

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



**An Assessment Tool for
Determining Facility Readiness**

1

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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Suggested citation:

PATH. Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—An Assessment Tool for Determining Facility Readiness. Seattle, Washington, USA: PATH; 2019.

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STRENGTHENING HUMAN MILK BANKING

ACKNOWLEDGEMENTS

PATH gratefully acknowledges the human milk bank technical experts, nutritionists and lactation advocates, microbiologists, neonatologists and clinical staff, regulatory and policy officials, and food scientists from around the world who contributed to the conceptualization and creation of this toolkit, and ensured that the information presented is inclusive and representative of human milk bank programs globally. For this *Assessment Tool for Determining Facility Readiness*, we would like to specifically thank global human milk bank leaders that collaborated in the preparation of this tool, including Gillian Weaver (United Kingdom), Sertac Arslanoglu (Turkey), Sandra Reid (South Africa), and Jay Ward (PATH) for guiding the direction of this tool.

This work would not have been possible without the generous financial support from the Family Larsson-Rosenquist Foundation for embracing PATH's vision around the development of globally accessible resources and standards to save newborn lives—*Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Banks*.

Technical leadership for the conceptualization and development of this 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.

ABBREVIATIONS

DHM *donor human milk*

HMB *human milk bank*

ISO *International Organization for
Standardization*

KMC *Kangaroo Mother Care*

MOM *mother's own milk*

NICU *neonatal intensive care unit*

WHO *World Health Organization*



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Photo: Northwest Mothers Milk Bank

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STRENGTHENING HUMAN MILK BANKING



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OBJECTIVES OF THIS GUIDE

- ▶ To aid the planning and development of safe and sustainable human milk banking systems.
- ▶ To assess if other interventions are needed prior to the integration of a human milk bank.
- ▶ To assist leadership in assessing the readiness for all the steps needed to create a comprehensive, safe, and sustainable human milk bank, including general planning for equipment, budgeting, and use-cases for donor human milk.
- ▶ To prevent the overuse of donor human milk by ensuring that systems are in place to protect, promote, and support the use of mother's own milk first.

ABOUT THIS GUIDE

Human milk banks (HMBs) are most impactful when integrated into systems that have prioritized maternal lactation support and the use of mother's own milk. Assessing readiness for an HMB is essential to ensure appropriate timing and resource allocation so that mothers and infants are supported for optimal early infant nutrition. The suggested pathways included in this tool will guide decision-makers at hospital, national, regional, and local levels when considering integration of an HMB system into nutrition and newborn programming. Additionally, this tool will help identify gap areas that need to be addressed prior to implementation.



Photo: PATH/Tom Furtwangler

HOW TO USE THIS GUIDE

It is recommended to follow three steps to assess readiness for the integration of an HMB and explore how best to proceed if this is an optimal option to improve newborn health and maternal lactation support.

Step 1: Identify a multidisciplinary team to assess readiness.

Objective: To identify a leadership team to assess the readiness to establish an HMB within a country or within a country or region or the development of a national or regional service.

Action: Convene a multi-disciplinary leadership team to assess readiness and identify optimal integration. A multi-faceted approach is needed to ensure all infants receive human milk. Suggestions for the leadership team include experts from the following areas of expertise:

- ▶ Local authority representation including:
 - National and/or provincial department or ministry of health, specifically from:
 - Nutrition, maternal, and newborn health.
 - Facility management, regulation, and quality control.
 - National scientific societies (neonatal/pediatric, nutrition, microbiology).
- ▶ Facility leadership including:
 - Microbiology/quality control.
 - Clinical leadership (neonatology, nutrition, nursing, midwifery, lactation, etc.).
 - Health economics.

Step 2: Gather data for informed decision-making.

Objective: To accurately assess the current neonatal nutrition and maternal lactation environment. This includes raising awareness of the challenges currently being faced and the potential benefits that may result from the establishment of a safe and sustainable HMB. Additionally, to examine relevant data for informed decision-making.

Action: Gather national, regional and/or facility-level data to inform discussions and strategic planning. Compare national, regional, or hospital data with relevant global/regional datasets to indicate where improvements may be needed. Refer to the Sustainable Development Goal indicators,¹ national health data sets, and the Global Breastfeeding Collective Breastfeeding Scorecard.² For further examples of indicators, see Appendix 1.

Step 3: Assess readiness by answering key questions.

Objective: To identify potential system improvements that will create an enabling environment for optimal introduction and integration of an HMB. As a multidisciplinary team, answering these questions will prevent future overuse of donor human milk, ensure support structures are in place to promote sustainability, and align with the mission to improve rather than undermine breastfeeding and lactation support.

Action: Proceed through the following nine sections, answering each question to assess readiness and to prioritize subsequent action steps; it is recommended to review the resources provided for each question found in the [Additional Resources](#) section at the end of this document. Where the answer is **yes**, continue to the next question. Where the answer is **no**, then determine how this will be addressed; suggestions are provided to guide meeting the identified goal, including additional resources for reference. Each question is ranked for importance to identify priority areas.



APPENDICES

The appendices contain further information to help inform the answer to each question.

Priority ranking key:

1

Priority 1: Highly recommended—only move forward if addressed.

2

Priority 2: Recommended—determine prior to the full operation of the human milk bank.

3

Priority 3: Preferred—but not required for operation.

SECTION 1: IDENTIFYING THE NEED FOR DONOR HUMAN MILK

Identifying the reasons for requiring donor human milk (DHM) will help with the planning of the proposed human milk bank (HMB).

1

QUESTION 1: *Are there specific reasons identified for insufficient maternal milk supply, and for why DHM is being proposed?*

If no, then follow this guidance:	Determine reasons why the provision of maternal milk is insufficient, and identify support mechanisms that will lead to improved maternal milk supply for her own infant. Prior to investing in an HMB system, it is recommended to invest in sufficient staff and resources to support maternal lactation.
Explanation of importance:	All babies benefit most from being fed with maternal milk and this should be prioritized. DHM is the second best option as recommended by the World Health Organization (WHO), ³ the American Academy of Pediatrics, ⁴ and the European Society for Paediatric Gastroenterology Hepatology and Nutrition. ⁵ Freshly expressed maternal milk contains the full complement of all the immune boosting and nutritional components. This is because they have not been damaged or reduced by the processing techniques used when storing and heat-treating DHM. In addition, an infant’s own mother’s milk will contain antibodies to the antigens that the mother and infant dyad are exposed to, including the pathogenic organisms likely to be found within the hospital.

IF YES

See Appendix 2 for identifying example reasons for insufficient supply of mother’s own milk (MOM).

2

QUESTION 2: *Have additional lactation support interventions been utilized to maximize provision of maternal milk? (i.e., interventions to support availability of/ access to maternal milk)*

If no, then follow this guidance:	It is recommended that any factors that impact maternal provision of breast milk be identified to reduce the need for DHM and to increase the potential donor pool.
Explanation of importance:	Minimizing the demand and/or need for DHM will increase its availability for additional clinical uses, as well as enable additional infants groups to have access to DHM. When more mothers successfully breastfeed, this results in a greater pool of potential donors.

IF YES

See Appendix 2 to help identify reasons for insufficient maternal milk supply.

2 **QUESTION 3:** *Has equity of access to DHM for all qualifying infants been addressed for this facility and the surrounding area?*

<p>If no, then follow this guidance:</p>	<p>Recommend making contact with any other HMBs in the city/region/country, as well as with all possible DHM users. This is to identify other potential providers as well as calculating the expected needs, and help ensure equity of access. Review alternative funding sources for DHM, if that is a barrier to equitable access. Explore developing satellite bank facilities and/or human milk depot sites as a means of facilitating equity of access across the region.</p>
<p>Explanation of importance:</p>	<p>Focus on the rights of the child; all vulnerable neonates should have access to DHM as a potential life-saving intervention if their own mother’s milk is unavailable. This requires collaborating with other sites to support equity of access and the importance of equity of treatment for all children.</p>

IF YES



See Appendix 3 for more information about satellite milk banks and milk bank depots.

2 **QUESTION 4:** *Is the request for DHM coming from a leading clinical authority (e.g., national neonatal society or local/regional group of neonatal/pediatric specialists)?*

<p>If no, then follow this guidance:</p>	<p>Discuss with the relevant clinical authorities the development of an HMB and the potential for availability of DHM to achieve the highest level of clinical endorsement for the establishment of HMB(s) and for the wider use of DHM.</p>
<p>Explanation of importance:</p>	<p>Without buy-in and endorsement from clinical leads, DHM may not be appropriately used, nor prioritized. It is vital to have neonatologist support for the appropriate use of DHM and prioritization. When DHM is not optimally utilized, it can lead to wastage or potentially undermine the optimal nutrition source for the vulnerable infant: MOM. When the leading clinical authority identifies a need for DHM, the HMB is more likely to receive adequate support—including approval and facility prioritization for financial support for the HMB.</p>

IF YES

2 QUESTION 5: *Have the future DHM recipients been determined and prioritized?*

<p>If no, then follow this guidance:</p>	<p>Discuss and explore with clinical experts which infants will benefit from DHM, and work with them to develop a prioritization tool that will ensure the donor milk is used optimally, especially in regard to optimal infant health and for the sustainable support of protecting, promoting, and supporting breastfeeding.</p>
<p>Explanation of importance:</p>	<p>There will be a need to determine the criteria for use of DHM. Without this, it is not possible to estimate demand or plan effectively, and there may be higher risk of inappropriate use of DHM, especially overuse which will undermine prioritizing feeding MOM as the first choice.</p>

IF YES



See Appendix 4 for examples of clinical uses of DHM.

SEE TOOL #4

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Training Curriculum Template for Human Milk Bank and Hospital Staff, Appendix 2. Donor human milk decision tree.

2 QUESTION 6: *Have the estimated volumes of DHM that will be needed been established?*

<p>If no, then follow this guidance:</p>	<p>Perform a scoping exercise to estimate the volumes of donor milk that would be needed, given the current enteral feeding policies and potential changes in need over time. Determining expected future DHM requirements can be done by retrospectively using medical notes and feeding charts; however, a prospective audit of potential use within predicted criteria will provide more robust evidence for planning.</p>
<p>Explanation of importance:</p>	<p>Estimating the predicted volumes of DHM required ensures the planning for the future system can accommodate true need and potential growth, which will impact the resources required including staffing, facilities, and equipment.</p>

IF YES



See Appendix 5 for calculating the estimated volumes of DHM needed.

3 **QUESTION 7:** *Is the estimated volume of DHM required expected to remain consistent over time?*

IF YES

<p>If no, then follow this guidance:</p>	<p>Consider how the needs for DHM may change over time, depending on future changes to the neonatal care ward, number of beds, acuity of infants, and potential consideration of DHM for alternative populations than those admitted to the neonatal intensive care unit (NICU). It is recommended that future volumes also be considered when planning for the establishment of an HMB.</p>
<p>Explanation of importance:</p>	<p>When an HMB is successfully operating, it is often possible to increase the criteria for which DHM may be available. However, inadequate space and facilities may hinder donor recruitment, DHM storage and pasteurization, and future facility expansion.</p>



See Appendix 4 for examples of clinical uses of DHM.



See Appendix 5 for calculating the estimated volumes of DHM needed.

SECTION 2: IDENTIFYING THE DONOR POOL

There are a variety of circumstances in which mothers may wish to donate their surplus breast milk. When assessing the feasibility for establishing an HMB, it is important to identify the donors that will be most suitable to meet the need for donating milk including for providing future sustainability.

2 **QUESTION 8:** *Have potential future human milk donor populations been identified?*

If no, then follow this guidance:	Consider which donor populations may be available and willing to donate their excess milk.
Explanation of importance:	Each donor population will offer different advantages and challenges in terms of duration of donation, volumes of DHM available, potential milk storage, collection and transport costs, and nutritional and immunological content of the milk.

IF YES



See Appendix 6 for example ideas of potential human milk donors.

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.

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.

3 **QUESTION 9:** *Can the identified donor pool provide sufficient volumes of DHM to meet the identified estimated need?*

IF YES

<p>If no, then follow this guidance:</p>	<p>Explore potential ideas and feasibility of extending the recruitment of donors to ensure sustainability and consistently adequate volumes of DHM available.</p>
<p>Explanation of importance:</p>	<p>A variety of donors is important for the sustainability of DHM supply. Restricting the potential donor pool to neonatal unit mothers, inpatients and/or Kangaroo Mother Care (KMC) wards may not ensure adequate and/or consistent supplies of donor milk. However, it does have the initial advantage for a newly established milk bank service of being able to work within start-up staffing constraints, as training is undertaken and staffing expertise grows.</p> <p>When community—i.e., home-based donor recruitment—commences, the buildup of expectation within breastfeeding communities can lead to a large influx of women volunteering to donate their milk. Every mother needs to be consulted with, have a brief initial history taken, and schedule appointments for follow-up recruitment and screening. The time taken to process all of the applications may overwhelm the newly recruited milk bank staff and lead to donor recruitment delay, and inevitably donor disappointment, if not all volunteers are able to be accepted. The latter happens as a result of the storage capabilities of the milk bank potentially being quickly exceeded. This adds pressure to the new milk bank, which may need to increase milk testing and processing beyond what had been envisaged.</p> <p>For these reasons, initial plans should include a gradual extension of recruitment; this should be made clear during all initial correspondence, promotion, and media involvement. It is advisable to explore the future acceptability of becoming milk donors throughout the wider breastfeeding community. This can be done through the use of social media groups as well as through focus groups within breastfeeding networks and organizations.</p>



See Appendix 6 for example ideas of potential human milk donors.

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.

SECTION 3: IDENTIFYING EXISTING RELEVANT POLICIES

Newly developed and existing policies that protect, promote, and support breastfeeding, in addition to any available guidance on HMBs, are essential to support the provision of MOM, the establishment of safe and sustainable HMBs, and the optimal use of DHM.

1 QUESTION 10: *Have national infant feeding policies that impact the establishment and the use of DHM been identified?*

<p>If no, then follow this guidance:</p>	<p>It is recommended that available policies supporting the establishment of the HMBs are identified, such as those supporting the protection of maternal lactation, breastfeeding promotion, baby friendly hospital policies, neonatal nutrition, and protection of vulnerable infants.</p>
<p>Explanation of importance:</p>	<p>There are many international, national, and local policies that will impact the safe establishment and operation of HMBs. It is helpful to be familiar with the recommendations that will support safety, sustainability, and accessibility of DHM. In the absence of regulatory frameworks, these will help to inform best practices during the establishment of the HMB services.</p>

IF YES

 See Appendix 7 for example policies related to human milk banking.

3 QUESTION 11: *Have national/regional policies been incorporated into local infant feeding protocols?*

<p>If no, then follow this guidance:</p>	<p>Update local infant feeding protocols in accordance with current accepted national recommendations to ensure optimal care practices related to infant feeding are first in place, prior to making DHM available.</p>
<p>Explanation of importance:</p>	<p>Local infant feeding protocols should be in line with national recommendations to ensure optimal breastfeeding support for infants, both in the hospital and at home. In order for the HMB to have positive impacts on neonatal nutrition and maternal lactation, policies should be in place to protect, promote, and support breastfeeding.</p>

IF YES

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, specifically see the training on breastfeeding support and the Baby-friendly Hospital Initiative.

Figure 1. Ten Steps to Successful Breastfeeding.⁶

The TEN STEPS to Successful Breastfeeding

1 HOSPITAL POLICIES

Hospitals support mothers to breastfeed by...

- Not promoting infant formula, bottles or teats
- Making breastfeeding care standard practice
- Keeping track of support for breastfeeding

2 STAFF COMPETENCY

Hospitals support mothers to breastfeed by...

- Training staff on supporting mothers to breastfeed
- Assessing health workers' knowledge and skills

3 ANTENATAL CARE

Hospitals support mothers to breastfeed by...

- Discussing the importance of breastfeeding for babies and mothers
- Preparing women in how to feed their baby

4 CARE RIGHT AFTER BIRTH

Hospitals support mothers to breastfeed by...

- Encouraging skin-to-skin contact between mother and baby soon after birth
- Helping mothers to put their baby to the breast right away

5 SUPPORT MOTHERS WITH BREASTFEEDING

Hospitals support mothers to breastfeed by...

- Checking positioning, attachment and sucking
- Giving practical breastfeeding support
- Helping mothers with common breastfeeding problems

6 SUPPLEMENTING

Hospitals support mothers to breastfeed by...

- Giving only breast milk unless there are medical reasons
- Prioritizing donor human milk when a supplement is needed
- Helping mothers who want to formula feed to do so safely

7 ROOMING-IN

Hospitals support mothers to breastfeed by...

- Letting mothers and babies stay together day and night
- Making sure that mothers of sick babies can stay near their baby

8 RESPONSIVE FEEDING

Hospitals support mothers to breastfeed by...

- Helping mothers know when their baby is hungry
- Not limiting breastfeeding times

9 BOTTLES, TEATS AND PACIFIERS

Hospitals support mothers to breastfeed by...

- Counsel mothers on the use and risks of feeding bottles, teats, and pacifiers

10 DISCHARGE

Hospitals support mothers to breastfeed by...

- Referring mothers to community resources for breastfeeding support
- Working with communities to improve breastfeeding support services



World Health Organization



unicef

SECTION 4: IDENTIFYING LOCAL LEADERSHIP AND SUPPORT

When developing a new service such as an HMB, whether to provide DHM to a region or to an individual hospital, it is important that there is an understanding of the requirements for the leadership team that will need to be assembled. The requirements will inevitably differ according to the size, location, and scope of the planned HMB(s). The breadth of support and the approvals required to proceed will be determined by the specific HMB model chosen and should be identified early on in the process of establishing a successful integrated system. Also, consider likely opposition and potential obstacles to the success of integrating an HMB to proactively address any concerns as they are raised.

1 QUESTION 12: <i>Is there an identified champion dedicated and committed to the promotion and establishment of a milk bank?</i>	
If no, then follow this guidance:	<p>Identify who has the appropriate authority and will serve as the champion for the need for DHM. When choosing a champion, consider the required clinical and operational expertise as well as seniority, influence, and ability to communicate.</p> <p>This person could be a neonatologist, pediatrician, nurse in charge, lactation specialist, midwife, or another individual with the required clinical authority.</p>
Explanation of importance:	<p>A champion is required for every HMB to advocate for, represent, and promote breastfeeding generally and the importance of the integrated HMB services more specifically. The champion ensures the quality assurance methods are in place and provides or is able to gain clinical guidance for the use of donor milk. The champion ensures that the HMB is discussed and promoted at all relevant strategy and planning meetings and events.</p>

IF YES

SEE FRAMEWORK

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Global Implementation Framework.

1 **QUESTION 13:** *Have members of the HMB multidisciplinary leadership team been identified?*

IF YES

<p>If no, then follow this guidance:</p>	<p>Identify the multidisciplinary leadership team, which may include:</p> <ul style="list-style-type: none"> ▶ Neonatologist/pediatrician ▶ Nurse/midwife ▶ Lactation support ▶ Infection control consultant ▶ Nutrition ▶ Microbiologist ▶ Finance/administrative/strategy person
<p>Explanation of importance:</p>	<p>The above-mentioned multidisciplinary positions are the recommended leadership to support the decisions made in the safety of the establishment of the HMB. They ensure quality control, safety, and maintenance of the operations of the HMB and its coordination with other services. They comprise a suggested team structure for a model that works well in many settings, which will bring the necessary expertise that can facilitate the smooth and safe running of an HMB. In the event of staff with recognized HMB expertise or exposure being available locally, they should be prioritized to lead/guide the group.</p> <p>The neonatologist/pediatrician typically acts as the clinical director/administrator of the bank. The nurse/midwife typically manages or oversees the HMB and supports the donors and optimal use of DHM, together with the lactation consultant.</p> <p>The infection control consultant will be consulted as a monitor for infections and when there is any kind of contamination problem. The microbiologist establishes the coordination system to support microbiological testing for DHM safety.</p> <p>Access to the services of a qualified nutritionist/dietitian is also essential for determining optimal use of DHM in coordination with nursing and providers. Additionally, a trained or experienced biomedical technician may provide welcome expertise as will technical support for equipment.</p>

1 **QUESTION 14:** *Has facility leadership provided approval for the integration of the HMB?*

If no, then follow this guidance:	Inform the facility leader and seek their approval. The provision of an evidence-based approach to the development of an HMB and an example of a costed business case or budget plan estimate are highly recommended when seeking approval.
Explanation of importance:	The facility leadership team is in a key position in the establishment and sustainability of the HMB, in terms of the financial and logistic support as well as the provision of the staff.

IF YES

1 **QUESTION 15:** *Did the leaders at regional and/or national level provide approval for the HMB?*

If no, then follow this guidance:	Make contact with appropriate leaders and seek their support. These will include ministry of health (maternity and child health) department leads, lead personnel within national baby friendly hospital initiative, national and regional breastfeeding support organizations, neonatal and pediatric society officers, and leading midwifery and nursing counsel officers. The approval of local or provincial health authority leaders will also be helpful, if not required.
Explanation of importance:	The health and the governing authorities at the national and regional levels should be informed and in support of the HMB. Their support is essential to ensure sustainability of the project.

IF YES

2 **QUESTION 16:** *Have the potential religious and cultural barriers for the collection, donation, and acceptance of the donor milk been identified or explored?*

<p>If no, then follow this guidance:</p>	<p>Evaluate and identify potential religious and cultural barriers using formative research, if possible.</p>
<p>Explanation of importance:</p>	<p>In some populations, religious beliefs and/or cultural tendencies can be perceived or real barriers for the donation and acceptance of the donor milk. Examples include milk kinship, the avoidance of colostrum in some communities, or more generalized barriers to the acceptance of another mother’s milk.</p> <p>The approach should be based on the individual country, religion, or culture. In the presence of a potential religious barrier, relevant religious authorities should be consulted. In the example of Islamic beliefs, an alternative milk banking model is required; while in the presence of a cultural barrier, scientific information regarding the benefits of the use of human milk should be provided to the key influential leaders.</p>

IF YES

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.

SECTION 5: IDENTIFYING ESSENTIAL INFRASTRUCTURE, SPACE, AND EQUIPMENT

HMBs have specific facility, infrastructure, and equipment requirements that will need to be considered as part of the decision-making process.

1 QUESTION 17: *Has the location and the space for the establishment of the HMB been determined?*

<p>If no, then follow this guidance:</p>	<p>Identify the location and consider the space, logistics, and the required infrastructure at the specific facility.</p>
<p>Explanation of importance:</p>	<p>Decisions regarding the HMB’s location and the provision of adequate space are important to optimize the location of the equipment, as well as to provide optimal facilities for the counseling of mothers for lactation and hygienic breast milk expression. Together, these will affect the HMB’s ability to recruit donors and interact with local services and service users, including the neonatal unit. Easy and safe access to the HMB’s facilities should be prioritized, including consideration for the donors, potential visitors, and staffing requirements. Consistent water and electricity supply are essential for the DHM collection, handling, and HMB procedures. Allocation of space should be considered to enable separation of tasks (e.g., storage area, clean area, privacy, office, etc.).</p> <p>For an example setup of an HMB, see the virtual reality tour of the Da Nang Hospital for Women and Children, available here: http://venue.rsdesigns.xyz/3d-model/human-milk-bank-da-nang/skinned/</p>

IF YES

1 QUESTION 18: *Was the required equipment for the establishment of the HMB identified for procurement?*

<p>If no, then follow this guidance:</p>	<p>Make a list of the required equipment.</p>
<p>Explanation of importance:</p>	<p>There are a number of specialized equipment needs, both essential and preferable, when establishing an HMB, and decisions regarding equipment will influence the design of internal spaces as well as the provision of suitable infrastructure and services. Consumables will require adequate and suitable storage provision, and it is advisable to explore this when making any decisions regarding equipment.</p>

IF YES



See Appendix 8 for example equipment needed in the HMB process.

SECTION 6: IDENTIFYING STAFFING REQUIREMENTS

HMBs require trained staff to ensure safety and quality, and to carry out the mission to protect, promote, and support breastfeeding. It is essential that all staff interacting with the HMB have basic training on supporting maternal lactation to provide MOM in all cases possible, and understand the appropriate use of DHM. Furthermore, HMB staff need additional advocates to help recruit donors, support mothers, and ensure a sustainable system for the HMB.

1

QUESTION 19: *Have the operational model and the staffing needs of your HMB been identified?*

If no, then follow this guidance:	First, identify the operational model of the HMB, and based on this model, identify your staffing needs.
Explanation of importance:	<p>Different operational models may be more demanding than others in terms of staffing and staff training. It is important to consider the availability of levels of trained staff that can receive HMB training and acquire HMB-related skills. Especially where there are staff shortages, such as within the neonatal nursing team, it will be important to identify necessary staffing needs to not overburden other services.</p> <p>The availability of staff to design and deliver the training is a further consideration. The chosen operational model of HMB will determine the number and qualifications of the required persons and the staffing needs. The needs of a large, centralized HMB for a region will differ from those of a local HMB within a facility.</p>

IF YES

SEE TOOL #3

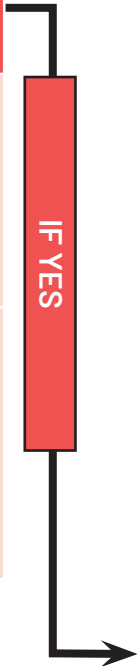
Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Guide for Conducting Monitoring and Evaluation.

**SECTION 7:
QUALITY CONTROL SYSTEMS**

Quality and safety are key pillars of a successful HMB.

1 QUESTION 20: Does the facility have access to a certified lab that is able to perform microbial testing with human milk?

<p>If no, then follow this guidance:</p>	<p>Identify the closest accredited laboratory system and what may be required (e.g., transportation) to coordinate with this laboratory.</p> <p>Or undertake to certify (or train) hospital laboratory staff to be able to perform identified microbial tests on human milk.</p>
<p>Explanation of importance:</p>	<p>All HMB systems need a quality control check of the microbial contamination of the human milk. Different systems perform microbial testing at different time points (pre-pasteurization vs. post-pasteurization); however, each site needs the guidance of laboratory expertise to determine the optimal tests and provide assistance with the required standard operating procedures.</p>



SEE FRAMEWORK

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Global Implementation Framework for examples of human milk bank guidelines globally.

2 QUESTION 21: *Do you have a plan for quality assurance (e.g., hazard analysis and critical control point)?*

If no, then follow this guidance:	Perform quality assurance planning (i.e., HACCP training/workshop) to ensure a plan is in place for when the HMB will begin operating.
Explanation of importance:	Quality assurance is essential to maintaining the quality and safety of the end product being given to a vulnerable population. Hazards need to be identified to know how to monitor the HMB process in the facility for quality and safety.

IF YES

SEE TOOLS #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 \(Trainee Workbook\)](#) and [\(Trainer Guide\)](#).

2 QUESTION 22: *Do you have engaged personnel with infection control expertise to monitor the safety and quality of the HMB?*

If no, then follow this guidance:	Identify who is able to serve on the HMB infection control or quality assurance team with relevant expertise—such as infection control, microbiology, or an understanding of human milk and the risks that come with using DHM.
Explanation of importance:	A multidisciplinary team of engaged quality control experts will help to form the quality assurance/audit team to monitor the quality and safety of the HMB processes and the provision of DHM. When this is not clearly defined from the beginning, there can be concerns of safety.

IF YES

1 **QUESTION 23:** *Does the facility have available appropriate hospital cleaning, disinfection, and equipment maintenance services?*

<p>If no, then follow this guidance:</p>	<p>Identify appropriate cleaning, disinfection, and equipment maintenance services. Consider appropriate disinfecting/cleaning of surfaces, containers, equipment, etc.</p> <p>Develop necessary cleaning standard operating procedures to ensure that this is performed appropriately and monitored.</p>
<p>Explanation of importance:</p>	<p>Given the handling of human milk has the potential to spread disease, appropriate cleaning and maintenance is needed to ensure safety for all involved. All equipment is to be maintained according to manufacturer’s instructions/protocols for the safety and quality of the end product.</p>

IF YES

3 **QUESTION 24:** *Is there an identified auditing and regulatory service for the HMB?*

<p>If no, then follow this guidance:</p>	<p>Identify the internal or external team that will perform audits and regulate the HMB. This may change over time as more attention is given from local agencies, or as national regulation and guidelines are developed.</p>
<p>Explanation of importance:</p>	<p>Auditing and tracking the services of the HMB is essential to know that DHM is being used appropriately to support breastfeeding and performed in a safe way for all those involved in the process. Until there is local/national regulation, this may be an internal auditing process. Auditing and regulation are essential for the sustainability of the HMB system.</p>

IF YES

SEE TOOL #2d

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—Establishing Quality Assurance: An Audit Template.

3 **QUESTION 25:** *Have local blood and tissue banking systems been included in the planning process?*

If no, then follow this guidance:	Make contact with appropriate blood and tissue banking agencies.
Explanation of importance:	Networking with the local blood and tissue banking services will give access to relevant expertise. Their guidelines will be useful for identifying potential similarities in screening donors, track/trace systems, labeling, and communication to potential donors.

IF YES

1 **QUESTION 26:** *Have local and/or relevant compliance regulations, accreditations, or certifications been identified? (If available.)*

If no, then follow this guidance:	Determine if the planned HMB will need to abide by select safety standards (e.g., ISO certification, health and safety legislation).
Explanation of importance:	If relevant facility and/or process regulations, accreditations, or certifications exist, then the HMB will benefit from obtaining these certifications for safety standards and potentially streamlining local approval. Many countries do not yet have these systems in place.

IF YES

SECTION 8: FINANCIAL CONSIDERATIONS

In addition to the set-up costs, HMBs will require ongoing budgetary support and planning that is based upon a comprehensive overview of what is required and what is envisaged for the future.

1

QUESTION 27: *Has an initial budget been prepared that plans for start-up and ongoing costs?*

<p>If no, then follow this guidance:</p>	<p>Varying budgetary considerations are essential for each phase of implementation. Use facility budget considerations and guidance to align with facility’s operational structure and build an initial budget plan to support start-up and ongoing budgetary needs.</p>
<p>Explanation of importance:</p>	<p>Budgeting for both the start-up and ongoing costs of the HMB operation is essential for the sustainability of the HMB. It is important to budget for future expansion, personnel changes, and other costs that may incur.</p>

IF YES



See Appendix 9 for HMB start-up and ongoing budget considerations.

1

QUESTION 28: *Have appropriate funding sources been identified?*

<p>If no, then follow this guidance:</p>	<p>First, determine if the facility is able to provide funding for all or a portion of the start-up and ongoing costs. Alternative funding sources may need to be identified, such as grants, sponsorship, and other fundraising activities that will be able to cover start-up and ongoing costs incurred by the planned HMB. Ideally, the facility is able to include at minimum a portion of the ongoing costs, such as staff time, to show support and sustainability.</p>
<p>Explanation of importance:</p>	<p>Identifying sustainable funding sources will be essential for the facility changes, staffing, training, and ongoing operational costs of the HMB. Consider appropriate funding sources that support the mission of the HMB to protect, promote, and support breastfeeding and that do not have a conflict of interest (i.e., sources that abide by the International Code of Marketing of Breastmilk Substitutes).</p>

IF YES

SECTION 9: BUILDING A NETWORK

An important early step involves reaching out to all milk banking facilities and breastfeeding support organizations locally, regionally, and nationally or in neighboring countries, as they may be able to offer valuable support.

2 **QUESTION 29:** *Have other HMB sites, locally or regionally, been identified that can serve as learning sites and partners in a learning network?*

<p>If no, then follow this guidance:</p>	<p>Identify the closest (or most relevant) HMB or HMB association locally, regionally, or globally. If possible, facilitate a learning exchange to observe practices and gain an understanding to inform HMB planning and implementation.</p>	IF YES
<p>Explanation of importance:</p>	<p>Connecting with other HMB sites will be essential for forming a learning network, and for building out the initial knowledge base. Site visits are a best practice for both clinical staff and leadership—such as the ministry of health—to understand the actual responsibilities, scope, and operation of the HMB. Throughout the set-up process, it is helpful to have a reliable and experienced source that can help answer questions and guide the process. Networking will allow for future knowledge sharing, potential associations, support, learning opportunities, and accountability for building optimal HMB systems.</p>	

SEE FRAMEWORK

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Global Implementation Framework.

2 **QUESTION 30:** *Has there been planning for potential external needs of DHM beyond the associated facility, accounting for the equity of access of DHM for vulnerable infants in the region/nation?*

<p>If no, then follow this guidance:</p>	<p>Consider the potential local/regional need for DHM, external to the associated facility. Consult local authorities to determine a plan for services to provide equity of access for all vulnerable infants, if possible.</p>	IF YES
<p>Explanation of importance:</p>	<p>It is important to recognize additional needs beyond the associated facility, especially when donations are coming from outside the facility. Equity of access takes a coordinated local/regional/national effort, which will depend on the health system's structure, and where the most vulnerable infants are provided care.</p>	

3 **QUESTION 31:** *Have additional support organizations and/or associations that are relevant to the HMB been identified for collaboration?*

If no, then follow this guidance:	Consider other organizations that support breastfeeding, early infant nutrition, parenting, and neonatal health that would be supportive for collaboration and networking.
Explanation of importance:	Partner organizations are able to support with communication, accountability, sourcing added resources and funding, and providing additional learning opportunities.

IF YES

3 **QUESTION 32:** *Have communication platforms been identified (e.g., website, social media, etc.)?*

If no, then follow this guidance:	Identify appropriate communication and networking platforms that the HMB will use for providing information and connecting with internal staff, mothers, and community support.
Explanation of importance:	Communication platforms are essential for spreading information and ideas for understanding milk banking, especially where the use of DHM may be unfamiliar. This is also a helpful process for recruiting donors and building awareness internally with staff and externally with additional stakeholders.

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.

CONCLUSION

This assessment tool has been developed to provide recommendations in preparation for the establishment of an appropriately designed, resourced, and integrated HMB. It is important to prioritize these considerations early in the process for ensuring sustainable support and the ability to equitably meet demands for safe supplies of DHM for infants without access to their own mother’s milk. Each HMB planning team will be able to use this tool to determine feasibility and attainability of a suitably resourced HMB for their context, while weighing this against the risks of not providing DHM to vulnerable infants.

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APPENDIX 1. DATA AND INDICATORS TO REVIEW

Examples of indicators and data to review are below. Ensure that all actions are taken to improve these indicators prior to the opening of the HMB, so that the HMB will be most effective in providing for true needs without undermining breastfeeding.

- ▶ Birth statistics for facility/region/nation:
 - Birth rate.
 - Rate of preterm birth.
 - Rate of low-birthweight.
 - NICU admission rates.
 - Length of stay in the NICU.
 - Number of orphan infants.
- ▶ Neonatal mortality and morbidity:
 - Rate of necrotizing enterocolitis.
 - Neonatal morbidity (sepsis, retinopathy of prematurity, etc.).
- ▶ Breastfeeding data:
 - Early initiation of breastfeeding within the first hour of life.
 - Exclusive breastfeeding at discharge from neonatal unit.
 - Any breastfeeding rates.
- ▶ Baby-friendly Hospital Initiative: accreditation achieved, or working towards accreditation.
- ▶ Kangaroo Mother Care (KMC):
 - KMC ward admission rates.
 - Length of stay in the KMC ward.
- ▶ Current feeding methods and feeding data:
 - How many infants receive no maternal milk?
 - Informal milk sharing (use of non-pasteurized other mother's milk in the hospital).
 - Is wet nursing happening?
 - Availability of appropriate alternative feeds.
- ▶ Infant feeding and lactation support:
 - Has a facility assessment and needs assessment been performed to inform scale of operations?
 - Is there consistent data collection, data reporting, and data reviewing process?

APPENDIX 2. IDENTIFYING REASONS FOR INSUFFICIENT MATERNAL MILK

There are many reasons why there may be insufficient maternal milk for an infant. If possible, these should be addressed prior to the opening of the HMB. Practitioners have provided the following examples:

- ▶ Routine and prolonged separation of mother and infant following delivery.
- ▶ Lack of well-trained lactation support staff, including all relevant health care professionals, and as a result, inadequate maternal education on breastfeeding and solutions to common breastfeeding problems.
- ▶ Midwives/neonatal nurses too busy to support new mother's lactation and breastfeeding needs.
- ▶ Inadequate and untimely help for new mothers to collect their colostrum and initiate their lactation when their infant is unable to breastfeed. This is best done by providing teaching of both hand and pump expressing, as required (mothers should be taught to express their colostrum within the first few hours of delivery and preferably within the first hour).
- ▶ Lack of privacy for mothers to express at the bed side.
- ▶ Lack of safe, comfortable, and well-equipped expressing rooms.
- ▶ Inadequate availability of good quality breast pumps/pump accessories—including different size flanges to accommodate variable size and shape of breasts, nipples, and areolas.
- ▶ Inadequate education on hand expression or how to use a breast pump.
- ▶ Inadequate breast milk storage facilities (i.e., refrigerators and freezers).
- ▶ Lack of encouragement for mothers to practice optimal skin-to-skin or KMC with their infants.
- ▶ Sub-optimal KMC facilities—lack of space and suitable furniture/beds.
- ▶ Too few rooms in facilities.
- ▶ Mothers unable to be with their infant; hospital protocols interfering with mother-baby bonding time.
- ▶ Lack of nursery facilities for siblings to enable mother to be with the hospitalized baby.
- ▶ Inaccurate information given about medications and breastfeeding.

APPENDIX 3.

SATELLITE MILK BANKS AND MILK BANK DEPOTS

Throughout the world, there are examples of how HMBs increase their operational capacity and DHM provision, including over a wider geographical area, through the establishment of satellite milk banks and milk bank depots.

A satellite milk bank is an additional HMB facility under the same management as the main HMB. The satellite milk bank usually undertakes most if not all of the main HMB activities, using the same protocols, guidelines, and operational standards. The satellite milk bank will provide a less costly solution to the need for increased DHM provision within an area or region than the establishment of an additional HMB. This is done by sharing overall staff management, transport facilities, and other resources. In some cases, the donated milk may be transported to the main milk bank for processing, thus making better use of equipment in the main HMB.

A milk bank depot is a storage facility for raw and/or processed DHM that enables an HMB to extend its area of operations. The depot may be managed by the main HMB staff, however, staff and/or volunteers in the facility where it is housed (this may be within a hospital or alternative health care facility) will provide additional staffing to ensure the depot is fully monitored and that it runs safely and efficiently in accordance with the main HMB's requirements.

APPENDIX 4.

USE CASES FOR DONOR HUMAN MILK

DHM is prioritized in the absence of any or sufficient MOM in the following clinical scenarios:

- ▶ Preterm infants.
- ▶ Low-birthweight and very low-birthweight infants.
- ▶ Infants having undergone invasive surgery.

DHM is used occasionally in the following clinical scenarios:

- ▶ Infants born to HIV-positive mothers.
- ▶ Infants born with cardiac anomalies.
- ▶ Neonatal hypoglycemia protocols.

AN ASSESSMENT TOOL FOR DETERMINING FACILITY READINESS

- ▶ Neonatal jaundice.
- ▶ Neonatal renal disease.

DHM is used rarely in the following clinical scenarios:

- ▶ Post-transplant surgery.
- ▶ Maternal double mastectomy.
- ▶ Maternal cancer treatment.
- ▶ Maternal death.
- ▶ Maternal intensive care.

DHM is used rarely and/or inconsistently in the following non-clinical scenarios:

- ▶ Adopted infants.
- ▶ Surrogacy.

APPENDIX 5.

CALCULATING BASIC ESTIMATES FOR THE NEED FOR DONOR HUMAN MILK

For determining very basic estimates for the current DHM needs in any neonatal ward or hospital, consider the following suggested ways to audit feeding practices:

1. A theoretical exercise based on average gestations and weights of infants cared for. This will be determined by looking at audit data previously collected or by using data relating to current occupancy. A total expected volume of enteral feeds required throughout the period of hospitalization by a 'theoretical infant' can be calculated using the unit's feeding protocols, including the day when feeds started, initial feed volumes (in accordance with the infant's weights), and the rates of advancement of feeds. This does not take into consideration any periods when feeds do not advance or are stopped because of clinical concerns.
 - ▶ Number of beds in the NICU.
 - ▶ Percentage of infants at any given time (or over an average of three days, including a weekday and a weekend day) that may require DHM. (This is typically estimated for a high-intensity neonatal ward to be 15–40 percent, at any given time, need at least one feed of DHM.)
 - ▶ For infants requiring DHM, percentage of daily feeds of MOM versus DHM.
 - ▶ Average weight of the admitted infants to determine estimated feeding volumes.

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2. Prospectively using the feeding charts in the medical notes to gather data on the exact feeds given for the current infants being cared for. For this to provide an accurate snapshot, it is essential that the charts are fully completed and that the exact type of feed being used is entered.

Additionally, the following are considerations to assess requirements for DHM, in order to account for potential growth in the development and planning of the HMB:

1. Retrospectively:
 - ▶ Clinicians and nurses agree criteria for eligibility for DHM for infants on the neonatal unit(s). Similar agreement made for infants on the pediatric unit, infant surgical ward, KMC unit, etc.
 - ▶ Identify all infants meeting the criteria in the previous three months (or six months depending upon time and resources available to this task).
 - ▶ Obtain the nursing and medical notes for each child identified.
 - ▶ Use feeding charts in the nursing notes and information from the medical notes to assess for each day of each infant's stay when the volume of MOM was less than the total enteral feed volume required.
 - ▶ Note the volume of supplement needed or, if prior to the provision of an alternative enteral supplement, the difference between the volume of MOM delivered and the volume that would have been given if available. This volume provides an estimate of the volume of DHM that would have been required to ensure exclusive human milk feeds and to avoid formula use.
 - ▶ Conduct a survey of the parents or caretakers of the infants included in this data collection to discover if DHM would have been acceptable to them as a supplement. Provide relevant information about DHM to enable an informed decision by the parents or caretakers.
2. Prospectively:
 - ▶ Agree on criteria for use of DHM for infants on the neonatal unit(s) and any other units where DHM will be used.
 - ▶ Collect data showing the shortfall in MOM and the volumes of enteral supplement required to achieve the recommended feed volumes for each infant.
 - ▶ Conduct a survey of the parents or caretakers of the infants included to discover if DHM would be acceptable to them as a supplement. Provide relevant information about DHM to enable an informed decision by the parents or caretakers.
 - ▶ In practice, in each case, as DHM is better tolerated than infant formula and as the use of DHM usually leads to increased provision of MOM, the required volume of DHM may be less than the calculated volume.

APPENDIX 6. IDENTIFYING POTENTIAL HUMAN MILK DONORS

The table below provides an explanation of different groups of donors together with their expected length of donation period.

Type of donor	Expected volumes of milk donated	Expected length of donation period	Comments
<p>Single-time donor (in hospital)</p>	<p>Single donations will vary from small volumes of less than 1 liter (a minimum accepted volume may be desirable to ensure such donations are economically feasible) to several hundred liters or more in exceptional circumstances.</p>	<p>The donor provides the stored milk once she (and usually also the hospital staff) are confident that her own baby will not need it. The duration of donation varies from a few days to several months. This is dependent upon individual circumstances of the infant and the mother.</p>	<p>The milk donated is usually very suitable for feeding to other neonates, as it will have been expressed during the early weeks post-delivery of the infant and may be preterm milk with its potentially higher nutritional and immunological content.</p> <p>The milk is usually expressed prior to the donor being aware of the restrictions imposed by milk banks, and so some or all of the proposed donation may not be acceptable to the milk bank. This is because there are often different restrictions on medication use, alcohol intake, and recommendations for the storage of MOM compared to DHM. The information needed may not be available retrospectively unless written on the label at the time of collection/freezing.</p> <p>Most of the donors are recruited once the infant has been discharged to ensure he/she and the mother is fully meeting the needs of her infant.</p>

STRENGTHENING HUMAN MILK BANKING

Type of donor	Expected volumes of milk donated	Expected length of donation period	Comments
Single-time donor (from home)	Varies—usually several liters or more.	This may be from a few weeks up to the maximum storage time accepted by the milk bank.	Some milk banks will not accept milk previously expressed and stored at home due to the lack of assurance of the freezer and storage conditions. The milk is unlikely to be adequately labeled for milk bank purposes—so this may need to be remedied. A careful history is required to ensure any medications taken during the donation period are accurately recalled and documented.
Ongoing donor	Milk banks often impose a minimum volume, which may be 2–4 liters. Uppermost volumes will depend on the length of the donation period, which may be restricted by local/national guidelines.	Usually up to at least one year of age of the donor’s child. This varies internationally.	It is the responsibility of milk bank staff to ensure that the donor is providing milk that is surplus to her own child’s needs and that is safe for her to do so.
Bereaved donor (single time)	Milk banks will often avoid placing a minimum donation volume in the case of bereaved donors. There may be large volumes, up to 50 or more liters, where the infant survived in hospital for several weeks or months.	This will vary from a few days to several weeks or months.	The milk bank staff have additional duties of care in respect to bereaved donors, who will be making decisions about donating their stored milk at a very difficult time. They will often be in need of general lactation support and advice about stopping their milk supply in a way that will be optimal in terms of timing and health considerations.
Bereaved donor (ongoing)		This may be several months up to the HMB’s maximum time period (which varies).	

APPENDIX 7.

EXAMPLES OF NATIONAL/REGIONAL POLICIES THAT IMPACT INFANT FEEDING

- ▶ National infant feeding policies: All policies that have been designed to support and improve breastfeeding rates will positively impact on potential numbers of human milk donors and may also reduce the need for DHM for sick and preterm infants.
- ▶ WHO International Code for the Marketing of Breastmilk Substitutes.
- ▶ WHO Recommendations for Infant Feeding: Provides recommendations for decisions regarding infant feeding prioritization.
- ▶ International or national newborn care policies (e.g., Early Essential Newborn Care, KMC): Such policies when enacted lead to improved lactation and breastfeeding and so increase potential donor numbers and reduce the requirement for DHM.
- ▶ National and local maternity leave policies: Minimum maternity leave provision may impact the availability of DHM as mothers will be returning to work and may choose to stop breastfeeding. Those who continue to breastfeed may not have enough surplus milk to donate to the milk bank.
- ▶ Baby-friendly Hospital Initiative: These will support maternal lactation and help to reduce DHM requirement, as well as increase donor numbers.
- ▶ Hospital rooming-in policies: Keeping mothers and babies together has been shown to support lactation and breastfeeding and will reduce the need for DHM, as well as increase potential donor numbers.
- ▶ Human milk policies in hospital (e.g., storage, acceptance of outside stored milk): Where the availability of maternal milk provision is optimally supported by safe and adequate storage and optimal breast milk handling policies, there will be a reduced need for DHM as these facilitate access to maternal milk and minimize wastage. Delaying or reducing the availability of MOM by inadequate hospital storage facilities may increase the demand for DHM.
- ▶ National maternal lactation guidance: All policies that support or optimize lactation and the availability of MOM will impact HMBs by reducing demand for and increasing the potential supply of DHM.
 - Ways of expression supported (hand vs. pump).
 - Lactation support—general lactation support (all mothers).
 - Lactation support in the NICU, for human milk expression and storage.
- ▶ Local maternal lactation guidance.
 - Availability of storage options, including containers, and refrigerators and/or freezers.
- ▶ Blood banking and tissue policies: There are many similarities between the banking of human milk and the banking of blood and tissues. Policies that have been designed to support and optimize donation of blood and tissues may be relevant to and inform the development of HMBs.

STRENGTHENING HUMAN MILK BANKING

- ▶ Prevention of mother-to-child transmission and HIV policies that impact infant feeding: Where policies include recommendations that impact the availability of a MOM, these will in turn affect the demand for DHM.
- ▶ Health and safety policies including manual handling policies, and those policies that support employees to express and store breast milk when they return to work.
- ▶ Standards and protocol for infant feeding.
- ▶ Enteral feeding protocols.
- ▶ Medical products of human origin.

APPENDIX 8.

EXAMPLE EQUIPMENT TO BE PROCURED FOR THE HUMAN MILK BANK

- ▶ Equipment to consider:
 - Refrigerator(s)
 - Freezer(s)
 - Pasteurizer
 - Laminar flow cabinet
 - Air conditioning system
 - Breast pumps
- ▶ Additional questions to consider when procuring equipment:
 - Are supplies and equipment available locally or will procurement internationally be required?
 - Are supplies available and within budget for the human milk bank (labels, containers, paper supplies, etc.)?
 - What disinfection options are available onsite? For example, is there access to an autoclave or industrial dishwashing machine? If no, consider optimal equipment for disinfecting supplies and equipment.
 - Is there a consistent supply of electricity source? Are there sufficient outlets? If no, consider equipment that will supplement current electricity sources to meet facility needs.
 - Is there a consistent supply of safe water? If no, invest in equipment that will assist to provide safe water when needed.

APPENDIX 9. BUDGETARY CONSIDERATIONS

Here is a preliminary list of budgetary considerations when planning for the basic start-up and ongoing stages of an HMB operation. This list is not exhaustive of what is required for the start-up of an HMB.

- ▶ Start-up costs:
 - Training and stakeholder meetings.
 - Infrastructure and renovations.
 - Equipment for DHM collection, storage, treatment, and microbial testing.
 - Legal and administrative costs.
- ▶ Ongoing budget considerations:
 - Supplies: cleaning, record keeping, DHM storage containers, administrative supplies.
 - Personnel: consider days/hours of HMB operation, and staff time dedicated towards:
 - o Lactation support.
 - o Donor recruitment and screening.
 - o DHM preparation, pasteurization, and testing sampling.
 - o Coordination with related services.
 - o Cleaning containers and supplies.
 - o Administrative duties—including record keeping, stock keeping, data collection, data interpretation and dissemination.
 - Continuing education/training.
 - Lab testing, or coordination with lab services.
 - Community awareness, marketing, and fundraising.
 - Transportation.

ADDITIONAL RESOURCES

How to use this guide

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STRENGTHENING HUMAN MILK BANKING



Photo: United States Breastfeeding Committee

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