



Strengthening
Human Milk Banking
A GLOBAL IMPLEMENTATION FRAMEWORK



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PATH contact:

Kiersten Israel-Ballard, DrPH
Technical Officer, Maternal and Child Health/Nutrition;
kisrael-ballard@path.org; info@path.org. 206.285.3500.

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ABBREVIATIONS

BANK	Base, Awareness/Advocacy, Network, and Key Protocols
BF	breastfeeding
BFHI	Baby-Friendly Hospital Initiative
CCP	critical control point
EMBA	European Milk Bank Association
GMP	good manufacturing practice
HACCP	hazard analysis and critical control points
Hep B/C	hepatitis B and C
HIV	human immunodeficiency virus
HMB	human milk bank
HMBANA	Human Milk Banking Association of North America
HMBASA	Human Milk Banking Association of South Africa
HTLV	human T-lymphotropic virus
IberBLH	Programa Iberoamericano de Bancos de Leche Humana
MBFI	Mother-Baby Friendly Initiative
NICU	neonatal intensive care unit
RedeBLH	Rede Brasileira de Bancos de Leite Humano
UKAMB	United Kingdom Association for Milk Banking
UNICEF	United Nations Children's Fund
WHO	World Health Organization

FOREWORD

Incomparable to any other mammalian milk, breast milk is a unique bioactive substance. In addition to meeting all the nutritional needs for the growing infant during the first six months of life, its bioactive substances are essential to the development of the newborn's immature immune system. Because of these attributes, breastfeeding has been shown to be the single most cost-effective preventive intervention to reduce child mortality. While all newborns stand to benefit from breast milk, not all are able to breastfeed at birth. These include those born very pre-term, very low birth weight, or too ill to suckle. In short, the newborns most vulnerable to morbidity and mortality are those at greatest risk of not receiving the lifesaving benefits of breast milk. For these newborns, breast milk from their own mother is the first best option. When this is not possible, the next best option is donor human milk from an established human milk bank.

Human milk banks require donor milk and, therefore, cannot exist in the absence of a well-established and vibrant breastfeeding culture. For this reason, breastfeeding protection, promotion and support are needed for all infants: those who breastfeed, those fed their mother's breast milk, and those fed donor milk. The elements of a well-established and vibrant breastfeeding culture include implementation and monitoring of the International Code of Marketing of Breast-milk Substitutes, implementation

and monitoring of the Baby Friendly Hospital Initiative, and community support and counseling of breastfeeding mothers. Because a human milk bank cannot function in the absence of a well-established and robust breastfeeding program, the Pan American Health Organization encourages Ministries of Health in the Americas to establish human milk banks only in hospitals certified as Baby Friendly.

The Government of Brazil is a global leader in human milk banking. As a result of its leadership and technical cooperation, almost all countries in Central and South America have established human milk banks. It is now providing technical support to countries in Africa and beyond. As the number of countries establishing human milk banks expands, a common framework and set of core practices that should be universal for all human milk banks is required. The present document provides this framework and set of core practices, thus providing a resource for Ministries of Health, hospital directors, as well as the broader public health community committed to providing this lifesaving intervention for the world's most vulnerable newborns.

Dr. Chessa Lutter
Senior Advisor, Food and Nutrition
Pan American Health Organization/World Health Organization

ABOUT THIS DOCUMENT

Donating breastmilk is an ancient practice for infants in need. Throughout history, women have breastfed infants who were not their own. Greek and Roman mythology, the Bible, the Torah, and Islamic scripture describe wet nurses who nourished infants who would become prominent figures, such as the Prophet Muhammad. Provision of donor milk continues today as an effective strategy for promoting the benefits of breast milk and saving newborns' lives. Yet despite the irrefutable evidence in support of provision of donor milk, the majority of vulnerable infants around the world in need of this lifesaving intervention do not have access to it, largely due to lack of awareness, supportive policy, and resources.

More than 37 countries, however, have developed human milk bank systems with robust quality control systems to offer safe donor milk, foster community support for breastfeeding, and meet local needs. This global human milk banking community possesses vast knowledge, experience, and evidence to inform the creation and expansion of human milk bank programs and the integration of these programs into infant care systems. PATH, an international health organization that drives transformative innovation to save the lives of women and children, sought to develop a toolkit to simplify access to this global knowledge base. Increasing understanding of existing human milk bank

processes is an important step in increasing awareness and informing policy. Drawing on the experiences of milk banks around the world, PATH developed this document, *Strengthening Human Milk Banking: A Global Implementation Framework*, as a toolkit that ministries of health, policymakers, and implementers can use to identify the critical components required for an effective human milk bank program.

This framework outlines the core requirements and quality principles that should be universal for all human milk banks. We present a compilation of key factors and current practices, based on solid evidence, which implementers and policymakers can use as a guide when developing context-specific guidelines for each facility, region, or country. This toolkit is not intended to provide specific recommendations, since universal human milk banking guidelines are neither feasible nor appropriate due to diversity of resources, risks, and cultures. Rather, our goal is that this framework serves as a powerful resource, facilitating communication with the global human milk banking community, empowering policymakers with the tools and information they need to develop and support locally appropriate human milk banks and ultimately ensuring that vulnerable infants around the world have access to this lifesaving intervention.

OVERVIEW OF HUMAN MILK BANKING

Breast milk: Providing optimal infant nutrition

A mother's breast milk provides the optimal nutrition for growing infants and is globally considered a pillar of child survival because of its protective effects.¹ Access to breast milk, which is both immunologically and nutritionally rich, is especially important for vulnerable neonates, such as those born preterm or in resource-limited settings. Suboptimal breastfeeding increases the risk of child mortality, annually resulting in 800,000 deaths worldwide according to 2013 figures published in *The Lancet*.²⁻⁴

In recognition of the vital role breast milk plays in boosting infants' health, the World Health Organization (WHO) recommends exclusive breastfeeding for the first six months of a child's life, followed by continued breastfeeding up to two years of age.^{5,6} To further this recommendation and ensure more families around the world have the support they need for breastfeeding and infant health, the WHO and the United Nations Children's Fund (UNICEF) established the Baby-Friendly Hospital Initiative (BFHI) and, more recently, the Mother-Baby Friendly Initiative (MBFI).^{7,8} These initiatives encourage health facilities to provide a supportive, family-centered environment for breastfeeding and continuity of care before, during, and after birth, including support after hospital discharge.

Unfortunately, some infants do not have access to his or her own mother's milk, leaving them particularly vulnerable.⁹ Infant abandonment, a mother's death, disease, or delay in milk production may impede the child's access to breast milk. Nonetheless, it is crucial that vulnerable infants—such as those who are born preterm or with low birth weight, are orphaned, or are severely malnourished—have access to human breast milk for proper

WHO ranking of feeding options for newborns

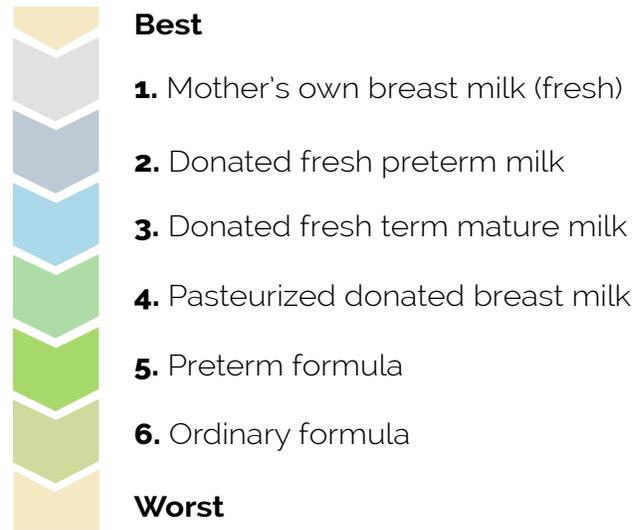


Figure 1: Donor human milk is the second choice, directly after mother's own breast milk, for feeding newborns.

growth, nutrition, and the prevention of infections or other complications that may lead to longer-term care, expenses, or premature death.¹⁰⁻¹²

Because of the demonstrated benefits of breast milk for all infants, WHO recommends donor human milk as the next best infant feeding option when the mother's milk is unavailable, as shown in Figure 1.^{13,14} It has called on member nations to investigate the safe use of donor milk through human milk banks (HMBs) for vulnerable infants. By investing in establishing an effective HMB system, governments can ensure that infants receive optimal care through access to a safe, high-quality, sustainable supply of donor milk, thus giving them the best chance at a healthy start in life.¹⁵



What is a human milk bank?

A human milk bank (HMB) is a service established to recruit breast milk donors, collect donated milk, and then process, screen, store, and distribute the milk to meet infants' specific needs for optimal health. A high-performing HMB is grounded in four foundational activities, with key pillars that support HMB operations (see Figure 2). The mission of a HMB is to promote and support breastfeeding by providing safe, high-quality donor milk to fill a gap for those who need mother's milk but cannot receive it.



Foundation and key pillars of a human milk bank

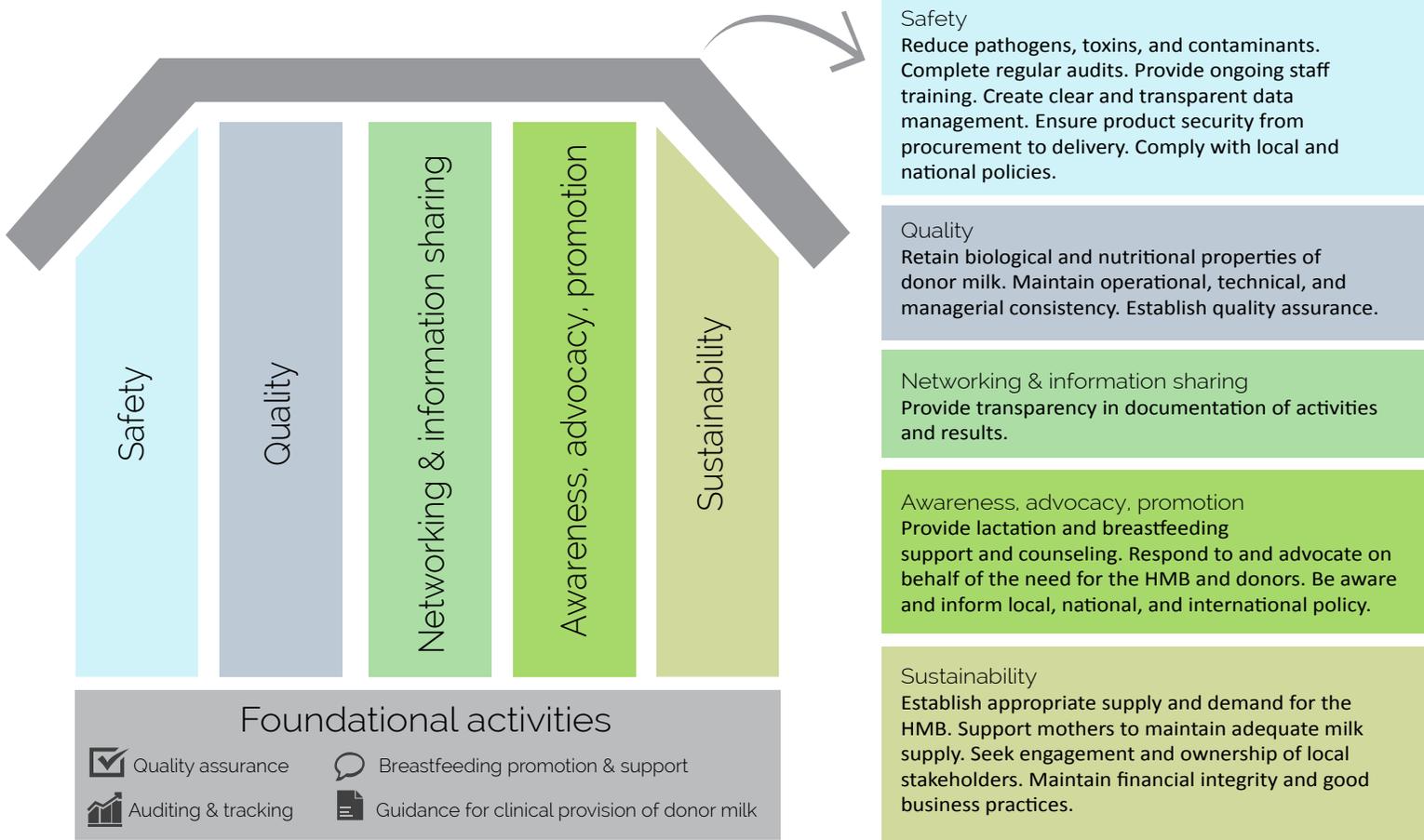


Figure 2: A human milk bank (HMB) is grounded in four foundational activities, which lay a base for the key pillars that support HMB operations.

To provide safe and high quality donor milk, a human milk bank must have a firm foundation. All milk banks adapt to the restrictions and needs of their local area, yet they share a similar foundation built on key pillars and activities as shown in Figure 2.

Photo: Richard Franco



Breastfeeding: the cornerstone of ensuring effective human milk banks

Human milk banks and breastfeeding promotion are inextricably linked. HMBs rely on a robust donor breastfeeding population to ensure adequate supply. When women receive sufficient information about and support for breastfeeding, their chances for successful breastfeeding increase, which in turn increases the likelihood for them to also be breast milk donors. Women benefit from receiving strong community support and resources to embrace and prioritize breastfeeding as an integral part of caring for their babies. When a community places a high value on mother's milk and recognizes its nutritional and immunological benefits, women experiencing breastfeeding challenges are more likely to seek lactation assistance before turning to infant formula or other options.

Protecting, promoting, and supporting breastfeeding is critical to ensuring the effectiveness of HMBs. Advocating for policy implementation through governmental

leadership and community support to improve optimal breastfeeding practices will subsequently result in a stronger and more effective HMB system. A critical first step in this process includes supporting existing policy efforts such as BFHI/MBFI and the WHO International Code of Marketing of Breast-milk Substitutes.¹⁶ The code, when enforced, protects mothers from marketing that may reduce the use of breast milk as the first choice for feeding infants.

As shown in figure 3, strong governmental commitment establishes and supports policy to protect, promote, and support breastfeeding, creating a positive breastfeeding environment in the community for breastfeeding mothers and health care providers.⁶ While many steps are integral to the development of HMB systems, protecting, promoting, and supporting breastfeeding is the cornerstone needed to build sustainable and effective systems.



Protecting, promoting, and supporting breastfeeding: translating policy into effective human milk banking

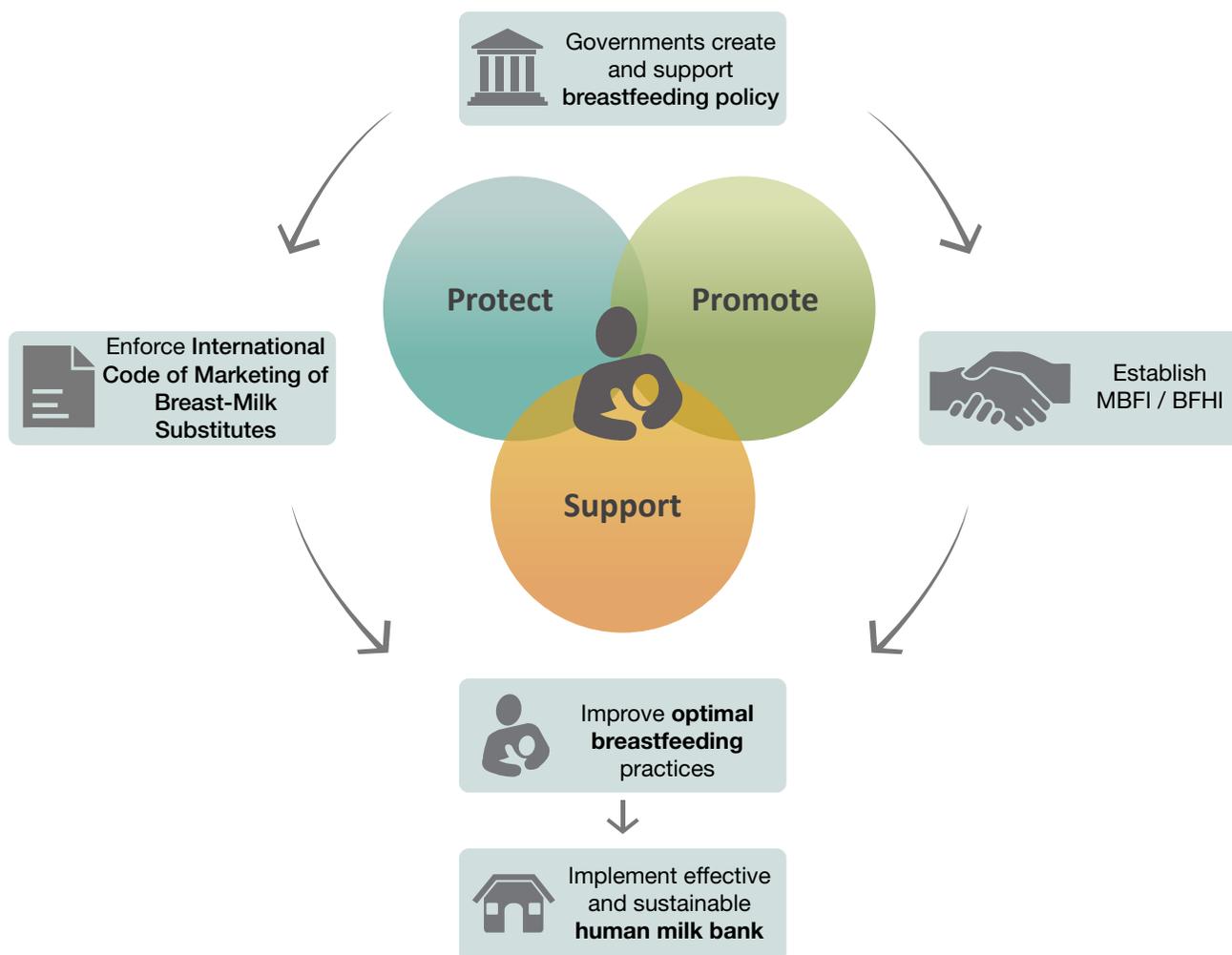


Figure 3: Effective HMB implementation requires investment by the government to protect, promote, and support breastfeeding.

Promoting breastfeeding through human milk banks

Data from HMBs suggest that the presence of a milk bank in a hospital, neonatal intensive care unit (NICU), or other facility increases women's and communities' awareness of the importance of breastfeeding and subsequently improves breastfeeding practices and rates. The exclusive breastfeeding rates for infants upon discharge from NICUs with an HMB were significantly higher (29.6%) compared with those rates from NICUs without an HMB (16.0%).¹⁷ Milk banks raise awareness of the importance of breastfeeding and fill the gap when a mother's own milk is not available, creating a powerful and self-reinforcing cycle of optimal breastfeeding practices.

A comprehensive approach is needed to promote exclusive breastfeeding and increase awareness among prospective donors and recipients while ensuring access

to donor milk. Establishing an HMB can help to develop an integrated system for providing optimal newborn care, building on the MBFI approach, and provide a solid foundation to promote breastfeeding, kangaroo mother care (skin-to-skin contact), and other best practices for neonatal care. One mechanism for doing this is integration of HMBs into existing newborn care systems, which provide a solid foundation to promote breastfeeding and other best practices. For example, the WHO/UNICEF Ten Steps to Successful Breastfeeding were expanded in 2011 for use in NICUs, where newborn babies are especially vulnerable to illness (see text box, right).¹⁸ HMBs could fulfill many of these steps and roles, serving as a centralized community hub to accept, process, and provide donor milk while functioning as a resource center for lactation support and promotion of MBFI goals (see Figure 4).

The Rede Brasileira de Bancos de Leite Humano (Brazilian Network of Human Milk Banks) and its expanded Programa Iberoamericano de Bancos de Leche Humana (Ibero-Ameri-

Mother-Baby Friendly Initiative: Integrating human milk banks

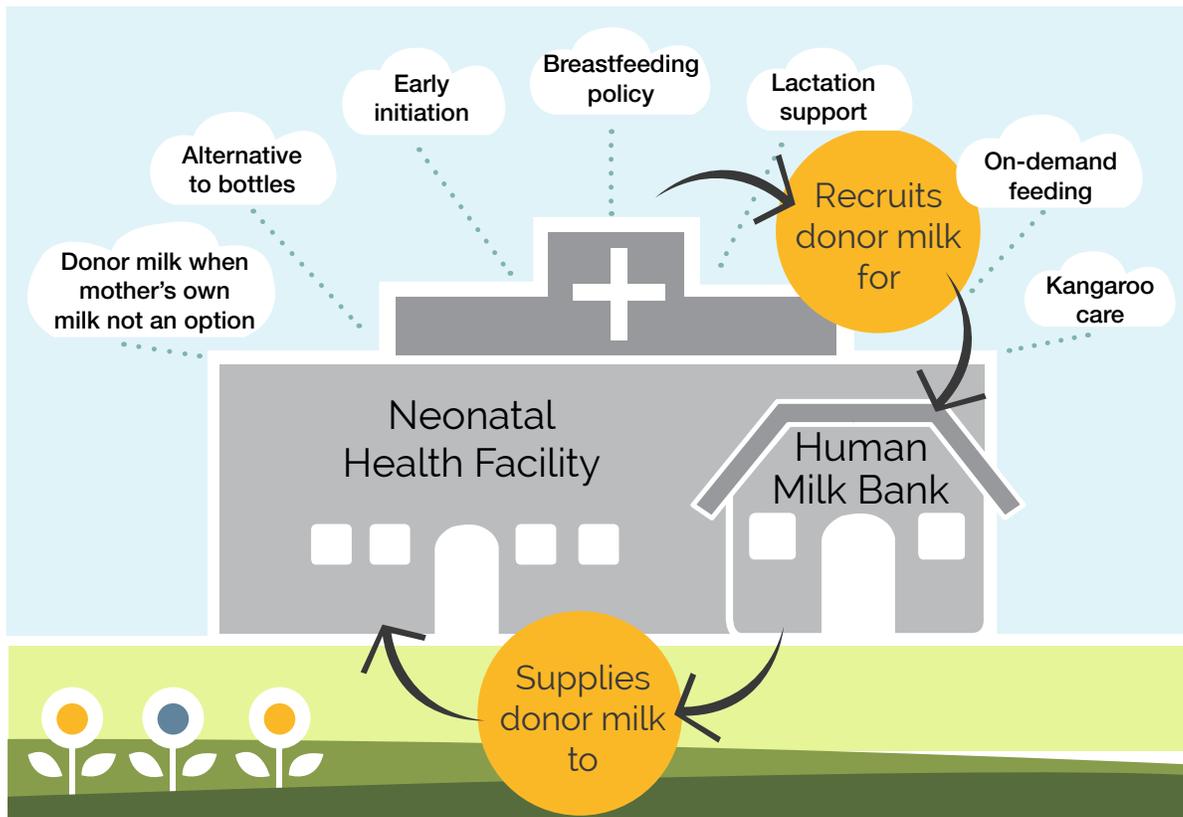


Figure 4: Human milk banks play an integral role in supporting and protecting breastfeeding by providing safe donor human milk.

Ten steps to successful breastfeeding in the neonatal intensive care unit

(as identified by the Baby-Friendly Hospital Initiative and the Mother-Baby Friendly Initiative)

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Educate and train all staff in the specific knowledge and skills necessary to implement this policy.
3. Inform all hospitalized pregnant women at risk for preterm delivery or birth of a sick infant about the management of lactation and breastfeeding and the benefits of breastfeeding.
4. Encourage early, continuous, and prolonged mother-infant skin-to-skin contact (kangaroo mother care) without unjustified restrictions. Place babies in skin-to-skin contact with their mothers immediately following birth for at least an hour. Encourage mothers to recognize when their babies are ready to breastfeed and offer help if needed.
5. Show mothers how to initiate and maintain lactation and establish early breastfeeding with infant stability as the only criterion.
6. Give newborns no food or drink other than breast milk, unless medically indicated.
7. Enable mothers and infants to remain together 24 hours a day.
8. Encourage demand feeding or, when needed, semi-demand feeding as a transitional strategy for preterm and sick infants.
9. Use alternatives to bottle-feeding at least until breastfeeding is well established, and use pacifiers and nipple shields only for justifiable reasons.
10. Prepare parents for continued breastfeeding and ensure access to support services/groups after hospital discharge.

can Network of Human Milk Banks) have successfully demonstrated the effectiveness of a nationalized, integrated human milk bank program that includes breastfeeding promotion, lactation support, and provision of donor milk when necessary.¹⁹ Considered to be a leading global model, Brazil operates more than 220 HMBs and provides outreach to more than 25 countries. To protect, promote, and support breastfeeding, Brazil establishes mother/baby centers for donor milk donation and lactation support.^{20,21} Practices such as kangaroo mother care, rooming-in, and peer support are effective for supporting early initiation of breastfeeding and maintenance of milk production.²² Facilities promote human milk banking by increasing awareness of breastfeeding among mothers during antenatal care and delivery and by providing in-service training for health care staff. These integrated efforts clearly illustrate the impact of synergistically supporting breastfeeding initiatives by exposing community members to mother- and baby-friendly practices and instilling a culture of breastfeeding both within the facility and throughout the community.

Photo: Mother's Milk Bank Austin, Texas



OVERVIEW OF HUMAN MILK BANKING

Establishing a sustainable system

Developing an integrated HMB system requires local, national, and global support to ensure that the system is sustainable and appropriate for the local context. Milk banks must align with a community’s needs and resources to effectively provide a lasting solution for infant care.

Planning, designing, and implementing a successful HMB system are accomplished through four key steps—the BANK approach—for building a solid foundation (Figure 5):

1. Establish a Base.
2. Raise Awareness and conduct Advocacy.
3. Create a Network.
4. Develop Key protocols.

Whether HMB leaders are planning a single milk bank attached to a hospital neonatal ward or developing a network of milk banks, taking these steps will ensure safety, sustainability, quality control, and integration into the larger goal of supporting breastfeeding and optimal infant health. Each step in the BANK approach requires adaptation to the local context. Observing the four BANK steps and their subprocesses will help HMB leaders optimize effectiveness and anticipate potential risks, such as mishandling of donor milk. See Section 2 for a detailed description of the process, and Section 3 to guide considerations in the classification of donor milk for regulation purposes.

BANK: Establishing a human milk bank

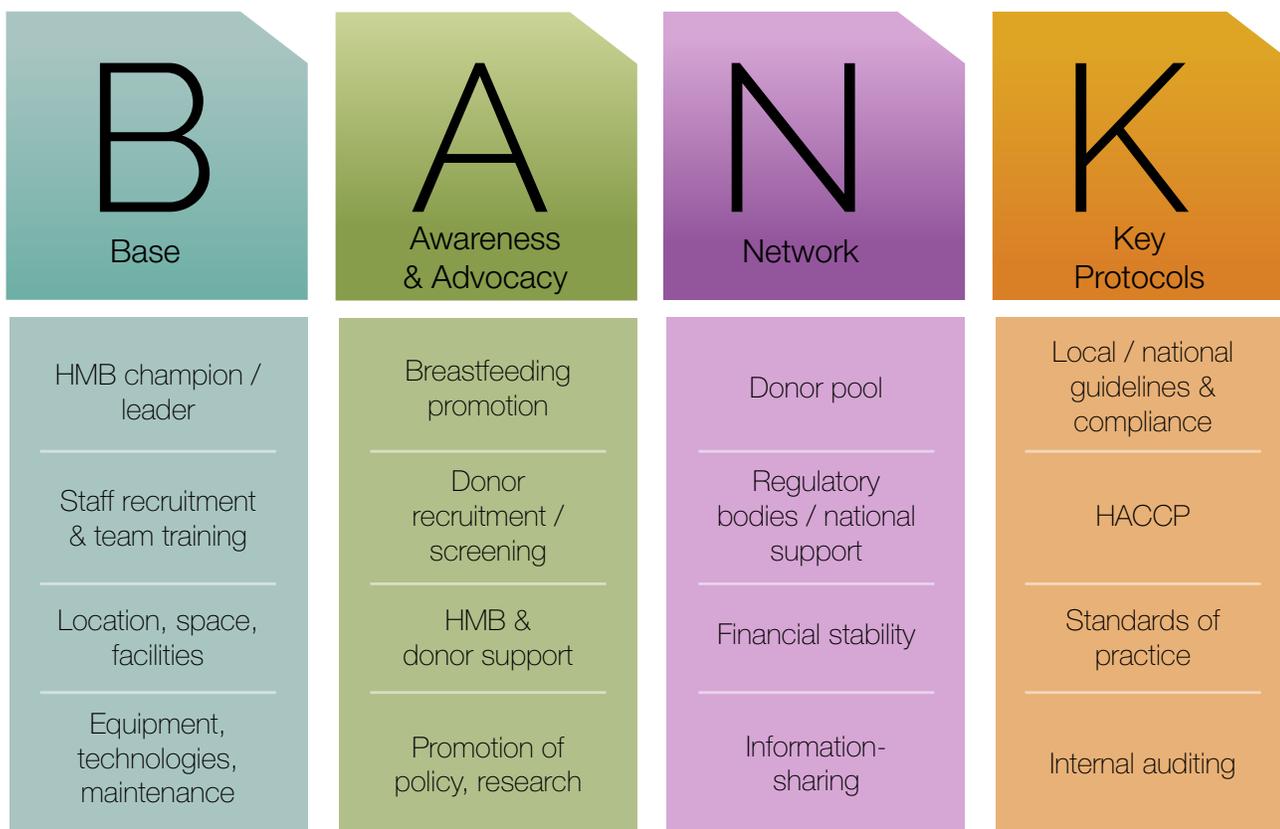


Figure 5: Four key steps required to establish a human milk bank: Base, Awareness/Advocacy, Network, and Key Protocols. (HACCP: hazard analysis and critical control points; HMB: human milk bank)



One effective approach to help develop local systems is implementing a hazard analysis and critical control points (HACCP) process, a management system originally designed to address food safety from production through consumption (Figure 6). This rigorous, systematic approach

is important to consider during the very early stages of HMB development so leaders can assess risks in their setting and focus on achieving the highest quality of donor milk attainable at each step of the process. Section 4 provides additional guidance on using the HACCP process.

Implementing hazard analysis and critical control points (HACCP)²³

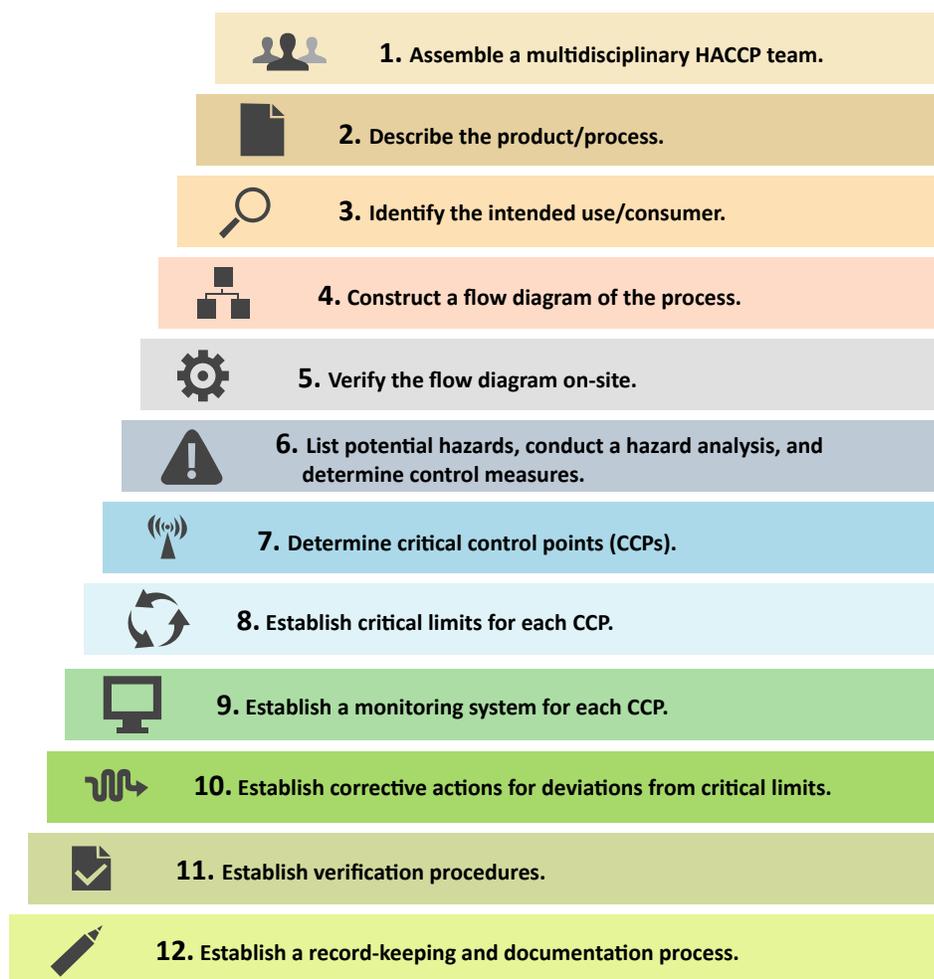


Figure 6: The 12 action steps in implementation of a hazard analysis and critical control points process in a human milk bank system.

OVERVIEW OF HUMAN MILK BANKING

Compiling current global practices in human milk banking

An effective HMB system performs numerous operational processes to provide safe, high-quality donor milk. These process steps, or standards of practice, start with the recruitment of donors, continue with the handling and processing of donor human milk, and finish with the allocation of the donor milk to the recipient (Figure 7). Each HMB must determine how each practice will be performed most appropriately for the local context and must make decisions on specific practices such as pasteuriza-

tion, storage, transportation methods, and prioritization in donor milk allocation. As the figure shows, some practices are performed in the HMB—principally those involving treatment of the donor milk—while others, such as donor recruitment, screening, and milk expression, may be performed in outside locations deemed appropriate by the HMB. Section 5 details each of these HMB process steps and Section 7 summarizes current practices implemented by HMBs around the world.

Flow of process practices in human milk banking

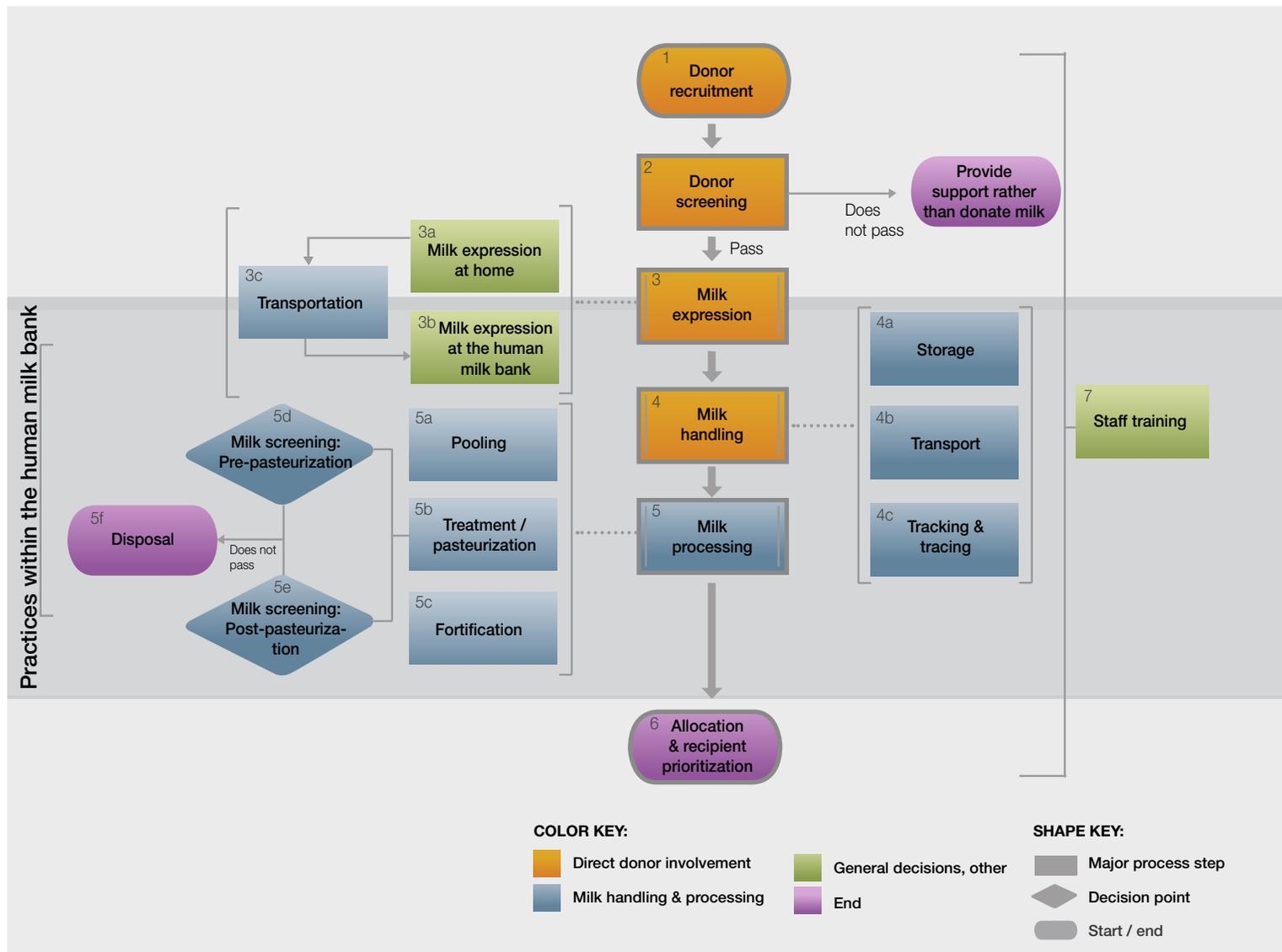


Figure 7: From donor to recipient, choose the best practices for each setting.



Moving forward in human milk banking

Integration of HMBs into maternal and infant health systems is a vital step in supporting vulnerable infants. HMBs are crucial to protect, promote, and support breastfeeding for all by providing safe, high-quality donor human milk to infants without access to their own mother's milk. By adopting and integrating HMBs into existing health systems, communities can teach women and their families about optimal breastfeeding and infant feeding practices and provide infants with a strong start to life.

The remaining sections of this document provide detailed information that can serve as a framework to establish an effective human milk bank. The content includes necessary steps to start a human milk bank system, classification of donor human milk, integration of safety measures through HACCP, and current practices performed by human milk banks around the world. While these sections do not directly serve as guidelines, they do provide guidance on the process of creating a successful human milk bank system to be adapted to specific requirements.



Lactation support being provided through model breasts.
Photo: Brazilian National Network of Human Milk Banks

ESTABLISHING A HUMAN MILK BANK SYSTEM

As noted in Section 1, establishing a successful HMB system requires four key steps, which together form the BANK approach (Figure 8):

1. Establish a Base.
2. Raise Awareness and conduct Advocacy.
3. Create a Network.
4. Develop Key protocols.

The following pages describe core components of each step and their subprocesses.

BANK: Establishing a human milk bank

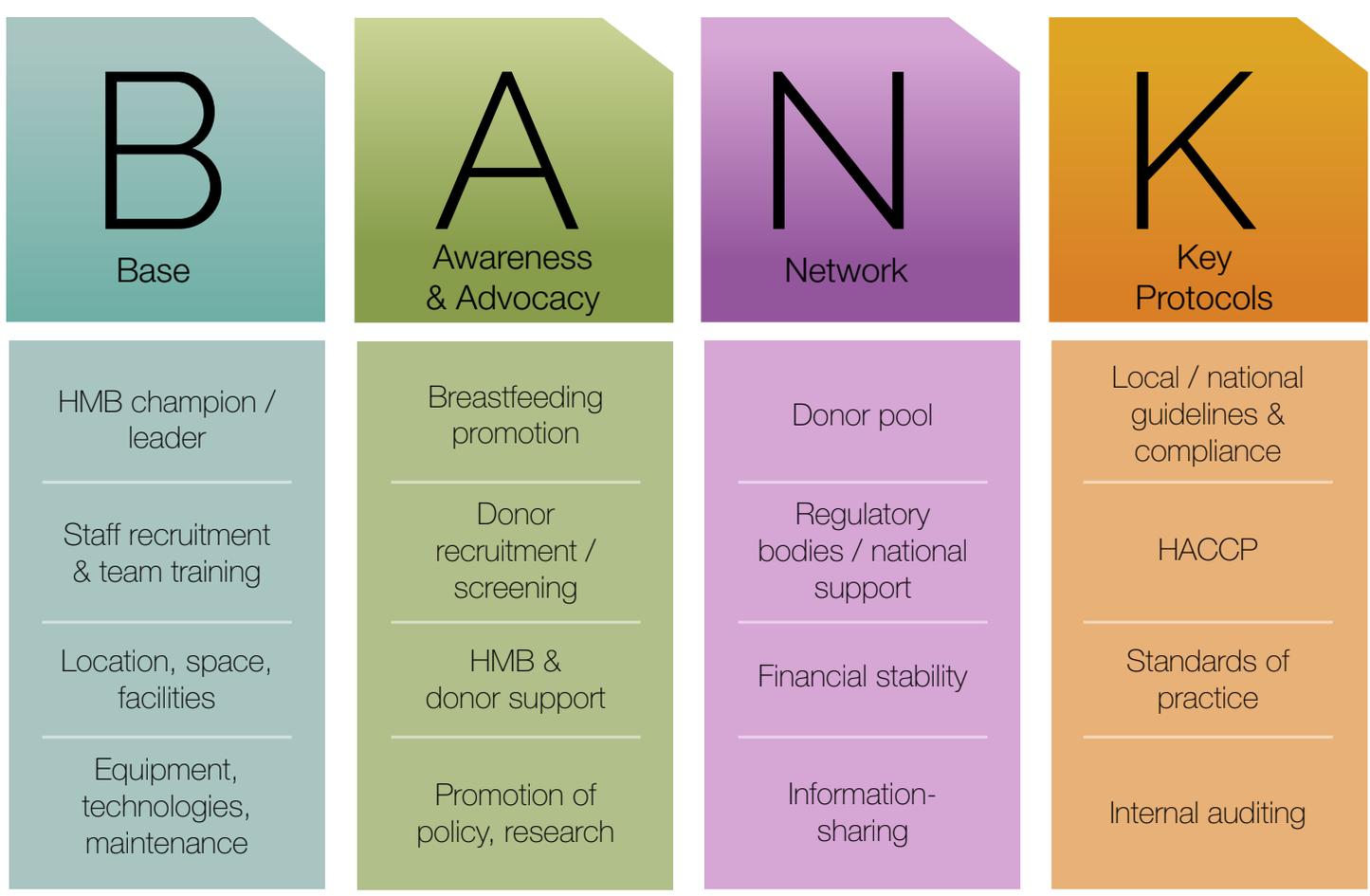


Figure 8: Four key steps required to establish a human milk bank: Base, Awareness/Advocacy, Network, and Key Protocols. (HACCP: hazard analysis and critical control points; HMB: human milk bank)



Photo: PATH



Photo: Mother's Milk Bank Austin, Texas



Photo: Brazilian National Network of Human Milk Banks

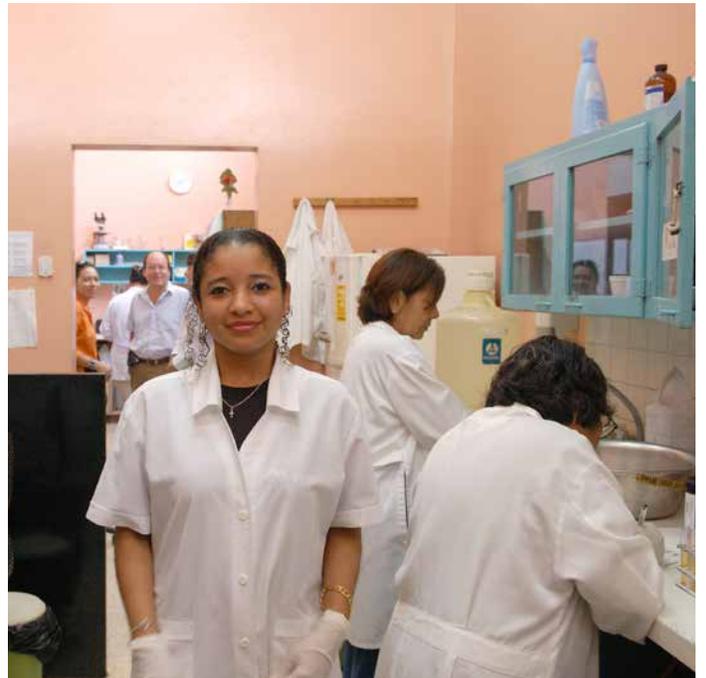


Photo: PATH

ESTABLISHING A HUMAN MILK BANK SYSTEM

1. Establishing a base

Establishing a solid base, or foundation, for an HMB is crucial to ensuring a properly functioning system. The base consists of personnel, facilities, and equipment, all requiring continual investment in training or maintenance.

HMB and breastfeeding champion. Every HMB needs a champion to advocate for, represent, and promote the milk bank and breastfeeding while providing clinical and operations expertise. This person could be a neonatologist, pediatrician, nurse in charge, lactation specialist, midwife, or other individual with clinical authority. This champion is the primary breastfeeding advocate and coordinator for internal and external activities. The champion ensures that quality assurance methods are in place, shares lessons learned with other HMBs, and provides clinical guidance for the use of donor milk.

Qualified HMB team. A qualified team needs to be established to guide the development and operation of the HMB. An effective team consists of the HMB and breastfeeding champion, health professionals, and other staff who ensure the highest quality, safety, and ethical practices in donor milk collection, treatment, and provision. Although the number of staff needed depends on the demands on the HMB, the team should include representatives from a range of disciplines, including microbiology, lactation and nutrition support, medicine/neonatology/pediatrics, infection control, management/administration, and community relations. The broader team should include an advisory committee for decision-making as well as support staff. Regular reviews of performance and continual staff training on HACCP protocols, operating procedures, quality control systems, safety regulations, and technical skills are imperative for quality assurance.

Location, space, and facilities. An HMB's location affects overall visibility as a lactation support center, including how potential donors will reach the facility and how donor milk will be transported to recipients. As HMB planners consider location, they should also consider whether the facility will be attached to a hospital, which can affect an HMB's ability to recruit donors and interact with the neonatal unit. Inside the facility, an HMB needs

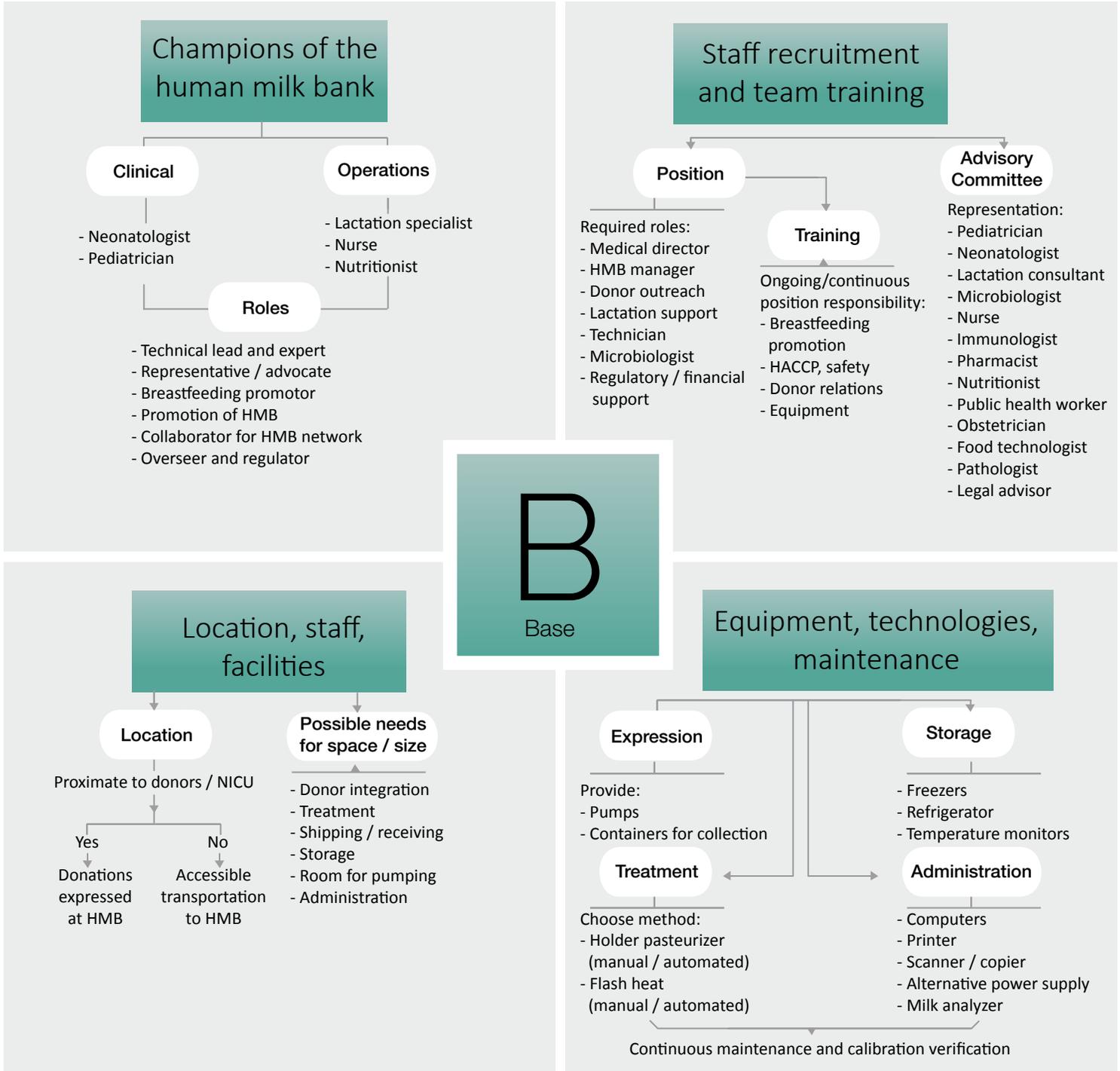
sufficient space to prepare, screen, pasteurize, and store donor milk and to make donors feel comfortable donating their breast milk. Women who will donate at the facility need lactation support rooms and private rooms for breastfeeding and pumping or manually expressing breast milk. Donors and receiving families also need a room, for counseling and support. Finally, an HMB needs space for shipping and receiving, organizing and storing documents and files, and potentially expanding activities as the facility grows.

Equipment, technology, and maintenance. An HMB's equipment needs depend on the facility's capacity and its method of treating donated milk. Equipment generally falls into four categories:

1. **Milk expression.** This includes breast pumps (electrical or manual) and milk storage containers (typically food-grade and either plastic, glass, or stainless steel).
2. **Processing, screening, and treatment.** Processing equipment includes pasteurizers and other treatment equipment, such as homogenizers or monitoring equipment. Microbial screening could be a localized process housed within the HMB or at a clinical laboratory. In addition, milk analyzers may be used to test the nutritional composition of the donor breast milk to determine nutritional adequacy and improve donor-recipient matching. To prevent mishandling or contamination of milk, strict quality control measures must be in place to ensure that all equipment is cleaned and well maintained.
3. **Storage.** Storage equipment includes refrigerators and freezers with temperature monitoring capability and space to allow pretreated and post-treated milk to be clearly identified and stored separately. Storage recommendations for donor human milk vary slightly from that of mother's own milk storage.²⁴
4. **Administration.** Administrative responsibilities include maintaining quality control records and tracking and tracing all donor samples and milk processing data. These activities require access to computers, printers/copiers (e.g., for producing labels), and other communications equipment. In settings where electrical power may be unreliable, an alternative power supply is necessary.



Establishing a base



(HACCP: hazard analysis and critical control points; HMB: human milk bank; NICU: neonatal intensive care unit)

2. Establishing awareness and advocacy

The HMB serves as a visible symbol for optimal infant feeding practices, a role that includes increasing awareness of the HMB itself.

Breastfeeding promotion. The primary goal of the HMB system is to protect, promote, and support breastfeeding for all mothers and their infants. HMBs raise awareness of the importance of breastfeeding and provide donor milk options when a mother's own milk is not available, creating a self-reinforcing cycle of ideal breastfeeding practices. When supported by national and regional government engagement in a comprehensive push for prioritizing breastfeeding promotion, an HMB can serve as an integral component of a community breastfeeding program by providing lactation promotion, infant feeding support, and education on maternal and infant health. The existence of HMBs in communities helps to increase breastfeeding rates by highlighting the value of breast milk and the importance of early and exclusive feeding of human milk. Increased community knowledge about the importance of breast milk builds a larger donor pool, establishing a solid foundation for HMBs to ensure that safe donor milk is available.

Comprehensive promotion of exclusive breastfeeding must target all infants, including infants without access to breast milk from their own mothers. Donor milk is the secondary choice for infant feeding after a mother's own milk. HMBs should encourage donation only from mothers with milk in excess of their own infant's current and potential future needs to ensure that donation will not harm the donors' supply for their own infants.

Donor recruitment and screening. HMBs can use a variety of promotional methods to recruit as many donors as necessary to meet the area's donor milk needs. It is important that HMBs use clear, nontechnical language in the promotion of donor milk and activities. Promotional methods can target the facility and the community and can include word of mouth, print media, and other media, as discussed in Section 5.

Potential donors need to undergo a screening process, which involves oral and written screening and a serologic blood test for infectious diseases such as HIV, hepatitis B or C, and syphilis. See Section 5 for further information on donor recruitment and screening.

HMB and donor support. HMB systems require consistent community support for adequate awareness of breastfeeding and the milk donation system. This includes policy-level support as well as outreach staff or volunteers who, for example, may transport milk to the milk bank when the mothers cannot provide transportation. To support donors and encourage exclusive breastfeeding, HMBs need to provide education on milk expression. Additionally, the provision of milk expression equipment and containers for milk storage and transportation helps to simplify the donation process by reducing potential barriers.

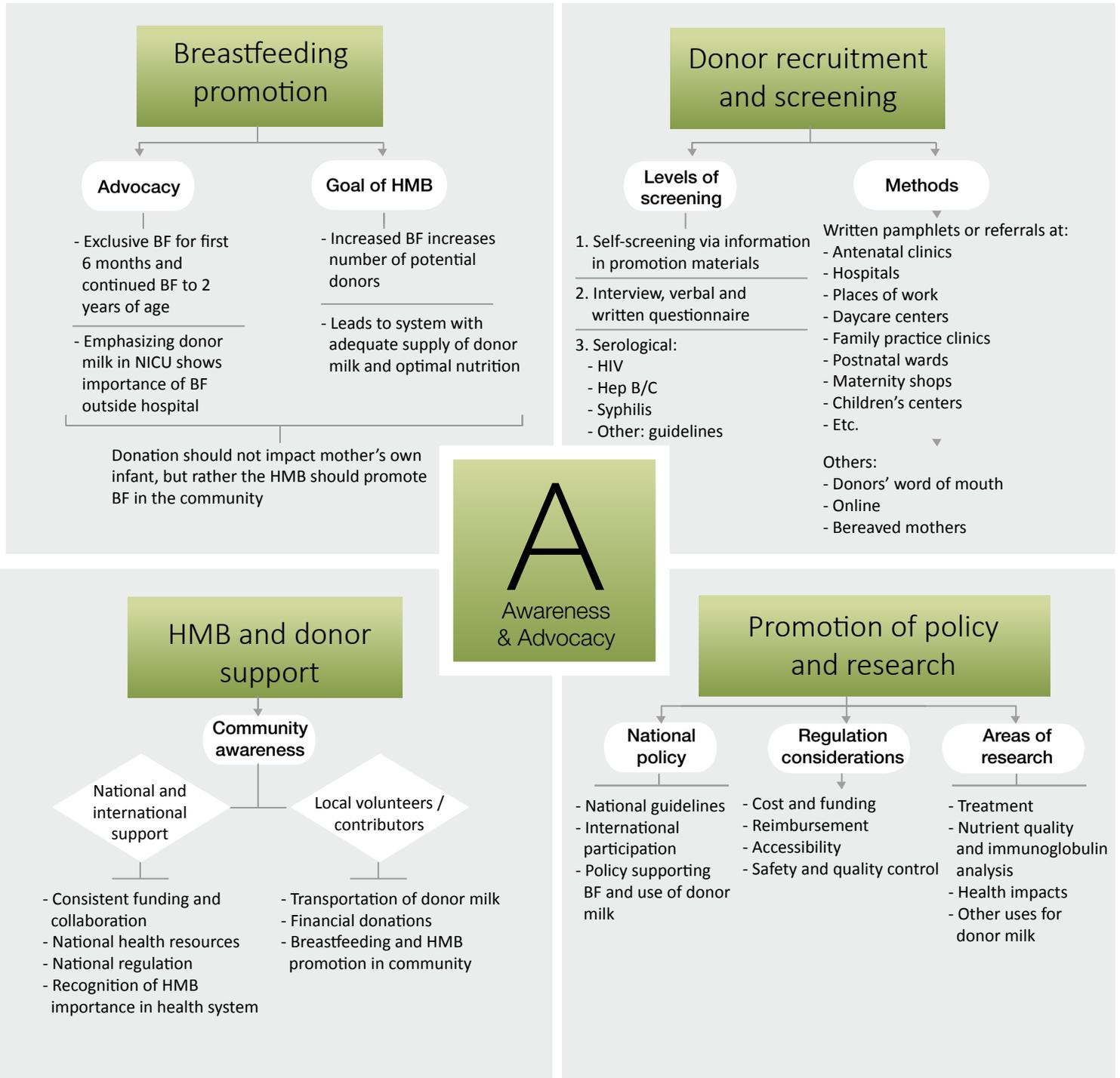
Promotion of policy and research. Including HMB operations and criteria for provision of donor breast milk in national policies and guidelines on infant and young child nutrition and newborn care is critical to ensure shared strategies and adequate support for the HMB system. Examples of this are the WHO/UNICEF BFHI and MBFI strategies as well as the WHO International Code of Marketing of Breast-milk Substitutes, which protects mothers from marketing that may reduce the use of breast milk as the first choice for feeding infants.^{6,7,24}

Regulatory requirements for HMBs and donor milk differ across countries and regulatory agencies and significantly influence the selection of appropriate operational procedures. Section 3 shows considerations for determining the appropriate classification of donor milk, as food, tissue, nutrition therapy, or medical/functional food.

As part of a robust monitoring and evaluation system, it is important that data collected can be disseminated in order to further add to the evidence base for demonstration of the short- and long-term impacts of donor milk on infant health. Human milk banking research can provide the basis for critical advocacy and informs policy. Additional research is needed to support improved systems for screening donor milk and for treatment/pasteurization to improve milk content/quality; simplified methods for homogenization and determining milk composition; the cost-effectiveness of using donor milk versus formula; and the impact of human milk fortification on clinical outcomes of preterm infants.



Establishing awareness and advocacy



(BF: breastfeeding; Hep B/C: hepatitis B and C; HIV: human immunodeficiency virus; HMB: human milk bank; NICU: neonatal intensive care unit)

3. Establishing the HMB network

An HMB system does not function independently. Effective operation requires multiple support networks.

Donor pool. An HMB supports its network of donors to ensure a sufficient supply of donated milk. When a woman is interested in donating, the HMB should provide lactation support, expression equipment, and ready-labeled serologic blood testing kits for screening at the donor’s own clinic while minimizing the burden of the screening process. Establishing strong relationships with donors creates a sense of trust and encourages donation.

HMBs support donors by making the donation process as convenient as possible, such as by providing transportation services, offering milk collection supplies, and answering donors’ questions. When a potential donor does not meet the criteria for donating, the HMB should continue to teach the importance of breastfeeding and provide lactation support, allowing her to serve in other roles, such as in promotion and advocacy. Each HMB decides the length of time that a woman can donate and how long after delivery she can start donating breast milk based on HMB donor milk needs and the recipient population.

Regulating bodies and national support. HMBs should be familiar with national regulations and guidelines around breastfeeding, breast milk donation, and expected practices in human milk banking. If regulations do not already exist, HMB teams can provide technical assistance for integrating HMB strategies into policies. By creating a network for policy promotion and continuing to increase awareness of the need for HMBs at the national level, HMBs can foster sustainability and acceptance of breastfeeding and breast milk donation in the community.

Financial sustainability. HMBs require consistent, adequate funding. This support may come through national health funds and government resources or other local

sources, such as charitable organizations. Funding can be provided directly from the hospital to cover the costs of staffing, equipment, office space, and milk handling and treatment. Even if national bodies or local health trusts provide financial support and external medical facilities purchase donor milk from the human milk bank, HMBs can establish a network of other financial supporters to ease the burden of costs and enable investments in additional technology, equipment, and research.

Information sharing. Information sharing is a key pillar in the establishment of an HMB system. HMBs should build a network of advisors and other experts in the field to create a sense of community among milk banks and also to serve as a valuable resource when questions or challenges arise. Many regions have established collaborative networks for information sharing and self-regulation in the development of network guidelines. Examples include the European Milk Banking Association, the Human Milk Banking Association of North America, the Human Milk Banking Association of South Africa, Programa Iberoamericano de Bancos de Leche Humana (Central and South America and partner sites in Africa and Europe), Rede Brasileira de Bancos de Leite Humano (Brazil), and the United Kingdom Association for Milk Banking. See Contacts and Resources in Section 7 for more information.

Sharing information and establishing clear communication channels through a collaborative network helps all HMBs embrace best practices and remain up to date on research, policies, and technologies, with the goal of ensuring the highest level of safety and quality. As an extensive and diverse group of experts, the international HMB community provides an outlet for advancing the goals of HMBs, promoting breastfeeding for all infants, and increasing access to donor milk worldwide. Participation in an HMB network provides transparency in documentation of processes and results to better inform and support other HMB systems worldwide.

Cost Considerations in the investment of a human milk bank:

Startup costs:

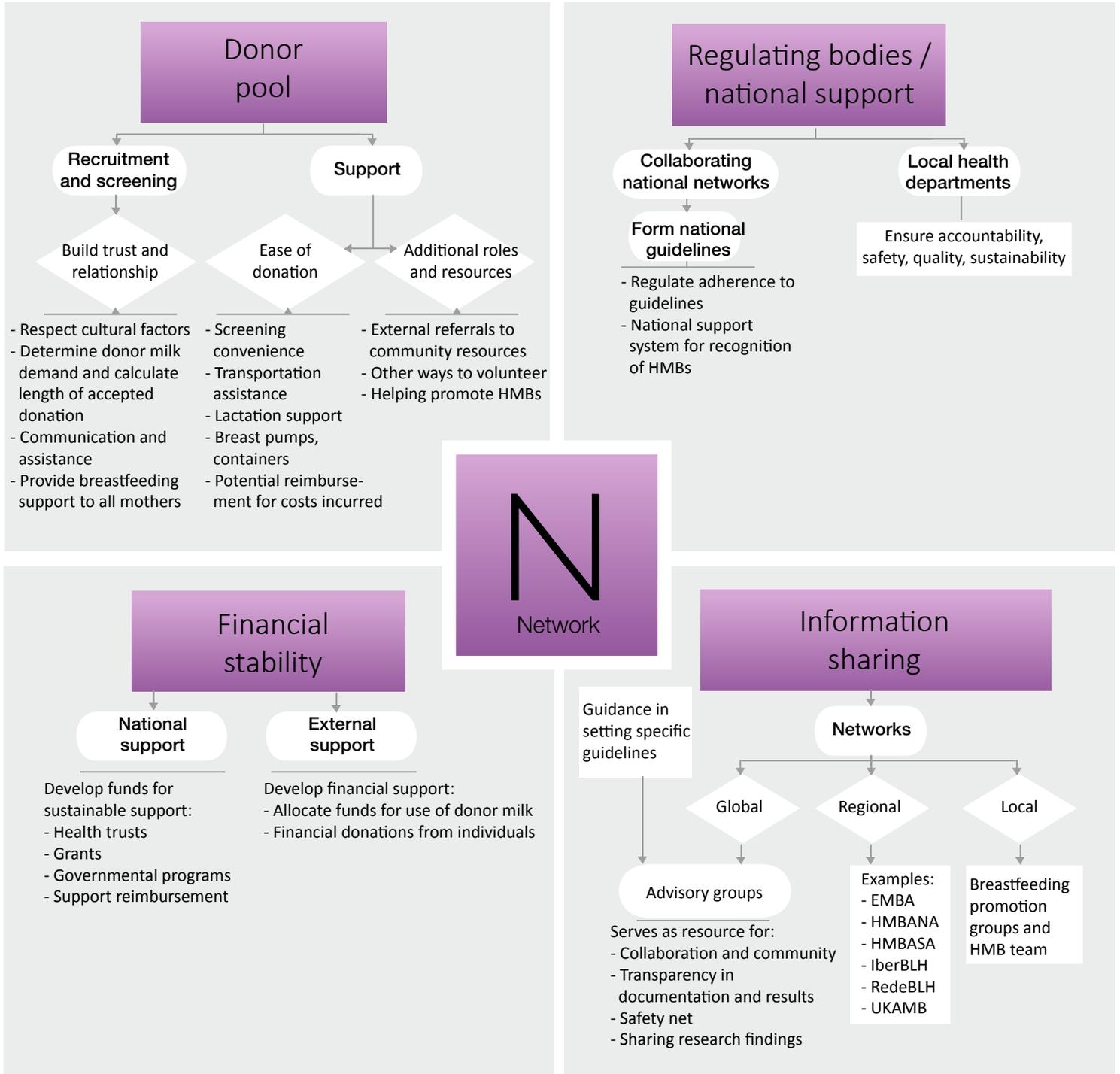
- Training
- Pasteurizer
- Freezer and refrigerator

Ongoing costs:

- Facility and infrastructure (rent, electricity, water, telephone)
- Staffing
- Donor serological testing
- Microbiology equipment or service fee
- Milk storage containers
- Milk transportation
- Cleaning/sterilization supplies
- Equipment maintenance
- Refresher training



Establishing a network



(EMBA: European Milk Bank Association; HMB: human milk bank; HMBANA: Human Milk Banking Association of North America; HMBASA: Human Milk Banking Association of South Africa; IberBLH: Programa Iberoamericano de Bancos de Leche Humana; RedeBLH: Rede Brasileira de Bancos de Leite Humano; UKAMB: United Kingdom Association for Milk Banking)

4. Establishing key protocols

Key protocols are necessary for standardizing processes and ensuring adherence to rigorous quality control methods.

Local and national guidelines and compliance. HMB guidelines should align with infant and young child nutrition guidelines as well as newborn care guidelines. HMBs should develop specific guidelines that adhere to the highest standards possible for the local context to ensure proper practices and support for auditing. In some countries, guidelines are not enforced at the national level, and HMBs must self-regulate as an independent body or network. Comprehensive and accessible record keeping for compliance is essential in the event of any issues that require rapid tracking and tracing of donors, recipients, or batches of milk. If national guidelines do not already exist, they should be developed to provide the basis for supporting human milk banking.

Hazard analysis and critical control points (HACCP). The HACCP process provides a rigorous safety analysis and action plan for the handling and treatment of donor milk. By mapping out the process steps and identifying the points of potential hazards, contamination, or mishandling, HACCP creates checkpoints for preventing issues before they arise. This systematically reduces the risk of spreading disease

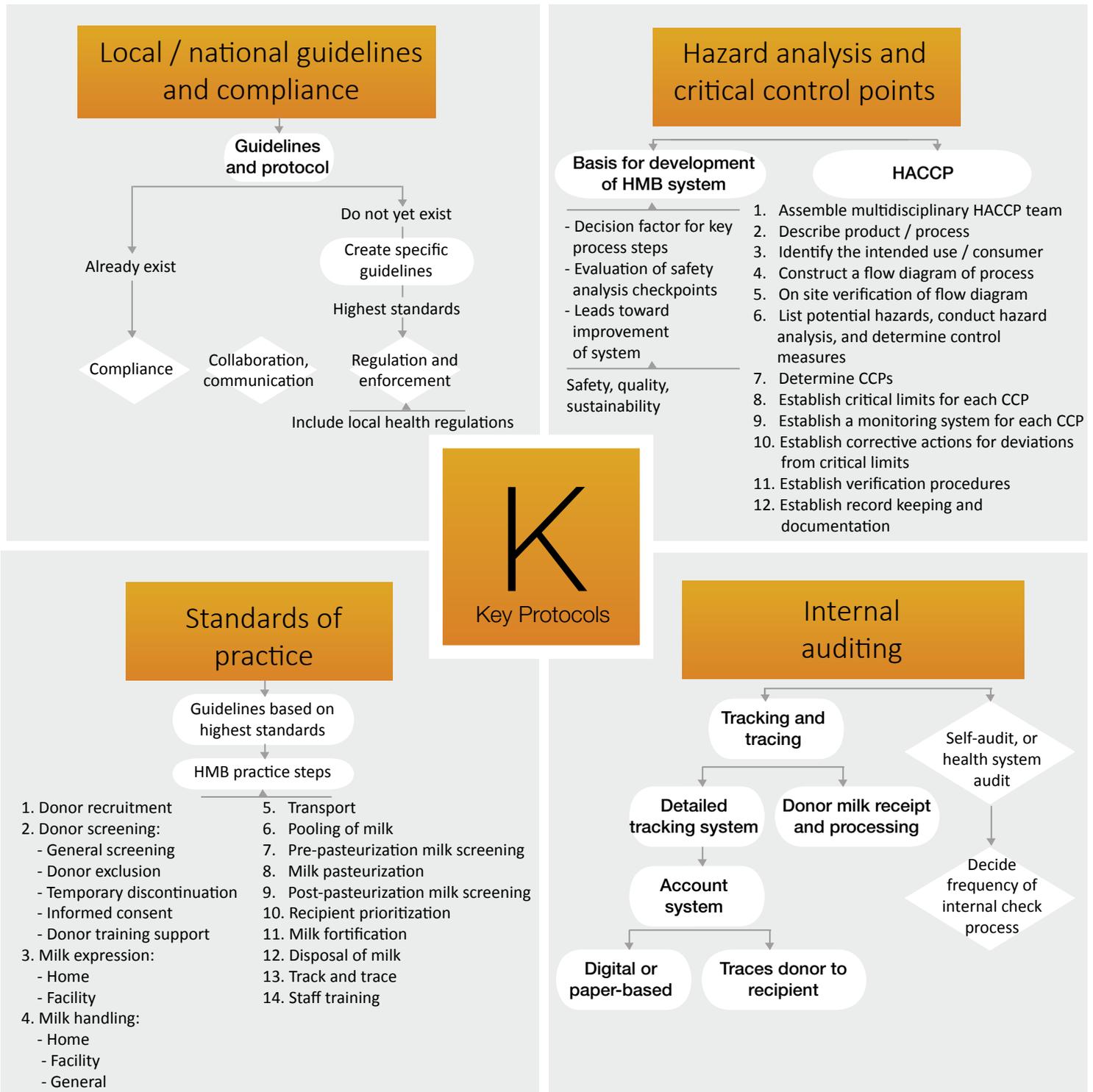
or infection to milk recipients. HMB teams must conduct a unique HACCP assessment for their specific setting to guide operations appropriate for their environment and be adequately equipped to ensure optimal quality and safety. This process is further described in Section 4.

Standards of practice. HMBs need to develop operational guidelines and procedures for each site or system to determine the best practices in each setting. Because requirements vary across settings, each location must decide on the highest standards of practice that can be achieved and which criteria are necessary to screen donors based on the risks involved. Standards of practice encompass every step, from donor recruitment and screening, to milk processing and handling, to delivery to the recipient. For a compilation of current practices from HMBs around the world, see Section 7.

Internal auditing. Every HMB system must account for the receipt, processing, and use of donor milk. Detailed records must allow for immediate tracking and tracing should a rapid recall of milk be needed. Quality control checks of such systems through “recall drills” prepare staff should such a situation arise. Additionally, the accuracy of the record-keeping system should be validated periodically.



Establishing key protocols



(CCP: critical control point; HACCP: hazard analysis and critical control points; HMB: human milk bank)

REGULATION OF DONOR HUMAN MILK

The following table outlines considerations when determining the classification of donor human milk for regulation purposes. Each particular classification can affect accessibility of donor milk as well as costs associated with regulatory

CLASSIFICATION	DEFINITION	REGULATION
<p>Donor Human Milk as a Food</p>	<p>A nutritious substance, optimal for growth and development. Human milk contains the appropriate amounts of fat, carbohydrates, protein, vitamins, minerals, digestive enzymes, hormones, and protective antibodies to help infants resist infections as well as optimally grow and develop physically and neurologically.</p>	<p>The food industry is responsible for producing safe food, with a focus on preventing contamination.</p> <p>Authoritative agencies set food safety standards, conduct inspections, ensure standards are met (compliance), and maintain a strong enforcement program, including recalling contaminated items.</p>
<p>Donor Human Milk as a Tissue</p>	<p>Any human cell, group of cells, tissue, or organ, including the cornea, sclera, or vitreous humor and other segments of the whole eye, bones, skin, arteries, sperm, blood, other fluids, and any other portion of the human body.</p>	<p>Involves a comprehensive regulatory framework which defines a system of reference, such as standards, that provides legally mandated specifications for human milk, a system for ensuring compliance and enforcement, a surveillance system, and accreditation.</p> <p>It is important that regulation address public as well as private activities. An agreement should be reached on requirements and best practices, in particular through the input of professional societies and all stakeholders.</p>



compliance. This table is meant to serve as a guide for governments to determine the most suitable level of regulatory oversight in order to increase accessibility while ensuring the highest level of quality and safety.

POTENTIAL BENEFITS

Signifies the nutritional properties of donor milk.

Regulation may be less arduous and less costly than other types of regulation.

The principles of hazard analysis and critical control points are already instituted for management of critical control points in food safety.

Food regulation is not as rigid or imposing as tissue regulation but still provides safeguards and checkpoints.

May be more economical to the recipient (given the recipient is responsible for the the cost of the donor milk) if it is already included in the hospital's cost of care.

Standardization enhances public protection through consistency of product quality and safety.

POTENTIAL CHALLENGES

Possible barriers to insurance reimbursement.

Possible public perception that the milk is not adequately regulated.

Donor milk has risks as a nonmanufactured product unique from risks associated with the food industry, possibly making it more difficult to regulate than a simple food. Example countries are provided; to obtain country-specific guidelines, see Section 7.

Example country: Brazil

May support insurance reimbursement if recognized nationally as a tissue.

Public may perceive that donor milk is safer due to more specific regulation for tissues since the regulation system is already well established.

Ability to use other tissue-regulating bodies, guiding principles, and tools already developed for donor human tissue.

Allows for accountability and traceability through a high-level quality management system to control the process from donor selection through distribution and use.

Enhances public protection by subjecting donor milk to a standard form of regulation.

Depending on a country's health care system, reimbursement for donor milk is not an issue; therefore, the added cost of tissue regulation may be unnecessary.

Increased regulation may create barriers to accessing donor milk due to cost or product procurement.

May not be the best use of limited resources for maximum impact on public health considering that the risks associated with human milk are unique from the risks associated with human tissue.

Requires national consistency of regulations and guidelines. Countries' limited resources may inhibit the ability to comply with quality and safety requirements.

Costs associated with regulation can be high, such as registration fees and preparation for inspection and surveillance. Many countries lack regulatory frameworks for human tissue.

Example country: France

REGULATION OF DONOR HUMAN MILK

CLASSIFICATION	DEFINITION	REGULATION
<p>Donor Human Milk as a Nutrition Therapy or Medical/Functional Food</p>	<p>A food that is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.</p> <p>Specially formulated and processed food consumed or administered generally under the supervision of a physician. It is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation.</p>	<p>Government bodies for food and drug safety and regulation provide classification criteria, safety protocols, and restrictions for the sale of nutritional therapy and supplement products.</p> <p>Products must meet certain safety requirements through Good Manufacturing Practices and show that there is no harm to the individual receiving the product.</p>
<p>Donor Human Milk as an Undefined Class</p>	<p>Excess human milk expressed by a mother, given voluntarily and without remuneration, that is then processed by a donor milk bank for use by a recipient that is not the mother’s own baby.</p>	<p>A human milk bank regulatory body serves as a liaison between member institutions and government regulatory agencies.</p> <p>Quality control of donor milk is ensured through inspections and adherence to guidelines under which all member banks must operate.</p> <p>Guidelines establish best practices based on current evidence. Just as with other donor tissue banking, milk banks rely on extensive testing and processing procedures as well as self-reported health information.</p>



POTENTIAL BENEFITS

May be more economical to the recipient if it is included in the hospital's bundled costs for room and board.

Classification represents the preventive benefits of donor milk as well as the protective properties of immunoglobulins.

Insurance companies are likely to cover donor milk if viewed as therapeutic because of the savings realized in future health care costs.

Potentially greater attention given to regulation for safety than if solely a food.

Individual medical food products may not require registration with a governing body; however, facilities may be subject to registration, depending on the country.

POTENTIAL CHALLENGES

Heavy regulation may create barriers to access.

Costs associated with regulation, especially if it is in a unique classification category that needs new regulation procedures.

Example country: unknown

Current systems that do not classify donor milk have seen success and have a longstanding record of safety without incident.

Comprehensive guidelines that address the collection, processing, and distribution of donor milk are well established and have been utilized effectively in several countries.

Recognizing human milk as its own category acknowledges its distinctiveness in comparison to food, tissue, and nutritional therapy.

Use of the health department for inspection and audit can offer authoritative oversight.

Extra costs associated with regulation may be minimized.

Would require national endorsement by an existing regulatory body, or in some countries, development of a unique regulatory body.

Depending on the health care system, ability to receive insurance reimbursement for donor milk may be difficult.

Example country: United Kingdom

HAZARD ANALYSIS AND CRITICAL CONTROL POINTS

A key to providing safe, high-quality donor breast milk is ensuring that appropriate safety and quality processes are in place. Because environmental and cultural differences among regions served by HMBs lead to differences in risk profiles with respect to donor and recipient populations, it is impossible to establish a single global model for milk banking. Additionally, because each step in the process may introduce a risk of contamination or alter the nutritional and immunological value of the milk, milk banks must develop processes that balance safety and quality within their own contextual needs and limitations.

One approach to developing safety and quality systems in a robust, systematic way is to use the HACCP process (see Figure 9). This process was developed as a management system in which food safety is addressed through the

analysis and control of biological, chemical, and physical hazards from raw materials production, procurement, and handling to manufacturing, distribution, and consumption of the finished product. HACCP is more than quality assurance; it is an action plan.

When HACCP is applied to an HMB, it ensures that each process in the HMB system foundationally supports safety and quality requirements appropriate for that specific environment. Using HACCP when planning for an HMB helps to identify, evaluate, and control hazards, and it provides a systematic way to document this approach, allowing transparency.²⁵ The methodology leverages multidisciplinary teams to map and document high-priority concerns and then develop and monitor improvements that must be made to prevent those concerns from lead-

Implementing hazard analysis and critical control points (HACCP)²³

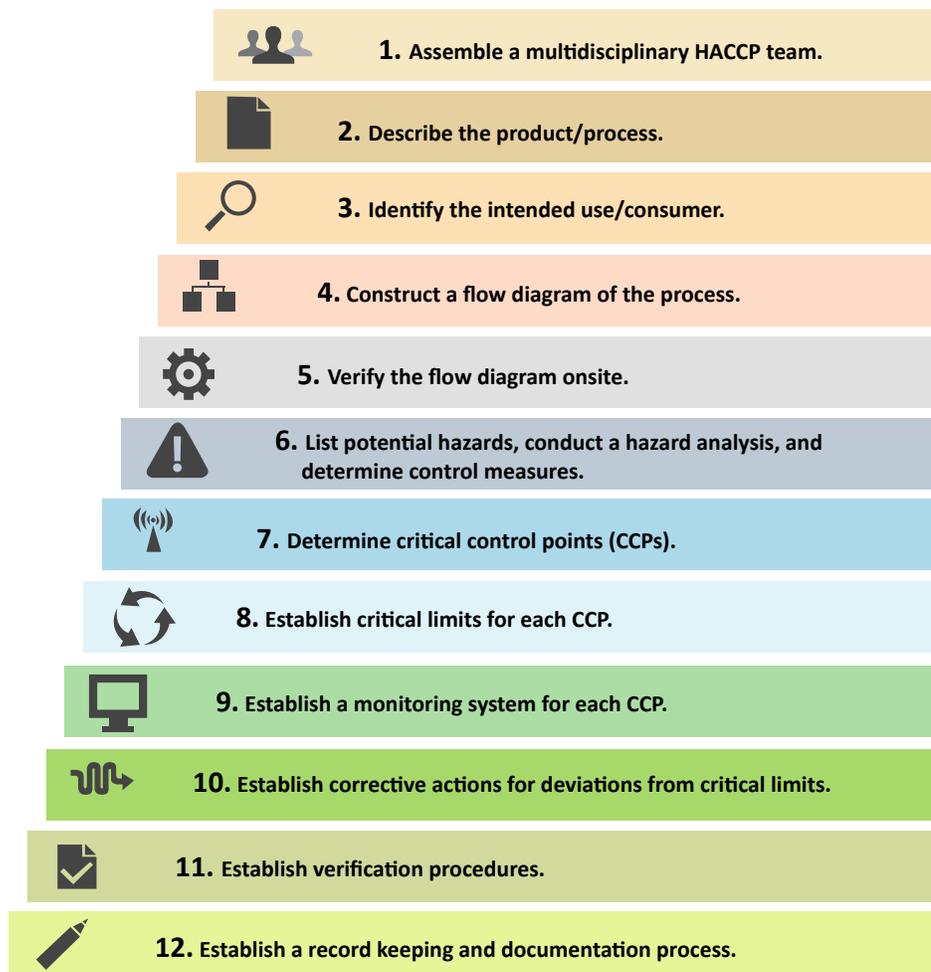


Figure 9: The 12 action steps in implementation of a hazard analysis and critical control points process in a human milk bank system.



ing to safety or quality problems. Both national regulations and self-regulation rely on the HACCP process to determine how to systematically prevent the spread of disease through the mishandling of milk. The following information summarizes the HACCP process and provides resources to learn more.

HACCP identifies additional steps in the HMB process that need to be monitored even though they do not have quantifiable critical limits. These steps are considered Good Manufacturing Practices (GMPs), and may include practices that require specific training or that need to be followed to ensure safety. After determining critical control points (CCPs) or those steps that should follow GMPs, HMB staff must take precautions to ensure that the hazard cannot reach a point of potential harm. When a CCP

does not fall within the established protocol range, corrective measures must be taken to prevent further risk. This system helps to proactively correct steps to ensure safety.

Each setting will have unique process points and corrective measures based on local needs. For example, donor selection and screening may focus on diseases with a higher prevalence in the area served by the HMB, or milk processing may use different technologies for pasteurization based on available resources and electricity. Each country must decide how to use its available resources to ensure the safest and highest-quality donor milk.

Figure 10 shows an example, based on guidelines used in Italy, of recognizing CCPs and GMPs in the process flow.

Determining critical control points²⁶



Figure 10: Classifying hazards as critical control points.

Applying hazard analysis and critical control points in human milk banking²⁷

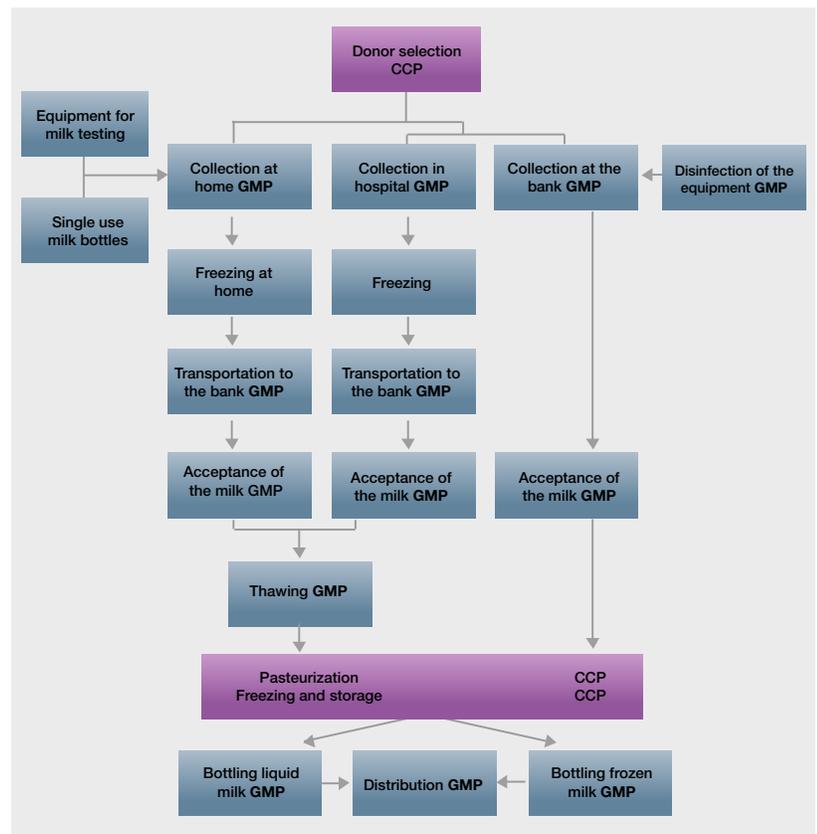


Figure 11: Example of critical control point (CCP) and Good Manufacturing Practice (GMP) identification from Italian HMB Guidelines.

CURRENT PRACTICES IN HUMAN MILK BANKING

Flow of process practices in human milk banking

A human milk bank carries out numerous, complex processes (see Figure 11). This section provides a brief description of each core process. Section 7 presents a compilation of current practices for each of these processes from many of the HMBs around the world.

Donor recruitment

To reach as many potential donors as possible, HMBs use a variety of communication methods. In recruitment efforts, HMBs should ensure that messaging is clear, easy to read, and suitable for all reading levels, avoiding technical language. Also, HMBs may disseminate screening criteria in

their materials so mothers can self-screen before contacting the HMB. Recommended promotional methods include:

- **Media.** This includes print media, such as informational pamphlets left in antenatal clinics, hospitals, places of work, daycare centers, family practice facilities, postnatal wards, maternity shops, children's centers, and other areas. Materials can be widely distributed, especially throughout key health facility areas such as antenatal and maternity wards and well-baby clinics. Other promotional media include online sources, television, and radio, all of which can reach a large, broad audience.

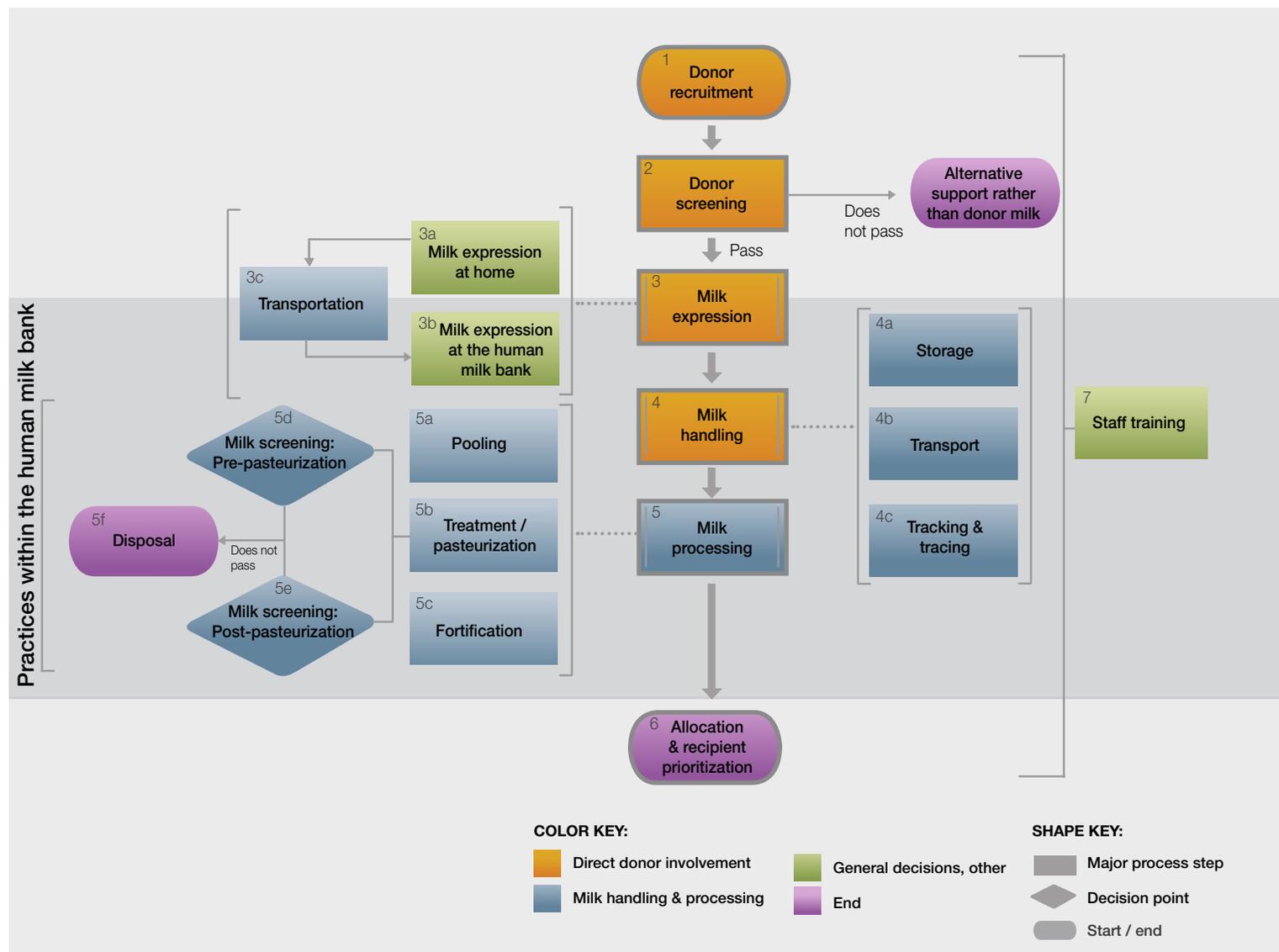


Figure 12: From donor to recipient, choose the best practices for each setting.



- Referrals and recommendations. Antenatal staff, physicians, midwives, nurses, NICU staff, lactation consultants, maternity wards, and nutritionists can promote breastfeeding, and refer and recommend donation to the HMB. During routine care, classes, and support groups for pregnant women or bereaved mothers who have recently lost infants, health personnel can refer mothers to the milk bank. Donating breast milk can be a helpful step in the grieving and healing process.
- Word of mouth. Donors themselves often serve as the best recruiting tool as they talk to friends and family. Because donor mothers are some of the best promoters and recruiters of other donor mothers through word of mouth, follow-up—such as with thank-you notes or newsletters—and continual lactation support is important for future recruitment
- High-visibility advocates. Celebrities, sports stars, or other influential people can serve as powerful community advocates.

Donor screening

Although screening criteria in each setting must be tailored to local concerns and needs, the general guidelines outlined below should be followed to help ensure quality and safety:

- General screening. Potential donors who contact the milk bank should be screened initially through an oral

interview or written questionnaire or a combination of the two. An interview can screen for major criteria such as general health, alcohol consumption, medication and drug use, and previous positive tests for key infections (hepatitis B or C, syphilis, HIV type 1 or 2, and human T-lymphotropic virus [HTLV] type I or II). A follow-up questionnaire completed by the donor can be used to screen for other criteria, such as environmental contaminants, her baby's health, complications, and other health considerations. Finally, the HMB should provide detailed process information to donors to ensure they fully understand the donation process.

- Exclusion criteria. A donor is excluded if she uses recreational drugs or tobacco products, including nicotine patches and gum, drinks excessive quantities of alcohol, takes medications contraindicated during breastfeeding, or tests positive for any of the aforementioned viruses.
- Temporary exclusion. If the donor meets any of the previously mentioned exclusion criteria or develops other adverse health problems during the period of being a donor, she must contact the HMB immediately to determine whether she must stop donating, even if temporarily.
- Informed consent. HMBs obtain written informed consent from each donor, ensuring she understands her responsibility in maintaining the safety and quality of the donor milk. Further consent by the donor's physician or the physician of the donor's baby may be required to

Photo: PATH



CURRENT PRACTICES IN HUMAN MILK BANKING

confirm the ability to donate breast milk. Consent forms should be stored for a specified period of time to provide proof of the donor agreement to donate.

- **Serologic testing.** All donors must undergo serologic testing to confirm their health. HMBs request serologic testing from donors to screen for hepatitis B or C, syphilis, HIV type 1 or 2, HTLV type I or II, and other diseases occurring in the area that may be transmitted in donated milk. Appropriate confidentiality and support systems must be established to ensure patient privacy in revealing the results and referring the woman to her physician for any needed follow-up. This testing may be done onsite at the hospital, or a kit may be sent to the mother for blood testing at her nearest clinic.
- **Excluding mothers.** If a mother does not meet eligibility criteria and is excluded from donation, it should be emphasized that her breast milk is not “bad” and she can safely breastfeed her baby. In special circumstances, such as new HIV diagnosis, the mother may be referred for further information to ensure treatment and safe infant feeding practices. HMBs promote and support exclusive breastfeeding for the first six months of life and continued breastfeeding up to two years of age and beyond if no other concerns arise.

Milk expression

Photo: Brazilian National Network of Human Milk Banks



Mothers can express milk in a variety of locations, including the home, HMB, or hospital. Each HMB decides—based on distance, infrastructure, access to refrigerators and freezers, and transportation availability—locations from where it will accept expressed milk.

- **Home.** The amount of breast milk available for donation is greater when mothers express milk at home rather than at the HMB. When expressing milk at home, donors should store their milk properly and then send it to the HMB when convenient. Expression at home requires a temperature-controlled supply chain (cold chain system) during transportation to ensure the milk remains frozen. Instructions for proper milk expression, storage, and transport are included in informational packets sent to the donor electronically or via mail. Further follow-up and lactation support are provided as requested and needed. HMBs must emphasize the importance of maintaining proper hygiene, handwashing, and storage of milk in suitable containers—preferably plastic, glass, or stainless steel food-grade containers offered by the facility or readily available in the community (such as plastic breast milk bags or standard jars). A variety of guidelines address how long milk can be stored in a refrigerator, whether multiple expressions should be allowed in the same container, and the length of time milk can be frozen at home before transportation to a milk bank (see Section 7 for a summary of global practices).

Additionally, detailed instructions should be provided to donors regarding how to label milk, including the donor’s identification and expression date. Although milk bags are sometimes accepted, they tend to be burdensome to defrost and may make it difficult to pour the milk into containers for treatment. HMBs need to carefully consider the local setting when deciding on specific practices.

- **Facility.** Milk expressed in the hospital or HMB must be immediately transferred to a refrigerator or freezer and must be frozen within 24 hours. Detailed labeling to differentiate and track milk is mandatory. Raw milk should be kept in a clearly labeled location, separate from pasteurized milk, to prevent confusion.
- **Equipment.** Some HMB systems accept only hand-expressed milk, reducing the risk of contamination from milk pump aids. Lactation support and education about the expression of milk, including how to use and clean a mechanical or automatic breast pump, is essential to support the donor mother. Sharing of equipment is rarely recommended unless a proper cleaning system is in place. When possible, HMBs provide breast pumps to mothers, as needed, with detailed cleaning instructions.



Milk handling

Maintaining the highest level of quality control is necessary at all stages of milk handling to avoid contamination. Key guidelines for handling donor milk are outlined below:

- **Home.** Donor milk should be placed in a freezer immediately after expression. When possible, milk is stored in containers provided by the HMB and labeled with the date of expression/freezing, as well as the donor's identification. Donor milk is transported to the HMB for processing within the time frame specified by the HMB, often within three weeks to one month of expression or when the expressed milk has reached the requested volume.
- **HMB.** Donor milk is immediately stored in the freezer unless it will be treated or used within the same day. Containers must be food-grade, sanitary, and labeled with a tracking identification number, along with the donor mother's information and date of collection/freezing.
- **General.** Donors must wash their hands thoroughly before expressing or handling milk. Frozen raw breast milk can be stored for three to six months before pasteurization.

Photo: Queen Charlotte's and Chelsea Hospital Milk Bank, London



Photo: Queen Charlotte's and Chelsea Hospital Milk Bank, London

Transport

Maintaining appropriate refrigeration or freezing temperatures throughout the transportation process is critical to avoid degradation of milk and bacterial growth. Milk that has been at room temperature for more than six hours should not be accepted for donation. In some settings, volunteers provide transportation of donor milk and other medical tissues, such as blood. Other HMB systems use postal services, medical carriers, or first responders for transport. Donor milk is packed in appropriate containers with proper insulation and ice packs to keep the milk at appropriate temperatures.

Pooling of milk

Some HMBs combine, or pool, milk from multiple donors. This practice may increase uniformity in the milk and provide more consistent nutrient content; however, pooling of milk may make it difficult to trace the source of contaminated milk if contamination occurs. If milk pooling is accepted, the HMB must carefully decide whether pooling will be allowed between different donors, the maximum number of donors whose milk may be pooled, and when pooling will take place (before or after pasteurization).

Donor milk treatment options

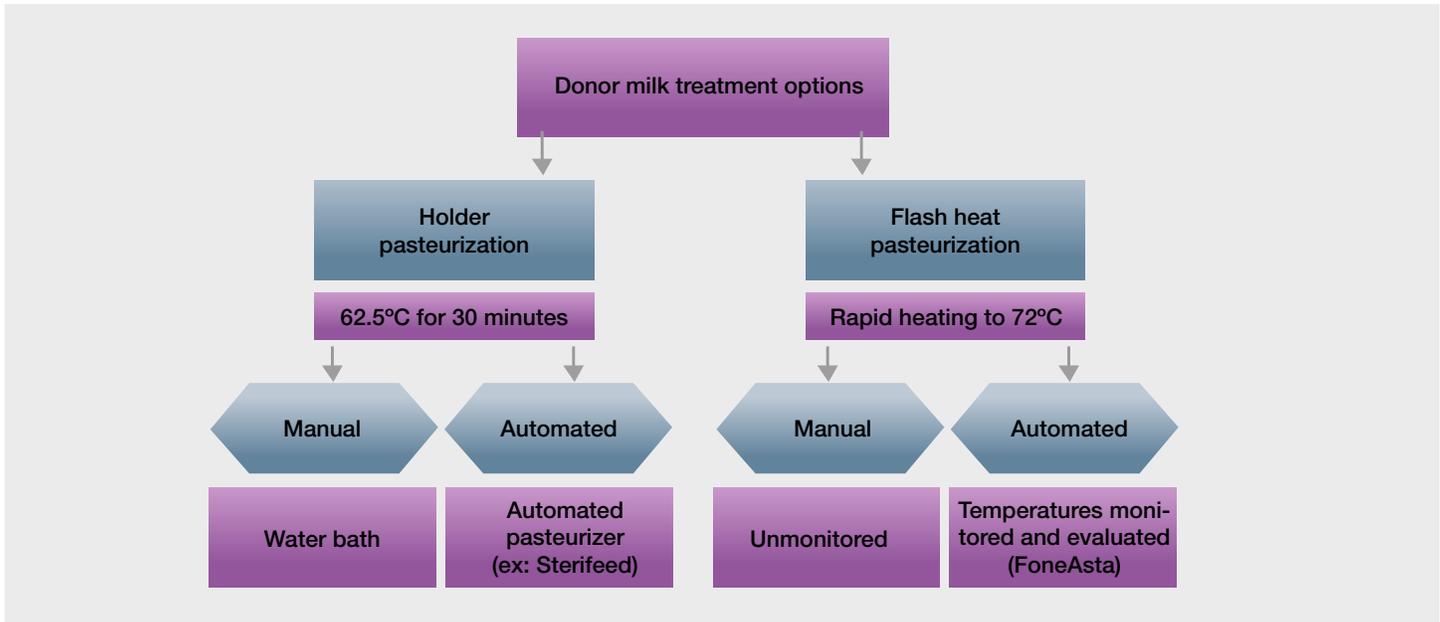


Figure 13: Different treatments for donor human milk currently practiced.

Pre-pasteurization screening

Various pre-pasteurization screening procedures for donor milk exist. Some HMBs choose to test samples of pre-pasteurized milk for microbial content and possible contamination, and others test a single sample of milk for every batch of milk that is eventually pasteurized. Still others test the first batch of milk from each donor at every donation, especially when there is concern about the milk's

Photo: Cheshire and North Wales Human Milk Bank



safety or any change in the mother's practices. Milk can be tested (whether pre-pasteurization, post-pasteurization, or both) for total viable microbial content, Enterobacteriaceae, Staphylococcus aureus, and other undesirable microbes and contaminants. Other testing methods may include qualitative assessment measures.

Pasteurization

Precise pasteurization methods are necessary to heat milk to temperatures capable of inactivating bacteria, viruses, and other potential pathogens while limiting the impact on the milk's protective elements, such as proteins, antibodies, and vitamins. The method of pasteurization varies by HMB setting and includes both lower-cost manual systems and automated systems. The most common practice is considered a long-time, low-temperature pasteurization method known as Holder pasteurization, which involves heating donor milk at 62.5°C for 30 minutes (see Figure 13).

Higher-temperature methods of shorter duration—such as flash pasteurization, which the dairy industry uses to heat milk to 72.0°C for 15 seconds—may be more effective at retaining milk properties. However, a feasible mechanism that is low cost and simplified for an HMB's lower breast milk volumes does not currently exist. A simplified alternative could be flash-heat pasteurization, which involves heating milk in a water bath to 72.0°C, then rapidly cooling



the milk. Each HMB must select a pasteurization method based on its financial, staffing, and energy resources.

Post-pasteurization screening

Screening donor milk after pasteurization is a good practice to monitor for contamination introduced after the pasteurization process or to monitor for failed pasteurization. Levels of screening are dictated by resources; some HMB systems test each sample, whereas others test batches only on a designated schedule. Although post-pasteurization screening is an additional cost, the greater the screening, the greater the likelihood of identifying contaminated milk and preventing problems. To ensure the safety of donor milk recipients, pasteurized milk must be discarded if any microbial content is found. In some facilities, milk is tested for nutritional content using a nutrient content analyzer.

Disposal of milk

Depending on local disposal requirements, an HMB determines whether donor milk is discarded down the drain or treated as other clinical waste.

Milk fortification

Although donor human milk may be fortified to increase macro- and micronutrient content based on an infant's individual needs, it is not a universal practice. Further research is required for the benefits of milk fortification in preterm infants.²⁹ The attending physician and clinical staff determine whether the donor milk should be altered in any way to meet the specific needs of the infant.

Recipient prioritization

Although it is beyond the scope of many current HMBs to determine recipient criteria, they do work closely with attending physicians to appropriately determine how to best use the donor milk currently in stock. HMBs should prioritize the use of milk from the infant's own mother when available, then donor milk when necessary. Infants designated as high priority typically include preterm infants or those of very low birth-weight, as well as infants with necrotizing enterocolitis.²⁸ Recipient prioritization is a continual process, determined at the clinical level, especially where donor milk availability is limited.



Photo: Brazilian National Network of Human Milk Banks

Delivery to the recipient

Stored donor milk is generally defrosted by refrigeration before it is fed to the infant. Caregivers follow feeding protocols as determined by the clinic, and feeding tubes should be changed at appropriate intervals to prevent bacterial contamination. HMBs and clinics accepting milk from the HMB should jointly establish a documentation system for monitoring how donor milk is used to allow for potential tracking and tracing.

Track and trace

Most HMBs establish a system to track donor milk from donor to recipient or recipient hospital. Tracking includes recording the temperatures of storage equipment, pasteurization processes, dates of expression and pasteurization, and batch information. Records are kept for the period of time specified in the local protocol for clinical records. HMBs establish a method to test the tracking/tracing system at a predetermined frequency.

Staff training

Comprehensive training should be provided to all staff and should cover lactation support, technical procedures/practices, hygiene, quality and safety controls, and policies. Continual refresher trainings are needed to reinforce appropriate procedures and practices. In-service training should also be incorporated, to allow students of medicine, nursing, nutrition, microbiology, midwifery, and psychology to rotate through the HMB to gain an understanding of the process and, in turn, become HMB advocates.

CONCLUSION

Breast milk is critical for newborn health and provides optimal nutrition, laying the best foundation for a healthy and productive life. As such, breast milk is considered a pillar of child survival, as highlighted in the recent 2013 Lancet illustrating that effective breastfeeding has greater impact than water and sanitation interventions.² It has unique immunological and nutritional properties that help infants get a healthy start in life.

Provision of donor milk fills an important role in ensuring availability of breast milk for vulnerable newborns and in doing so, supports exclusive breastfeeding. In cases where a mother's own milk is not available, the WHO criteria states that donor milk should be considered as the next option. Human milk banks are a critical mechanism for providing safe donor milk to such infants who need it most, such as pre-term or low birth weight infants in a neonate ward or those who are orphaned.

Milk banks save lives and should be a key part of any integrated newborn health and nutrition program. They fill the tangible unmet need for donor milk as well as provide an anchor for exclusive breastfeeding promotion and support, serving the broader community and improving breast feeding utilization. In light of the significant impact human milk banks can have on infant health outcomes, the WHO has asked member countries "to promote the safe use of donor milk through human milk banks for vulnerable infants."

This framework presented the critical components required for an effective human milk bank program. Regardless of geographic location or available resources, core requirements and quality principles should be universal for all HMBs. Key pillars that support HMB operations should include safety and compliance with local and national policies, quality assurance to provide the best nutritional benefit possible, networking and information sharing, advocacy and promotion for all breastfeeding mothers, and sustainability of donor milk supply through sound business practices. The information presented in this framework

should be used as a toolkit to build upon these principles and develop processes specific to meet local needs. Processes for collecting, handling and processing donor milk should be based on current practices and the existing evidence base as well as developed in alignment with a community's needs and resources to effectively provide a lasting solution for infant care.

Breastfeeding is the cornerstone of the HMB system; raising awareness of breastfeeding increases donor availability, creating a cycle of optimal breastfeeding practices. HMBs can serve a dual role as lactation centers throughout a country, extending the capacity for providing for support for optimal breastfeeding and infant feeding practices, as well as providing safe donor milk to neonates in need. A mother-and-baby-friendly integrated approach to HMB instills a culture of breastfeeding both within the facility and throughout the community.

To achieve this, effective HMBs must be built upon effective strategies to protect, promote and support breastfeeding. Protecting breastfeeding in turn promotes and protects human milk banking. Global, national and regional level policies should be established to ensure that robust infant and young child feeding guidelines are in place, in addition to legislation that protects, promotes, and supports breastfeeding mothers. National commitment and coordination is required to guarantee that policy translates into action; adequate resources must be provided for developing strategies and implementation plans for safely and effectively integrating human milk banking into breastfeeding promotion and newborn care programs.

The global health community has an ethical obligation to strengthen human milk banking systems around the world. It is a shared responsibility among governments, medical professionals, non-governmental organizations, and policymakers to establish and enforce robust and collaborative systems that ensure safe donor breast milk is available to all infants who require it.



SUMMARY OF CURRENT PRACTICES IN HUMAN MILK BANKING

Current human milk banking practices in country - specific guidelines

Donor recruitment

Recruit through a variety of channels, including: W=written material (in antenatal clinics, maternity shops, etc.), R=referrals (by donors, physicians, staff), M=mass media, P=programs/educational guidance

Use clear, nontechnical language when recruiting

Recruit bereaved mothers

Donor screening - general

Screening involves an oral or written (informal) interview

Statement of health is required by donor's physician and by donor's child's physician

Screening information includes: G=general health, C=donor's child's information, M=medications, E=environmental exposure, I=infection exposure, V=vaccination

Serological testing of donor is required (asterisk [*] indicates testing required if finances available for hepatitis B and C testing)

Antenatal/pregnancy tests are acceptable to show test results

Donor screening - exclusion criteria

Potential donors are excluded for drinking more than ____ units of alcoholic beverages per ____ (time period) (C=consistent alcohol intake)

Potential donors are excluded for: S=smoking, D=recreational drugs, I=infection (with HIV, hepatitis B or C, HTLV (human T-lymphotrophic virus), or syphilis, or increased risk of CJD), M=medication, B=blood transfusion recipient, P=body piercing or tattoos, T=transplant of organ or tissue in last 12 months, V=vegetarian/vegan (doesn't supplement with B12), X=at risk sexual partner in last 12 m, J=incarceration in last 12 m, R=renal dialysis, A=artificial insemination

Exclusion for spending three months or more in United Kingdom (between 1980 and 1996) or five years or more in Europe from 1980 to present (or risk for Creutzfeldt-Jakob Disease)



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W,R,M	R,W,M	•	W,R,M	W,R,M	W,R,M,P	•	W,R	•	W,R,M	•
√	•	•	•	√	•	•	√	•	√	•
√	√	•	•	√	•	•	•	•	√	•
√	√	√	√	√	√	√	√	√	√	√
—	√	—	—	—	—	—	—	—	•	•
G,C,M,E,I,V	G,C,M,I,V	G,I,V	G,I	G,C,M,E	G,C,M,I	•	G,C,M,E,I,V	G,M,E,I	G,C,M,E,I,V	G,M,E,I,V
√	√	√*	√	√	√	√	√	√	√	√
—	—	√	—	—	√	•	—	—	—	—
1 to 2 units, 1-2 times weekly	2 oz, daily	50 ml, weekly	1 drink daily	2 units, week	Any	30-40cc daily or 100cc wine	1 to 2 units, 1-2 times weekly	•	C	Occasional
S,D,I	S,D,I,M,B,P,T,V,X,J	S,D,I,M,B,P,V	S,D,I,M	S,D,I,M,B	S,I,M	S,D,I,P,T,X	S,D,I,M,B,P	S,D,I,M,T,X,R,A	S,D,V,X	S,D,I,B,P,T,V,X
—	√	—	—	—	—	√	√	√(1yr in UK)	—	•

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SUMMARY OF CURRENT PRACTICES IN HUMAN MILK BANKING

Current human milk banking practices in country - specific guidelines

Donor screening - temporary discontinuation

Donor must inform the HMB if there are any changes, and donor is followed up frequently with general health questions, as donations may be stopped

Based on local HMB donor milk requirements/stock, mothers of children older than a certain age may be asked to stop donating (age of infant)

Informed consent

Before accepting donor's milk, informed consent is necessary from donor

Before administration of donor milk, informed consent is required from recipient's mother

Donor education / support / training

Train new donors in: H=hand washing and hygiene; E=expressing milk, S=storing, cooling, freezing milk; L=labeling, T=transportation, BF=breastfeeding

Ongoing support should be provided, especially for those who repeatedly donate contaminated milk

Milk expression-specific home / HMB / hospital

Advise donors to collect expressed milk rather than drip milk

Encourage hand-expressed milk (especially at home)

Accept pump-expressed milk

If accepting pump-expressed milk, ensure sterilization of pump

When using pumps, provide the most effective for each mother's specific situation



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√	√	•	√	√	√	√	√	√	√	√
√ 12month	•	•	•	•	•	•	•	√ 6month	√ 6month	•
√	√	•	√	√	•	•	√	√	√	√
•	√	√	√	√	•	•	√	•	√	√
H,E,S,L,T	H,E,S,L,T,BF	H,E,S,C,L,BF	H,E,S	H,E,S,L,T,BF	BF,E,S,H	S,E,H	H,E,S,L,T	H	H,E,S,L,T,BF	H,E,BF
√	√	√	√	√	√	•	√	√	√	•
√	√	•	•	√	•	√	√	•	√	√
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√	√	√	•	√	√	√	√	√	√	√
√	√	√	•	√	•	√	√	√	√	√
•	√	√	•	√	—	√	√	•	√	√

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SUMMARY OF CURRENT PRACTICES IN HUMAN MILK BANKING

Current human milk banking practices in country - specific guidelines

Milk expression-specific home / HMB / hospital (continued)

Emphasize hygiene and hand washing

Discourage sharing of breast pumps

Express at least 6, but preferably 8, times every 24 hours

Handling milk - home

Freeze milk for storage (as soon as possible) at home (V=varies)

Maximum storage time length from date of collection before donation to HMB (V=varies)

(Preferably) Only containers provided by HMB should be used (for storage/freezing)

Refrigerate collection of multiple expressions in single container

Do not add freshly expressed milk to already frozen milk

Instructions for defrosting and using milk at home

Handling milk - hospital / HMB

Donated milk immediately placed in freezer, or placed in freezer after testing

Refrigeration/freezer equipment used only for HMB milk purposes

Freezer temperature monitored every... (C=consistently)

Raw and pasteurized milk stored in separate refrigerators / freezers / compartments



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√	√	√	•	√	√	√	√	√	√	√
•	•	√	•	√	•	•	—	•	•	•
•	√	•	•	√	•	•	•	•	•	√
√	√	√	•	√	√	—	√	•	√	•
3months	√	—	•	√	15days	—	3months	•	3months	•
√	—	√	•	√	—	—	√	√	√	√
√	—	•	•	—	•	√	√	•	√	—
•	—	—	•	√	•	√	•	√	•	√
—	—	—	•	√	√	—	•	•	•	—
√	√	•	√	√	√	•	√	√	•	•
√	√	√	•	√	√	•	√	√	√	√
—	24hours	—	Day	Day	Day	•	Day	•	C	C
√	√	√	√	√	√	•	√	√	√	√

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SUMMARY OF CURRENT PRACTICES IN HUMAN MILK BANKING

Current human milk banking practices in country specific guidelines

Handling milk hospital / HMB (continued)

Emphasize hygienic conditions for processing (sterile conditions not necessary)

Wear gloves when handling milk (*=except when working with large volumes in the HMB)

Frozen raw milk is thawed in refrigerator (R) or on counter (C) before pasteurizing

Breast milk from donors is discarded if it does not meet criteria

Storage containers should be labelled with: N=name of donor, DC=date of collection/expression, P=pasteurization, PD=date of pasteurization, #= donor's number, I= identification of bank, F=date of freezing, B=batch number, T=date to be transported to central breast milk bank, M=medications taken by donor

Fresh milk can be kept safely at room temperature for this amount of time

Raw milk can be stored in freezer before pasteurization for a maximum of...

Raw milk can be stored in refrigerator before pasteurization for a maximum of...

Maximum storage freezer temperature

Maximum storage refrigerator temperature

Pasteurized milk can be stored in freezer for a maximum of this number of months (preterm neonate):

After defrosting, pasteurized milk can be refrigerated for maximum of this number of hours

Defrost method: WB=water bath, M=microwave, R=refrigerator, RT=room temperature

Pasteurized milk can be dried and vacuum packed



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√	√	•	√	√	√	√	√	√	√	√
√	—*	•	√	√	√	•	√	•	√	•
—	R	R,C	•	R	R	R	•	•	R	R
√	√	•	•	√	√	•	√	√	•	•
N,DC	DC,P,#,F	N,DC,P,PD,#	DC,#,F,B,T	N,DC,P,PD,#,B	DC,#	DC,P,#,I	DC,P,#	N,DC,P	N,DC,PD,#,I,F,B	PD,#
•	•	6h	•	6h	•	•	•	•	•	•
3m	12m	3m	•	6m	15d	3m	•	•	3m	6m
24h	4-8d	48h	•	24h	12h (-3°C)	72h	•	48h	24h	48h
-20°C	-20°C	-18°C	-20°C	-18°C	-3°C	-20°C	-18°C	-18°C	-20°C	-20°C
—	4°C	4°C	•	4°C	5°C	4°C	•	4°C	4°C	4–6°C
—	12m	6m	6m (3m)	3m	6m	6m (3m)	6m	•	3m	6m
—	24h	24h	24h	24h	24h	24h	24h	•	24h	48h
—	WB,R,RT	WB,R,RT	WB,R	WB,R,RT	WB,M	WB,R	R	•	WB,R	WB,R
•	•	•	•	•	√	•	•	•	—	•

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SUMMARY OF CURRENT PRACTICES IN HUMAN MILK BANKING

Current human milk banking practices in country specific guidelines

Milk handling general

Acceptable containers for storing milk include: F=food grade materials, G=glass bottles/containers, P=plastic bottles / containers, C=clean nonsterile containers, S=strong/rupture-free or resistant containers

Milk bags or plastic bags are not recommended for storage

Seal containers with solid lids

Do not overfill containers; fill to about 3/4 full

Minimize exposure to sunlight and/or phototherapy lights

In places with power supply fluctuations, equipment must be connected to generator

Milk pooling

Pooling allowed of pre-pasteurized breast milk from the same donor; *if milk will be pasteurized, pooling not allowed of non-pasteurized raw milk

Acceptable raw breast milk from different donors can be pooled

Do not pool milk from different donors

Do not pool milk if it has already been pasteurized

Multiple batches (set of bottles that fit into pasteurizer or shaking water bath) can be created from one pool



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F	G,P,C	G,P,C	•	G,P	S	G,P	F	G,P	G,P	F,G,P
—	—	√	•	√	•	√	√	•	√	•
√	√	√	•	•	•	•	•	•	√	√
•	√	√	•	•	•	•	√	•	√	√
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•	•	√	•	•	√	•	•	•	•	•
√	√	•	•	√	√	√	√	√	√	√*
—	√	•	•	—	√	√	—	—	—	—
√	—	•	•	√	—	—	√	•	√	√
√	—	•	•	√	√	√	√	•	√	•
•	√	•	•	√	•	•	•	√	•	•

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SUMMARY OF CURRENT PRACTICES IN HUMAN MILK BANKING

Current human milk banking practices in country specific guidelines

Transport

Ensure donor milk remains frozen during transport

Third-party transport allowed; set up contract to maintain conditions needed

Transport between milk banks is allowed; additional labeling/tracking may be required

Freshly expressed milk is kept safe for up to 24 hours in cooler with frozen gel packs

Small amounts of dry ice can be used in very warm climates to keep ice cold

Pack tightly in cooler, filling all spaces

Container must be insulated, rigid, and easily cleaned

Check and record temperatures throughout transport

Milk screening pre-pasteurization

First donation from donor undergoes bacteriological testing (V=varies)

Further bacteriological testing when donor does not seem to guarantee appropriate hygienic conditions (V=varies)

Random-sample bacteriological testing performed before pasteurization (V=varies)

Milk is bacteriologically screened prior to pasteurization, every batch

Milk is screened for total viable microorganisms

Milk is screened for Enterobacteriaceae (gram-negative bacteria)



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√	√	√	√	√	√	√	√	√	√	√
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•	√	√	•	•	•	√	•	•	•	•
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—	√	—	√	—	—	√	—	•	√	—
√	—	—	•	—	•	—	√	√	—	√
√	—	•	•	—	•	√	√	√	√	√
√	—	•	•	—	•	√	√	—	√	√

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SUMMARY OF CURRENT PRACTICES IN HUMAN MILK BANKING

Current human milk banking practices in country specific guidelines

Milk screening pre-pasteurization (continued)

Milk is screened for *Staphylococcus aureus*

Milk is evaluated / screened for color, off-flavor, foreign bodies/impurities

Technical verification of Dornic acidity

Technical verification of content/creamatocrit

Quality control checks include hazard analysis and critical control point (HACCP) principles

Milk treatment

Type of treatment possible (P=human milk pasteurizer or Holder pasteurization, FH=flash heat pasteurization and shaking water bath (manual), FA=FoneAstra (flash heat, automated); (MOM=Mother's Own Milk)

Treatment/pasteurization temperature

Do not exceed treatment/pasteurization temperature (in monitored controlled bottle) or allow temperatures to oscillate more than

Treatment / pasteurization time length

Rapidly cool sample to at least _____ (temperature) or below (RT=room temperature)

Do not use flash heat pasteurization for frozen/thawed milk

If no automatic stirrer, shake container every 5 min during treatment

Monitor process and record temperatures during treatment



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√	—	•	•	•	•	√	√	√	√	√
•	•	•	•	•	√	•	•	•	•	•
•	•	•	•	•	√	•	•	•	•	•
•	•	•	•	•	√	•	•	•	•	√
√	•	√	√	•	•	√	√	•	•	•
P	P,FH	P,FA, FN	P	P (FH for MOM)	P	P	none, raw milk used + P in some cases	P	P	P (majority) FH
62.5°C	62.5°C	62.5°C	62.5°C	62.5°C	62.5°C	62.5°C	62.5°C	62.5°C	62.5°C	62.5°C
•	63.5°C	•	•	•	0.1°C	•	—	•	± 0.5°C	•
30m	30m	30m	30m	30m	30m	30m	30m	30m	30m	30m
4°C	4°C	•	10°C	10°C	5°C	10°C	4°C	4°C	10°C	RT
•	—	√	•	•	•	•	√	•	•	•
•	√	•	•	•	√	•	—	•	•	•
•	√	•	•	√	√	•	—	•	√	•

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SUMMARY OF CURRENT PRACTICES IN HUMAN MILK BANKING

Current human milk banking practices in country specific guidelines

Milk screening post-pasteurization

Post-pasteurization tests that may be used: T= titratable acidity, P= phosphatase test, M= microbiological cultures, B= bright green bile 2% lactose test

Test milk for microbial content post-pasteurization for every batch

Test milk for microbial content post-pasteurization randomly (V=varies)

Test milk for microbial content post-pasteurization at least once per month, or every 10 cycles, whichever comes first

Discard milk that has ____ total viable microbial content or more post-pasteurization

Re-pasteurize and retest milk that shows contamination; discard if sample still shows contamination after re-pasteurization

Discard opened bottle's milk that is used for testing

Recipient prioritization

All recipients of donor milk will receive heat - processed milk, unless physician requests raw

Donor milk is given only by prescription or hospital purchase order

If need for donor milk is greater than supply, other HMBs are contacted

If demand is greater than supply, prioritization criteria for infants are pre-planned and recorded

Priority feeding is mother's own milk rather than donor milk when possible

Physician is in charge of prescribing or initiating provision of donor milk

Prioritize preterm newborn or low birth - weight newborn



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M	M	T,P,M	M	M	B	M	M	M	M	M
—	√	—	√	√	√	—	√	√	—	—
√	√	√	—	—	—	√	—	—	√	—
√	•	√	—	—	•	√	—	—	•	•
10 CFU/ml	any	any	any	10 CFU/ml	any	any	any	any	any	•
—	—	—	—	√	—	—	—	—	—	•
√	√	√	•	√	—	•	•	—	•	•
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•	√	√	•	√	•	•	√	√	√	√
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SUMMARY OF CURRENT PRACTICES IN HUMAN MILK BANKING

Current human milk banking practices in country specific guidelines

Recipient prioritization (continued)

Prioritize infants with necrotizing enterocolitis

Prioritize infants without access to their own mother's milk or when the mother has a contraindication to breastfeeding/expressing milk (contraindicated medication, sickness, etc.)

Prioritize infants with infections, such as those with gastroenteritis

Prioritize infants taking enteral nutrition

Fortifying donor milk

HMB staff are not responsible for adding anything to the donor milk, or the HMB is not allowed to use additives

Donor milk needs fortification to meet the needs of preterm infants

Use fortifiers at room temperature

Ensure record keeping for any additives

Disposing of donor milk

Dispose of donor milk as with any other clinical waste

Pour down drain or put in sewerage system

Mass quantities of frozen bottles can be discarded as biological waste



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•	√	•	√	•	√	•	√	•	•	√
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SUMMARY OF CURRENT PRACTICES IN HUMAN MILK BANKING

Current human milk banking practices in country specific guidelines

Delivery to recipient

For preterm infants provide warmed milk (W) or hindmilk (H)

Never microwave to defrost or warm milk

Prepare milk according to specifications provided

Change syringes / tubes for feeding every 4 hours

When possible, use fresh milk not frozen

Prioritize preterm infants to receive milk expressed during first 4 weeks

Best feeding methods involve: S=syringe tip pointed up system, B=bolus feedings, ST=shortest tube length, T=shortest possible time to feed, M=mix thoroughly after thawing, C=cup feeding, NB=no bottles, CTF=continuous tube feeding

Match gestational ages of recipient and donor milk expressed

Tracking / tracing

Tracking for HMB should be done from donor to: H=recipient hospital, R=recipient

Tracking includes F=freezer temps, R=refrigerator temps, P=pasteurization processes, S=stock control, D=dates (administration, expression, defrost time, expiration)

All donor milk and containers should be labeled at each stage

Records should be kept for D=donor, C=container before pasteurization, P=pasteurized container, B=batch

Receiving hospital should record / document how donor milk is used



United Kingdom (National Institute for Health & Clinical Excellence)	United States & Canada (Human Milk Banking Association of North America)	South Africa (Human Milk Banking Association of South Africa)	South Africa (KwaZulu-Natal)	South Africa (Milk Matters)	Brazil (Rede Brasileira de Bancos de Leite Humano)	Italy (Associazione Italiana Banche del Latte Umano Donato)	Norway	France (Association Des Lactariums de France)	Switzerland	Sweden
•	W,H	•	•	•	W	•	•	•	•	•
•	√	√	•	√	•	•	√	•	√	√
•	√	√	•	√	√	•	√	√	•	√
•	√	√	•	√	•	•	√	•	√	•
•	√	•	•	—	•	•	√	•	•	√
•	√	•	•	√	•	•	•	•	√	√
•	S,B,ST,T	S,B,ST, M,C,NB	•	S,B,C, NB,CTF	C,NB	•	•	•	S,B,ST, T,CTF	•
•	•	√	•	—	•	•	•	•	√	•
H	R	R	R	R	R	•	R	R	H,R	R
F,P,S	F,R,P,D	F,P,S	F,P,S	F,P,S,D	•	•	F,P,S,D	F,R,P,S,D	F,R,P,D	F,R,P,D
√	√	√	√	√	√	•	√	√	√	√
D,C,P	D,C,P,B	D,C,P,B	D,C,P	D,C,P,B	D,C,P,B	•	D,C,P,B	D,C,P,B	D,C,P,B	D,C,P,B
√	√	√	√	√	√	•	√	√	•	√

Table Key: √ = practice included in guidelines — = not a practice performed • = information not available in guidelines

SUMMARY OF CURRENT PRACTICES IN HUMAN MILK BANKING

Current human milk banking practices in country specific guidelines

Tracking / tracing (continued)

Records should be kept for at least ____ years after expiry date, use, or disposal of donor milk (*or when last recipient reaches 21 years)

When transferring milk from one HMB to another, donor ID and labeling must also transfer to the new HMB

Internal tracking process initiated

Mock recall or recorded test of system done at least every ____ years

Staffing and staff training

HMB staff includes: M=medical officer or neonatologist, C=coordinator, S=specialist in infant feeding or nutritionist, N=nurse, I=infection control specialist, P=personnel or general staff, O=others

Staff are updated and trained at this frequency (C=continuously, Y=yearly)

Staff training includes: H=hygiene, Q=quality control, safety, and tracking/tracing, T=technical procedures (collection, storage, pasteurization), N=infant nutrition, R=legal and ethical regulations)

Staff should be trained in and promote breastfeeding

Staff should have performance evaluations and health checks and be immunized (* performance evaluations only)

Using raw milk / mother's own milk

Milk bank will offer raw milk or mother's own milk

Fresh raw milk can be kept safely for ____ hours at room temperature

Fresh raw milk should be used within ____ hours after expression/collection



United Kingdom (National Institute for Health & Clinical Excellence)	United States & Canada (Human Milk Banking Association of North America)	South Africa (Human Milk Banking Association of South Africa)	South Africa (KwaZulu-Natal)	South Africa (Milk Matters)	Brazil (Rede Brasileira de Bancos de Leite Humano)	Italy (Associazione Italiana Banche del Latte Umano Donato)	Norway	France (Association Des Lactariums de France)	Switzerland	Sweden
30	10*	•	5	10*	•	•	10	•	•	30
•	√	•	•	•	•	•	√	√	•	•
√	√	•	√	√	√	•	√	•	√	√
•	3	•	•	Periodic	•	•	Periodic	•	•	•
•	M,C,S, N,I,P,O	•	M,C,S, N,I,P	M,C,S,N, I,P,O	M,N,I, P,O	•	M,C,S, I,P	M,N, P,O	M,C,S, N,P,O	M,C,O
C	Y	C	Y	C	C	•	C	C	C	•
H,Q,T, N,R	•	H,Q,T,R	H,Q,T, N,R	H,Q,T,R	T,N,R	•	H,Q,T,R	H,Q,T	H,Q,T, N,R	•
•	•	√	√	√	√	•	√	•	•	•
•	•	√	•	√*	√	•	•	•	√	√
—	√	√	•	√	•	√	√	—	√	√
—	•	6	•	6	•	•	•	•	4	•
—	•	48	•	24	•	24	48	•	•	48

Table Key: √ = practice included in guidelines — = not a practice performed • = information not available in guidelines

CONTACTS AND RESOURCES

Guidelines and Milk Bank Contacts

Regional Association	Country	Reference Guideline	Contact Information
Programa Iberoamericano de Bancos de Leche Humana (Ibero-American Network of Human Milk Banks) http://www.iberblh.icict.fiocruz.br/	Brazil, national and regional guidance for outreach countries	Banco de leite humano: funcionamento, prevenção e controle de riscos/Agência Nacional de Vigilância Sanitária. – Brasília, Anvisa; 2008.	http://www.fiocruz.br/redeblh/cgi/cgi-lua.exe/sys/start.htm?tpl=falecomarede_forumulario&natureza=SolicitacaoE7%E3o#
Human Milk Banking Association of North America (HMBANA) https://www.hmbana.org/	United States and Canada	Human Milk Banking Association of North America (HMBANA). Guidelines for the establishment and operation of a donor human milk bank. https://www.hmbana.org/products/publications Published 2011.	info@hmbana.org Kim Updegrove, kim@milkbank.org Frances Jones, francesjones@shaw.ca Pauline Sakamoto, pauline.sakamoto@mothermilk.org
European Milk Banking Association (EMBA) http://www.european-milkbanking.com/	United Kingdom	United Kingdom National Institute of Health and Care Excellence (NICE) Guidelines: Donor breast milk banks: the operation of donor breast milk bank services. http://guidance.nice.org.uk/CG93/Guidance	Gillian Weaver gillian.weaver@yahoo.com
	Italy	Arslanoglu S, Bertino E, Tonetto P, et al. Guidelines for the establishment and operation of a donor human milk bank. Italian Association of Human Milk Banks (Associazione Italiana Banche del Latte Umano Donato). <i>Journal of Maternal-Fetal and Neonatal Medicine</i> , September 2010; 23(S2): 1–20.	Professor Guido Moro guidoemoro@tiscali.it
	France	Marimbert J. The Director General of the French health care products safety agency: considering the public health code, and especially article L.2323-1, L. 5311-1 (8) and R. 2323-1, 2, 3, 4 Decrees. December 2007.	Professor Jean-Charles Picaud jean-charles.picaud@chulyon.fr
	Switzerland	Frishknecht K, Walchli C, Annen V, Fuhrer T, Gianoli P, Stocker M. Recommendations pour l'organisation et le fonctionnement d'une banque de lait en Suisse. <i>Paediatrica</i> ; 2010 : 21 (4).	Kerri Frischknecht kerri.jane@gmail.com



Regional Association	Country	Guideline	Contact Information
European Milk Banking Association (EMBA) http://www.european-milkbanking.com/ (continued)	Sweden	Polberger S, Bonn S, Domelloff M, Ewald U, et al. Guidelines for use of human milk and milk handling in Sweden. Milknet, version 2.0; 2001. English Translation: 2013.	Professor Staffan Polberger Staffan.polberger@skane.se
	Norway	Study on the operation and organization of human milk banks. Utredning om drift og Organisering av morsmelkbanker. IK-2760. Oslo: January 2002.	Anne Hagen Grovslie AnneHagen.Grovslie@rikshospitalet.no
South Africa	South Africa	Human Milk Banking Association of South Africa (HMBASA). Guidelines for the operation of a donor human milk bank in South Africa. Best practice for the collection, storage and handling of human milk. Compiled 2008, updated 2011.	info@hmbasa.org.za Anna Coutsoudis, coutsoud@ukzn.ac.za Louise Goosen, louise@milkatters.org
	South Africa	Milk Matters. South Africa. Operational guidelines: the operation of donor milk bank services. Developed by the Management Committee of Milk Matters. Updated 2014.	info@milkatters.org

Other Resources

Hazard analysis and critical control point resources:

WHO support with HACCP materials:

<http://www.icd-online.org/an/html/courseshacpp.html>

http://www.who.int/foodsafety/publications/fs_management/hacpp_teachers/en/

The Baby-Friendly Hospital Initiative, (BFHI)

<http://www.who.int/nutrition/topics/bfhi/en/>

http://www.unicef.org/nutrition/index_24806.html

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