to preserve HM bioactive components without affecting microbiological safety. More research is also needed on the impact of fortifiers on long-term refrigerated and frozen PDHM.

Conclusion

HMB are specialized services, responsible for DHM promotion, protection, and support. HMB perform HM collection, processing, quality control, and distribution.

The process used to define the quality of expressed human milk results from adequate hygienic-sanitary conditions, from expression to administration, and the joint evaluation of several parameters, including nutritional, immunological, chemical, and microbiological characteristics, thus confirming the final product's safety. Hospital support of optimal breastfeeding practices, and thoughtful integration of DHM policies for those infants **References** that need it most is key.

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