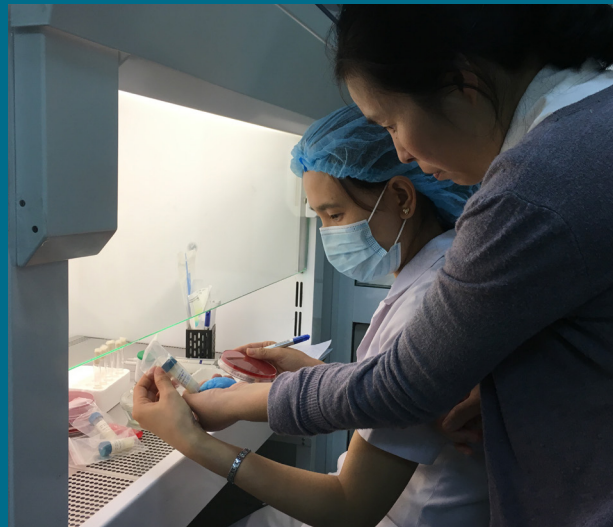


STRENGTHENING HUMAN MILK BANKING:
A Resource Toolkit for Establishing &
Integrating Human Milk Bank Programs



Establishing Quality Assurance:
A Guide for Creating
Operational Standards

2c

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.

PHOTOS: Cover (left to right): Northwest Mothers Milk Bank; PATH/Kimberly Mansen; Laerdal Global Health; Back cover (left to right): United States Breastfeeding Committee; Mothers' Milk Bank Austin, Texas; Northwest Mothers Milk Bank.

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ABBREVIATIONS

DHM *donor human milk*

HMB *human milk bank*

HACCP *hazard analysis critical control points*

HTLV *human T-lymphotropic virus*

HIV *human immunodeficiency virus*

SOP *standard operating procedure*



Photo: Northwest Mothers Milk Bank

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OBJECTIVES OF THIS GUIDE

- ▶ To provide a layout and template for developing guidelines for human milk banking.
- ▶ To provide advice for the setup, organization, coordination, and quality control necessary for a human milk bank program.
- ▶ To facilitate the establishment of human milk bank systems to protect, promote, and support breastfeeding.
- ▶ To facilitate the development of locally appropriate guidelines and national standards for integrated human milk bank programs.

ABOUT THIS GUIDE

The purpose of this guide is to provide a layout and template for developing guidelines for human milk banking. This includes advice for the overall processes necessary for a human milk bank (HMB) to function in a way that protects, promotes, and supports breastfeeding and access to human milk. This guide is intended to assist local policymakers and HMB stakeholders in creating national-level guidelines for the operation of an HMB. The creation of the subsequent guideline does not replace the standard operating procedures of individual HMBs but should instead set national-level standards for local HMB operation. This is a quality assurance guide based on current research and best practices. Institutions must keep up to date with evidence to ensure the best outcomes in their own settings.



Photo: PATH/Kimberly Mansen

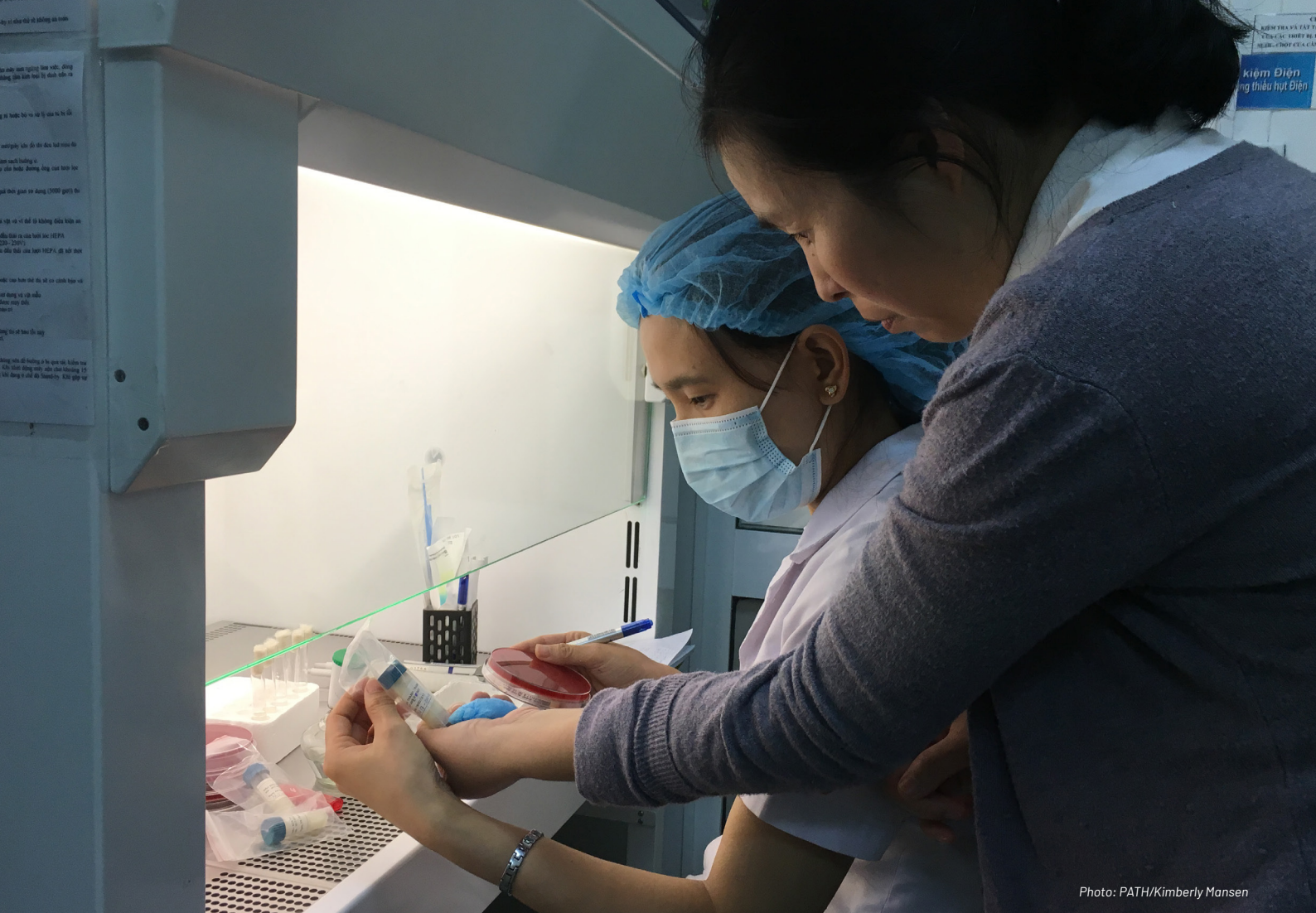


Photo: PATH/Kimberly Mansen

HOW TO USE THIS GUIDE

The headings and content provided in this template are meant to drive local discussion and consensus on the development of appropriate HMB guidelines. This template and the guideline it produces should be continually reassessed for quality assurance throughout the running of milk bank processes. Guidelines should be updated as needed to reflect changing research, population needs, disease risk, and resources.

This template lists the minimum recommended topics and information to include in a national-level human milk banking guideline.



Text highlighted in **blue** is provided for your instruction and will prompt you to insert additional information specific to your hospital/ HMB and regional policies and guidelines. This text must be removed to finalize the national-level guidelines that are created. Information listed for each section should be adapted and expanded based on local policies, resources, culture, disease risk, needs, and HMB standard operating procedures.

SECTION 1: INTRODUCTION

The purpose of this section is to provide an overall background of human milk banking in your setting.



- ▶ Information in this section should be adapted and expanded based on local policies, resources, and culture.

Suggested content for this section:

- ▶ Country or regional statistics for:
 - Infant and neonatal mortality.
 - Breastfeeding initiation and exclusivity.
 - Length of stay in the neonatal intensive care unit.
- ▶ Discussion of the benefits of breastfeeding and human milk to both mother and infant.
 - Include a statement on the benefits for bereaved mothers.
- ▶ Overview of human milk banking.
- ▶ Rationale for human milk banking in your country.

SECTION 2: ESTABLISHING A HUMAN MILK BANK

Pre-qualifications for establishing a human milk bank

The purpose of this section is to provide guidance on the considerations prior to establishing a human milk bank (HMB)..



- ▶ Information in this section should be adapted and expanded based on local policies, resources, needs, and HMB standard operating procedures (SOPs).

Suggested content for this section:

- ▶ Nationally determined pre-qualifications for establishing an HMB.
- ▶ Assess regional readiness and need for an HMB, including identifying and evaluating the following topics:
 - The regional need for donor human milk (DHM) and equitable access to human milk.
 - The potential donor pool.
 - Existing and needed breastfeeding support services.

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- Existing and needed policies to support breastfeeding and use of DHM.
- Local leadership and support.
- Essential infrastructure, space, equipment, and staffing needs.
- Recommendations for integrating HMBs with existing hospitals, and community health centers.

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.

Human milk bank staff training

The purpose of this section is to provide guidance on identifying multidisciplinary HMB team members and their roles.



- ▶ Information in this section should be adapted and expanded based on local policies, resources, disease risk, needs, and HMB SOPs.

Suggested content for this section:

- ▶ All HMB and clinical staff using DHM at sites where an HMB is present should receive formal training on the following topics:
 - HMB SOPs.
 - Hygienic and safety practices.
 - Importance of external and internal auditing.
 - Hazard analysis and critical control points (HACCP).
 - Baby-friendly Hospital Initiative.
- ▶ Determine the frequency of retraining.
- ▶ If certification is common, consider qualifications to be certified in HMB practices.

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.

Facility and equipment

The purpose of this section is to provide suggestions and requirements for facility space and equipment.



- ▶ Information in this section should be adapted and expanded based on local policies, resources, needs, and HMB SOPs.

Suggested content for this section:

- ▶ Facility requirements:
 - Space for reception, processing, and storing DHM.
 - Administrative space.
 - Adequate air ventilation.
 - Free of pests.
- ▶ Equipment requirements:
 - Determine the frequency of inspection, and service equipment accordingly.
 - Recommended that all equipment used in DHM handling and processing is cleaned, sterilized, and calibrated according to manufacturer's instruction.
 - Freezer for storing raw milk.
 - Freezer for storing pasteurized milk.
 - Food-grade milk storage containers.
 - Traceable milk labels.
 - Calibrated temperature recorders.
 - Pasteurizer and treatment equipment:
 - o Autoclave.
 - o Refrigerator.
 - o Laminar flow hood.
 - o Cleaning manual and logbook.
 - o Administrative supplies.
 - o Supplies for maintaining a hygienic environment.
 - o Calibrated temperature control recorder.
 - o Sensors and alarms on equipment that affects temperature levels.

SECTION 3: HUMAN MILK DONORS

Donor recruitment

The purpose of this section is to provide guidance about the donor recruitment process.



MODIFY

- ▶ Information in this section should be adapted and expanded based on local policies, resources, disease risk, culture, needs, and HMB SOPs.

Suggested content for this section:

- ▶ Donors should be mothers who are willing to donate their surplus milk after meeting their own infant's current and future needs.
- ▶ Recruit using different communication channels such as:
 - Media channels (i.e., written material distributed in antenatal clinics, television, and radio).
 - Personal channels (i.e., referrals from antenatal staff, physicians, midwives, and lactation consultants).
 - Community-orientated channels (i.e., word of mouth within social networks).
- ▶ Use clear, nontechnical language to provide information to potential donors.
- ▶ Obtain written consent from potential donors before screening.

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 be used to 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.

Donor screening

The purpose of this section is to provide guidance on donor screening.



MODIFY

- ▶ Information in this section should be adapted and expanded based on local policies, resources, disease risk, culture, needs, and HMB SOPs.

Suggested content for this section:

- ▶ General screening steps:
 - Informal oral or written interview.
 - Statement of health by donor's physician and by donor's child physician.
 - Screening information can include but is not limited to:
 - o General health of donor.
 - o General health of donor's child.
 - o Donor's recent vaccinations and current medication uses.
 - o Significant environmental exposures.
 - o Infectious exposures.
- ▶ Serological testing of donor is required for:
 - HIV-1 and 2.
 - Human T-lymphotropic virus (HTLV) I and II.
 - Hepatitis B and C.
 - Syphilis.
- ▶ Exclusion criteria:
 - Tobacco use or exposure to second-hand smoke.
 - Alcohol use that exceeds more than the recommended amount (1-2 units of alcohol once or twice a week).
 - Use of recreational drugs in the past 12 months.
 - Tests positive for HIV 1 or 2, hepatitis B or C, HTLV I or II, or syphilis.
 - Has an increased risk for Creutzfeldt-Jakob disease.
- ▶ Advise mothers who are using alcohol, tobacco, or illicit drugs to stop, as this puts them and their infant at risk.
- ▶ Temporary disqualification:
 - Localized breast disease.
 - Donation that compromises the nutritional intake of mother's own infant.
 - Poor nutritional intake.

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- Medication or vaccination that is contraindicated for breastfeeding.
- Significant environmental exposures.
- High-risk behavior (e.g., recent tattoo or body piercing, acupuncture, IV drug use, recipient of organ or tissue transplant, recipient of blood transfusion, and accidental needle sticks occurring in the medical field.)

Donor consent

The purpose of this section is to provide guidance on obtaining donor consent.



- ▶ Information in this section should be adapted and expanded based on local policies, resources, culture, needs, and HMB SOPs.

Suggested content for this section:

- ▶ Informed consent must be obtained from potential donors before serological testing and any handling donor's milk.
- ▶ Informed consent documents must be saved and stored.
- ▶ Informed consent needs to describe intended use of donated milk.

Training, education, and support for donors

The purpose of this section is to provide guidance on the type of support and education donors need to provide safe and quality DHM.



- ▶ Information in this section should be adapted and expanded based on local policies, resources, disease risk, culture, needs, and HMB SOPs.

Suggested content for this section:

- ▶ Provide donors with education in proper methods for expression, handling, storage, and transportation of DHM to help improve milk safety and quality.
- ▶ Education should include information on safe expressing, handling, and storing of milk intended for the mother's own infant as well as for donation.
- ▶ Lactation education should be available to all mothers, regardless of their ability to donate milk.
- ▶ Extra support should be provided to bereaved mothers, as they may donate as part of the healing process.
- ▶ Education for donors can include:
 - Lactation support and counseling on breastfeeding practices.
 - Emotional support.

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- Handwashing and personal hygiene.
- Techniques for milk expression and collection.
- Use of breast pumps or techniques for manual expression.
- Milk storage including choosing appropriate containers and safe storage in a freezer.
- Cleaning storage containers and pumping equipment.
- Labeling with time and date of expression.
- Coordinating transportation of DHM to the HMB, including temperature and time limit.

SECTION 4: HANDLING AND PROCESSING OF DONOR HUMAN MILK

Handling donor human milk at home

The purpose of this section is to provide guidance on how to handle milk at home.



MODIFY

- ▶ Information in this section should be adapted and expanded based on local policies, resources, disease risk, and HMB SOPs.

Suggested content for this section:

- ▶ Emphasize proper hygiene and handwashing.
- ▶ Discourage the sharing of breast pumps.
- ▶ Express 6–8 times a day.
- ▶ Freeze milk intended for donation as soon as expression is complete.
- ▶ Store containers of DHM in the back of the freezer.
- ▶ Define maximum length of time for storage.
- ▶ Preferably, use containers provided by the HMB.
- ▶ Do not add freshly expressed milk to already frozen milk.
- ▶ Provide instructions for defrosting and using the milk at home.

Handling donor human milk at the hospital or human milk bank

The purpose of this section is to provide guidance on how to handle DHM at the hospital or HMB.



- ▶ Information in this section should be adapted and expanded based on local policies, resources, disease risk, and HMB SOPs.

Suggested content for this section:

- ▶ DHM must always be handled and processed hygienically; these practices include:
 - Handwashing.
 - Use of protecting garments.
 - Clean surfaces.
 - Adequate air ventilation.
 - Free of pests.
- ▶ Maximum storage temperatures.
- ▶ Maximum storage duration.
- ▶ Recommendations for storing raw and processed milk separately.
- ▶ Local recommendations and guidance for milk preparation (thawing, pooling, nutrient analysis homogenization).
- ▶ Safe transportation and distribution to maintain the cold chain.
- ▶ Procedures that permit tracking and tracing of all milk through processing in the HMB.
- ▶ Recommendations for discarding milk that does not meet selection criteria.

Milk screening

The purpose of this section is to provide guidance on how to handle milk at the hospital or HMB.



- ▶ Information in this section should be adapted and expanded based on local policies, resources, disease risk, and HMB SOPs.

Suggested content for this section:

- ▶ Process for testing milk batches pre-pasteurization for microbial content and possible contamination.
- ▶ Repatriated milk is screened for:
 - Total viable microbial content.
 - *Enterobacteriaceae*.
 - *Staphylococcus aureus*.

A GUIDE FOR CREATING OPERATIONAL STANDARDS

- ▶ Methods for communicating laboratory test results for accurate and timely interpretation.
- ▶ Frequency of post-pasteurization microbial screening is dependent on the availability of local resources.
- ▶ Recommendations for discarding milk that does not meet microbial testing specifications.
- ▶ Discard all DHM used for testing.

Donor human milk pasteurization

The purpose of this section is to provide guidance on how to handle milk at the hospital or HMB.



MODIFY

- ▶ Information in this section should be adapted and expanded based on local policies, resources, disease risk, and HMB SOPs.

Suggested content for this section:

- ▶ Method of pasteurization is selected based on the financial, staffing, and energy resources of the HMB.
- ▶ Verification protocols should be utilized to ensure adequate pasteurization.
- ▶ All pasteurization is temperature and time controlled.
- ▶ Pasteurizing equipment should be regularly calibrated, inspected, and cleaned to meet performance specifications.
- ▶ After pasteurization, milk is rapidly cooled using either processing equipment manufactured to cool milk or ice baths.
- ▶ Milk should be moved to a freezer following pasteurization and cooling.
- ▶ Determine the length of time pasteurized milk can be stored in a freezer before distribution and consumption.

SEE TOOL #2d

Strengthening Human 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 and Appendix 2. Performance specification for a Holder pasteurization device.

SECTION 5: RECIPIENTS OF DONATED HUMAN MILK

Selection and prioritization of recipients

The purpose of this section is to provide guidance for relevant aspects of the process of receiving DHM.



MODIFY

- ▶ Information in this section should be adapted and expanded based on local policies, resources, disease risk, needs, and HMB SOPs.

Suggested content for this section:

- ▶ When possible, prioritize feeding mother's own milk and increasing the mother's milk supply before providing DHM.
- ▶ All recipients of DHM will receive heat-treated milk, unless otherwise requested by physician or local policies.
- ▶ DHM is dispensed only by prescription or hospital purchase order.
- ▶ Prioritize preterm and low-birthweight newborns.
 - Other priority infants include those struggling with malabsorption, feeding intolerance, immunologic deficiencies, and congenital anomalies.
- ▶ Physicians must assess the need for DHM prescription.
- ▶ If the need for DHM is greater than the supply, other HMBs should be contacted.
- ▶ If DHM supply is sufficient, it may be dispensed by prescription for other situations including lactation failure, adoption, and death of the mother.

Consent for receiving donor human milk

The purpose of this section is to provide guidance on obtaining consent for receiving DHM.

MODIFY

- ▶ Information in this section should be adapted and expanded based on local policies, resources, disease risk, culture, needs, and HMB SOPs.

Suggested content for this section:

- ▶ Consent must be obtained from infant's guardian prior to dispensing DHM.
- ▶ Consent documents must be saved and stored.
- ▶ Informed consent needs to describe all potential risks and benefits of receiving DHM.

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, Appendix 2. [Donor human milk decision tree](#) provides a flow chart to determine the prioritization of donor human milk.



Photo: United States Breastfeeding Committee

SECTION 6: QUALITY CONTROL

Hazard analysis critical control points

The purpose of this section is to provide recommendations for implementing and adhering to HACCP principles at all human milk banking processes.



MODIFY

- ▶ Information in this section should be adapted and expanded based on local policies, resources, disease risk, and HMB SOPs.

Suggested content for this section:

- ▶ Development of a site-specific HACCP plan and quality control system to ensure the safety of DHM.
- ▶ Identification of appropriate reference manuals for applying HACCP.
- ▶ Staff training for understanding the importance of using HACCP in human milk banking, and understand and identify each of the 12 steps used in creating a HACCP plan.
 - Trainings should ensure that staff members are able to complete their tasks, understand regulations, and follow HACCP principles.
- ▶ Continuous assessment and improvement of the HACCP plan as needed.

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) 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.

Tracking, tracing, and record keeping

The purpose of this section is to provide guidance to ensure traceability of DHM and continuous assessment of HMB activities to improve the processes.

MODIFY

- ▶ Information in this section should be adapted and expanded based on local policies, resources, disease risk, needs, and HMB SOPs.
- ▶ HMB staff should perform tracking of DHM, from donor to recipient.
- ▶ Tracking includes monitoring and recording: date of expression, date received by the HMB, storage freezer temperatures, storage refrigerator temperatures, defrost time and temperature, pasteurization processes, microbial testing processes, and the date of expiration.
- ▶ All DHM and containers should be relabeled or updated during processing.
- ▶ Records should be kept on milk collection, transportation, storage, processing, and allocation.
- ▶ Receiving hospital should document how DHM is used.
- ▶ Records should be kept for a designated set of years after the date of expiration, use or disposal of donor milk, or age of DHM recipient.
- ▶ When transferring milk from one HMB to another, donor ID and labeling must also transfer to the new HMB.
- ▶ Mock recalls or recorded tests of system are recommended.

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.

Auditing

The purpose of this section is to provide guidance to for implementing internal and external auditing of HMBs.

MODIFY

- ▶ Information in this section should be adapted and expanded based on local policies, resources, disease risk, needs, and HMB SOPs.
- ▶ Internal auditing should be done at least annually by an HMB advisory committee.

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- ▶ External auditing can be conducted through the ministry of health.
- ▶ Continuous quality improvement and evaluation of the effectiveness of all SOPs should be conducted to uphold best practices and systems that ensure ongoing quality.
 - Ensure safety and best practices during the collection, transportation, testing, processing, storage, and allocation of milk.
- ▶ Maintenance and regular inspection of equipment and facility.

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 internal guidelines and regional requirements.

Monitoring, evaluation, and operational research

The purpose of this section is to provide guidance to ensure traceability of DHM and continuous assessment of HMB activities to improve the processes.



MODIFY

- ▶ Information in this section should be adapted and expanded based on local policies, resources, disease risk, needs, and HMB SOPs.
- ▶ Establish an operational research plan to keep track of breastfeeding rates, newborn nutrition, and health outcomes.
- ▶ Monitor the use and distribution of DHM, as well as infant outcomes from those receiving DHM.
- ▶ Evaluate how regional HMBs protect promotes, and support breastfeeding.

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 an integrated human milk bank system through evidence generation.

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