

Review Article

The Lifeline of Donor Human Milk: Understanding Human Milk Banking in India and Future Prospects

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ABSTRACT

Human milk banking, also known as breast milk banking or lactarium, is a vital service that collects, screens, processes, pasteurizes, and dispenses donated human milk to infants who cannot receive their mother's milk. When a mother's milk is unavailable, donor human milk is the best alternative for babies who are born premature and low birth weight. Donor human milk acts as a lifeline for infants who can't receive their mother's milk. This practice plays a crucial role in providing optimal nutrition and crucial health benefits, particularly for premature, sick, and vulnerable newborns. Growing recognition of the benefits of donor human milk has led to increasing global interest in creating and sustaining human milk banks to fulfill the need for donor human milk. This article will focus on the basics of Human Milk Banking and its continuously evolving areas of interest.

Key words: Human milk banking, Vital service, Mother's milk, Best alternative for babies, crucial health benefits

This review article focuses on the basics of human milk banking. It includes the importance of donor human milk for infant or preterm Nutrition and its benefits in reducing the morbidity and mortality in preterm and low birth weight babies. It also focuses on human milk banking, donor selection, and ethical and legal aspects of human milk banking. The safety protocols that need to be followed while processing the donor human milk have been discussed vividly. The evolution of human milk banks globally and in India has been discussed with a focus on the Program for Appropriate Technology in Health (PATH), which is an international, non-profit global health organization that plays a significant role in promoting and strengthening human milk banking around the world, including India. This review article also discusses measures for improving the safety, efficiency, and accessibility of human milk banks.

METHODOLOGY

A rigorous, pre-defined, non-biased article selection was done. It was multifaceted, designed to identify the most relevant, high-quality, original research articles, systematic reviews, and practice guidelines, peer-reviewed journals to ensure high-quality research and reviews about human milk banking. We adhered to a rigorous approach to minimize bias and ensure a thorough representation of the current evidence. Research question that involved identifying the key aspects of human milk banking (e.g., Establishment and operation, benefits for

infants, donor screening, processing, safety, ethical considerations, global perspectives). Comprehensive searches across multiple reputable electronic databases like PubMed/MEDLINE, Scopus, Cochrane Library, Google Scholar and a reputed Newspaper article by Convenor of Human Milk Banking Association of India with comprehensive search strategy using combination of Medical Subject Headings(MESH terms), keywords like "Human Milk Banking", "Breast Milk banking", "pasteurization", "preterm nutrition", "Milk safety" "ethical aspects", "guidelines" to ensure a broad coverage of the literature was done.

DISCUSSION

A. Human milk bank and Donor Human Milk

Human milk bank is a service established to (i) recruit and screen human milk donors, (ii) collect donated human milk, (iii) screen, process, and store donor human milk, and (iv) distribute this milk to meet an infant's specific needs for optimal health [1]. Ideally, the service should be linked with support for breastfeeding mothers, which is called Comprehensive Lactation Management Centres (CLMCs). Of the 27 million babies born in India annually, approximately 13 percent (3.5 million) are born preterm and 28 percent (7.6 million) with low birth weight, increasing their risk of dying in the neonatal period [2, 3]. Worldwide, feasible and cost-effective interventions exist that can save a staggering 71 percent of premature babies. Of these, human milk has the

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greatest potential impact on child survival. When sufficient maternal breast milk is not available, alternative forms of enteral nutrition for preterm or low birth weight (LBW) infants are either donor breast milk or artificial formula.

Donor breast milk may retain some of the non-nutritive benefits of maternal breast milk for preterm or LBW infants. In preterm and LBW infants, moderate-certainty evidence indicates that feeding with formula compared with donor breast milk, either as a supplement to maternal expressed breast milk or as a sole diet, results in a higher risk of developing necrotising enterocolitis [1]. Compared with those who receive infant formula, both term and preterm infants fed their mother's milk are at significantly lower risk for developing a wide range of medical problems both in the immediate neonatal period and later in life, including sepsis, Necrotising Enterocolitis (NEC), Retinopathy of Prematurity, Reduction in length of stay of Neonate in Neonatal Intensive Care unit (NICU), Higher discharge rates indirectly cutting cost of treatment, and improved Neurodevelopmental Outcomes and Long term benefits [6-10]. Pasteurized milk from donor mothers (donor milk) is therefore a logical preference for feeding sick and premature infants when the mother's milk is unavailable. It can also serve the infants with certain medical conditions or whose mothers are critically ill or unavailable, or those mothers with insufficient milk supply.

The Process of Human Milk Banking

Human milk banking is a vital process that provides screened, pasteurized, and often fortified donor human milk to infants who need it but cannot receive it directly from their mothers. This is particularly crucial for premature, ill, or vulnerable infants. Standard guidelines for the process are formulated [11]. The process is briefly categorized into several key stages:

This meticulous process ensures that donor human milk is a safe and effective nutritional intervention, offering life-saving benefits to the most vulnerable infants.

Donor Screening and Selection: Potential donors are rigorously screened through detailed medical and lifestyle history questionnaires, and blood tests to rule out infectious diseases such as HIV, HTLV, Hepatitis B and C, and syphilis. Donors must be in good health, adhere to specific lifestyle habits (e.g., non-smokers, limited alcohol intake), and avoid certain medications.

Milk Collection: Donating mothers express their milk using clean techniques and store it in sterile, labelled containers. They are given instructions on proper hand hygiene, cleaning of pump parts, and optimal freezing and storage of milk at home.

Transportation and Storage: Donated milk is transported safely to the milk bank in secure cool boxes and immediately stored in freezers.

Processing and Pasteurization

The frozen milk is thawed overnight in a refrigerator. Milk from

multiple approved donors is often pooled together to ensure a more consistent nutrient profile. The pooled milk is then pasteurized using the Holder Method, which involves heating the milk to a specific temperature (typically 62.5°C) for a set duration (30 minutes) to eliminate harmful bacteria and viruses while retaining most of the beneficial components. After pasteurization, the milk is rapidly cooled and refrozen.

Quality Control and Testing: A sample from each pasteurized batch is sent to an independent laboratory to test for bacterial growth. Only milk that passes these stringent tests is approved for dispensing.

Dispensing: The safe, pasteurized donor milk is then dispensed by prescription, primarily to hospitals (especially neonatal intensive care units or NICUs) for premature and ill infants, and sometimes to outpatient families.

Integrating technology into human milk banks (HMBs)

The integration of technology in Human Milk Banks (HMBs) is a critical development, enhancing the safety, efficiency, and accessibility of Donor Human Milk (DHM) for vulnerable infants. This integration spans various operational aspects, from donor management to milk processing and distribution, aiming to optimize the entire milk banking process. Key Areas of Technology Integration:

1. Data Management and Tracking Systems

Modern HMBs are increasingly adopting sophisticated software solutions for comprehensive data management. These systems streamline the entire journey of DHM, from the donor to the recipient.

Specialized Software: Dedicated Milk Bank Management Systems are used to track every step, including donor screening details, milk collection dates, processing parameters (e.g., pasteurization batch numbers), storage locations, and distribution records. This ensures complete traceability and accountability.

Cloud-Based Solutions: The use of cloud-based platforms (e.g., those built with Salesforce technology) facilitates real-time data access, improved donor information management, and efficient inventory control across multiple locations or departments within a milk bank network. This improves the overall supply chain efficiency and helps to meet demand for DHM.

Unique Identifiers and Barcoding: Implementing unique, scannable labels (e.g., 2D barcodes) on milk containers allows for precise tracking of individual donations. This technology captures critical information such as donor ID, collection date, nutritional analysis, batch number, and expiration date, significantly reducing the risk of human error and enhancing patient safety [12].

Geographic Information Systems (GIS): Some milk banks are leveraging GIS to analyze donor demographics, identify high-potential donor areas, and optimize logistics for milk collection and distribution. This data-driven approach helps in strategic

planning and outreach efforts to increase the donor milk supply [13].

2. Quality Control and Monitoring

Technology plays a crucial role in maintaining the integrity and safety of DHM throughout the supply chain.

Internet of Things (IoT) Sensors: IoT sensors embedded in insulated transport bags monitor real-time conditions such as temperature and humidity during milk transportation from the donor's home or hospital to the HMB. This continuous monitoring helps prevent spoilage and ensures milk quality [12, 14].

Automated Alert Systems: Algorithms are designed to trigger immediate alerts if milk temperatures exceed pre-defined thresholds (e.g., above -20°C for frozen milk). This allows for timely intervention, mitigating the risk of milk degradation and wastage [12, 14].

Advanced Milk Analysis: Technologies like infrared spectroscopy are used for rapid and accurate macronutrient analysis of milk samples (e.g., estimating fat and protein content). This "lacto-engineering" helps in tailoring milk for specific infant needs, particularly for preterm or critically ill babies [15].

Alternative Pasteurization Methods: While Holder Pasteurization (HoP) is the standard, research and pilot implementations are exploring advanced thermal and non-thermal processing technologies. These include High-Temperature Short-Time (HTST) pasteurization, High-Pressure Processing (HPP), microwave heating, and UV-C irradiation. The goal is to preserve more of the milk's bioactive components and nutritional value while ensuring microbial safety [16, 17]. Freeze-drying (lyophilization) is also being explored for its potential in room-temperature storage and transport [16].

3. Operational Efficiency and Logistics

Technological advancements streamline HMB operations, leading to improved throughput and resource management.

Optimized Inventory Management: Digital systems provide clear visibility into milk inventory, including detailed information on processed batches, expiry dates, and specific milk types (e.g., preterm vs. term milk). This ensures efficient retrieval and allocation of milk.

Streamlined Processes: Automation of certain administrative and logistical tasks reduces manual workload and minimizes human error, improving overall staff productivity.

Supply Chain Optimization: Technology aids in optimizing transportation routes and schedules for milk collection and delivery, reducing operational costs and ensuring timely delivery to hospitals and recipients [12].

4. Donor and Recipient Engagement

While sensitive, technology is also being explored to enhance interaction with donors and recipients through the following means.

Online Platforms and Mobile Applications: These can facilitate donor registration, provide information about the donation process, and potentially offer support resources for breastfeeding mothers.

Telehealth Consultations: In some contexts, technology may enable remote consultations with lactation counsellors or HMB staff, making information and support more accessible.

Innovations in Human Milk Banking

Human milk banking is an evolving field, and recent innovations are primarily focused on improving safety, efficiency, and accessibility. Here are some key areas of new developments:

1. Enhanced Pasteurization Methods

High-Pressure Processing (HPP): This is a promising alternative to traditional Holder pasteurization. HPP involves applying high hydrostatic pressure to milk, which has shown to be as effective at destroying pathogens while potentially preserving more heat-sensitive nutrients and beneficial proteins (like lactoferrin) compared to Holder pasteurization. Research is ongoing, and clinical trials are needed before widespread implementation [18, 19].

Optimized Thermal Pasteurization: Researchers are exploring if lower temperatures than the current standard (62.5°C for 30 min) can effectively destroy pathogens while minimizing the degradation of beneficial milk components. High-temperature short-time (HTST) pasteurization is also being investigated [19].

2. Smart Technologies for Quality Control and Logistics

IoT (Internet of Things) Sensors: These sensors are being used to monitor critical conditions like temperature and humidity during the transportation of human milk from donors to milk banks and within the milk bank itself. This helps in reducing spoilage, assuring quality, and optimizing logistical operations. Alerts can be sent if milk temperature goes beyond a predefined threshold [20].

Automated Processes: Efforts are being made to automate manual processes in milk banking, such as milk mixing and analytical procedures. This aims to improve efficiency, ensure nutritional uniformity, and provide better data for targeted pooling of milk [21].

Traceability Systems: Barcode tracking and other robust systems are being implemented to ensure complete traceability of every container of milk donated and issued from the bank, enhancing safety and record-keeping, especially in larger milk banks [22].

3. Improved Nutritional Analysis and Tailored Fortification

Advanced Milk Analyzers: Milk banks are utilizing advanced equipment, like the MilkoScan FT120, to accurately and precisely analyze the macronutrient content of donor human milk [23].

Target Pooling: This process involves pooling milk deposits from different donors to achieve a specific caloric and protein content, allowing for more tailored nutrition for vulnerable infants, particularly in NICUs.

4. Expanding Access and Models of Care

Low-Technology Solutions: In resource-limited settings, innovations are focusing on developing low-cost, cell-phone-based networked sensing systems for safety monitoring of flash-heating pasteurization. The goal is to scale up human milk banking for vulnerable infants in these areas [24].

Integrated Milk Bank-Blood Bank Models: Some regions are exploring integrated models where human milk banks operate in conjunction with blood or tissue banks to streamline operations and reinforce lactation support within healthcare systems [25].

5. Research into Milk Composition and Handling

Ongoing research is delving deeper into the composition of human milk, how handling practices affect its properties (e.g., peptide release and bioactivity), and the impact of donor milk on infant growth and development. This includes understanding the effects of medications on milk composition and exploring ways to improve the preservation of bioactive components [26].

These advancements collectively aim to make human milk banking safer, more efficient, and more accessible, ultimately benefiting vulnerable infants who rely on donor human milk for optimal health and development.

Growth of milk banks globally

The number of human milk banks globally has been steadily increasing, reflecting a growing recognition of the vital role donor human milk plays, especially for vulnerable infants. Since the first human milk bank opened in Vienna in 1909, the network has expanded dramatically. As of recent reports (late 2022 to early 2024), there are over 756 human milk banks in 66 countries, with some sources even stating over 800 milk banks operating in 66 countries. Brazil is a global leader, with an extensive network of 217 milk banks and an additional 126 milk collection points. Europe also has a strong presence, with over 210 active human milk banks, led by countries like Italy (39 milk banks) and France.

North America (including the US and Canada) has a well-developed network, with 32 accredited non-profit milk banks under HMBANA. Asia Pacific is expected to see rapid growth due to increasing awareness of the benefits of donor human milk for premature and sick infants. There are still notable gaps in South Asia and Africa, where the lack of infrastructure and resources limits access to donated milk, although a small but increasing number of milk banks are being established in low and middle-income countries.

Human Milk Banks in India

The first human milk bank in Asia was established in 1989 in Lokmanya Tilak General Hospital, Mumbai, India, by Dr.

Armida Fernandez [27]. Today, the country has 21 milk banks, mostly in the western region. This number, however, is inadequate to meet the massive need for donor human milk. Enforcing and establishing more human milk banks (HMBs) in India is crucial for improving infant health. As of early 2024, the number of human milk banks in India has reached approximately 125. The founder convener of the Human Milk Banking Association of India stated in August 2024 that the country now has 125 milk banks [28].

A comprehensive approach to enforce and expand human milk banks in India includes -

- 1) Strengthening Policy and Regulatory Frameworks.
- 2) Integrate HMBs into National Health Programs.
- 3) Strengthen the integration of HMBs within existing maternal and child health
- 4) Legal Framework for Milk Banking.
- 5) Capacity Building and Infrastructure Development.
- 6) Awareness and Community Engagement.
- 7) Research and Monitoring.

Program for Appropriate Technology in Health (PATH) is an international, non-profit global health organization that plays a significant role in promoting and strengthening human milk banking systems around the world, including in India. In India, PATH collaborates with government, technical, and policy leaders to successfully implement and expand an India-specific Mother-Baby Friendly Initiative Plus (MBFI+) integrated system [29]. In India, PATH collaborates with government, technical, and policy leaders to successfully implement and expand an India-specific MBFI+ integrated system.

PATH's activities include:

1. Providing technical guidance. PATH is supporting the government of India to formulate evidence-backed guidelines and standards to ensure the safety and quality of human milk banking systems.
2. Supporting capacity building and advocacy. As a trusted convener, PATH leads efforts to build capacity among stakeholders. Supported the establishment of the Network Chapter of the Human Milk Banking Association of India, whose aim is to improve coordination, share expertise, and strengthen systems. It is creating local ownership of MBFI+ by supporting stakeholders to develop robust HMB processes.
3. Research and innovation. PATH continues to facilitate research to build evidence for human milk banking systems in India. PATH is Supporting a study to evaluate the impact of the MBFI+ model on newborn health outcomes and breastfeeding practices in a network of hospitals in Mumbai. Engaged in efforts to encourage produce of affordable, easy-to-use equipment to help HMBs operate safely and effectively in India, for use in India and in other low-resource settings around the globe. It is working with

government organizations and other partners to support further research and innovations in human milk banking.

4. PATH acts as a catalyst in global health, leveraging expertise in science, technology, and advocacy to create sustainable solutions. In the context of human milk banking, they are a key player in ensuring that more vulnerable infants have access to life-saving donor human milk by strengthening the systems and practices around it.

Ethical considerations

Human milk banking, while offering significant benefits for vulnerable infants (especially premature, low birth weight, and critically ill newborns), also presents a range of ethical concerns that require careful consideration. These concerns often revolve around issues of equity, safety, informed consent, and the potential for commercialization. Some of the key ethical concerns include -

1. Safety and Disease Transmission:

A primary ethical concern is ensuring the safety of donated milk. This necessitates stringent screening of donors for infectious diseases (e.g., HIV, hepatitis), medications, and lifestyle factors that could impact milk quality [30]. Any lapse in screening could pose serious health risks to recipient infants. Proper pasteurization, handling, and storage protocols are crucial to eliminate pathogens and maintain milk integrity. Ethical concerns arise if these standards are not consistently met, potentially leading to contamination.

2. Donor Rights and Informed Consent:

Milk donation should be purely voluntary and free from coercion or undue influence. Ethical guidelines emphasize that donors should not be pressured to provide more milk than is safe or optimal for themselves or their infant. Donors must receive comprehensive information about the milk banking process, including how their milk will be used, the screening procedures, and the non-profit nature of the donation (in most cases) [31]. This ensures truly informed consent. The privacy of both donors and recipients should be protected. Information about donors should be kept confidential, and recipients should not have access to donor identities.

3. Commercialization and Exploitation:

The ethical framework for human milk banking is generally rooted in altruism, where milk is donated to help vulnerable infants. The emergence of commercial milk banks that pay donors and sell processed milk at high prices raises significant ethical questions. Paying for milk could potentially exploit women in vulnerable economic situations, incentivizing them to donate more milk than is healthy for them or their child. This can also lead to non-disclosure of health conditions or behaviors that could compromise milk safety [32].

Some ethicists argue that commercializing human milk commodifies a bodily fluid, potentially undermining the altruistic nature of donation and creating a market where access

is determined by wealth rather than need. Commercialization could exacerbate existing health disparities, as wealthier parents may be more likely to afford donor milk, while those in lower socioeconomic brackets may have limited access.

4. Equity and Allocation of a Scarce Resource [33].

Donor milk is a scarce resource. Ethical dilemmas arise in determining how to allocate it fairly, especially in regions with high demand and limited supply. Prioritization is often given to the most vulnerable infants (e.g., premature infants in NICUs). Many human milk banks are concentrated in high-income countries, limiting access for infants in low-resource settings where the need may be greatest. Ethical considerations include working towards more equitable access globally. There's an ethical responsibility for milk banks to ensure that donor milk is not used in a way that undermines a mother's breastfeeding journey. Donor milk should complement, not replace, a mother's attempt to breastfeed her child, and resources should be available to support mothers in establishing and maintaining their milk supply.

5. Lack of Standardized Guidelines:

In some regions, the absence of universally standardized guidelines for human milk banking can lead to inconsistencies in donor screening, processing, and distribution, raising ethical concerns about safety and quality control [34]. The number of human milk banks around the world that aim to improve neonatal health through the provision of donor human milk is increasing. In 2020, it was estimated that there were 756 milk banks in 66 countries, with an increasing number of milk banks being established in low- and middle-income countries [34]. However, there is no global coordinating body issuing minimum quality, safety, and ethical standards to inform national policies on donor human milk. While milk banks may need to adapt to the restrictions, resources, and needs of their local area, they need to apply similar baseline processes to provide safe and high-quality donor milk [1].

Safety Protocols and Guidelines

Human milk banks adhere to rigorous safety protocols and quality assurance practices to protect infants. Organizations like the Human Milk Banking Association of North America (HMBANA) set international guidelines for pasteurized donor human milk, which include [35]:

- Comprehensive donor screening and serological testing.
- Standardized operating procedures (SOPs) for every step of the process, from collection to dispensing.
- Strict sanitation and good manufacturing practices.
- Regular equipment maintenance and calibration.
- Detailed record-keeping for traceability.

The World Health Organization (WHO) has also prioritized the development of global guidelines for donor human milk banking to ensure minimum standards of quality, safety, and ethical considerations.

CONCLUSION

Human milk banking is a vital service that can help provide essential nutrition to infants in need, particularly in developing countries with high infant mortality rates. Balancing the need verses the cost in human milk bank establishment and running costs, skilled workers, trained staff is a tough job. Collaborations like private-public and Non-Government Organisations (NGO's) provide financial and logistical support, which helps extend the reach of Human milk bank services and enables more hospitals and regions to establish similar facilities. We believe such partnerships can lead to improved neonatal outcomes and a reduction in infant mortality.

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