A Guide for Track and Trace Documentation

Starting every life with mothers’ milk
STRENGTHENING HUMAN MILK BANKING: 
A Resource Toolkit for Establishing & Integrating Human Milk Bank Programs

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0.</td>
<td>A Global Implementation Framework</td>
</tr>
<tr>
<td>1.</td>
<td>An Assessment Tool for Determining Facility Readiness</td>
</tr>
<tr>
<td>2.</td>
<td>Establishing Quality Assurance:</td>
</tr>
<tr>
<td></td>
<td>a. A Workshop for Developing a Hazard Analysis Critical Control Points Plan—Trainee Workbook</td>
</tr>
<tr>
<td></td>
<td>c. A Guide for Creating Operational Standards</td>
</tr>
<tr>
<td></td>
<td>d. An Audit Template</td>
</tr>
<tr>
<td>4.</td>
<td>A Training Curriculum Template for Hospital and Human Bank Staff</td>
</tr>
<tr>
<td>5.</td>
<td>A Guide for Track and Trace Documentation</td>
</tr>
<tr>
<td>7.</td>
<td>A Counseling Guide for Engaging Bereaved Mothers</td>
</tr>
</tbody>
</table>

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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## ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DHM</td>
<td>donor human milk</td>
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<td>HIV</td>
<td>human immunodeficiency virus</td>
</tr>
<tr>
<td>HMB</td>
<td>human milk bank</td>
</tr>
<tr>
<td>SOP</td>
<td>standard operating procedure</td>
</tr>
</tbody>
</table>
# Strengthening Human Milk Banking

## Objectives of This Guide
6

## About This Guide
6

## How to Use This Guide
7

## Introduction
8

### Section 1: Donor Recruitment, Screening, and Consent
9

- Form 1: Donor Screening Questionnaire
10
- Form 2: Donor Consent Form
10
- Form 3: Donor Consent Log
11

### Section 2: Donor Human Milk Expression, Collection, and Transportation
12

- Form 4: Donor Human Milk Handling and Transportation Log
12
- Form 5: Expression Log
14
- Form 6: Hospital Donor Human Milk Log
14

### Section 3: Donor Human Milk Handling, Treatment, and Storage
15

- Form 7: Donor Human Milk Register
15
- Form 8: Temperature Log
16
- Form 9: Thawing and Pooling Log
17
- Form 10: Microbial Screening Log
17
- Form 11: Donor Human Milk Pasteurization Log
18

### Section 4: Donor Human Milk Distribution
19

- Form 12: First Donor Human Milk Prescription Form
20
- Form 13: Daily Donor Human Milk Order Form
21
- Form 14: Recipient Consent Form
21
- Form 15: Recipient Donor Human Milk Log
22
- Form 16: Hospital Receiving Form
23
- Form 17: Hospital Report to Donor Human Milk
23

### Appendix 1: Templates for Tracking and Tracing Donor Human Milk
25
Safety and quality are both foundational pillars in the human milk banking process. The handling and processing of human milk needs to be tracked from collection from the donor mother to allocation for the recipient, to prevent harm and ensure optimal practices for safe delivery to the infant in need. Records documenting the donor human milk (DHM) handling process are essential for documenting evidence-based interventions and decisions, as well as ensuring that staff follow regulatory processes for DHM handling. Quality record and tracking systems are needed to promote quality environments for safe handling and sharing of DHM and reduce the risks that can come from poor records management.

A human milk bank (HMB) tracking and tracing system integrated into existing local neonatal nutrition and maternal and infant health systems can simplify knowledge sharing as well as evidenced-based data to scale up the effectiveness of HMBs in countries where they are yet to be started. Quality record and tracking systems generate evidence to inform improvements in practice and highlight the role of DHM and HMBs to protect, promote, and support breastfeeding. Using examples shared from different countries (including illustrative examples from India, the United Kingdom, the United States, and Vietnam), this tool has been developed to guide tracking and tracing across DHM handling processes.

The development of a track and trace documentation system is paramount to maintaining quality and ensuring safety in the human milk banking process. This toolkit is a guide for HMB leadership responsible for documentation, record keeping, and improving and ensuring the safety of the HMB. The step-by-step processes detailed in this guide are accompanied with template logs, forms, and registers adaptable to the local standard operating procedures.
HOW TO USE THIS GUIDE

This guide informs the formation of an active and efficient track and trace system for local HMBs. It provides an adaptable template that can be integrated into regional contexts. This guide can be used to develop logs and forms consistent with local health systems and institutions. Not all logs and registers in this guide apply to every local HMB or regional guidelines. These templates can be used to develop a track and trace guide that is applicable to locally available resources and existing documentation systems.

MODIFY
Use the instructions and special notes in blue to guide on how to best use this document and respective templates.
INTRODUCTION

This guide is designed to support human milk banking leadership to develop safe and effective track and trace systems across all steps of donor human milk (DHM) collection, processing, handling, and distribution. The following steps outline a systematic approach to creating locally appropriate track and trace systems.

1. Review local standard operating procedures (SOPs) for each of the human milk bank (HMB) processes.
2. Review existing country and regional guidelines for track and trace to ensure required information and sections for each SOP are included in the logs and forms created.
3. Review existing country and regional track and trace systems for neonatal nutrition and maternal and infant health.
4. Identify relevant logs and forms based on the local setting or country’s needs for an HMB.
   - From the provided templates, only choose and customize those relevant to setting-specific needs.
   - When possible, integrate HMB track and trace systems with existing record-keeping.

Documentation stages in human milk banking

Creating track and trace documentation requires detailed knowledge of all of the stages of the HMB process. The stages of HMB processing guide the information that needs to be collected and documented. The documentation stages in Figure 1 are based on the overall HMB processes and do not necessarily apply to all settings. Use this diagram to create logs and forms based on the operations available in the local context.

Figure 1. Human milk bank documentation stages.

(DHM: donor human milk; HMB: human milk bank)
SECTION 1: DONOR RECRUITMENT, SCREENING, AND CONSENT

Form 1: Donor Screening Questionnaire

Purpose: A screening process must be performed to ensure that the donor is eligible to donate surplus breast milk. The milk intended for donation has to be in excess of her infant’s current and future needs. The purpose of completing the Donor Screening Questionnaire is to assess for potential health complications, lifestyle behaviors, and diseases or medications that may make a mother’s milk unsuitable for consumption by another vulnerable infant, even if her milk is still safe for her baby. The information collected provides a record of the number of mothers screened for donation and ensures the quality and safety of DHM.

Questions aimed at eliciting transmissible infection risks offer the donor an opportunity to self-screen. The assessment aims to exclude donations from individuals at high risk of infections, particularly from those with a recently acquired infection that cannot or may not be detected by routine screening tests, or with infections for which no effective screening tests are available.

Outcome:

- Documentation of the total number of mothers who are fully screened for donation, including a passing rate of eligible donors.
- Verification of donor screening.

Steps to create the Donor Screening Questionnaire:

- Review the country health management information system on mandatory demographics to include in the Donor Screening Questionnaire.
- Review the SOPs and country-specific guidelines and recommendations for mandatory conditions or diseases to be screened and exclusion criteria for donors.
- Identify a screening location.
- Verify accessibility to donors’ previous medical and obstetric records (i.e., antenatal and postnatal care).
The Donor Screening Questionnaire should include the following components (see Appendix 1, Form 1):

- Date of screening.
- Donor identification number or unique identifier.
- Donor demographic information (e.g., name, age, address, contact information).
- Health summary of mother’s infant.
- Medical and familial disease history for HIV, hepatitis, risk of sexually transmitted diseases, and blood transfusion history.
- Serology testing results, as per country-specific guidelines for donation.
- Recreational drug use or exposure (e.g., alcohol, marijuana, cocaine, passive smoker).
- Prescription drug, vitamin, or herbal therapy use (e.g., anti-coagulants, vaccinations, radiotherapy).
- Section for HMB staff details, including date of screening, signature of staff, and name of staff.

Consider other optional elements to include:

- Access to lactation support resources (or refer mother to lactation or breastfeeding support resources, as recommended in the local setting).
- Communications and marketing channels: how the donor heard about human milk banking (e.g., website, referral).
- Screening method used (e.g., face-to-face interview, telephone interview, questionnaire, survey).

Form 2: Donor Consent Form

Purpose: To ensure that potential donors understand the donation process. The Donor Consent Form should provide sufficient information for donors to decide on whether or not to donate their surplus milk. The informed consent process will ensure the mother understands her responsibility in maintaining the safety and quality of the surplus milk she donates.

Outcome:

- Documentation of the donor’s full consent to donate her surplus milk to another infant, and the donor’s understanding of what informed consent means.
- Documentation of the number of screened mothers who provide informed consent to donate their expressed milk.
STRENGTHENING HUMAN MILK BANKING

Steps to create the Donor Consent Form:
- Review the SOPs and country-specific guidelines and recommendations for consent to donate human milk and other related human tissues (blood).
- Develop Donor Consent Forms in local language(s) of each setting/country.

The Donor Consent Form should include the following components (see Appendix 1, Form 2):

- Date, time, and signature of consent.
- Document translated into local language that is familiar to mother.
- Donor’s consent for the HMB to access the donor’s antenatal care medical records, and permission to release them to the appropriate HMB staff and health department officials.
- Donor’s consent to process and provide her breast milk to an infant other than her own child.
- Section for HMB staff details, including date of informed consent, signature of staff, and name of staff.

Consider other optional elements to include:

- Detailed summary of the donation process, including milk handling, collection, treatment, processing, storage, and distribution.
- Donors’ rights to limit or discontinue the use of their DHM.
- Option of receiving acknowledgment for their gifts of donated human milk.
- Record of supplementary information on the donation process offered to the donor.

Form 3: Donor Consent Log

Purpose: To provide a quantitative and organized record of the number of screened donors who consent to donate their surplus milk to an infant other than their own child.

Outcome:
- Documentation of the total number of donors who consent to donate their excess breast milk.
Steps to creating a Donor Consent Log:

- Review the SOPs and country-specific guidelines and recommendations for mandatory information to include in Donor Consent Log.
- Ensure all potential donors are recorded in real-time after giving consent to donate.
- Consider completing the Donor Consent Log concurrently with the informed consent process.

The Donor Consent Log should include the following components (see Appendix 1, Form 3):

- Validation of the donor's identity.
- Donor identification number or unique identifier.
- Date of giving consent.
- Date of initial donation.
- Section for HMB staff details, including date received, signature of staff, and name of staff.

SECTION 2: DONOR HUMAN MILK EXPRESSION, COLLECTION, AND TRANSPORTATION

Form 4: Donor Human Milk Handling and Transportation Log

**Purpose:** To guide the donor mothers who are expressing/pumping breast milk to correctly track how they are handling their milk. To verify the mother’s current health status, as well as lifestyle choices, during the time of donation. To verify that milk is safely transported to the HMB.

**Outcome:**
- Documentation of the total number of donor mothers correctly logging their breast milk supply intended for donation.
- Documentation of the volume of DHM collected that meets the HMB requirements for safety.
Steps to creating a DHM Handling and Transportation Log:

- Review the SOPs and country-specific guidelines and recommendations for mandatory information to include in the DHM Handling and Transportation Log.
- Review lactation support guidelines to ensure donors are provided with information, resources, and equipment necessary for safe human milk handling and storage conditions.
- Consult with the HMB team on transportation logistics of DHM.
- Emphasize the importance of labeling to the donor, and distribute labels/stickers for home use when available.
- Create a context-specific criterion for approving donors to collect DHM from home. These criteria could include:
  - Availability of a working refrigerator and freezer.
  - Sufficient knowledge of safely handling and storing breast milk.
  - The time commitment to keeping records.
- Ensure the health center/hospital/neonatal intensive care unit DHM collection points are accessible for donor mothers to store expressed/pumped milk.

The DHM Handling and Transportation Log should include the following components (see Appendix 1, Form 4):

- Donor identification number or unique identifier.
- Date of first and last expression for donation.
- Volume of DHM pumped/expressed.
- Temperature storage details (for both the refrigerator and freezer).
- Checklist of lifestyle questions during donation period.
- Section for completed HMB labels—labels should include date of expression, donor I.D., type of DHM (term or pre-term).
- How the milk was transported to the HMB (transportation method and type of container used).
- If available, storage container temperature during transportation.
- Confirmation that DHM is frozen upon arrival at the HMB.
- HMB receiving staff details, including date received, signature of staff, and name of staff.
A GUIDE FOR TRACK AND TRACE DOCUMENTATION

Form 5: Expression Log

Purpose: To guide the donor mothers who are expressing/pumping breast milk to correctly track their milk for both their own infant and donation. The log can be used by mothers both at home and at the hospital.

Outcome:
- Documentation of the mother’s total number of expressions and volumes of expressed milk for her infant as well as for donation.
- Documentation of the volume of DHM collected per day.

Steps to creating the Expression Log:
- Review the SOPs and country-specific guidelines and recommendations for mandatory information to include in a donor’s Expression Log.
- Review lactation support guidelines to ensure donors are provided with information, resources, and support necessary to maintain sufficient lactation for their infant.

The Expression Log should include the following components (see Appendix 1, Form 5):

- Donor identification number or unique identifier.
- Volume of each individual expression.
- Time of each individual expression.
- HMB receiving staff details, including date received, signature of staff, and name of staff.
- Time of each ind. expression: Designation of which expressions are intended for donation.

Form 6: Hospital Donor Human Milk Log

Purpose: To record the volume of DHM collected for purposes of planning and storage. The log is meant to guide DHM distribution based on expression dates.

Outcome:
- Documentation of the volume of DHM collected during a specific period within the hospital.

Steps to creating a Hospital DHM Log:
- Review the hospital’s SOPs and country-specific guidelines and recommendations for mandatory information to include in the Hospital DHM Log.
The Hospital DHM Log should include the following components (see Appendix 1, Form 6):

- Donor identification number or unique identifier.
  - Preferably use the same labels/stickers given for donor pack labels.
- Date of donation.
- Date of expression.
- Last date of safe pasteurization.
- Volume of DHM collected.
- Section for receiving staff details, including date received, signature of donor, and name of donor.

SECTION 3:
DONOR HUMAN MILK HANDLING, TREATMENT, AND STORAGE

Form 7: Donor Human Milk Register

Purpose: To monitor and keep a record of the amount of DHM received by the HMB. To monitor storage conditions of DHM until time for distribution and consumption.

Outcome:
- Documentation of the volume of DHM received by HMB.
- Documentation and verification that DHM was stored and handled according to regional guidelines and recommendations.

Steps to creating the DHM Register:
- Review the SOPs and country-specific guidelines and recommendations for mandatory information to include in the DHM Register.
- Review the SOPs and country-specific guidelines and recommendations for storage conditions of raw and pasteurized DHM.
A GUIDE FOR TRACK AND TRACE DOCUMENTATION

The DHM Register should include the following components (see Appendix 1, Form 7):

- Date DHM was received.
- Donor identification number or unique identifier.
- Volume of DHM received.
- Temperature of DHM when received.
- Storage location before pasteurization.
- Date and time of pasteurization.
- Storage location after pasteurization.
- Date DHM is distributed.
- Section for HMB staff details, including date of storage, signature of staff, and name of staff.

Form 8: Temperature Log

Purpose: To monitor and keep a record of the storage and handling temperatures of DHM.

Outcome:
- Documentation and verification of storage and handling temperatures of DHM.

Steps to creating the Temperature log:
- Review the SOPs and country-specific guidelines and recommendations for storage and handling temperatures of raw and pasteurized DHM.

The Temperature Log should include the following components (see Appendix 1, Form 8):

- Daily freezer temperate for unpasteurized DHM.
- Daily freezer temperature for pasteurized DHM.
- Daily refrigerator temperature for thawing milk.
- Daily room temperature of the HMB.
- Section for HMB staff details, including date of storage, signature of staff, and name of staff.
Form 9: Thawing and Pooling Log

Purpose: To record the handling of DHM and to verify that recommended procedures for thawing and pooling are followed.

Outcome:
- Documentation of the volume of DHM thawed (defrosted) before microbial testing and pasteurization.
- Verification of safe thawing and pooling methods.

Steps to create a Thawing and Pooling Log
- Review the SOPs and country-specific guidelines and recommendations for mandatory information to include in the Thawing and Pooling Log.
- Review the SOPs and country-specific guidelines and recommendations thawing and pooling.

The Thawing and Pooling Log should include the following components (see Appendix 1, Form 9):

- Donor identification number or unique identifier for all pooled DHM units.
- Batch number.
- Total volume of thawed DHM.
- Date and time of DHM thawing.
- Time DHM is processed.
- Section for contaminated units that need to be discarded.
- Section for HMB staff details, including date of thawing/pooling, signature of staff, and name of staff.

Form 10: Microbial Screening Log

Purpose: To ensure DHM samples meet safety and quality requirements for microbial content.

Outcome:
- Documentation of the volume or number of batches of DHM passing or found to be contaminated during microbial screening.
- Verification of DHM safety.
Steps to create the Microbial Screening Log:
- Review the SOPs and country-specific guidelines and recommendations for mandatory information to include in the Microbial Screening Log.
- Review the SOPs and country-specific guidelines and recommendations for DHM pre- and post-pasteurization screening.

The Microbial Screening Log should include the following components (see Appendix 1, Form 10):

- Donor identification number or unique identifier.
- Volume of DHM screened.
- Date and time of pre-pasteurization screening.
- Microorganisms screened for during pre-pasteurization screening.
- Results from pre-pasteurization screening (i.e., quantity of colony forming units in pre-pasteurized DHM samples).
- Volume of DHM discarded after pre-pasteurization screening.
- Date and time of post-pasteurization screening.
- Microorganisms screened for during post-pasteurizations screening.
- Results from post-pasteurization screening (i.e., quantity of colony forming units in post-pasteurized DHM samples).
- Volume of DHM discarded after post-pasteurization screening.
- Section for HMB staff details, including signature of staff and name of staff.

Form 11: Donor Human Milk Pasteurization Log

Purpose: To verify pasteurization SOPs, and to verify and have a record of pasteurization.

Outcome:
- Documentation of the safe processes and volume of DHM pasteurized over a specific period.

Steps to creating the DHM Pasteurization Log:
- Review the SOPs and country-specific guidelines and recommendations for mandatory information to include in the Donor Human Milk Pasteurization Log.
- Review the SOPs and country-specific guidelines and recommendations for DHM pasteurization.
The DHM Pasteurization Log should include the following components (see Appendix 1, Form 11):

- Donor identification number or unique identifier.
- Date and time of pasteurization.
- Volume of DHM pasteurized.
- Pasteurization start time.
- Verification of pasteurization temperatures (temperatures should align with local setting chosen method: flash heat or Holder pasteurization).
- Verification of pasteurization duration.
- Cooling start and end time.
- Storage location after cooling to maintain cold chain.
- Time of refrigeration/freezing post-pasteurization.
- Section for HMB staff details, including signature of staff and name of staff.

SECTION 4: DONOR HUMAN MILK DISTRIBUTION

Form 12: First Donor Human Milk Prescription Form

Purpose: To monitor and verify the reasons for dispensing DHM at initial order.

Outcome:
- Documentation of the diagnosis or reason DHM is needed.
- Verification of appropriate prioritization of infants for receiving DHM.

Steps to creating the First DHM Prescription Form:
- Review the SOPs and country-specific guidelines and recommendations for mandatory information to include in the First DHM Order Form.
- Review the SOPs and country-specific guidelines and recommendations for prescribing DHM.
- Review the SOPs and country-specific guidelines and recommendations for infant prioritization of receiving DHM.
The First DHM Prescription Form should include the following components (see Appendix 1, Form 12):

- Patient diagnosis or reason for requesting DHM.
- Patient details including gestational age, birth weight, and Apgar score.
- Information on the prioritization of DHM, including material criteria.
- Recipient infant and mother's identification details.
- Hospital contact information.
- Section for comments and clinical notes.
- Section for requested volume of DHM and duration of the prescription.
- Section for hospital staff details, including signature of staff and name of staff.

**Form 13: Daily Donor Human Milk Order Form**

**Purpose:** To maintain records of hospital ordering/distribution in order to review and prevent over-ordering DHM and possible wasting of DHM.

**Outcome:**
- Documentation of the volume of DHM distributed to each hospital/unit.
- Documentation of the proportion of preterm and term infants receiving DHM.

**Steps to creating the Daily DHM Order Form:**
- Review the SOPs and country-specific guidelines and recommendations for mandatory information to include in the Daily DHM Order Form.
- Review the SOPs and country-specific guidelines and recommendations for DHM ordering.
  - Create this log based on the health care delivery system in the local setting.
- Inform/communicate to the hospital/neonatal intensive care unit staff about their role in making large orders of DHM.
The Daily DHM Order form should include the following components (see Appendix 1, Form 13):

MODIFY

- Date of order.
- Hospital order number.
- Hospital contact information.
- Total volume requested.
- Recipient name(s) and/or number(s).
- Diagnosis for DHM request.
- Volume prescribed for each recipient per day.
- HMB authorization including signature of staff and name of staff.
- Section for requesting hospital staff details, including signature of staff and name of staff.

Form 14: Recipient Consent Form

Purpose: To ensure that the recipient’s caregiver understands the donation process. Caregivers should be provided with an overview of the risks as well as benefits associated with receiving DHM. The informed consent process will verify that all caregivers understand the benefits of the DHM for their infants.

Outcome:

- Documentation of the total number/proportion of infants whose parents consent to them receiving DHM.
- Documentation of the proportion of infants of vulnerable infants whose parents/caregivers consent to them receiving DHM.

Steps to creating a Recipient Consent Form:

- Review the SOPs and country-specific guidelines and recommendations for mandatory information to include in the Recipient Consent Form.
- Review the SOPs and country-specific guidelines and recommendations for recipient consent.
  - Provide caregiver counseling on benefits and risks of DHM to determine consent.
The Recipient Consent Form should include the following components (see Appendix 1, Form 14):

- Translations in local languages for informed consent.
- A general explanation of the systems to ensure safety in human milk banking: donor screening, donation process, DHM handling, collection, treatment, processing, storage, and distribution.
- Benefits and risks of receiving DHM.
- Parent’s rights to discontinue use of DHM for their infant.
- Date, time, and signature of recipient’s informed consent.
- Section for hospital staff details, including signature of staff and name of staff.

Form 15: Recipient Donor Human Milk Log
Purpose: To monitor the purpose, volume, and dosage of DHM received by the infants, and record possible waste of DHM.

Outcome:
- Documentation of the total volume and number of DHM feeds dispensed.
- Documentation of the volume of DHM actually consumed by each preterm/term infant.

Steps to creating the Recipient DHM Log:
- Review the SOPs and country-specific guidelines and recommendations for mandatory information to include in the Recipient DHM Log.
- Review the SOPs and country-specific guidelines and recommendations for DHM recipients.

The Recipient DHM Log should include the following components (see Appendix 1, Form 15):

- Recipient details.
- Feeding method used (nasogastric tube, syringe).
- Reason for prescribing DHM.
- Date DHM was received.
- Total volume of DHM dispensed each day.
- Amount consumed and amount discarded.
- Dispensing staff name and signature.
- Ward location.
- Section for hospital staff details, including signature of staff and name of staff.
Form 16: Hospital Receiving Form

Purpose: To monitor and report the total volume of DHM received by the hospital/health center and verify the condition of DHM when received.

Outcome:
- Documentation of the total volume of DHM received.
- Documentation and verification of cold chain during transportation of DHM.

Steps to creating the Hospital Receiving Form:
- Review the SOPs and country-specific guidelines and recommendations for mandatory information to include in the Hospital Receiving Form.
- Review the SOPs and country-specific guidelines and recommendations for maintaining the cold chain during DHM transportation.

The Hospital Receiving Form should include the following components (see Appendix 1, Form 16):

- Name of site requesting DHM.
- Order date.
- Date DHM was packaged.
- HMB contact details.
- Number of containers/volume shipped.
- Expiration date for each DHM batch.
- Verification that DHM was frozen when packaged.
- Verification that DHM was frozen when received by hospital.
- Section for receiving hospital staff details, including signature of staff and name of staff.

Form 17: Hospital Report to Human Milk Bank

Purpose: To provide a high-level summary of DHM consumption from each hospital.

Outcome:
- Documentation of the total volume of DHM consumed and discarded each month.
- Documentation of the reasons for DHM use.
- Documentation of the number of human milk donors recruited by the hospital.
- Documentation of the number of mother’s receiving lactation support.
Steps to creating the Hospital Report to HMB:

- Review the SOPs and country-specific guidelines and recommendations for mandatory information to include in the Hospital Report to HMB.
- Review the SOPs and country-specific guidelines and recommendations for monitoring DHM usage.

The Hospital Report to HMB should include the following components (see Appendix 1, Form 17):

- Hospital information.
- Quantity of DHM consumed and discarded.
- Reasons for DHM usage and number of infants and volume of DHM consumed for each reason.
- Number of donors recruited by the hospital.
- Number of mothers receiving lactation support at the hospital.
- Section for hospital staff details, including signature of staff and name of staff.
APPENDIX 1.
TEMPLATES FOR TRACKING AND TRACING DONOR HUMAN MILK

- Form 1: Donor Screening Questionnaire.
- Form 2: Donor Consent Form.
- Form 3: Donor Consent Log.
- Form 4: Donor's Human Milk Handling and Transportation Log.
- Form 5: Expression Log.
- Form 6: Hospital Donor Human Milk Log.
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- Form 10: Microbial Screening Log.
- Form 11: Donor Human Milk Pasteurization Log.
- Form 12: First Donor Human Milk Prescription Form.
- Form 13: Daily Donor Human Milk Order Form.
- Form 14: Recipient Consent Form.
- Form 15: Recipient Donor Human Milk Log.
- Form 16: Hospital Receiving Form.
- Form 17: Hospital Report to Human Milk Bank.
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