

STRENGTHENING HUMAN MILK BANKING:
A Resource Toolkit for Establishing &
Integrating Human Milk Bank Programs



**A Global Implementation
Framework**

Version 2.0

Starting every life with mothers' milk

STRENGTHENING HUMAN MILK BANKING: A Resource Toolkit for Establishing & Integrating Human Milk Bank Programs

0. A Global Implementation Framework
1. An Assessment Tool for Determining Facility Readiness
2. Establishing Quality Assurance:
 - a. A Workshop for Developing a Hazard Analysis Critical Control Points Plan—Trainee Workbook
 - b. A Workshop for Developing a Hazard Analysis Critical Control Points Plan—Trainer Guide
 - c. A Guide for Creating Operational Standards
 - d. An Audit Template
3. A Guide for Conducting Monitoring & Evaluation
4. A Training Curriculum Template for Hospital and Human Bank Staff
5. A Guide for Track and Trace Documentation
6. A Guide for Developing a Communications Strategy
7. A Counseling Guide for Engaging Bereaved Mothers

This toolkit was developed as a comprehensive set of templates, standards, and tools to guide critical steps for establishing human milk banking as an integrated component within breastfeeding support and neonatal care, with in-depth focus on readiness, quality assurance, operations, auditing, training, monitoring and evaluation, and communications. These resources are freely available, globally accessible, and should be adapted to the local context to maximize effectiveness.

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FOREWORD

Victor M. Aguayo, Associate Director, Programme Division Chief, Nutrition Programme, UNICEF

Breastfeeding gives children the best start in life. Human milk banks, if embedded in a national programme to protect, promote, and support breastfeeding, can ensure access to human milk for infants who cannot benefit from their own mother's milk. The Global Implementation Framework provides comprehensive information and guidance for countries who are considering the establishment or updating of a human milk bank system.

Laurence M Grummer-Strawn, World Health Organization

World Health Organization guidelines recommend that low birthweight infants who cannot be fed their mother's own milk should be fed donor human milk. Exclusive human milk feeding has been shown to save lives, especially among preterm newborns. In 2008, the World Health Assembly urged Member States to investigate the "use of safe donor milk through human milk banks, and to promote appropriate hygienic measures for storage, conservation, and use of human milk." The documents in this toolkit should help countries to improve methods for ensuring vulnerable babies receive the benefits of human milk, even when their own mothers are not able to breastfeed them.

Hoang Tran, Neonatologist and Vice Director, Da Nang Hospital for Women and Children

All sick and vulnerable neonates need access to life saving human milk, especially in the most critical, first few days of life. Essential guidance, as is provided in this Global Implementation Framework, is vital to support to ensure that hospitals around the world develop safe and effective human milk bank systems that are fully integrated with lactation support and early essential newborn care. Serving as the first human milk bank in Vietnam integrated into a newborn care system, our hospital values the international guidance and opportunities for networking with other human milk banks to ensure safety, learn best practices, and protect, promote, and support breastfeeding.

Ajay Khera, Deputy Commissioner and Public Health Specialist, Ministry of Health & Family Welfare, Government of India

'*Strengthening Human Milk Banking: A Global Implementation Framework*' by PATH focuses on an integrated approach to human milk banking. The 'National Guidelines of Lactation Management Centres in Public Health Facilities' recently released in India has adopted a similar approach to ensure equitable access to human milk for all babies. The earlier version of this document helped understand the global best practices and served as a helpful reference for developing the guidelines.

The guidelines form a part of the national breastfeeding program and propose to establish Comprehensive Lactation Management Centers (CLMCs), which provide breastfeeding and milk expression support to mothers, encourage skin-to-skin contact between mother and baby, and provide safe donor milk to vulnerable babies lacking access to mother's own milk. As we scale up CLMCs in India, this document by PATH will offer valuable guidance in operationalizing new CLMCs, evaluating the existing ones and ensuring their sustainable expansion. Implementing CLMCs as part of a comprehensive newborn care strategy will be critical to increase breastfeeding rates and ensure that every baby receives an exclusive human milk diet, thus improving neonatal health outcomes.

A GLOBAL IMPLEMENTATION FRAMEWORK

Karin Lapping, Program Director, Alive & Thrive

Newborn infants need the best care possible to survive and thrive, including the most sophisticated, personalized medicine available: human milk. Breastfeeding fosters strength, a healthy metabolism, good digestion, a robust immune system, and brain development. Nothing else can support immediate survival, short-term health outcomes, or lifelong benefits in the same way.

Human milk is especially critical for the estimated 32.4 million infants in low- and middle-income countries—27 percent of live births—who are born sick, low-birthweight, or premature. Unfortunately, some infants do not have access to their own mother's milk, often due to maternal illness, a delay in milk production, abandonment, or death. Human milk bank services can provide a diet exclusive to breast milk for newborns who cannot access their own mother's milk. By adapting the approach described in this Global Implementation Framework, we can ensure that every child, including the most at-risk newborns, can access human milk.

Jean-Charles Picaud, Past President of European Milk Bank Association, Department of Neonatal Intensive Care, Croix Rousse Hospital

Donor human milk is essential to reduce the risk of some major complications related to prematurity, both because of its preserved properties and because it helps to avoid the use of formula in preterm infants. It has been shown to increase maternal breastfeeding rates on discharge in this population. Minimum global requirements are needed to ensure safety and quality of donor human milk. **As there is not yet strong evidence to support recommendations for all steps of human milk banking—such as selection of donors, collection, and processing of milk—gathering information about current practices and guidelines worldwide is useful.** It can help to build coordinated and integrated systems essential to maximize impact on the health of recipients. The revised Global Implementation Framework was developed as a collaborative effort for linked, cohesive global momentum to scale up effective, safe, and sustainable human milk banks.

Lucy Martinez Sullivan, Executive Director, 1,000 Days

At 1,000 Days, we believe that every child—regardless of where he or she is born—deserves a healthy first 1,000 days and the opportunity to reach their full potential. Because we know that breastfeeding gives children the strongest start to life, we are passionate about supporting women to breastfeed and ensuring all babies can reap the incomparable health and brain-building benefits of breast milk. Breast milk is especially critical for babies born too small, too soon, or too sick who often struggle to breastfeed. For these babies, having access to breast milk can often mean the difference between life or death, a thriving future or a lifetime of hardship.

It is why we at 1,000 Days are excited to support efforts to expand access to human milk and to help mothers who want to give their newborns their own milk—a practice that is still too uncommon in neonatal intensive care settings. We are especially grateful to PATH for their leadership in this area and applaud their work to scale up access to high quality human milk banks across the globe.

Amy Manning Vickers, President of the Board of Directors, Human Milk Banking Association of North America

Ideally, every baby across the globe would receive human milk through direct breastfeeding. Human milk saves lives and improves short- and long-term health outcomes, particularly for pre-term and critically ill infants. However, a variety of barriers often prevent access to human milk for babies who need it most. The Human Milk Banking Association of North America (HMBANA) believes in a world where all infants have access to human milk. **HMBANA supports nonprofit milk banking through member accreditation, development of evidence-based best practices, and advocacy of breastfeeding and human lactation to ensure an ethically sourced and equitably distributed supply of donor human milk.**

Fellow partners such as PATH are essential to ensuring equitable access to human milk for babies everywhere. The following pages provide a comprehensive and vitally important resource for implementing solutions that are applicable and sustainable globally.



Photo: © 2008 Min Zaw, Courtesy of Photoshare

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PATH is grateful for the dedication and technical assistance from consultants and graduate student interns who contributed toward this work, especially Gillian Weaver for strategic direction and Alessandra DeMarchis for coordinating changes for this second version. PATH also acknowledges the nearly 700 human milk banks operating in more than 60 countries that are dedicated to providing safe donor human milk and saving infants' lives. The work to develop the Framework was supported by a grant initially from the Bill & Melinda Gates Foundation and recent updates for version 2 were supported by a grant from the Family Larsson-Rosenquist Foundation. The findings and conclusions

expressed herein are solely those of PATH and do not necessarily reflect the positions or policies of the Bill & Melinda Gates Foundation or the Family Larsson-Rosenquist Foundation. The development of *Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Banks*, a comprehensive package of globally accessible resources and standards to save newborn lives, was possible due to the generous financial support from the Family Larsson-Rosenquist Foundation.

Technical leadership for the conceptualization and development of this Framework and the overarching toolkit was provided by Kiersten Israel-Ballard and Kimberly Mansen in PATH's Maternal, Newborn, and Child Health and Nutrition Program.

We recognize the collaboration, dedication and innovation in global leadership from the PATH newborn nutrition and human milk banking teams (and numerous partners) around the world that have contributed towards informing the development and appropriateness of these tools—India: Ruchika Sachdeva, Praveen Kandasamy; Kenya: Angela Kithua, Rosemarie Muganda; United States: Cyril Engmann, Laura Meyer; Vietnam: Nga Nguyen Quynh, Nga Nguyen Tuyet.



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Photo: Northwest Mothers Milk Bank

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ABBREVIATIONS

BANK	<i>Base, Awareness/Advocacy, Network, and Key Protocols</i>	HMB	<i>human milk bank</i>
BFHI	<i>Baby-friendly Hospital Initiative</i>	HMBANA	<i>Human Milk Banking Association of North America</i>
BPD	<i>bronchopulmonary dysplasia</i>	HTLV	<i>human T-lymphotrophic virus</i>
CCP	<i>critical control point</i>	MOM	<i>mother's own milk</i>
DHM	<i>donor human milk</i>	NEC	<i>necrotizing enterocolitis</i>
GMP	<i>good manufacturing principles</i>	NICU	<i>neonatal intensive care unit</i>
HACCP	<i>hazard analysis and critical control points</i>	ROP	<i>retinopathy of prematurity</i>
Hep B/C	<i>hepatitis B and C</i>	UNICEF	<i>United Nations Children's Fund</i>
HIV	<i>human immunodeficiency virus</i>	WHO	<i>World Health Organization</i>

ABOUT THIS FRAMEWORK

Donating breast milk 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 to support and normalize breastfeeding and human milk while also educating communities on the disadvantages of formula feeding and saving newborns' lives when their mother's own milk is unavailable. Despite the irrefutable evidence in support of the provision of donor milk, the majority of vulnerable infants around the world in need of this lifesaving intervention do not have equitable access to it, primarily due to lack of awareness, supportive policy, and resources.

More than 60 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 the vast knowledge, experience, and evidence to inform the creation and expansion of human milk bank programs and the integration of these programs into existing maternal and infant health care systems. PATH, an international health organization that drives transformative innovation to save the lives of women and children, sought to develop a resource framework to simplify access to this global knowledge base. Increasing our understanding of existing human milk bank processes and lactation support resources is an essential step to ensuring equitable access to human milk and increasing public awareness and informing policy to support breastfeeding and the use of donor human milk if needed. Drawing on the experiences of milk banks and lactation support programs from around the world, PATH has developed this document as a resource framework that ministries of health, policymakers, implementers, and existing and emerging human milk banks can use to identify the critical components required for an effective human milk bank program and gain access to the knowledge and resources needed to strengthen and integrate human milk banking systems into existing maternal and newborn care systems.

This framework outlines the core requirements and quality principles that should be universal for all human milk banks. We present a compilation of critical 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 framework is not intended to provide specific recommendations since universal human milk banking guidelines are neither feasible nor appropriate due to the 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 and breastfeeding community, and empowering policymakers, health departments, health care facilities, and health workers with the tools and information they need to develop and support locally appropriate human milk banks as one strategy to protect, promote, and support breastfeeding. Ultimately, our goal is to ensure that all vulnerable infants around the world have equitable access to lifesaving human milk, through breastfeeding or donor human milk if needed.

Updated in 2018, the revised version of this Framework has the added strength of weaving together the human milk banking resources developed by PATH as part of the ***Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs***. In addition to helping programs identify the critical components required for an effective and individualized human milk bank program, the added contribution of this Framework provides access to tools, standards, and knowledge needed to establish a new human milk bank and evaluate, monitor, and improve those already existing. This updated Framework 2.0 also contains additional sections and content on sustainable systems, evidence generation and dissemination, safety systems, the breadth and range of practices and policies, ethical issues, and the impact and importance of human milk regulation and policy support for the equitable access of human milk for all infants.

SECTION 1: ENSURING AN EXCLUSIVE HUMAN MILK DIET FOR OUR MOST VULNERABLE

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 crucial for small babies—those born either prematurely or those born small for gestational age—and those born in resource-limited settings. These vulnerable neonates are at highest risk for poor outcomes related to morbidity and mortality. Compared to children who breastfeed for shorter periods of time or do not breastfeed, children who are able to breastfeed for longer time have lower infectious morbidity and mortality, fewer dental malocclusions, and higher intelligence.² Suboptimal breastfeeding increases the risk of child mortality, annually resulting in 823,000 deaths worldwide in children younger than five years, according to 2016 figures published in *The Lancet*.²

In recognition of the vital role breast milk plays in boosting infants' health, the World Health Organization (WHO) and United Nations Children's Fund (UNICEF) recommend supporting mothers to exclusively breastfeed

for the first six months of a child's life, followed by continued breastfeeding up to two years of age and beyond.³⁻⁵ To further this recommendation and ensure more mothers around the world have equitable access to the support and resources they need for maintaining breastfeeding and adequate milk supply, infant health and their own health, the WHO and UNICEF established the Baby-friendly Hospital Initiative (BFHI) with more recent recommendations calling for "mother-friendly care" and integration of maternal and newborn care into lactation support initiatives.^{6,7} These initiatives encourage health facilities to implement the Ten Steps to Successful Breastfeeding, which encourage a supportive, family-centered environment for breastfeeding and continuity of care before, during, and after birth, including critical support for the mother and infant after hospital discharge. Protection, promotion, and support of breastfeeding is also highlighted as essential for the achievement of many of the United Nation's Sustainable Development Goals by 2030, which include maternal and child health, poverty, education, inclusive economic growth, and reducing inequalities.²

BOX 1. FOCUS ON MOTHER'S OWN MILK.

Ensuring the provision of mother's own milk (MOM), through direct breastfeeding when possible and cup feeding or tube feeding human milk when necessary, is the ultimate goal for small babies. Donor human milk (DHM) should not be used to replace MOM but should instead serve only as a bridge to ensure an exclusive human milk diet as the mother is supported to build her milk supply. When possible, in the event of no or insufficient breastfeeding, it is essential to encourage and support mothers to frequently and fully express their own milk to provide to their infant and build their milk supply. To avoid undermining efforts to breastfeed, the proportion of DHM supplemented to an infant should decrease as the supply of MOM increases. Breastfeeding education and lactation support are crucial for demonstrating to mothers the superiority of their own milk compared to DHM.

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Unfortunately, some infants do not have access to their mother’s own milk (MOM), leaving them particularly vulnerable.⁸ 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 small babies and those who are orphaned, are severely malnourished, or are in resource-limited settings—have access to human milk. When MOM is limited or unavailable, donor human milk (DHM) can be used to supplement partial or provide full feeds, with lactation support simultaneously provided to the mother (Box 1). Access to human milk is essential for proper growth, nutrition, and the prevention of infections or other complications that

may lead to longer-term care, expenses, or premature death. Table 1 presents an overview of the research supporting the use of DHM for vulnerable infants without access to their MOM. Additional randomized controlled trials, observational studies, systematic reviews and meta-analyses are needed to confirm the impact of DHM on long-term cognitive and motor development, sepsis, retinopathy of prematurity, as well as additional cost components and long-term economic outcomes, especially associated with exclusive human milk diets through six months. Section 5 discusses the importance of evidence generation in increasing the impact and appropriate use of DHM.

Table 1. Studies demonstrating the impact of human milk and donor human milk on vulnerable infants.

NECROTIZING ENTEROCOLITIS (NEC)
▶ Human milk feedings, whether mother’s own milk or donor milk, significantly reduce the incidence of any NEC. ⁹⁻²¹
BRONCHOPULMONARY DYSPLASIA (BPD)
▶ There is a positive effect of donor human milk (DHM) supplementation on incidence of BPD in very preterm and very low birth weight infants. ^{13,22-25}
FEEDING TOLERANCE
▶ There is a higher incidence of diarrhea and feeding intolerance among formula-fed pre-term and low birth weight infants. ^{4,6,7,26-30}
BREASTFEEDING RATES
▶ A single systematic review shows a significant positive impact on any breastfeeding on discharge after the introduction of DHM to neonatal units. ^{3,10,31-33}
REDUCE LENGTH OF STAY IN NEONATAL INTENSIVE CARE UNIT (NICU)
▶ Human milk feeding reduces the hospital length of stay. ³⁴⁻³⁶ The cost of providing donor human milk to preterm infants is mitigated by a reduced risk of complications and shorter length of stay in NICU. ^{9,21,37}
SEPSIS
▶ The meta-analyses of observational studies show nearly significant reduction in the incidence of long-term sepsis with an exclusive human milk diet. ^{1,6,13,17,19,38}
RETINOPATHY OF PREMATURITY (ROP)
▶ Current meta-analyses show a potential protective effect of human milk feeding and exclusive human milk feeding in preventing any-stage ROP and severe ROP. ^{1,15,17,19,39}
COST SAVING
▶ Increasing the use of human milk can provide cost-savings through the reduction in NEC. ^{4,9,21,31,40-42}
NEURODEVELOPMENTAL OUTCOMES AND LONG-TERM BENEFITS
▶ Individual randomized control trials and observational studies show that preterm infants who receive human milk feedings have lower rates of metabolic syndrome, greater white matter, brain volumes, head circumference, and significantly higher scores for mental, motor and behavior ratings at later ages in childhood and adulthood. ^{28,43-50}

Because of the demonstrated disadvantages of formula feeding relative to human milk for all infants, WHO recommends DHM as the next best infant feeding option when MOM is unavailable, as shown in Figure 1.^{51,52} It has called on member nations to investigate the safe use of DHM through human milk banks (HMBs) for vulnerable infants (Box 2). By

investing in establishing an integrated newborn nutrition program, including an effective HMB system, governments can ensure that infants receive optimal care through access to a safe, high quality, sustainable supply of human milk, providing these infants a bridge to fully receiving MOM and ensuring them the best chance at a healthy start in life.^{53,54}

Figure 1. World Health Organization guidelines on optimal feeding of low-birth-weight infants (2011).

No.	Recommendation*	Type of recommendation	Quality of evidence (at least 1 critical outcome)
What to feed?			
a. Choice of milk			
1.	Low-birth-weight (LBW) infants, including those with very low birth weight (VLBW), should be fed mother's own milk.	<i>Strong</i>	<i>Moderate</i>
2.	LBW infants, including those with VLBW, who cannot be fed mother's own milk should be fed donor human milk (recommendation relevant for settings where safe and affordable milk-banking facilities are available or can be set up).	<i>Strong situational</i>	<i>High</i>
3.	LBW infants, including those with VLBW, who cannot be fed mother's own milk or donor human milk should be fed standard infant formula (recommendation relevant for resource-limited settings). VLBW infants who cannot be fed mother's own milk or donor human milk should be given preterm infant formula if they fail to gain weight despite adequate feeding with standard infant formula.	<i>Weak situational</i>	<i>Low</i>
4.	LBW infants, including those with VLBW, who cannot be fed mother's own milk or donor human milk should be fed standard infant formula from the time of discharge until 6 months of age (recommendation relevant for resource-limited settings).	<i>Weak situational</i>	<i>Low</i>

BOX 2. DEFINING HUMAN MILK BANK AND DONOR HUMAN MILK.

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. The mission of an 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. A high-performing HMB is grounded in four foundational activities, with key pillars that support HMB operations (Figure 1).

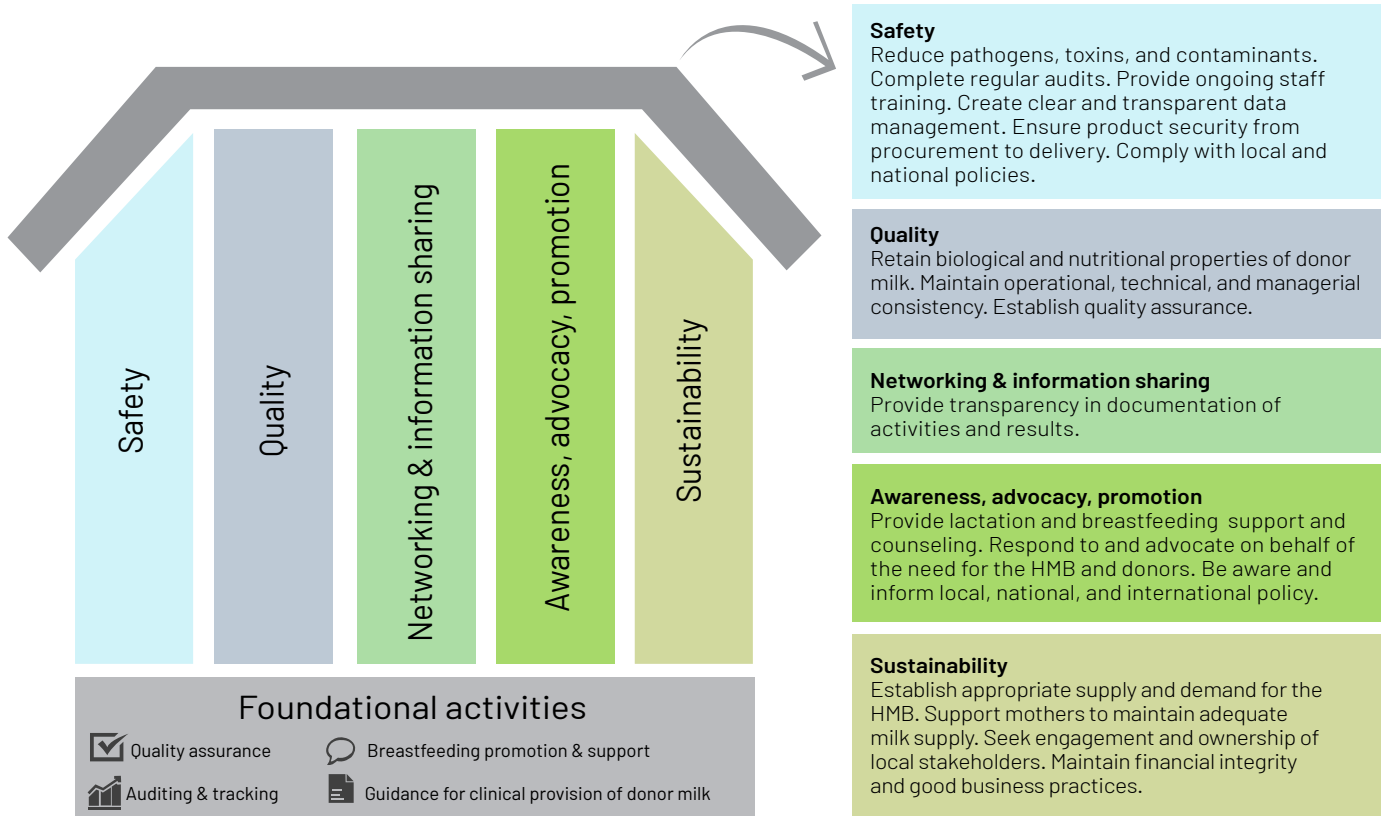
Donor human milk:

Donor human milk (DHM) is human milk in excess of an infant's current and future needs that is donated by a mother to an HMB for use by a recipient infant that is not the mother's own infant. DHM is offered voluntarily and without payment to the donor mother and is provided to the recipient infant based on clinical necessity. DHM is not an alternative to mother's own milk but is instead used as an alternative to formula to serve as a bridge to ensure an exclusive human milk diet as a mother is provided lactation support to build her milk supply for her own infant.

To provide safe and high-quality donor milk, an HMB should have a firm foundation. All milk banks adapt to the restrictions, resources, and

needs of their local area, yet they share a similar foundation built on key pillars and activities as shown in Figure 2.

Figure 2. Foundation and key pillars of a human milk bank.



Breastfeeding: The cornerstone of ensuring effective human milk banks

The primary goal of an HMB is to protect, promote, and support breastfeeding. For successful donations, 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, family, and peer support as well as resources to maintain their own health and 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 the nutritional and immunological disadvantages of formula feeding, women experiencing breastfeeding challenges are more likely to seek lactation assistance from both peers and professionals before turning to infant formula or other options. Supporting a mother's sustainable milk supply should always be prioritized, and DHM should never be used as a non-essential replacement for mother's milk or in place of providing necessary support for lactation.

Protecting, promoting, and supporting breastfeeding is critical to optimizing the effectiveness of HMBs. Advocating for policy implementation through governmental leadership and community protection to improve optimal breastfeeding practices and support mothers will subsequently result in a stronger and more effective HMB system. An essential first step in this process includes supporting existing policy efforts, such as the updated BFHI and the WHO International Code of Marketing of Breast-milk Substitutes.⁵⁵ The code, when enforced, protects mothers from marketing that may reduce the use of breast milk as the first choice for feeding infants.

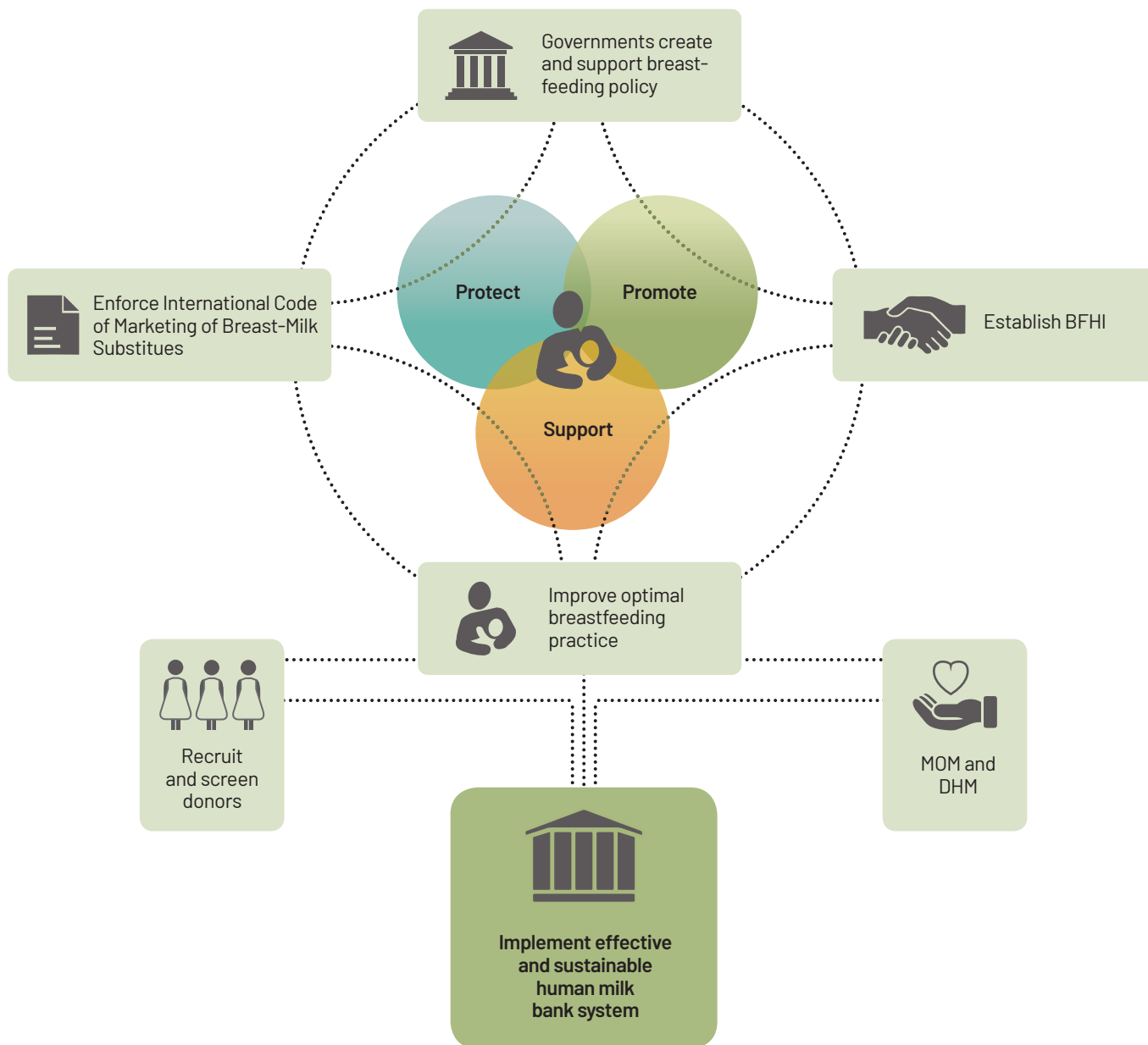
As shown in Figure 3, strong governmental commitment establishes and supports policies to protect, promote, and support breastfeeding, creating a positive breastfeeding environment in the community for breastfeeding mothers and health care providers.³ While many steps are integral to the development of HMB systems, protecting, promoting, and supporting breastfeeding mothers is the cornerstone needed to build sustainable and effective systems that can facilitate equitable access to DHM when MOM is not available.



Photo: PATH/Evelyn Hockstein

STRENGTHENING HUMAN MILK BANKING

Figure 3. Effective human milk bank implementation requires investment in policies by the government to protect, promote, and support breastfeeding.



(BFHI: Baby-friendly Hospital Initiative; DHM: donor human milk; MOM: mother's own milk)

Promoting breastfeeding through integrated human milk banks

HMBs and breastfeeding promotion are inextricably linked. 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%).³¹ In another study, exclusive breastfeeding rates were significantly higher (74.0%) after compared to before the establishment of an HMB (34.0%).¹⁸ HMBs raise awareness of the value of breastfeeding in the hospital and community and act as a bridge when MOM is temporarily unavailable. Particularly when supported by local health professionals, integrated HMB programs create a powerful and self-reinforcing

cycle that augment existing support for mothers to provide MOM to their infants and promote optimal breastfeeding practices.

Sustainability in human milk banking includes both establishing and protecting an appropriate supply and demand of DHM for the HMB as well as financial sustainability. Comprehensive support for and promotion of exclusive breastfeeding is the cornerstone not only to improve infant health but also is critical for building a sustainable milk supply by helping to build a larger milk donor pool and strengthen the foundation for HMBs. Mothers should be supported to maintain an adequate milk supply for their infant and encouraged to donate only in excess of their own infant's current and potential future needs.

A comprehensive approach is needed to promote exclusive breastfeeding and increase

BOX 3. TEN STEPS TO SUCCESSFUL BREASTFEEDING.²¹

Critical management procedures

- 1a. Comply fully with the International Code of Marketing of Breast-milk Substitutes and relevant World Health Assembly resolutions.
- 1b. Have a written infant feeding policy that is routinely communicated to staff and parents.
- 1c. Establish ongoing monitoring and data management systems.
2. Ensure that staff have sufficient knowledge, competence, and skills to support breastfeeding.

Key clinical practices

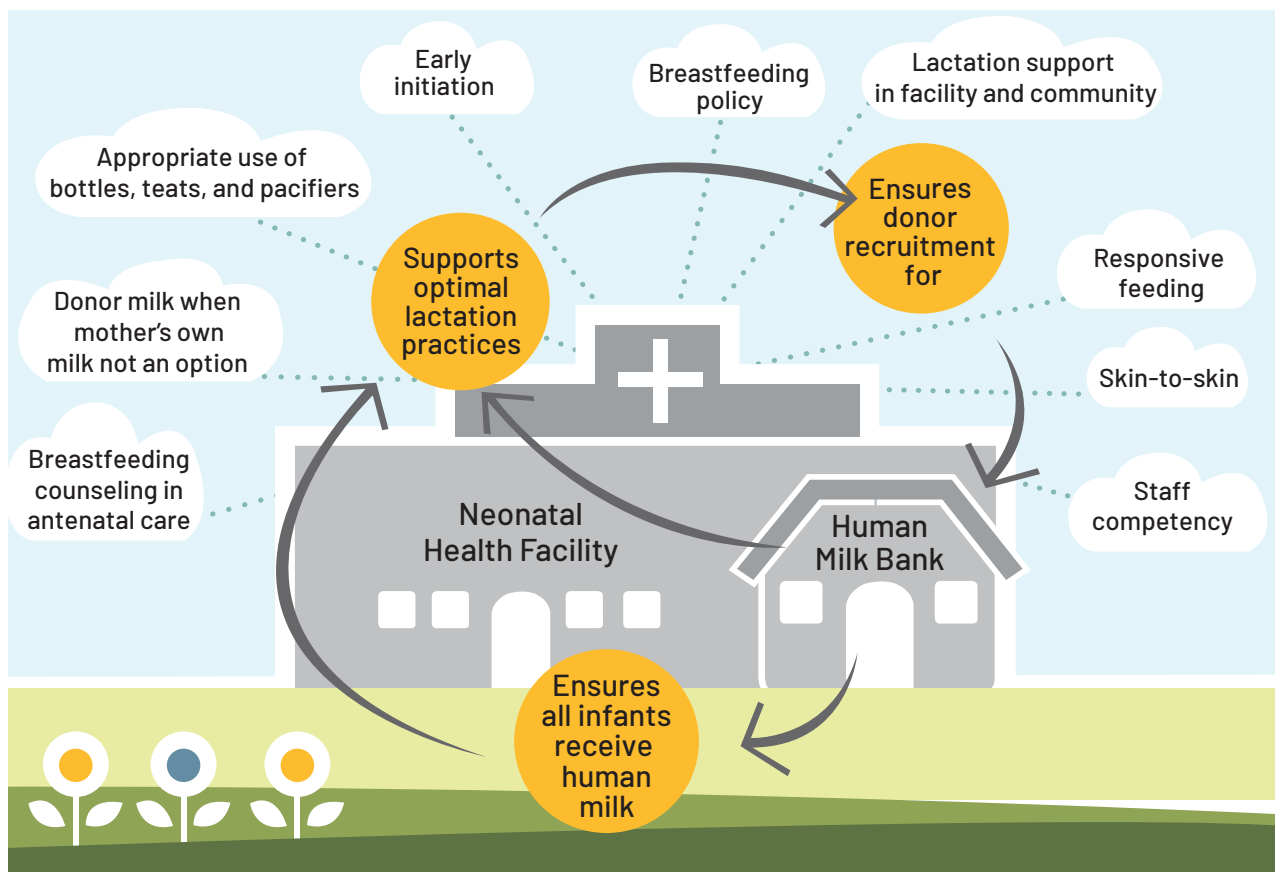
3. Discuss the importance and management of breastfeeding with pregnant women and their families.
4. Facilitate immediate and uninterrupted skin-to-skin contact and support mothers to initiate breastfeeding as soon as possible after birth.
5. Support mothers to initiate and maintain breastfeeding and manage common difficulties.
6. Do not provide breastfed newborns any food or fluids other than breast milk, unless medically indicated.
7. Enable mothers and their infants to remain together and to practice rooming-in 24 hours a day.
8. Support mothers to recognize and respond to their infant's cues for feeding.
9. Counsel mothers on the use and risks of feeding bottles, teats, and pacifiers.
10. Coordinate discharge so that parents and their infants have timely access to ongoing support and care.

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awareness among prospective donors and recipients with the primary aim of ensuring equitable access to human milk for all infants. Establishing an HMB can help to develop an integrated system for providing optimal newborn care, building on the updated BFHI approach calling on additional support for mothers, and can 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 the 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 align with the goals of the HMBs by advocating for early initiation of breastfeeding immediately after birth, exclusive breastfeeding and total duration of breastfeeding (Box 3).⁵⁶ Integrated HMBs could fulfill many of these steps and roles, serving as a centralized community hub whose primary aim is to function as a resource center to promote and reinforce the updated BFHI goals, through helping to establish lactation and provide mothers with the support they need to continue breastfeeding successfully, while simultaneously serving to accept, process, and provide donor milk to infants in need (Figure 4).

Figure 4. Components of an integrated human milk bank program as part of a Baby-friendly Hospital Initiative.



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

Banks) have successfully demonstrated the effectiveness of a nationalized, integrated HMB program that includes breastfeeding promotion, lactation support, and provision of donor milk when necessary; HMBs are known

as ‘houses of lactation’.⁵⁷ Considered to be a leading global model, Brazil operates more than 200 HMBs, with more than 150 collection points, and provides outreach to more than 25 countries.⁵⁸ In 2017, Brazil distributed over 158,000 liters of DHM collected from over 180,000 donors.⁵⁹ To protect, promote, and support breastfeeding and lactating mothers, Brazil establishes mother/baby centers for donor milk donation and lactation support.⁶⁰ Practices such as Kangaroo Mother Care, rooming-in, and mother-to-mother support and network building are effective for supporting mothers in early initiation of breastfeeding and

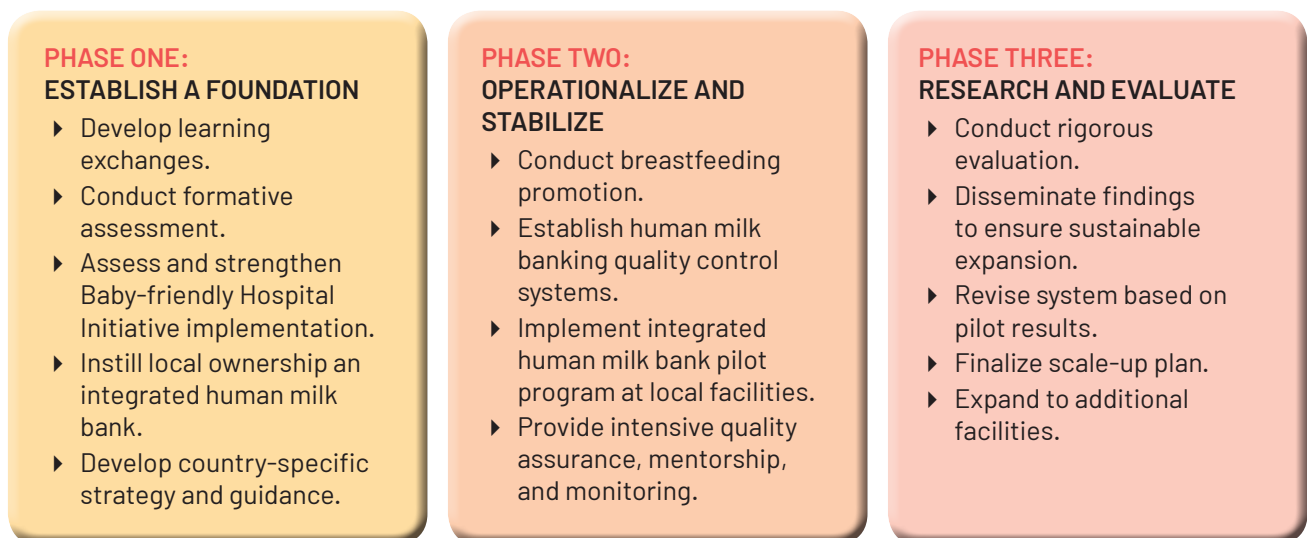
maintenance of their milk production.⁶¹ Facilities promote human milk banking by increasing awareness of breastfeeding among mothers during antenatal care and delivery, supporting and providing mothers crucial resources and guidance for breastfeeding, and by providing in-service training for health care staff. These integrated efforts clearly illustrate the impact of synergistically promoting initiatives to support breastfeeding mothers by exposing community members to mother- and baby-friendly practices and instilling a culture of breastfeeding both within the facility and throughout the community.

A phased approach for establishing a sustainable system

A phased approach should be used to build capacity, integrate nutrition, newborn systems, and increase rigor to demonstrate impact, working closely with local stakeholders and governments. From building a foundation for an HMB to the implementation of policies generating evidence on the impact of HMBs, steps should be followed to ensure ownership, sustainability, and improvement in human milk banking and infant health outcomes.

Phases of this approach could include 1) establishing local ownership and technical competency, through performing learning exchanges, conducting formative assessments, and developing country-specific strategies and guidance; 2) operationalizing and stabilizing breastfeeding promotion and HMB quality control systems; and 3) research and evaluation through rigorous monitoring and data to document impact and ensure sustainable expansion (Figure 5).

Figure 5. A phased approach for establishing a new human milk bank program.



STRENGTHENING HUMAN MILK BANKING

There are different models for HMBs including the community-based model and the hospital or health facility-based model (Table 2). Many HMBs incorporate components of different models, such as a community-based HMB that primarily recruits donors from local hospitals

and distributes DHM to hospitals within that region. Models that are able to integrate HMBs with newborn health care services, nutrition, and lactation support can strengthen systems to provide comprehensive early and essential newborn care.^{57,62} This integration, in turn,

Table 2. Human milk bank models.

Community-based model	The human milk bank operates independently from a hospital and is not physically connected to a health facility. Donor recruitment occurs primarily in the community. Milk collected by the milk bank is received by several hospitals and health facilities.
Hospital or health facility-based model	The human milk bank is located within a health facilities neonatal unit and run by neonatal unit staff. Donor recruitment occurs primarily in the hospital. Milk collected by the milk bank is predominantly received by the hospital's neonatal unit.

reinforces the infrastructure, human resources, and technical and financial means necessary for robust and sustainable milk banking systems and improves national strategies for reducing neonatal and infant mortality. Developing an integrated HMB system requires local, national, and global support to ensure that the system is sustainable and appropriate for the local context. HMBs should align with a community's needs and resources to effectively provide a lasting solution for infant care and maternal lactation support. This comprehensive approach to newborn care and nutrition permits an even greater impact on infant health. In an integrated model, stand-alone HMBs that collect, process, and store DHM can significantly expand their reach beyond the vulnerable neonates who need DHM. These integrated HMBs embody welcoming hubs within hospitals or community centers where all mothers, regardless of their desire to donate milk, can access support for breastfeeding and Kangaroo Mother Care, therefore raising awareness of the importance of breastfeeding and markedly expanding the impact of HMBs (Figure 6). HMBs integrated into hospital systems can have a greater influence on how the DHM they process is used, specifically to reduce overuse of DHM and ensure DHM is used to displace formula not

breastfeeding. Similarly, community-based HMBs can have a greater impact on supporting mothers to breastfeed when they are integrated with community-based lactation support programs. Comprehensive HMB programs can provide an active link to communities to improve neonatal health by acting as centers of care and resources for mothers and babies. When HMB activities are implemented this way, we can create a self-reinforcing cycle of optimal breastfeeding practices to improve both infant health and newborn care.⁶³

Figure 6. Integrated systems for increased access to human milk.



Key steps for establishing an integrated human milk bank

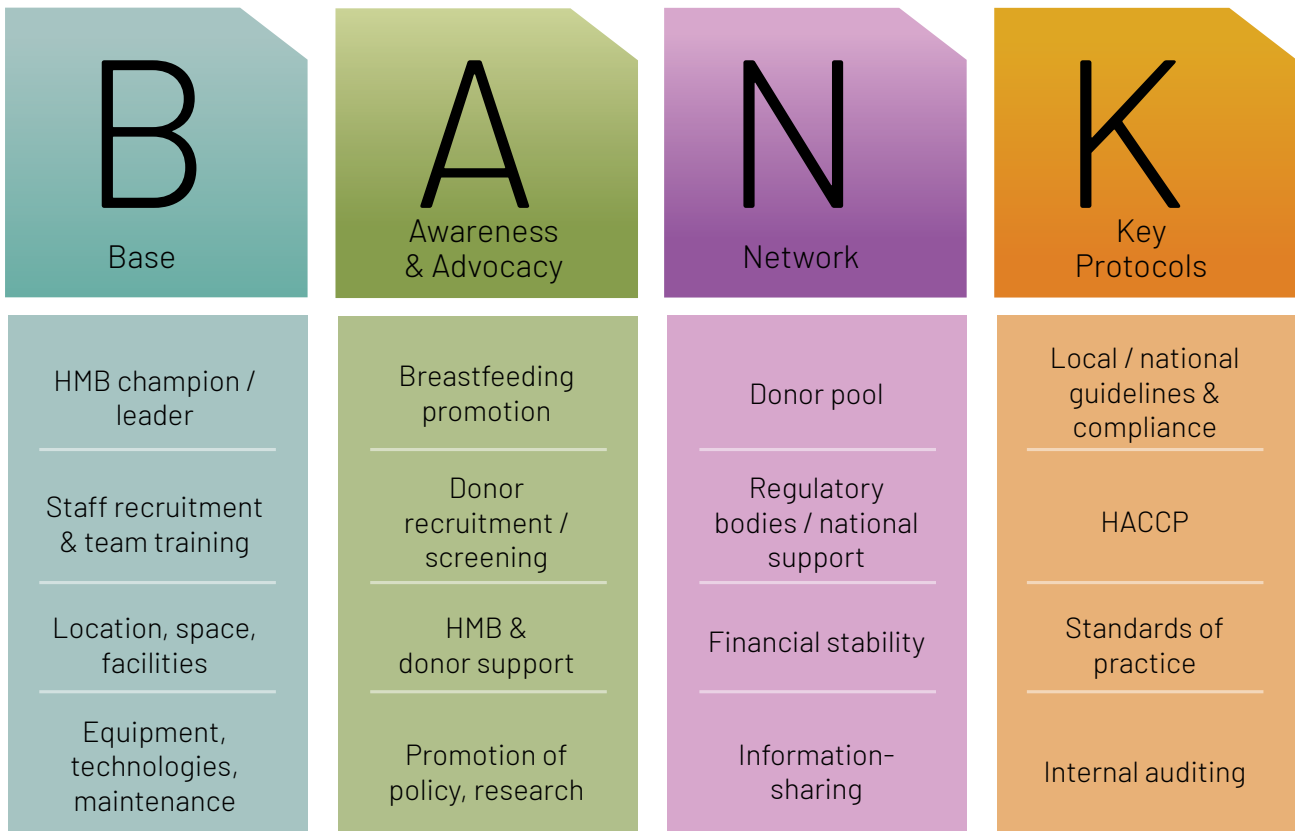
Planning, designing, and implementing a successful and sustainable and integrated HMB system are accomplished through four key steps—the BANK approach—for building a solid foundation (Figure 7):

1. Establish a **B**ase.
2. Raise **A**wareness and conduct **A**dvocacy.
3. Create a **N**etwork.
4. Develop **K**ey 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 broader goal of supporting mothers to breastfeeding ensuring 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 6 to guide considerations in the classification of donor milk for regulation purposes.

Figure 7. BANK: Four key steps required to establish a human milk bank.



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

Ensuring safety of donor human milk and equitable access to human milk

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 DHM, and finish with the allocation of the donor milk to the recipient. Each HMB should determine how each practice will be performed most appropriately for the local context and need make decisions on specific practices such as pasteurization, storage, transportation methods, and prioritization in donor milk allocation. 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. 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. 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 3 details each of these HMB process steps, and Section 8 summarizes the breadth and range of current practices implemented by HMBs around the world. Section 4 provides additional guidance on using the HACCP process.

Integration of HMBs into maternal and infant health systems is a vital step in supporting



Photo: Cheshire and North Wales Human Milk Bank

A GLOBAL IMPLEMENTATION FRAMEWORK

vulnerable infants. HMBs are crucial to protect, promote, and support breastfeeding for all by helping to normalize breastfeeding and human milk feeding and providing safe, high-quality DHM 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, provide mothers the support they need to continue breastfeeding, and provide all infants an equal opportunity to a healthy and strong start to life.

Human milk banking is most successful in countries where there is policy support from the local government, expansion of research, and cooperation between health authorities and human milk banking. Standardized quality control guidelines, effective communication, evidence generation, and policy change is needed to foster environments that support mothers to successfully breastfeed and are conducive to sustainable HMB systems.⁵² To improve newborn and infant health, there needs to be equitable access to human milk by expanding investments in HMB policies and research as part of integrated breastfeeding, maternal and newborn care, and infant nutrition programs.⁶⁴ Governments, health authorities, and research institutions can have a crucial role in providing the best possible nutrition for vulnerable infants by protecting, promoting, and supporting an integrated system of care that focuses on supporting the mother-infant dyad and also includes an HMB.⁶³

The remaining sections of this document provide detailed information that can serve as a framework to establish an effective HMB. The content includes necessary steps to start an HMB system, classification of DHM, considerations of the ethical use of DHM, the importance of policy support in creating a sustainable system, integration of safety measures through HACCP and auditing, the impact of evidence generation, and a summary of the breadth and range of practices performed by HMBs around the world. While these sections do not directly serve as specific guidelines, they do provide guidance on the process of creating a successful and integrated HMB system to be adapted to specific requirements. More detailed information on the policies needed to support human milk banking is described in Section 6.

Detailed lists of guides, templates, and standards are found in Section 9.

SEE TOOL #4

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Training Curriculum Template for Hospital and Human Milk Bank Staff provides an outline for human milk bank directors to create a customizable training course to meet the needs of their staff and facility.

SECTION 2: THE KEY STEPS FOR ESTABLISHING AN INTEGRATED HUMAN MILK BANK

As noted in Section 1, establishing a successful HMB system requires four key steps, which together form the BANK approach (Figure 7):

1. Establish a **B**ase.
2. Raise **A**wareness and conduct **A**dvocacy.
3. Create a **N**etwork.
4. Develop **K**ey protocols.

The following pages describe core components of each of the four key steps and their subprocesses to building a successful and integrated HMB system.



Photo: Brazilian National Network of Human Milk Banks

1. Establishing an HMB 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 (Figure 8).

HMB and breastfeeding champion. Every HMB needs a champion to advocate for, represent, and promote the milk bank and maternal support for 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 and equitable access to DHM.

Qualified HMB team. A qualified team needs to be established to guide the development, operation and integration 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.

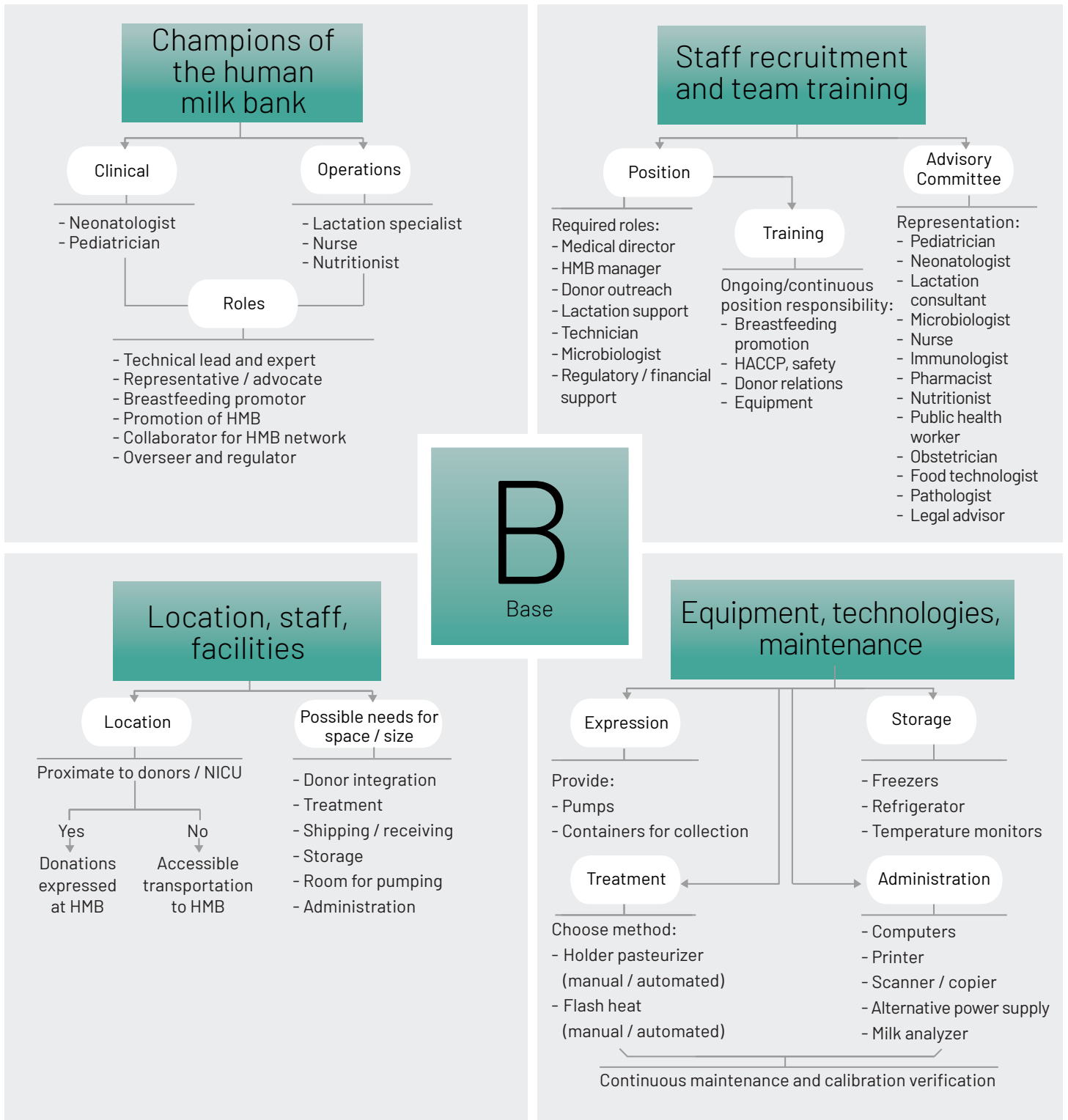
Location, space, and facilities. An HMB's location affects overall visibility as a lactation support center, including how potential donors will reach the facility and how donor milk will be transported to recipients. As HMB planners consider location, they should also consider whether the facility will be attached to a hospital, which can affect an HMB's ability to recruit donors and interact with the neonatal unit to provide guidance for the use of DHM. 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 peer-to-peer 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 should be in place to ensure that all equipment is cleaned and well maintained.

Figure 8. Establishing a base.



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

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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 DHM vary from that of MOM storage.⁶⁵
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 (e.g., for producing labels), and other communications equipment. In settings where electrical power may be unreliable, an alternative power supply is necessary.

SEE TOOL #1

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—An Assessment Tool for Determining Facility Readiness can help determine if establishing a human milk bank is an appropriate next step intervention for a hospital and what additional interventions may be needed for optimal newborn nutrition.

SEE TOOL #7

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Counseling Guide for Engaging Bereaved Mothers can provide valuable information to bereaved mothers as they decide whether to suppress or express their milk.

2. Establishing awareness and advocacy.

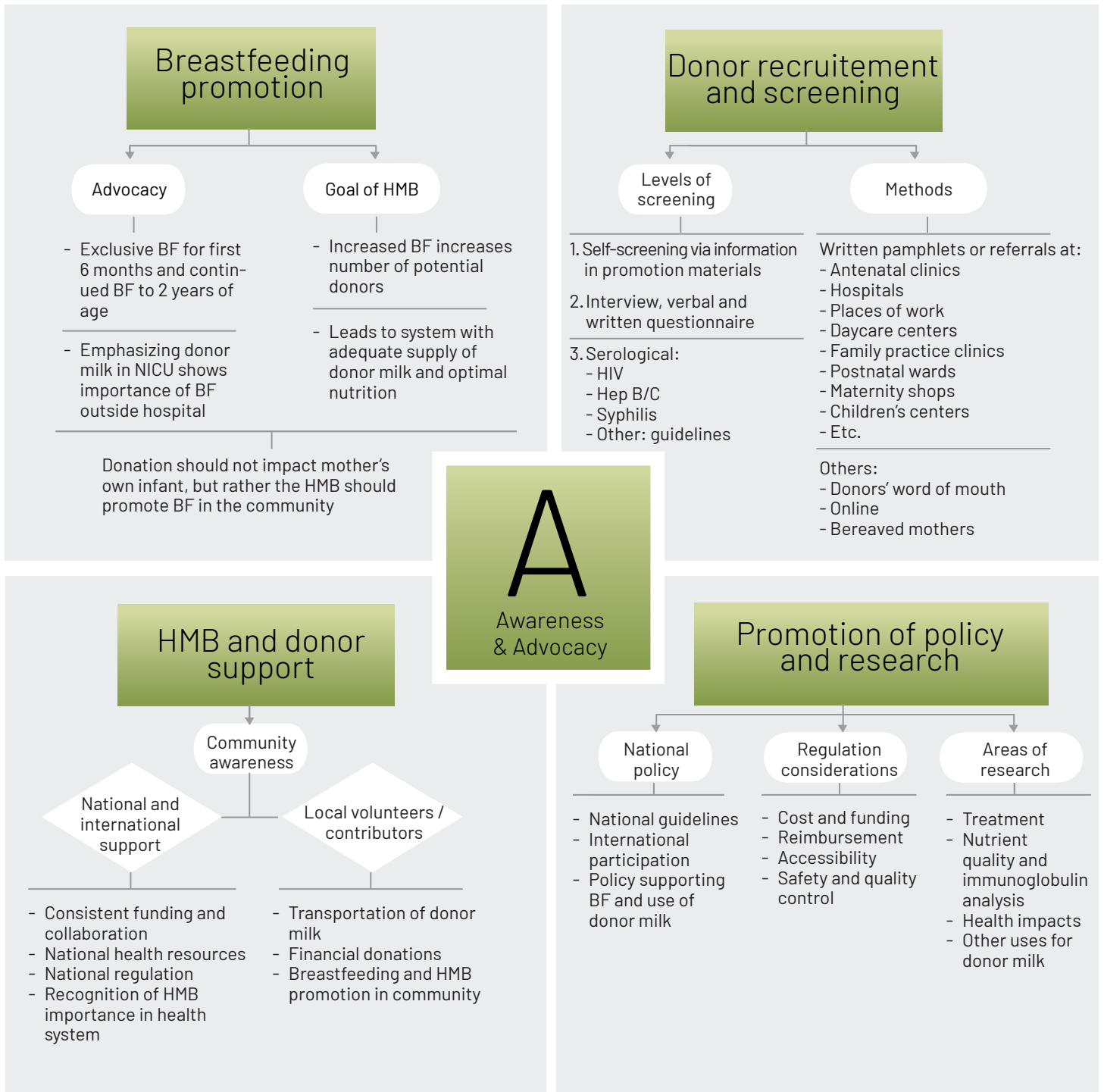
The HMB serves as a visible symbol for supporting optimal infant feeding practices, demonstrating the critical role that human milk plays in newborn health (Figure 9).

Breastfeeding promotion. The primary goal of the integrated HMB system is to protect, promote, and support breastfeeding for all mothers and their infants. Integrated HMBs raise awareness of the importance of breastfeeding and provide donor milk options when a mother is unable to provide any or sufficient maternal milk, creating a self-reinforcing cycle of ideal breastfeeding practices. When supported by national and regional government engagement in prioritizing breastfeeding promotion, an integrated HMB can serve as an integral component of a

community breastfeeding program by providing lactation promotion, infant feeding support, and education and guidance to promote maternal and infant health. The existence of integrated HMBs in facilities and 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 support for exclusive breastfeeding should target all mothers and infants, noting that special care and resources are needed for high-risk situations, such as in the NICU. Donor milk is the secondary choice for

Figure 9. Establishing advocacy and awareness.



(BF: breastfeeding; HMB: human milk bank; NICU: neonatal intensive care unit)

infant feeding after MOM. 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 3. Information for potential donors should highlight the importance of milk donation to an established HMB rather than informally sharing milk or selling milk to private companies as well as stressing the positive impact on DHM recipients in the NICU. The most effective method to strengthen donor recruitment is protecting, promoting, and supporting exclusive breastfeeding by providing sufficient and equitable lactation services to all mothers. Mothers who have experienced the loss of their infant may find it therapeutic to donate stored, expressed breast milk.

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 3 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 can help 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 updated WHO/UNICEF BFHI 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.^{3,7,65}

Regulatory requirements for HMBs and donor milk differ across countries and regulatory agencies and significantly influence the selection of appropriate operational procedures. Section 6 presents considerations for determining the appropriate classification of donor milk, as food, tissue, nutrition therapy, or medical/functional food. These are important elements to have in place for HMB systems to ensure ethical and safe use of DHM.

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 small babies.

SEE TOOL #6

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Guide for Developing a Communications Strategy can help create and increase advocacy, awareness and understanding of optimal nutrition for vulnerable infants by protecting, promoting, and supporting breastfeeding and ensuring all infants have equitable access to human milk.



Photo: PATH/Tom Furtwangler

3. Establishing the HMB network.

An HMB system does not function independently; effective operation requires multiple support networks (Figure 10).

Donor pool. An effective and integrated HMB supports its network of donors to ensure a sufficient supply of donated milk. When a woman is interested in donating, the integrated HMB should provide lactation support, referrals to necessary maternal health services, 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 maintaining milk supply, and provide lactation support as necessary, facilitating the mother 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. HMBs should be aware of the potential for mothers to want to donate milk that is more than is healthy for themselves or their infant and should educate mothers on maintaining their milk supply and prioritizing their own infant's nutritional needs.

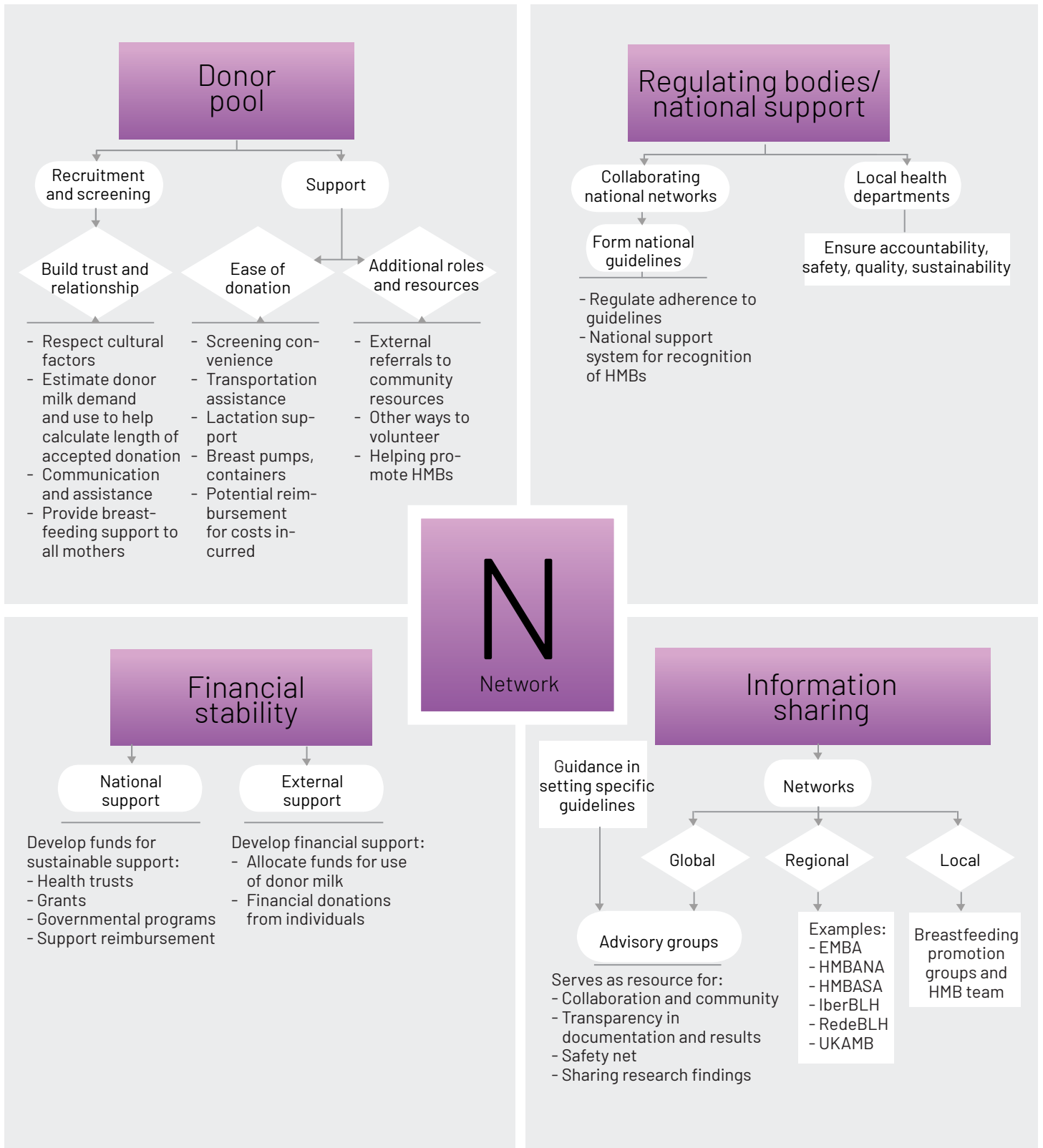
Regulating bodies and national support. HMBs should be familiar with national regulations and guidelines around breastfeeding, breast milk donation, and expected practices in human

milk banking. If regulations do not already exist, HMB teams can provide technical assistance for integrating HMB strategies into policies that already support maternal and newborn health. By creating a network for policy promotion and continuing to increase awareness of the need for DHM at the national level, integrated HMBs can foster sustainability and normalization of breastfeeding and breast milk donation in the community.

Financial sustainability. HMBs require consistent and adequate funding (Box 4). This support may come through national health funds and government resources or other local sources, such as charitable organizations. Funding can be provided directly by 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 milk bank, HMBs can establish a network of other financial supporters to ease the burden of costs to ensure equitable access to DHM 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

Figure 10. Establishing a network.



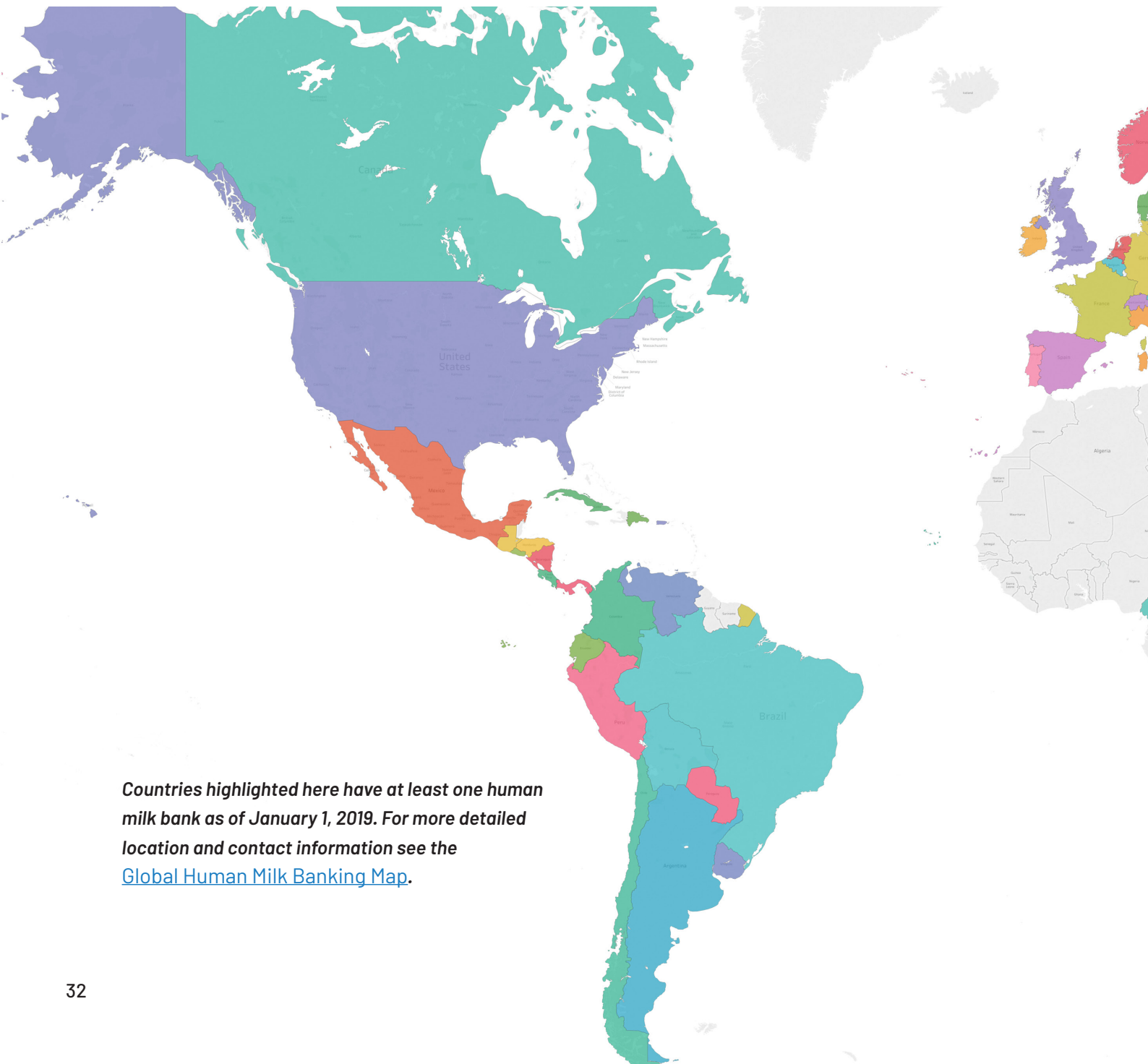
(EMBA: European Milk Bank Association; HMB: human milk bank; HMBANA: Human Milk Banking Association of North America; HMBASA: Human Milk Banking Association of South Africa; IberBLH: Programa Iberoamericano de Bancos de Leche Humana; RedeBLH: Rede Brasileira de Bancos de Leite Humano; UKAMB: United Kingdom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

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(Brazil), and the United Kingdom Association for Milk Banking. See Resources in Section 9 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 lactation support for all mothers and their infants, and increasing equitable access to DHM worldwide. Participation in an HMB network, which in turn is linked to regional newborn and nutrition networks, provides transparency in the documentation of processes and results to better inform and support other HMB systems worldwide.



Countries highlighted here have at least one human milk bank as of January 1, 2019. For more detailed location and contact information see the [Global Human Milk Banking Map](#).

BOX 4. COST CONSIDERATIONS IN THE INVESTMENT OF A HUMAN MILK BANK.

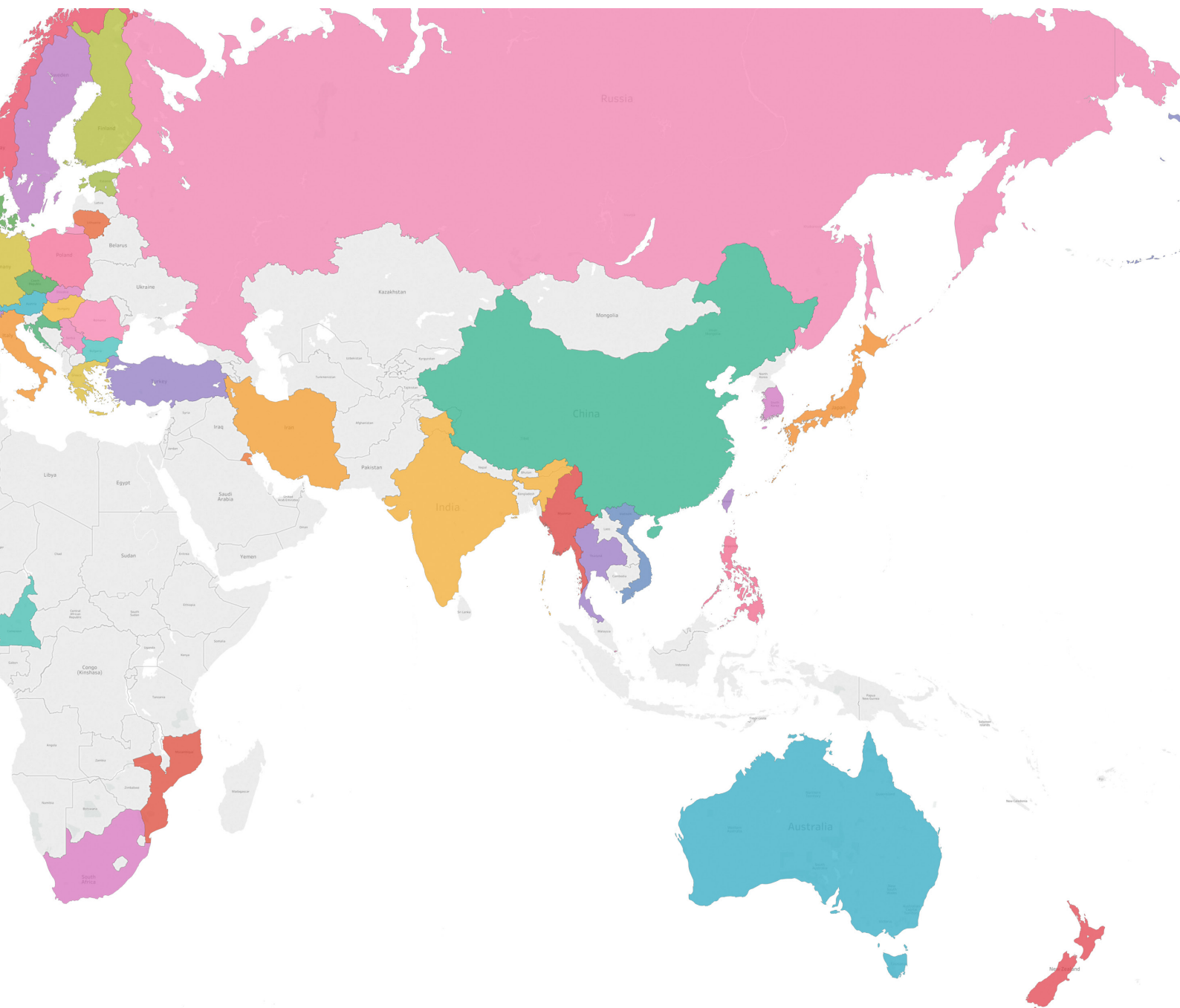
Startup costs:

- Training
- Pasteurizer
- Freezer(s) and refrigerator(s)

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



4. Establishing key protocols.

Key protocols from donor selection to milk allocation are necessary for standardizing processes and ensuring adherence to rigorous quality control methods (Figure 11).

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 should self-regulate as an independent body or network.

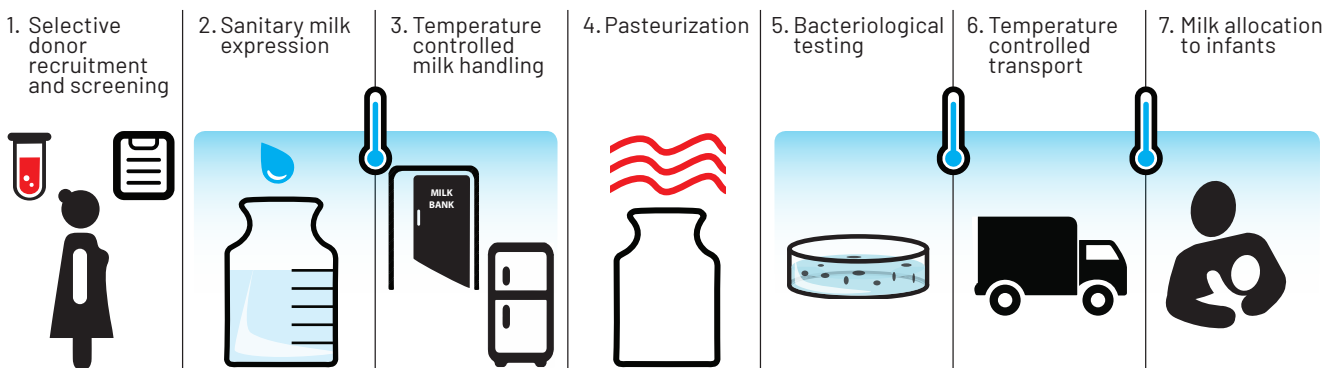
Comprehensive and accessible record keeping for compliance is essential in the event of any issues that require rapid tracking and tracing

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 need to 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 (Figure 12). This process is further described in Section 4.

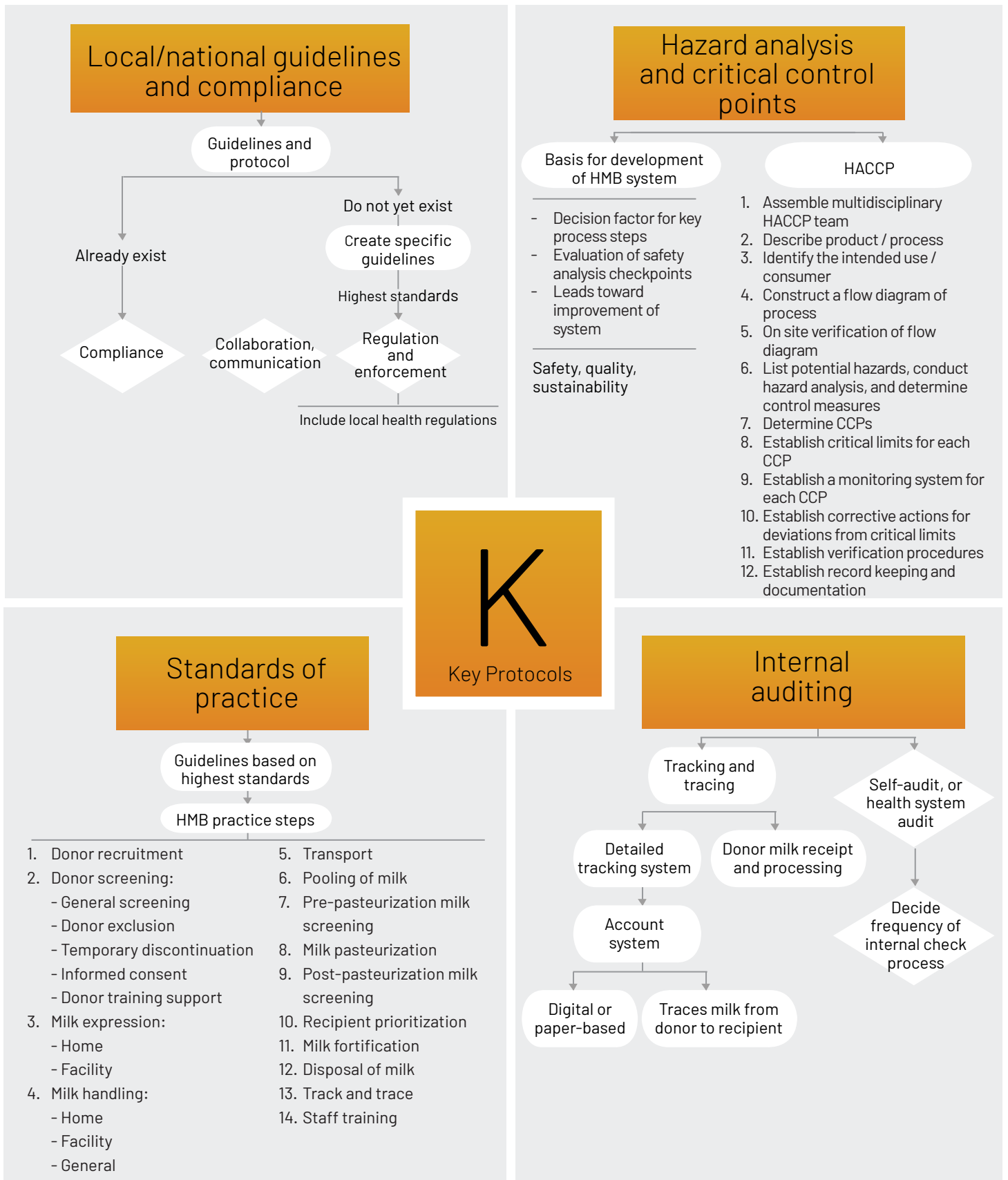
Figure 12. Steps for ensuring safety in human milk banking.



SEE TOOL #2a and #2b

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—Establishing Quality Assurance: A Workshop for Developing a Hazard Analysis Critical Control Points Plan (Trainer Guide) and (Trainee Workbook) provide the tools and knowledge necessary for human milk banks to conduct rigorous, human milk banks-specific HACCP training and develop their own site-specific HACCP plan.

Figure 11. Establishing key protocols.



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

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 needs to decide on the highest standards of practice that can be achieved and which criteria are necessary to screen donors and milk 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. HMBs need to develop staff training to ensure accurate implementation and application of their

guidelines and procedures. For a compilation of the breadth and range of current practices from HMBs around the world, see Section 8.

Internal auditing. Every HMB system has to account for the receipt, processing, and use of donor milk. Detailed records need to 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.

SEE TOOL #5

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Guide for Track and Trace Documentation is a guide for HMB leadership responsible for record keeping and approving the safety of the human milk bank to support the design of logs, forms, and registers for tracking and tracing the donor milk process.

SEE TOOL #2d

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—Establishing Quality Assurance: An Audit Template provides a template for human milk bank directors to create a customizable audit tool that meets the needs of their facility.

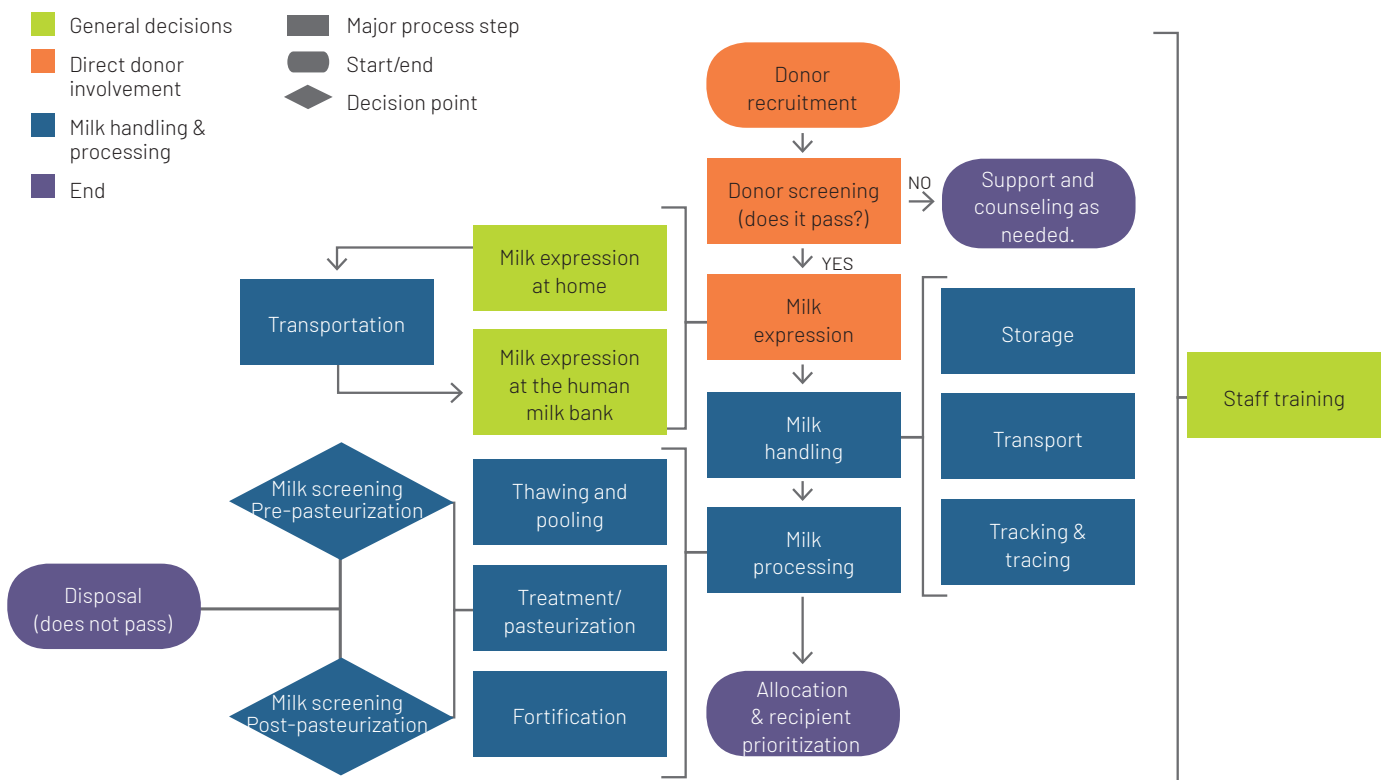
SECTION 3: CURRENT PRACTICES IN HUMAN MILK BANKING

Flow of process practices in human milk banking

An HMB carries out numerous, complex processes (Figure 13). This section provides a brief description of each core process. Section 8 presents a compilation of the breadth and

range of current practices for each of these processes from many of the HMBs around the world.

Figure 13. Flow diagram of process practices in human milk banking.



Breastfeeding and maternal support

The establishment of an HMB can raise awareness for breastfeeding in the hospital and community and can augment existing breastfeeding counselling and peer support

services to promote optimal breastfeeding practices. HMBs can also provide mothers with referrals for any needed follow-up and or maternal health services.

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. The following categories list recommended promotional methods by the different communication channels:

▶ **Mass media channels:**

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. Celebrities, sports stars, or other influential people can serve as powerful community advocates both in the media and within the community.

▶ **Interpersonal channels:**

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.

▶ **Community-oriented channels:**

This includes word of mouth in social networks such as families, peer support groups and community to help establish new behavior norms. 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—continual lactation support has the added benefit of enhanced future recruitment.

SEE TOOL #6

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Guide for Developing a Communications Strategy can help create and increase advocacy, awareness and understanding of optimal nutrition for vulnerable infants by protecting, promoting, and supporting breastfeeding and ensuring all infants have equitable access to human milk.

SEE TOOL #7

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Counseling Guide for Engaging Bereaved Mothers can provide valuable information to bereaved mothers as they decide whether to suppress or express their milk.

Donor screening

Although screening criteria in each setting should be tailored to local concerns and needs, following the general guidelines outlined below will 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 should contact the HMB immediately to determine whether she should 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 confirm the ability to donate breast milk. Consent forms should be stored for a specified period of me
- to provide proof of the donor's agreement to donate.
- ▶ **Serologic testing.** All donors need to undergo serologic testing to indicate lack of infection. 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 need to be established to ensure patient privacy in revealing the results and referring the woman to her physician for any needed follow-up. Testing performed during the antenatal period can sometimes be accepted, however, this testing is often 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. Integrated 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

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 in refrigerators and freezers that meet the temperature requirements laid out in local HMB guidelines, and then arrange for its collection or delivery when convenient for both donor and milk bank. 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 should 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 8 for a summary of the breadth and range 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 needs to be immediately transferred to a refrigerator or freezer and should 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 should 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 need to wash their hands thoroughly before expressing or handling milk. Depending on regional guidelines and whether a hospital-grade freezer is used, frozen raw breast milk can be stored for three to six months before pasteurization.

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, while others only allow mixing of a single donor's milk. Pooling from several donors 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 regional guidelines need to

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).

Pre-pasteurization screening

Various pre-pasteurization screening procedures for donor milk exist. Some HMBs choose to test samples from every pool 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, however, this will not detect any changes in the mother's practices or other means of subsequent contamination. 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. Each region has to determine the acceptable microbial level of their milk if pre-pasteurization screening is performed. Other testing methods may include qualitative assessment measures.



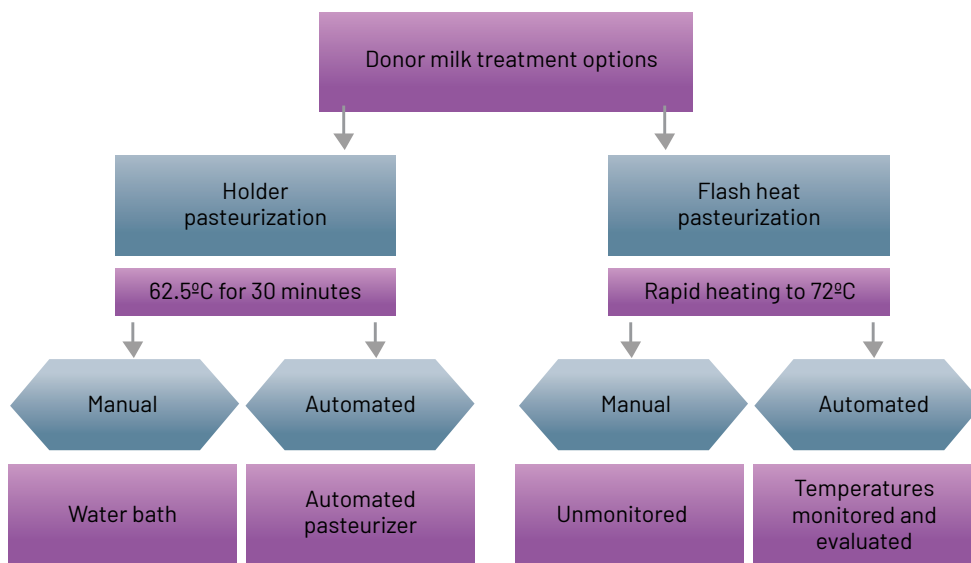
Photo: Cheshire and North Wales Human Milk Bank

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 followed by rapid cooling (see Figure 14).

Figure 14. Different treatments for donor human milk currently practiced.



SEE TOOL #2d

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—Establishing Quality Assurance: An Audit Template, Appendix 1. Verification protocol for a Holder pasteurization device can be used for human milk bank staff to conduct quality control verification of their pasteurizer.

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—is equivalent to Holder pasteurization in ensuring microbiological safety and 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 is flash-heat

pasteurization, which involves heating milk in a water bath to 72.0°C, then rapidly cooling the milk. High-pressure processing, ultraviolet irradiation, and ultrasonic processing are alternative treatments that require further research on their influence on milk components and microbiological safety before they can be used to treat DHM.⁶⁶ Each HMB should 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 detect failed pasteurization. Levels of screening are dictated by resources; some HMB systems test a sample from each pasteurization batch, 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 needs to be discarded if any microbial content is found.

Milk nutrient analysis

The nutrient content of breast milk is highly variable between individuals and is affected by postnatal age and gestational stage of the infant. In some HMBs or facilities, milk is tested for macro-nutritional content using a nutrient content analyzer. Data from the nutrient analysis can help inform milk pooling and recipient determination, however, more research is needed to set calibration standards for analyzers.

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 DHM may be fortified to increase macro- and micronutrient content based on an infant's individual needs, it is not a universal practice. Small babies have increased needs for protein, electrolytes, and calories, and should have greater access to preterm DHM. Care should be given to ensure fortification does not disrupt or displace the natural components of human milk.⁶⁷ Further research is required to identify the specific benefits of milk fortification in preterm infants as well as the potential benefits, costs, and ethical constraints of human milk-based fortifiers as compared with bovine milk-based fortifiers.^{68,69} 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.¹⁹ Recipient prioritization is a continual process, determined at the clinical level, especially where donor milk availability is limited.

SEE TOOL #4

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Training Curriculum Guide for Hospital and Human Milk Bank Staff, Appendix 1: Donor Human Milk Decision Tree can provide guidance to health care providers as they determine prioritization of donor human milk in their facility.

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. 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, using a tracking identification number. 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. Novel milk tracking systems used within the blood and organ transplant services are currently being applied to human milk tracking to employ additional safeguards to help eliminate possible human error in the storage, handling, and distribution of DHM.

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.

SEE TOOL #4

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Training Curriculum Guide for Hospital and Human Milk Bank Staff provides an outline for human milk bank directors to create a customizable training course to meet the needs of their staff and facility.

SEE TOOL #5

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Guide for Track and Trace Documentation is a guide for human milk bank leadership responsible for record keeping and approving the safety of the human milk bank to support the design of logs, forms, and registers for tracking and tracing the donor milk process.

SECTION 4: SAFETY SYSTEMS IN HUMAN MILK BANKING

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 should develop processes that balance safety and quality within their own contextual needs and limitations. Locally appropriate procedural safety requirements are necessary throughout the milk banking process in addition to procedures and policies to monitor operations and milk safety and quality.

BOX 5. WHAT IS HAZARD ANALYSIS AND CRITICAL CONTROL POINTS?

Hazard analysis and critical control points (HACCP) is an internationally recognized system used in the food industry to identify and reduce hazards during food processing. The objective of HACCP is to identify and prevent, eliminate, or reduce to acceptable levels any biological, chemical, or physical hazard that would be likely to occur in a food production or distribution environment.^{71,72} Through HACCP, food safety is addressed at every phase of the process including procurement, handling, distribution, processing, and consumption.

Hazard analysis and critical control points

One approach to developing safety and quality systems in a robust, systematic way is to use the HACCP process (Box 5). HACCP is more than quality assurance; it is a preventative and corrective 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 an HMB helps to identify, evaluate, and control hazards, and it provides a systematic way to document this approach, allowing transparency (Figure 15).⁷⁰

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 leading 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.

SEE TOOL #2c

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—Establishing Quality Assurance: A Guide for Creating Operational Standards.

Figure 15. Steps for developing a hazard analysis and critical control points plan.



Application of the HACCP system requires implementing a HACCP plan and utilizing and evaluating existing facility protocols used to control hazards and prevent contamination. There are 12 action steps involved in developing a HACCP plan (Figure 15). HACCP systems are designed to focus on control at CCPs (Box 6). After determining potential hazards in step 6 and identifying CCPs in step 7, HMB staff should take precautions to ensure that the identified hazard cannot reach a point of potential harm

(Figure 16). When monitoring of a CCP indicates a loss of control, corrective measures need to be taken to prevent further risk. This system helps to proactively correct steps to ensure safety. In order to maintain an effective HACCP system, activities within the HACCP plan need to be verified, updated, and revised as needed and all individuals involved in implementing the HACCP plan need to be properly trained in their roles and responsibilities.

BOX 6. DEFINING GOOD MANUFACTURING PRACTICES AND CRITICAL CONTROL POINTS.

What are critical control points?⁷³

A critical control point (CCP) is any step, point, or procedure in the food production process at which a food safety hazard can be prevented, eliminated, or reduced to an acceptable level. At these CCPs, failure to follow the standard operating procedures could result in unsafe milk and harm to infants. Identifying CCPs is the second principle of hazard analysis and critical control points (HACCP) and the seventh step in the process. Identifying CCPs helps identify steps in the human milk bank (HMB) process where teams should pay particular attention to risks. These steps often have clearly defined, quantifiable critical limits set by temperature and time. CCPs differ from other steps in the HMB process because a CCP does not have a subsequent step in the process that can reduce the hazard to an acceptable level. In other words, a CCP is the last step in the process that can control the hazard.

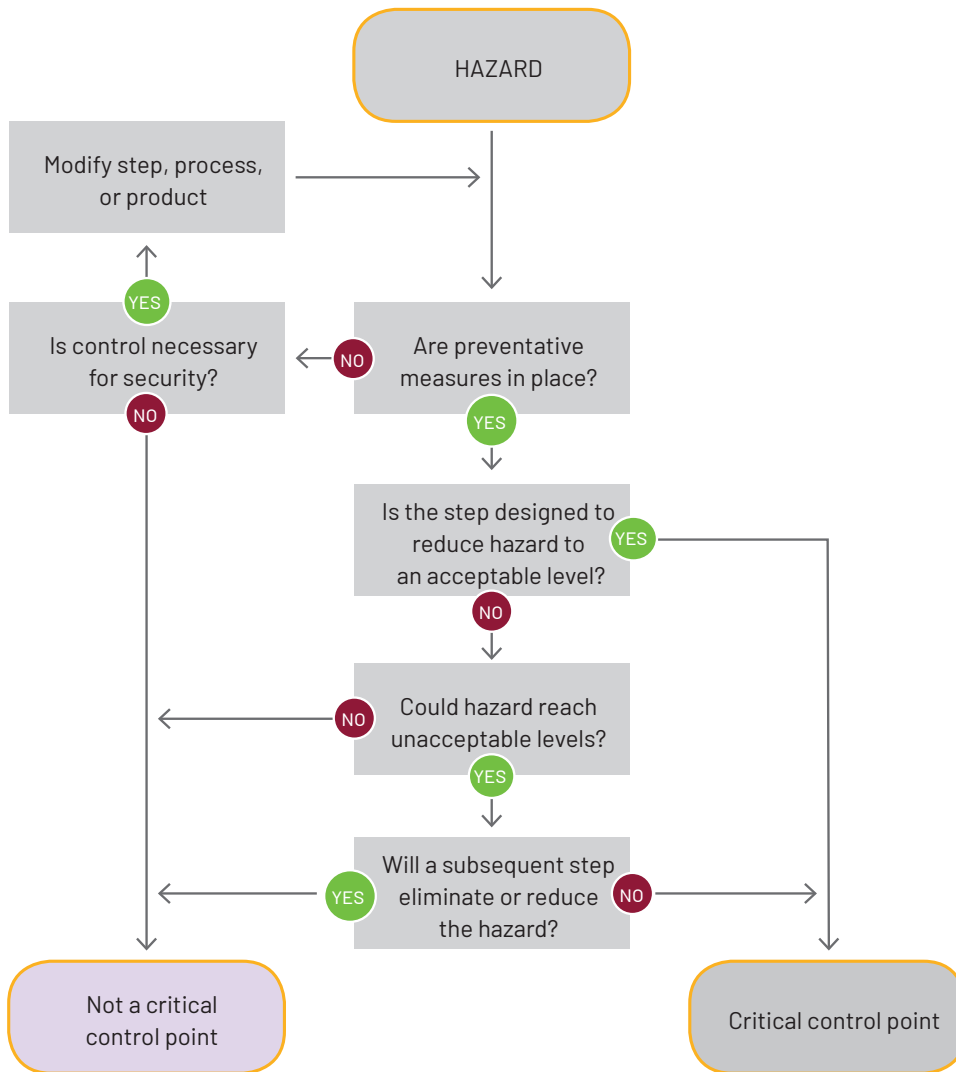
What are good manufacturing practices?^{72,74}

HACCP plans also help identify steps in the HMB process that need to be monitored but do not have quantifiable critical limits. They may not have a risk level as high as justifiable hazards. These steps are referred to as good manufacturing practices (GMPs). GMPs are the minimum sanitary and processing requirements necessary to ensure the production of safe, high-quality foods. GMPs include practices such as staff training and equipment disinfection. These practices reduce hazards to an acceptable level when followed appropriately.



Photo: Brazilian National Network of Human Milk Banks

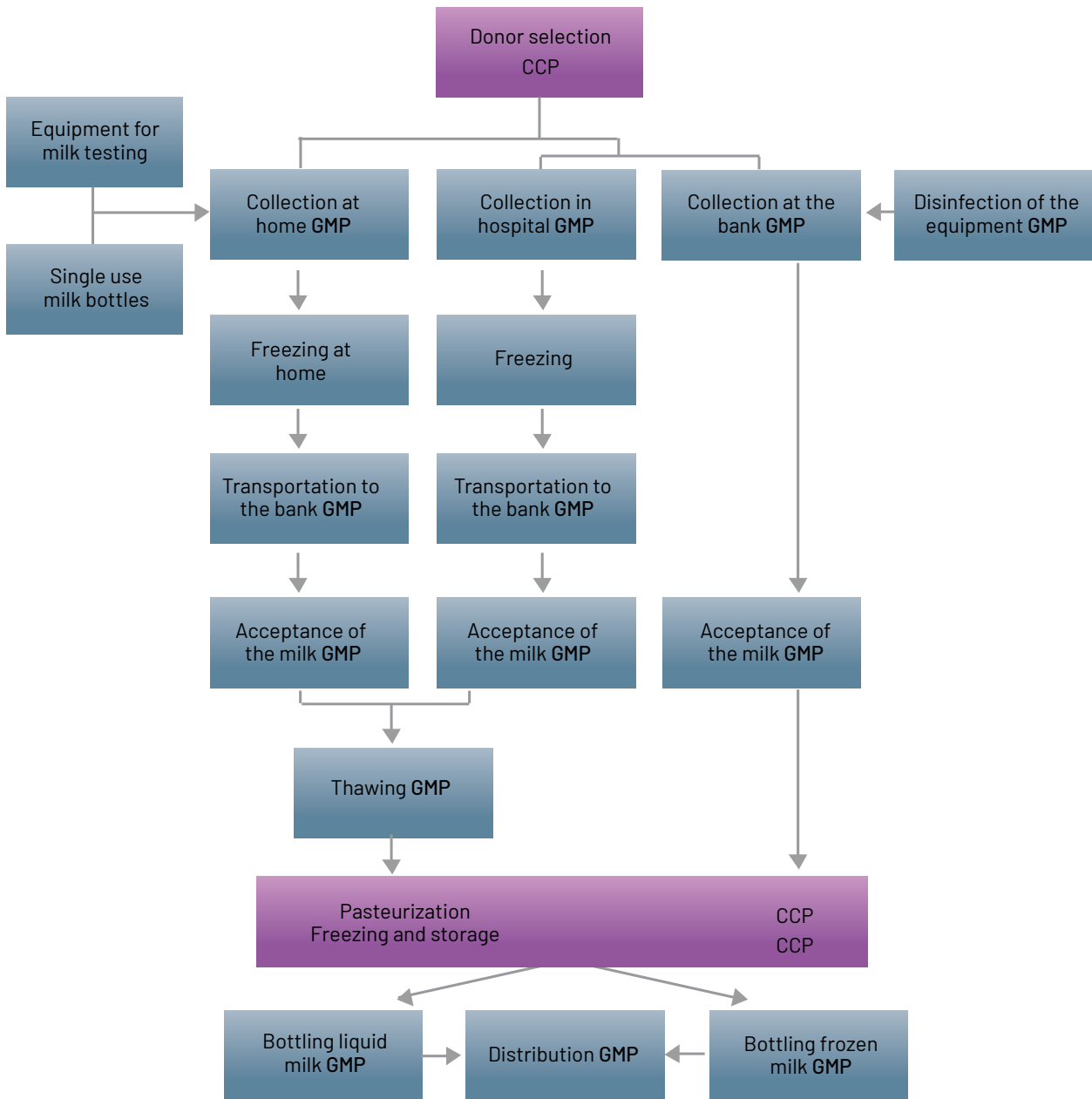
Figure 16. Decision tree for identifying process step as critical control points.⁷³



Each setting will have a unique HACCP plan as process points and corrective measures are 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 needs to decide how to use its available resources to ensure the safest and highest-quality donor milk.

Figure 17 shows an example, based on guidelines used in Italy, of recognizing CCPs and good manufacturing principles in the process flow. In this example, donor selection, pasteurization, and freezing and storage are identified as CCPs that need to have identified critical limits, continuous monitoring, as well as corrective actions that determine the cause of the deviation and actions that prevent a recurrence.

Figure 17. Critical control point and good manufacturing practice identification from Italian human milk bank guidelines.⁷⁵



(CCP: critical control point; GMP: good manufacturing practices)

SEE TOOL #2a and #2b

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—Establishing Quality Assurance: A Workshop for Developing a Hazard Analysis Critical Control Points Plan (Trainer Guide) and (Trainee Workbook) provide the tools and knowledge necessary for human milk banks to conduct rigorous, human milk bank-specific HACCP training and develop their own site-specific HACCP plan.

Internal and external auditing

HMBs should regularly conduct robust evaluations of their quality control systems, standard operating procedures, and staffing, equipment, and infrastructure requirements. An audit system is a means of continuous assessment and improvement for HMBs by evaluating facility performance and triggering and prioritizing an improvement process. An audit is typically a series of simple and direct questions, which when answered, can confirm if an HMB is correctly carrying out operating procedures, activities, and policies.

Audits may be performed internally and voluntarily or forced upon facilities through legally required external audits, and inspections.⁷⁶ Regular audits should be conducted following an established procedure to ensure compliance and implementation of quality management systems.⁷⁷ Audits should be conducted by trained individuals and should cover all parts of the milk banking operation,

including record keeping. Audits should be performed according to a formally approved system that evaluates compliance with internal regulations and guidelines as well as applicable regional requirements.⁷⁸ To secure resources and facilitate learning of HMB staff and lasting change throughout departments, audits should address and involve senior managers.⁷⁶

Both developing and existing HMBs require internal and external auditing to help identify areas to improve upon site-specific guidelines. An audit should cover the entire milk banking process from donor recruitment, donor screening, milk expression, handling, processing, and prioritization in the distribution to the recipients, and staff training. Regardless of local or national enforcement, evaluation of standard operating procedures in HMBs is essential to ensure the safety and quality of DHM.

SEE TOOL #2d

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—Establishing Quality Assurance: [An Audit Template](#) provides a template for human milk bank directors to create a customizable audit tool that meets the needs of their facility.

SECTION 5: GENERATING IMPACT THROUGH EVIDENCE GENERATION

An essential component of increasing effective newborn care is evidence generation (Box 7). Rigorously collected, distributed, and implemented scientific research is critical to strengthening the evidence base to ensure optimal nutrition is provided to vulnerable infants—this includes support for mothers to exclusively breastfeed and for integrated HMB systems. Research provides a base to inform policy, support consistent

regulatory and operational procedures, and strengthen advocacy. Partnerships between HMB programs, governmental agencies, and research institutions enable integrated HMBs to increase research generation and expand its impact. When networks of communication are improved to create innovative partnerships involving HMBs, connected HMB professionals, and experts can share information and evidence.

SEE TOOL #3

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Guide for Conducting Monitoring and Evaluation provides guidance for establishing rigorous monitoring and evaluation systems, as well as research protocols and data collection tools, to encourage and facilitate the broader impact of human milk banks through evidence generation.

A key component of increasing evidence generation is the strengthening of data tracking systems. Often health authorities and researchers neglect to include human milk consumption resulting in their inability to report on reliable and standardized indicators. Data tracking systems should include documenting the use of and consumption of human milk within the broader indicators for early initiation of breastfeeding. This includes documenting the actual infant feeding practices within neonatal care units, such as lactation support

provided to mothers, proportion of human milk feeds (MOM, informally shared other mother's milk, or DHM from an HMB) and formula feeds over time. Tracking the collection, processing, and distribution of DHM are needed to ensure the clinical standards for safety but can also improve systems for research generation. Monitoring and tracking data can produce additional evidence showing the cost-effectiveness of DHM in reducing the disease burden and associated costs in small babies during their NICU hospitalization.

SEE TOOL #5

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Guide for Track and Trace Documentation is a guide for human milk bank leadership responsible for record keeping and approving the safety of the human milk bank to support the design of logs, forms, and registers for tracking and tracing the donor milk process.

A GLOBAL IMPLEMENTATION FRAMEWORK

Evolving and improved technology for data tracking on the collection, storage, processing, microbial testing, and distribution of DHM can allow for faster tracking of DHM and help eliminate the risk of human error, such as the accidental distribution of milk that does not pass post-pasteurization microbial testing. Barcoded labels can track and trace DHM from donor mother to infant recipient, providing real-time updates on the movement of the milk through the HMB and eliminate identification, preparation, and feeding errors. In addition to serving as a validation tool, barcode systems for tracking DHM can function as a record management powerhouse for both HMB and hospital, providing long-term data on the usage and cost savings of DHM.

HMBs can often be isolated, limiting their ability to share evidence and reinforcing inconsistent collection, storage, handling, fortification, and DHM feeding practices even within the same region. The lack of global guidance around

consistent systems for tracking and tracing the treatment and use of DHM reinforces the isolation between HMB systems and variations in quality control. DHM is often believed to be unaffordable. Regional guidance on tracking can help produce costing data highlighting the cost savings provided by each additional milliliter of DHM and provide valuable information on the processing and use of DHM within local communities. Integrating HMB tracking programs with existing health care and nutrition tracking systems can help strengthen maternal and newborn care. Global leaders are rallying around the 2030 Sustainable Development Goals, emphasizing the need to implement evidence-based interventions to improve the health and survival of infants and children.² Human milk is a crucial intervention, and evidence generation will help establish quality improvement initiatives for enhancing the use of DHM. Clear data-driven methods for tracking the use of DHM and progress of maternal and newborn health will also hold countries accountable.⁷⁸



Photo: PATH/Georgina Goodwin

BOX 7. FUTURE RESEARCH DIRECTIONS FOR IMPROVING IMPACT IN HUMAN MILK BANKING.

- ▶ Analysis of the cost benefits of donor human milk (DHM) in inpatient as well as outpatient setting to help support continued use of DHM and integrated human milk bank (HMB) programs strengthening exclusive breastfeeding.
- ▶ Evaluation of local and national HMB policies on equitable access to DHM.
- ▶ Evaluation of integrated HMB systems on short-term and long-term breastfeeding rates.
- ▶ Development and evaluation of different pasteurization or alternative processing techniques that can maintain the biological and nutritional quality of human milk while also ensuring microbiological safety.²⁸
- ▶ Evaluation of the effectiveness and appropriateness of low-cost technologies to simplify HMB operations in resource-limited settings.
- ▶ Assessment of variations in the nutritional and hormonal composition of human milk.
- ▶ Evaluation of the effectiveness and application of milk nutrient analysis as well as determination of appropriate calibration standards for nutrient analysis.
- ▶ Development and evaluation of safeguard against acceptance of donated milk contaminated with illicit drugs, toxic products, or pollutants.²⁸
- ▶ Evaluation of the appropriate length of time that a woman can donate and how long after delivery she can start donating breast milk.
- ▶ Randomized clinical trials of DHM should investigate:
 - The long-term and short-term clinical outcomes of DHM feeding compared to preterm formula feeding.
 - The long-term and short-term clinical impact of feeding DHM with human milk-based fortifiers compared to DHM with bovine milk-based fortifiers.²⁸

SECTION 6: PROTECTING THE USE OF HUMAN MILK THROUGH POLICIES, CLASSIFICATION, AND REGULATION

Ethics of human milk banking

Throughout the processing and provision of DHM, HMBs have a substantial task of balancing the ethical principles of beneficence, nonmaleficence, justice, and patient autonomy. There is a considerable newborn population that could potentially benefit from access to DHM but are denied access due to a lack of knowledge or misconceptions about human milk banking.⁷⁹ As a limited resource, there is an ethical dilemma of how we decide to use DHM. Lack of policy regulation in the prioritization of DHM can lead to breast milk often not being given to the newborns who need it most. With the growing demand for DHM, there needs to be policy support to ensure equitable access.

Health care providers also have the ethical obligation of empowering women to breastfeed rather than undermining lactation support services that may ultimately limit the amount of DHM an infant requires. DHM can be misused or overused when health care staff apply it as a non-critical replacement for MOM or when it is used instead of providing support for mothers to breastfeed or increase their milk supply. DHM should be used only as a bridge to ensure an exclusive human milk diet when MOM is not available. Health care providers and HMB programs should strive to ensure babies feed at the breast as soon as possible.

Informal milk sharing, as well as commercial selling of human milk, can limit the amount of MOM available to the mother's own infant. Mothers may choose to sell their milk for profit or give milk to a family member or friend out of a sense of moral obligation, which can ultimately limit the amount of milk available to her own infant. Financial incentives for milk

provision can be problematic as they increase the risk of exploitation or coercion of donors and may increase the risk pool of donors. Lack of regulation of informal sharing as well as commercial selling of human milk can also negatively impact the number of voluntary donations to an HMB that prioritizes DHM for sick and vulnerable newborns. Women may risk their own health or the health of their infant when they have financial incentives to provide milk or have a strong feeling of moral obligation to donate. Local governments should establish a role in protecting the women, their own infants, and recipients of the milk that has been informally shared or sold for corporate profit.

Global and regional operational guidelines and policies are needed to protect and safeguard human milk, including establishing and managing ethical issues that can compromise the safety of DHM, donors, donor infants, and newborn recipients of DHM. When there is a lack of legal frameworks to classify and regulate human milk, it is a more significant challenge to protect human milk as well as the donors and recipients of human milk. As part of an integrated model of newborn health, the classification and regulation of human milk needs to be aligned with existing frameworks that strengthen maternal and newborn health care and nutrition. HMBs should be part of an integrated and comprehensive program to protect, promote, and support breastfeeding and provide an alternative feeding option to vulnerable newborns only when MOM is not available.

Classification of donor human milk

Table 3 outlines considerations when determining the classification of DHM for regulation purposes. Each particular classification can affect the fair accessibility of donor milk, as well as costs associated with regulatory 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.

Classification of DHM should align with local frameworks developed to strengthen maternal and newborn care and nutrition. The integration of HMB programs with larger frameworks supporting maternal and newborn health services can significantly increase equitable access to DHM and MOM, thereby increasing the impact of HMBs and helping to meet the growing demand for DHM worldwide.

SEE TOOL #4

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Training Curriculum Guide for Hospital and Human Milk Bank Staff, Appendix 1: Donor Human Milk Decision Tree can provide guidance to health care providers as they determine prioritization of donor human milk in their facility.



Photo: Mothers' Milk Bank Austin, Texas

Table 2. Classification of donor human milk.

Classification	Definition	Regulation	Potential benefits	Potential challenges
<p>Donor Human Milk as a Food</p> <p>Example country: Brazil</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>	<ul style="list-style-type: none"> ▶ Highlights 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 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. 	<ul style="list-style-type: none"> ▶ Possible barriers to insurance reimbursement. ▶ Possible public perception that the milk is not adequately regulated. ▶ Donor milk has risks as a non-manufactured 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 8. ▶ The informal sale of DHM and payment of donors can be legal when classified as a food product. ▶ Complying with food labeling legislation eg food constituents, nutritional composition etc.

STRENGTHENING HUMAN MILK BANKING

Classification	Definition	Regulation	Potential benefits	Potential challenges
<p>Donor Human Milk as a Medical Product of Human Origin^{80,81}</p> <p>Example country: France</p>	<p>Any biological material that is intended for clinical application and is derived in part or completely from the human body. They are anatomical components, secretions, or excretions, including organs for transplantation; blood and plasma products; ocular and musculoskeletal or other types of tissue; haematopoietic or other types of cells; ova and sperm; and breast milk.</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>	<ul style="list-style-type: none"> ▶ 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. ▶ Can prohibit the informal sale of DHM or payment to donors for milk. ▶ Government responsibility to ensure ethical and equitable procurement, distribution, and use. 	<ul style="list-style-type: none"> ▶ 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.

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Classification	Definition	Regulation	Potential benefits	Potential challenges
Donor Human Milk as a Nutrition Therapy or Medical/Functional Food	<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 GMPs and show that there is no harm to the individual receiving the product.</p>	<ul style="list-style-type: none"> ▶ 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. 	<ul style="list-style-type: none"> ▶ 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.

STRENGTHENING HUMAN MILK BANKING

Classification	Definition	Regulation	Potential benefits	Potential challenges
Donor Human Milk as an Undefined Class	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>A HMB 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>	<ul style="list-style-type: none"> ▶ 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. 	<ul style="list-style-type: none"> ▶ 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.

Policy support for exclusive human milk diets

Human milk banking is most successful in countries with written policy support and guidance, as well as cooperation between health authorities and human milk banking programs. Improved awareness of HMBs and DHM can also increase the perceived importance of lactation support programs and regulations. Governments and health authorities can have a crucial role in providing the best possible nutrition for vulnerable infants. Governments can foster environments that encourage exclusive human milk diets and protect HMBs through use of standardized quality-control guidelines, effective communication, evidence generation, and policy change.

Currently, more than 60 countries have developed systems to provide DHM through HMBs; however, most countries in the world have yet to establish national policies and programs that support the provision of DHM to infants in need. Global health policy advocates have placed increasing importance on protecting, promoting and supporting breastfeeding and in 2011, the WHO officially recommended providing DHM from an HMB as the next best option for feeding small babies when MOM is not available. Although the last five years have seen a greater emphasis on providing optimal feeding options for small and sick babies, there is still a lack of global guidance on how to best provide DHM to these

vulnerable infants. Box 8 lists a number of globally adopted frameworks and documents that discuss access to and intake of DHM for newborns in need.

Acceleration of global policy and guidance development that enables exclusive human milk diets includes those that are supportive of the use of DHM and the establishment of integrated HMBs to increase equitable access and intake of human milk for all newborns and expand lactation support programs.⁶⁴ Policy development will create a more enabling environment, which is a necessary element for strengthening health systems and improving newborn health and survival. Country-level actions to increase access to and intake of human milk need to be comprehensive and should aim to reinforce optimal breastfeeding practices and mother's access to lactation support services. Action needs to be taken to ensure that all newborns, including those sick and vulnerable, can fairly access and receive human milk. In addition to efforts to protect, promote, and support breastfeeding, additional efforts are needed to close the gap in the provision of care so that newborns who do not have access to their MOM are not fed formula unnecessarily. Governments miss an opportunity to improve infant health and economic outcomes when there is a lack of political leadership and support to provide equitable access to human milk.

SEE TOOL #6

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Guide for Developing a Communications Strategy.

BOX 8. TECHNICAL AND POLICY GUIDANCE DOCUMENTS THAT INCLUDE AND/OR SUPPORT ACCESS TO AND INTAKE OF DONOR HUMAN MILK FOR NEWBORNS IN NEED.

- ▶ *Global Strategy for Infant and Young Child Feeding* (United Nations Children’s Fund [UNICEF] and World Health Organization [WHO], 2003).
- ▶ World Health Assembly Resolution 61.20 (2008).
- ▶ *Guidelines on optimal feeding of low birth-weight infants in low- and middle-income countries* (WHO, 2011).
- ▶ The Surgeon General’s Call to Action to Support Breastfeeding (United States Department of Health and Human Services, 2011).
- ▶ Donor Human Milk for the High-Risk Infant: Preparation, Safety, and Usage Options in the United States (American Academy of Pediatrics, 2016).
- ▶ Breastfeeding and the Use of Human Milk (Academy of Breastfeeding Medicine, 2005).
- ▶ Academy of Breastfeeding Medicine Position on Breastfeeding (2015).
- ▶ *Guide to the quality and safety of tissues and cells for human application* (European Directorate for the Quality of Medicines and Health Care, 3rd ed., 2017).
- ▶ World Health Assembly, 70th Session. “Provisional agenda item 13.2” April 2017. *Principles on the donation and management of blood, blood components and other medical products of human origin.*
- ▶ *Baby-friendly Hospital Initiative: Revised, Updated and Expanded for Integrated Care* (UNICEF and WHO, 2009).
- ▶ *Pocket Book of Hospital Care for Children: Guidelines for the Management of Common Illnesses with Limited Resources* (WHO, 2013).
- ▶ Every Newborn Action Plan (UNICEF and WHO, 2014).
- ▶ *Integrated Management of Pregnancy and Childbirth: Pregnancy, Childbirth, Postpartum and Newborn Care: A guide for essential practice* (United Nations Population Fund, UNICEF, WHO and World Bank, 3rd ed., 2015).
- ▶ *Standards for improving quality of maternal and newborn care in health facilities* (WHO, 2016).

SECTION 7: CONCLUSION

Human milk is critical for newborn health and provides optimal nutrition, laying the best foundation for a healthy and productive life. As such, human milk is considered a pillar of child survival, as highlighted in the recent 2016 Lancet series illustrating the importance of breastfeeding in building a better world for future generations in both high- and low-resource countries.² Human milk has unique immunological and nutritional properties that characterize it as a personalized medicine for infants.² Both epidemiology and biology studies demonstrate the short- and long-term consequences of not breastfeeding on children's health, nutrition, and development, as well as women's health.² Support for frequent and exclusive human milk feeding is a necessary intervention for addressing newborn and maternal mortality worldwide.⁸²

Provision of donor milk fills a vital role in ensuring an exclusive human milk diet for vulnerable newborns. In cases where MOM is not available, the WHO criteria state that DHM should be considered as the next option and should be used to fill a gap while the mother is supported to increase her milk supply and continue to exclusively breastfeed. When MOM is unavailable, DHM is needed to help achieve the basic human right to survival for small and ill babies.⁸² HMBs are a critical mechanism for providing safe DHM to infants who need it most, such as small and sick babies in a neonatal ward or those who are orphaned. Access to human milk and lactation support services help to promote a healthier and more equitable world.⁸³

HMBs save lives and should be a key part of any integrated maternal and newborn health and nutrition program.⁸² They fill the tangible unmet need for human milk, as well as provide an anchor for exclusive breastfeeding promotion

and support, serving the broader community and improving breastfeeding utilization. In light of the significant impact HMBs can have on infant health outcomes, the WHO has asked member countries "to promote the safe use of donor milk through HMBs for vulnerable infants."

This Framework presented the critical components required for an effective HMB program and the knowledge and resources to strengthen and integrate human milk banking systems into maternal and newborn care. The revised version 2.0 of this Framework has the added strength of weaving together all of the resources developed by PATH as part of the **Strengthening Human Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs**. This toolkit provides comprehensive and globally accessible guides, templates, and standards needed to establish providing global and open access to tools and information needed to establish an integrated, robust HMB platform and strengthen systems, as well as evaluate and monitor those already existing.

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, breastfeeding advocacy, promotion, and clinical and peer support for breastfeeding mothers, and sustainability of DHM supply through sound business practices.

The information presented in this toolkit should be used to build upon these principles and develop processes specific to meet local needs. Methods for collecting, handling and processing

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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; providing clinical and peer support for mothers and raising awareness of breastfeeding increases donor availability, creating a reinforcing cycle of optimal breastfeeding practices. HMBs can serve a dual role as lactation support centers throughout a country, extending the capacity for providing mothers with the necessary support for optimal breastfeeding and infant feeding practices, as well as providing safe DHM to neonates in need. An integrated approach to human milk banking instills a culture of breastfeeding both within the facility and throughout the community.

To achieve this, effective HMBs should 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 policies should be established to ensure that robust

infant and young child feeding guidelines are in place, with enhanced focus on the small and sick infant, in addition to legislation that protects and promotes breastfeeding mothers while providing them with necessary clinical and peer support. National commitment and coordination are required to guarantee that policy translates into action; adequate resources need to be provided for developing strategies and implementation plans for safely and effectively integrating human milk banking into breastfeeding promotion and maternal and newborn care programs.

The global health community has an ethical obligation to collectively transform the field of newborn nutrition to ensure optimal nutrition, including provision of DHM when needed, is achievable. 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 and equitable access to human milk for all infants. With a higher level of commitment and investment around the world, transforming maternal and infant health is within reach.



SECTION 8: BREADTH AND RANGE OF HUMAN MILK BANKING PRACTICES AROUND THE WORLD

Listed recommendations in setting-specific human milk banking guidelines:	BRAZIL	FRANCE	INDIA	NORTH AMERICA ⁱ	POLAND	UNITED KINGDOM ⁱⁱ	VIETNAM ⁱⁱⁱ
Donor Recruitment							
Recruit through a variety of channels, including: W=written material (in antenatal clinics, maternity shops, etc.*), R=referrals (by donors, doctors, staff), M=mass medium, P=programs/educational guidance	R,W,M	R,M,P	X	W,R	*	W,R,M,P	W,R,M
Use clear, non-technical language when recruiting	X	X	X	*	*	*	X
Specifically recruit mothers who lost their own child	X	-	*	-	*	*	*
Donor Screening- General							
Screening involves a verbal or written (informal) interview	X	X	X	X	X	X	X
Statement of health is required by donor's physician and by their child's physician	X	*	*	-	-	-	-
Screening information includes: (G=general health, C=donor's child information, M=medications, E=environmental exposures, I=infection exposure, V=vaccination)	G,C,M, E,I,V	G,C, M,I,V	G,C,M, E,I,V	G,M, E,I,V	G,M, E,I	G,C, M,I	G,C,M, E,I,V
Serological testing of donor is required,* (=if finances available for Hep B and Hep C)	X	X	X	X	X	X	X
Antenatal/pregnancy tests are acceptable to show test results	X	X	X	X	-	X	-

TABLE KEY:

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iii = Da Nang Province

STRENGTHENING HUMAN MILK BANKING

Listed recommendations in setting-specific human milk banking guidelines:	BRAZIL	FRANCE	INDIA	NORTH AMERICA ⁱ	POLAND	UNITED KINGDOM ⁱⁱ	VIETNAM ⁱⁱⁱ
Donor Screening- Exclusion Criteria							
Potential donors are excluded for drinking more than ____units per _____ (time period)(C=consistent)	1.5 oz of hard liquor, 12 oz of beer, 5 oz of wine or 10 oz wine coolers in 24 hours	2 units, weekly	*	any, 24 hours	*	any	1 to 2 units, 1-2 times weekly
Potential donors are excluded for: S=smoking, D=recreational drugs, I=Infection (of HIV, Hepatitis B or C, HTLV, or syphilis, or increased risk of CJD), M=medications, 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 12m, J=incarceration in last 12m, R=Renal Dialysis, A=artificial insemination	S,D,M,I,B, P,T,V,X,J,	S,D,I, B,P,T, X	*	S,D,I, B,T,V, X,R	D,I,T,R, X,A,M, S,B	S,M,I	S,D,M,I
Exclusion for spending 3 months or more in UK (between 1980 and 1996) or 5 years or more in Europe between 1980 to present (or risk for Creutzfeldt-Jakob Disease)	X	-	*	*	X	-	-
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	X	X	-	X	X	X	X
Based on local HMB donor milk requirement/stock, mothers of children over a certain age may be asked to stop donating (age of infant)	*	X(12m)	*	*	*	*	X(12m)

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Informed Consent							
Before accepting donor's milk, informed consent is necessary from donor	X	X	X	X	X	*	X
Before administration of donor milk, informed consent is required from recipient's mother	X	X	X	X	*	*	*
Donor Education/Support/Training							
Train new donors in: H=hand washing & hygiene; E=expressing milk, S=storing, cooling, freezing milk, L=labeling, T=transportation, BF=breastfeeding	H,E,S, L,T,BF	H,E,S, L,BF	H,E,BF	H,E, S,L,T	H,S,L	BF,E, S,H	H,E,S, LT,
Ongoing support should be provided, especially those that donate repeated contaminated milk	X	X	*	X	X	X	X
Milk Expression- Specific Home or HMB/Hospital, and General							
Advise donors to collect expressed milk rather than drip milk	X	X	X	X	*	*	X
Encourage hand-expressed milk (especially at home)	*	*	X	*	*	X	X
Accept pump-expressed milk	X	X	X	X	X	X	X
If accepting pump-expressed milk, ensure sterilization of pump	X	X	X	X	X	*	*
When using pumps, provide the most effective for each mother's specific situation	X	*	X	*	*	-	*
Hygiene and handwashing should be emphasized	X	X	X	X	X	X	X
Discourage sharing of breast pumps	*	X	X	*	*	*	*
Express at least 6, but preferably 8, times every 24 hours	X	*	X	*	*	*	*
Handling Milk- Home							
Freeze milk for storage (as soon as possible) at home (V=varies)	V	X	*	X	X	X	X

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Maximum storage time length from date of collection before donation to HMB (V=varies)	V	*	*	V	*	15d	3m
(Preferably) Only containers provided by milk bank should be used (for storage/freezing)	-	X	*	X	X	-	X
Refrigerate collection of multiple expressions in single container	-	X	*	X	X	*	*
Recommends not adding freshly expressed milk to already frozen milk	-	*	*	X	X	*	*
Instructions for defrosting and using milk at home	-	*	*	-	*	X	-
Handling Milk- Hospital/HMB							
Donated milk immediately placed in freezer *=placed in freezer after testing	X	X	X	X	X	X	X
Refrigeration/freezer equipment used only for HMB milk purposes	X	X	X	X	X	X	X
Freezer temperature monitored every_____	24h	day	twice a day	day	X	day	-
Raw and pasteurized milk stored in separate refrigerators/freezers/ compartments	X	X	X	X	X	X	X
Emphasize hygienic conditions for processing (sterile conditions not necessary)	X	X	X	X	X	X	X
Wear gloves when handling milk (*=accept when working with large volumes in the HMB)	X	X	X	X	*	X	X
Frozen raw milk is thawed in ____ (F=fridge, C= counter) before pasteurizing	F	F	F,C	C	*	F	-
Breast milk from donors not meeting criteria is discarded	X	X	X	X	X	X	X

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Listed recommendations in setting-specific human milk banking guidelines:	BRAZIL	FRANCE	INDIA	NORTH AMERICAⁱ	POLAND	UNITED KINGDOMⁱⁱ	VIETNAMⁱⁱⁱ
Storage containers should be labelled with: N=name of donor, D=date of collection/expression, P=pasteurization, A=date of pasteurization, #= donor's #, I= ID of Bank, F=date of freezing, B=batch number, T=date to be transported to central milk bank, M=medications taken by donor	#,D,F,P,N	N,D,B	#,D,P,A,I,F,B	N,P,A,I	N,D,P,I,A,B,M	#,D	N,D,P,I,B,M
Fresh milk can be kept safely at room temperature for	*	-	6h	4-6 h	*	*	*
Maximum storage duration for raw milk in freezer before pasteurization	12m	3m	3m	3m	*	15d	3m
Maximum storage duration for raw milk in refrigerator before pasteurization	*	*	24h	24h	48h	12h (-3°C)	24h
Maximum storage freezer temperature	-18°C	-20°C	-20°C	-20°C	-18°C	-3°C	-20°C
Maximum storage refrigerator temperature	4°C	7°C	4°C	4°C	4°C	5°C	-
Maximum storage duration in freezer from expression until use (for preterm neonate)	1 yr	6m	3m	*	*		6m
Pasteurized milk can be stored in freezer for a maximum of; (preterm neonate):	12m	*	6m	3m	*	6m	6m
After defrosting, pasteurized milk can be refrigerated for maximum of:	48h	24h	24h	24h	*	24h	-
Defrost method: (WB=water bath, M=microwave, R=refrigerator, RT=room temperature, MW=Milk warmer, OI=orbital incubator)	R, WB, RT	R, WB	WB, R, RT, MW	WB	*	WB, M	-
Pasteurized milk can be dried and vacuum packed	*	*	*	-	X	X	*

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Handling Milk- General							
Acceptable containers for storing milk include: (F=food grade materials, G=glass bottles/containers, P=plastic bottles/containers, C=clean non-sterile containers, S=strong/rupture free/resistant containers)	G,F,P,C	G,P	F,P	F,P	G,P	S	F
Milk bags or plastic bags are not recommended for storage	-	*	X	X	*	*	-
Seal containers with solid lids	X	*	X	X	X	*	*
Don't overfill containers, fill to about 3/4	X	X	*	X	*	*	*
Minimize exposure to sunlight and/or phototherapy lights	X	*	*	*	*	*	*
In places with power supply fluctuations, equipment must be connected to generator	*	*	X	*	*	X	*
Pooling of Milk							
Pooling allowed in pre-pasteurized breast milk from the same donor *If milk will be pasteurized, not allowed in non-pasteurized raw milk	X	X	X	X	X	X	X
Acceptable raw breast milk from different donors can be pooled	X	-	X	-	-	X	-
Do not pool milk from different donors	-	X	-	X	*	-	X
Do not pool milk if it has already been pasteurized	X	X	*	X	*	X	X
Multiple batches (set of bottles that fit into pasteurizer or shaking water bath) can be created from one pool	X	*	X	X	X	*	*
Transport							
Ensure donor milk remains frozen during transport, cold chain	X	X	X	X	X	X	X

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Listed recommendations in setting-specific human milk banking guidelines:	BRAZIL	FRANCE	INDIA	NORTH AMERICAⁱ	POLAND	UNITED KINGDOMⁱⁱ	VIETNAMⁱⁱⁱ
Third party transport allowed, perform contract to maintain conditions needed	X	*	-	*	X	*	X
Transport between milk banks is allowed, potential labelling/tracking may be required	X	*	X	X	X	X	*
Freshly expressed milk is kept safe for up to 24 hours in cooler with frozen gel packs	X	*	*	X	*	*	*
Small amounts of dry-ice can be used in very warm climates to keep ice cold	X	X	*	*	*	*	*
Pack tightly in cooler, filling all spaces	X	*	X	X	*	X	*
Container must be insulated, rigid, and easily cleaned	*	*	X	X	*	X	*
Check and record temperatures throughout transport	*	*	*	X	*	X	*
Milk Screening- Pre-pasteurization							
First donation from donor undergoes bacteriologic testing (V=varies)	X	X	X	X	X	X	X
Further bacteriologic testing when donor does not seem to guarantee appropriate hygienic conditions (V=varies)	X	X	X	X	X	X	X
Random samples bacteriologic testing performed pre-pasteurization (V=varies)	V	V	-	-	*	-	-
Milk is bacteriologically screened prior to pasteurization, every batch	-	*	X	-	X	*	X
Milk is screened for total viable microorganisms	X	X	X	X	X	*	X
Milk is screened for <i>Enterobacteriaceae</i> (gram negative bacteria)	-	*	X	X	-	*	X
Milk is screened for <i>Staphylococcus aureus</i>	-	*	X	X	X	*	X

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Milk is evaluated/screened for color, off-flavor, foreign bodies/impurities	X	*	X	*	*	X	*
Technical verification of Dornic acidity	*	*	*	-	*	X	*
Technical verification of content/crematocrit	*	*	*	X	*	X	*
Quality control checks include HACCP principles	X	X	X	-	*	*	X
Milk Treatment							
Type of treatment possible (P= human milk pasteurizer or Holder pasteurization, FH=flash heat pasteurization and shaking water bath (manual), FN=FoneAstra (flash heat- automated)	P	P	P, FH	P	P	P	P
Treatment/pasteurization temperature	62.5°C	62.5°C	62.5°C	62.5°C	62.5°C	62.5°C	62.5°C
Do not exceed treatment/pasteurization temperature (in monitored controlled bottle) or allow temperatures to oscillate more than:	63.5°C	*	+/-0.5°C	0.1°C	*	0.1°C	*
Treatment/pasteurization time length	30m	30m	30m	30m	30m	30m	30m
Rapidly cool sample to at least_____ (temperature) or below (RT=room temperature)	4°C	4°C	4°C	4°C	4°C	5°C	4°C
Do not use flash heat pasteurization for frozen/thawed milk	X	*	X	*	-	*	*
If no automatic stirrer, shake container every 5 minutes during treatment	*	*	-	*	-	X	*
Monitor process and record temperatures during treatment	X	X	X	X	X	X	*

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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)	M	M	*	M	M	B	M
Test milk for microbial content post-pasteurization for every batch	X	-	X	X	X	X	-
Test milk for microbial content post-pasteurization randomly (V=varies)	X	X	X	V	-	-	X
Test milk for microbial content post-pasteurization at least once per month, or every 10 cycles, whichever comes first:	*	-	*	*	-	*	X
Discard milk that has _____ total viable microbial content or more post-pasteurization	any	10 CFU/ml	10 CFU/ml or more	10 CFU/ml	any	any	10 CFU/ml
Re-pasteurize and retest milk that shows contamination, discard if sample still shows contamination after re-pasteurization	-	X	*	-	-	-	-
Discard opened bottle's milk that is used for testing	X	-	*	X	-	-	X
Recipient Prioritization							
All recipients of donor milk will receive heat processed milk, unless physician requests raw	X	X	X	X	X	X	X
Donor milk is given only by prescription or hospital purchase order	X	X	X	X	X	*	*
If need for donor milk is greater than supply, other HMBs are contacted	X	*	*	*	*	*	*
If demand is greater than supply, prioritization criteria for infants is pre-planned and recorded	X	*	X	X	*	*	*
Priority feeding is first mother's own milk rather than donor milk when possible	X	X	X	X	*	X	X

TABLE KEY:

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i = Human Milk Banking Association of North America

ii = National Institute for Health and Care Excellence

iii = Da Nang Province

STRENGTHENING HUMAN MILK BANKING

Listed recommendations in setting-specific human milk banking guidelines:	BRAZIL	FRANCE	INDIA	NORTH AMERICAⁱ	POLAND	UNITED KINGDOMⁱⁱ	VIETNAMⁱⁱⁱ
Physician is in charge of prescribing or initiating provision of donor milk	X	X	X	X	X	X	*
Prioritized preterm newborn or low birth weight newborn	X	X	X	X	*	X	*
Prioritize infants with necrotizing enterocolitis	X	X	X	X	*	X	*
Prioritize infants that do not have access to their own mother's milk or is contraindicated for mother to breastfeed/express milk (contraindicated medication, sickness, etc.*)	X	X	X	X	*	X	*
Prioritize infected infants, such as with gastroenteritis	*	X	X	X	*	X	*
Prioritize infants taking enteral nutrition	*	*	*	X	*	X	*
Fortifying Donor Milk							
HMB staff is not responsible for adding anything to the donor milk or the HMB is not allowed to use additives	X	*	*	*	*	X	X
Donor Milk needs fortification to meet the needs of preterm infants	X	*	*	X	*	*	*
Use fortifiers at room temperature	X	*	*	X	*	*	*
Ensure record keeping for any additives	X	*	*	*	*	*	*
Disposing Donor Milk							
Dispose donor milk as any other clinical waste	X	*	X	*	*	*	X
Pour down drain or put in sewage system	X	*	*	*	*	X	-
Mass disposal of frozen bottles can be discarded as biological waste	X	*	*	*	*	*	*
Delivery to Recipient							
For preterm infants provide (W=warmed milk, H=hind milk)	W,H	*	*	W	*	X	*

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Listed recommendations in setting-specific human milk banking guidelines:	BRAZIL	FRANCE	INDIA	NORTH AMERICAⁱ	POLAND	UNITED KINGDOMⁱⁱ	VIETNAMⁱⁱⁱ
Never microwave to defrost or warm milk	X	X	X	X	*	*	*
Prepare milk according to specifications provided	X	X	X	X	X	X	*
Change syringes/tubes for feeding every 4 hours	X	*	X	X	*	*	*
When possible, use fresh milk not frozen	X	*	X	X	*	*	*
Preterm infants are prioritized to receive milk expressed during first 4 weeks	X	*	*	*	*	*	*
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)	S,B, ST, T	*	M, CTF	B,T,M, CFT	*	C, NB	*
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)	R	H	R	R	H or R	R	H
Tracking includes (F=freezer temps, R= refrigerator temps, P=pasteurization processes, S=stock control, D=Dates (administration, expression, defrost time, expiration))	F,P,R,D	F,R,P,D	F,R,P, S,D	F,R,P, S,D	F,R,P, S,D	*	F,P,S,D
All donor milk and containers should be labeled at each stage	X	X	X	X	X	X	X
Records should be kept for (D=Donor, C=container before pasteurization, P=pasteurized container, B=batch information)	D,C,P,B	D,P,B	D,C, P,B	D,C, P,B	D,C,P,B	D,C,P,B	D,C,P
Receiving hospital should record/ document how donor milk is used	X	X	X	*	X	X	X

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STRENGTHENING HUMAN MILK BANKING

Listed recommendations in setting-specific human milk banking guidelines:	BRAZIL	FRANCE	INDIA	NORTH AMERICAⁱ	POLAND	UNITED KINGDOMⁱⁱ	VIETNAMⁱⁱⁱ
Records should be kept for at least _____ years after expiry date, use, or disposal of donor milk)(*or last recipient reaches 21 years)	21	10	*	*	*	*	30
When transferring milk from one HMB to another, donor ID and labelling must also transfer to the new HMB	X	*	X	-	X	*	*
Internal tracking process initiated	X	X	X	X	X	X	X
Mock recall or recorded test of system done at least every ___years	3	*	*	-	X	*	*
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	M,C,I, N,S,P,O	M,C,I, N,S,P,O	M,C,N, P,O	M,C,O	M,N, P,O, I,C	M,N,I, P,O	*
Staff is updated and trained at least: (or C=continuous or periodically)	*	*	C	C	C	C	C
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)	*	H,Q,T,N	H,Q,T	H,Q,T, N,R	H,Q,T	T,N,H	H,Q,T, N,R
Staff should be trained in and promote breastfeeding	*	*	X	*	*	X	*
Staff should have evaluations, health checks and be immunized	*	*	*	*	*	X	*
Using Raw Milk/Mother's Own Milk							
Milk bank accepts to offer raw milk or mother's own milk	X	*	X	-	-	*	-
Fresh raw milk can be kept safely for ___ hours at room temperature	*	*	6h	-	*	*	-
Fresh raw milk should be used within _____ hours after expression/ collection	*	*	24h	-	*	*	-

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SECTION 9: RESOURCES

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs

1. An Assessment Tool for Determining Facility Readiness
2. Establishing Quality Assurance:
 - a. A Workshop for Developing a Hazard Analysis Critical Control Points Plan—Trainee Workbook
 - b. A Workshop for Developing a Hazard Analysis Critical Control Points Plan—Trainer Guide
 - c. A Guide for Creating Operational Standards
 - d. An Audit Template
3. A Guide for Conducting Monitoring and Evaluation
4. A Training Curriculum Template for Hospital and Human Milk Bank Staff
5. A Guide for Track and Trace Documentation
6. A Guide for Developing a Communications Strategy
7. A Counseling Guide for Engaging Bereaved Mothers

Examples of national and regional human milk banking guidelines:

Note this is a limited list of available guidelines, many more exist and are under development.

European Milk Banking Association

- ▶ Austria:
 - Ministerium Frauen Gesundheit. Leitlinie für Errichtung und Betrieb einer Humanmilchbank: sowie für Institutionen zur Bearbeitung von Muttermilchspenden. Bundesministerium für Gesundheit und Frauen (BMGF), Sektion III. 2017.
- ▶ France:
 - French Human Milk Bank Association. The good practice rules for the collection, preparation, qualification, treatment, storage, distribution and dispensing on medical prescription of human milk by the milk banks. Available at: http://sdp.perinat-france.org/ADLF/files/lactarium_guide_bonnes_pratiques_5_janvier_2008_traduction_anglais.pdf. Accessed August 2016.
- ▶ Italy:
 - Arslanoglu S, Bertino E, 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). The Journal of Maternal-Fetal & Neonatal Medicine. 2010; 23(S2):1-20.
- ▶ Norway:
 - Study on the operation and organization of human milk banks. Utredning om drift og Organisering av morsmelkbanker. IK-2760. Oslo: January 2002.
- ▶ Poland:
 - Bernatowicz-Łojko U, Olędzka G, Borszewska-Kornacka MK, Kociszewska-Najman B, Malinowska-Pańczyk E, Pietrzak B, Pawlus B, Paczesna I, Rosiak E, Sinkiewicz-Darol E, Studniczek A, Sawczuk D, Wesołowska A, Szlagatys-Sidorkiewicz A, Zagierski M, Wierzejska R. Banki Mleka w Polsce. Fundacja Bank Mleka. [Milk Banks in Poland. Bank Milk Foundation.] 2017.

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- ▶ Spain:
 - Calvo J, Lara NR, Gormaz M, Peña M, Lorenzo MJ, Murillo PO, Sabaté JM, Samaniego CM, Gayà A. Recommendations for the creation and operation of maternal milk banks in Spain. *Anales de Pediatría (English Edition)*. 23 May 2018. 89(1):65.e1-65.e6.
- ▶ Sweden:
 - Polberger S, et al. Guidelines for use of human milk and milk handling in Sweden. Milknet, version 3.0; 2016. English Translation: 2017.
- ▶ Switzerland:
 - Frischknecht 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. *Paediatrica*. 2010; 21(4): 24-28.
- ▶ United Kingdom:
 - National Institute for Health and Care Excellence (NICE)(UK). "Donor milk banks: Service Operation." 2010. <https://www.nice.org.uk/guidance/cg93>.

Human Milk Banking Association of North America

- ▶ United States of America and Canada:
 - Human Milk Banking Association of North America (HMBANA). "Guidelines for the Establishment and Operation of a Donor Human Milk Bank." 10th Edition. 2018. <https://www.hmbana.org/publications>.

Ministry of Health and Family Welfare Government of India

- ▶ India:
 - Child Health Division: Ministry of Health and Family Welfare: Government of India. National Guidelines on Lactation Management Centers in Public Health Facilities. Macro Graphics Pvt. Ltd. June 2017.

Programa Iberoamericano de Bancos de Leche Humana (Ibero-American Network of Human Milk Banks)

- ▶ Brazil:
 - Banco de leite humano: funcionamento, prevenção e controle de riscos/Angencia Nacional de Vigilancia Sanitaria. -Brasilia, Anvisa; 2008.

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.
- ▶ Human Milk Banking Association of South Africa (HMBASA). Guidelines for the operation of the donor human milk bank in South Africa. Best practice for the collection, storage and handling of human milk. Compiled 2008, updated 2011.
- ▶ KwaZulu-Natal Department of Health. 2016. Guidelines for the establishment and operation of human milk banks in KwaZulu-Natal. Pietermaritzburg: Natalia Building.

Australia:

- ▶ Hartmann BT, Pang WW, Keil AD, Hartmann PE, Simmer K. Best practice guidelines for the operation of a donor human milk bank in an Australian NICU. *Early human development*. 2007 Oct 1;83(10):667-73.

Philippines:

- ▶ Republic of the Philippines. Department of Health. Implementing Rules and Regulation of Republic Act No. 10028. 2011 Aug 2.

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Our vision is that **all children have the best nutrition for a healthy start in life**—through their own mother’s breast milk or, when that’s not possible, with safe donor human milk.



Of all the known approaches, breastfeeding has the greatest potential impact on child survival.

Scaling up breastfeeding to a near-universal level could prevent an estimated 823,000 deaths in children under the age of five worldwide every year.

It’s especially lifesaving in resource-limited settings, where a non-breastfed child’s risk of death is six

times that of a breastfed child. Integrating human milk banks into newborn and nutrition programs ensures that all infants have access to human milk, including vulnerable, preterm, and low-birthweight infants who lack sufficient mother’s own milk. This toolkit of

templates and resources serves as a systems strengthening guide for integrating human milk banking, making available safe and quality donor human milk for vulnerable infants, with a goal to ensure optimal lactation support and breastfeeding practices.

For more information, visit www.path.org