PATH

STRENGTHENING HUMAN MILK BANKING:

A Resource Toolkit for Establishing & Integrating Human Milk Bank Programs

A Guide for Conducting Monitoring & Evaluation | 3

Starting every life with mothers' milk

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

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.

ACKNOWLEDGEMENTS

ABBREVIATIONS

CAPA *corrective and preventative actions*

DHM *donor human milk*

HMB *human milk bank*

M&E *monitoring and evaluation*

MOM *mother's own milk*

NEC *necrotizing enterocolitis*

NICU *neonatal intensive care unit*

Contents

▸ To facilitate the development of rigorous monitoring and evaluation systems to measure the integration and effectiveness of comprehensive human milk bank systems on feeding practices and neonatal health outcomes.

▸ To improve human milk bank operational quality, safety, and impact.

▸ To strengthen the rigor of the evidence generated from human milk bank programs to inform appropriate and impactful interventions, policies, and systems to save newborn lives.

ABOUT THIS GUIDE

The purpose of this monitoring and evaluation (M&E) guide is to provide advice for developing rigorous systems to generate evidence through implementation science on the operations and impact of an integrated human milk bank (HMB) program. These resources will be useful for new HMBs as well as existing HMBs seeking to strengthen systems.

The goal of establishing M&E programs is ultimately as a gauge for optimizing performance and achieving results. It is an ongoing process, meant to continually provide feedback for current and future management of outputs, outcomes, and impact. Implementation science is conducted to address bottlenecks, test interventions, and evaluate actual impact of programs to inform practice. Through developing such systems for HMB programs, operational quality and safety will improve and evidence will be generated to document the impact on feeding practices and health outcomes. This guide is intended for HMB stakeholders and those in the newborn and nutrition research community to continually advance the rigor and comprehensive approach needed for newborn nutrition.

This guide does not replace the need to develop plans, protocols, and data collection tools specific to local settings. These are examples provided to facilitate the process and inform a global M&E standard for HMBs around the world.

HOW TO USE THIS GUIDE

This M&E guide is intended to be used as examples for prompting discussion around needs and goals for local settings. Included in this guide are examples of M&E plans, indicators for measurement, research protocols, and data collection tools for formative and pre- and post-intervention studies. These materials can be used as templates upon which to adapt the details of the local system, thereby facilitating the research process.

Implementation science research explores real world scenarios yet requires careful design and rigor. Collaboration with academic institutions is highly recommended, although not required. Formative research, including documenting readiness, acceptability and feasibility is critical to ensure the subsequent HMB intervention is a fit with local needs, culture, policies and systems. M&E plans should be developed at the outset to establish and clarify goals and overarching outcomes to be achieved. Rigorous documentation of feeding practices and neonatal health outcomes before and after the HMB intervention will provide the data to demonstrate impact, often required by policy leaders to inform scale-up strategies.

This guide consists primarily of examples of M&E plans and research tools. These are meant to serve as a starting point for discussion and thoughtful exploration of how to best adapt these tools to the local context, abiding by local ethical and policy requirements. The ultimate aim of this guide is to improve the rigor of the evidence generated from HMB programs and to translate the results into peer-reviewed publications and global policies to improve the health of newborns around the world.

SECTION 1:
DEVELOPING A ROADMAP: M&E FRAMEWORK AND PLAN

A first step in establishing rigorous research systems is the development of an monitoring and evaluation (M&E) framework and plan to identify the overall goal and subsequent outcomes to be achieved. The M&E plan builds on the M&E framework; both are presented below (Figure 1 and Table 1). This example M&E plan is intended to be used for facilities beginning to integrate a human milk bank (HMB) at their facility or for an HMB seeking to strengthen their measurement strategies for a comprehensive program. This section specifically explains the design and use of indicators to measure the integration and effectiveness of the HMB at the facility.

SEE TOOL #5

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—A Guide for Track and Trace Documentation provides examples of logs, registers, and forms to guide the safe and effective track and trace systems across all steps of donor human milk collection, processing, handling, and distribution.

Components and aim of an M&E plan

Indicators are a measure of what goes into a program **(input)** and what comes out of it **(outputs)**. In recent years, one largely agreed upon framework has emerged: the input-process-output-outcome-impact framework. For a program or project to achieve its goals, **inputs** such as funding and staff time must result in **outputs** such as new or improved services, trained staff, behavior change communication activities, etc. If these outputs are effective in reaching and influencing the populations for which they were intended, the program or project is likely to have **outcomes**, for example, improved health outcomes, behavior change, or implementation achievements (such as donor referrals from the facility with which an HMB is integrated). These outcomes should lead to changes in the longer-term **impact** of programs, measured, for example, in longer-term population-level health changes (such as neonatal sepsis incidence rate).

An M&E plan presents each level of the framework (goal, objectives) aligned with the indicators that are designed to measure it. Each indicator is designated as either an output, outcome, or impact indicator. These designations do not necessarily denote the importance of measuring the indicator (for a prioritized list of indicators, see "M&E plan: priority indicators"). The M&E plan also includes a definition of the indicator measurement parts, such as the numerator and denominator needed to calculate the indicator. Additionally, the potential data source is

included (note that this is a suggestion and should be adapted if there is a locally appropriate, existing form or register already used at the facility).

Finally, the M&E plan suggests a frequency of measurement for the indicator that explains how often the indicator is calculated. This may be different depending on facility systems and data collection processes. It is important to adjust this frequency to meet local needs based on the optimal frequency for your facility to follow. In addition, data elements or parts of the indicator could be collected on an ongoing basis, yet calculated less frequently. For example, for the indicator "Proportion of eligible infants who receive donor human milk (DHM)," the number of infants who receive DHM must be documented on a daily basis to keep track of infant feeding and to regulate the DHM needs at the facility. However, the proportion of infants is only calculated on a monthly basis in order to see the trends in the total infants receiving DHM. Considerations for how to document and keep track of these data parts for specified indicators will need to be adapted to the local context and included in planning considerations for the local facility.

Photo: PATH/Tom Furtwangler

Figure 1. Example monitoring and evaluation framework.

Goal: 100 percent of infants in the target facility receive optimal feeding as a part of early and essential newborn care during their stay at the facility, resulting in improved newborn health outcomes.

Objective 1. Increase human milk feeding.

Objective 2. Integrate the HMB with essential newborncare programming.

Objective 3. Facilitate quality, safety, and efficiency of HMB and hospital staff.

Objective 4. Facilitate enabling environment and expand the global evidence base of HMBs.

Outcome 1.1. Increased use of MOM.

Outcome 2.1. Enhanced provision of optimal newborn care.

Outcome 3.1. Improved staff lactation support competency through training and compliance.

Outcome 4.1. Increased evidence base of HMBs.

Outcome 1.2. Increased access to DHM for those infants without access to MOM.

Outcome 2.2. Improved institutionalization of the HMB with nutrition and newborn programming.

Outcome 3.2. Improved quality control and routine monitoring of the HMB.

Outcome 4.2. Improved perceptions and knowledge of human milk and DHM/HMBs.

Outcome 2.3. Institutionalized operations of the HMB.

Outcome 4.3. Guidelines aligned with national-level policies.

(DHM: donor human milk; HMB: human milk bank; MOM: mother's own milk)

M&E plan: priority indicators

This list of prioritized indicators is the highly recommended areas of measurement for creating a successful HMB integrated into a facility. These priority indicators are included as a narrowed list in order to provide facilities who are short of staff or resources with the most important areas to measure. As a best practice, these indicators will be used in conjunction with the complete M&E plan in order to understand the areas of measurement needed to fully demonstrate integration and effectiveness (see Appendix 1 for an example of a comprehensive M&E plan).

Photo: © 2012 Bassam Almohor/Chemonics International, Courtesy of Photoshare

Table 1. Priority indicators for measurement.

Framework	Priority Indicators
Goal: 100 percent of infants in the target facility receive optimal feeding as a part of early and essential newborn care during their stay at the facility, resulting in improved newborn health outcomes.	▸ NEC incidence rate.
Objective 1. Increase human milk feeding.	▸ Proportion of infants in first 3–5 days of life by feeding status disaggregated by human milk feeding (partial, exclusive, none) or other (MOM, DHM, formula).
Outcome 1.1. Increased use of MOM.	▸ Exclusive breastfeeding rate (MOM).
Outcome 1.2. Increased access to DHM for those infants without access to MOM.	▸ Proportion of infants in the NICU receiving daily recommended minimum DHM from the HMB at day 1, day 2, day 7, day 14, and entire NICU stay. ▸ Number of breast milk donors. ▸ Average volume of breast milk donated.
Objective 2. Integrate the HMB with essential newborn programming.	▸ Average monthly number of donor referrals from facility with which the HMB is integrated.
Outcome 2.1. Enhanced provision of optimal newborn care.	▸ Mean age in hours of life of infants at first human milk feeding.
Outcome 2.2. Improved institutionalization of the HMB with nutrition and newborn programming.	▸ Policies and procedures aligned with facility functions.
Objective 3. Facilitate quality, safety, and efficiency of HMB and hospital staff.	
Outcome 3.1. Improved staff lactation support competency through training and compliance.	▸ Proportion of mothers who received breastfeeding counseling or support at least once during postnatal period.
Outcome 3.2. Improved quality control and routine monitoring of HMB.	▸ Facility successfully passed system audit.
Objective 4. Facilitate the enabling environment and expand the global evidence base of HMBs.	
Outcome 4.1. Increased evidence base of HMBs.	▸ Data collection initiated for routine monitoring for rigorous measurement of HMB activities.

(DHM: donor human milk; HMB; human milk bank; MOM: mother's own milk; NEC: necrotizing enterocolitis; NICU: neonatal intensive care unit)

SECTION 2:
UNDERSTANDING THE LANDSCAPE: COLLECTING FORMATIVE DATA

The effectiveness of HMB programs depends on the potential fit, readiness, and cultural appropriateness of the intervention in the designated population. Collecting formative data is critical to inform communications strategies and implementation approaches that are specific to each individual country or region.

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.

This section provides guidance, templates, and examples for conducting qualitative and quantitative formative research, consisting of focus group discussions and in-depth interviews. The main objective of this formative work is to assess the perceptions and acceptability of DHM and to investigate the current state of infant feeding practices, lactation support, and facility systems, particularly for vulnerable infants, to determine the feasibility of an HMB as an appropriate intervention.

The following resources are included in Appendix 2 as templates and examples:

▸ A template to aid researchers in the development of a formative assessment research protocol for human milk banking.

- This template includes comprehensive information for both qualitative and quantitative methodology as a guide for preparing rigorous and comprehensive formative research protocols. This resource contains instructions throughout to guide the input of locally appropriate text, in blue.

▸ Examples of data collection tools.

- Qualitative tools.
   - o In-depth interview guides targeting mothers, fathers, community members, policy leaders, and health care workers.
   - o Focus group discussion guides targeting mothers, fathers, community members, and health care workers.
- Quantitative tools.
   - o In-depth interview tools with mothers to assess current practices and lactation support.
   - o In-depth interview tools with health care workers to assess current practices, facility systems, lactation support, and neonatal health.

SECTION 3:
MEASURING OPERATIONAL EFFECTIVENESS: BASELINE AND ENDLINE ASSESSMENTS

Documenting the changes that result due to the implementation of an integrated HMB is important, not only to determine if the intervention is working but also to demonstrate to policy leaders that the intervention is worthy of supporting and scaling up. Randomized controlled trials are considered to be the most rigorous method for determining cause and effect between an intervention and outcome; however, this study design is not always a feasible or ethical option for infant feeding studies. Control, or comparison, site data may not be feasible or appropriate due to lack of matching variables between facilities to accurately infer impact from a specific intervention. When these research designs are not possible, conducting baseline and endline assessments are considered a best practice for quantifying pre- and post-intervention differences in key indicators at a single facility.

The overall goal of conducting baseline and endline assessments is to determine the operational feasibility, effectiveness, acceptability, and cost estimate of establishing an integrated human milk banking program (including HMB and breastfeeding promotion). Key objectives could include:

1. To assess the potential effectiveness of an integrated model on breastfeeding/provision of human milk (initiation and exclusive breastfeeding during hospital stay).

2. To assess the feasibility of establishing and operating an HMB.

3. To explore the potential feasibility and acceptability of an integrated model.

4. To explore the barriers and facilitators to the implementation of the integrated model.

5. To estimate the cost of implementing the integrated HMB model from the implementer's perspective.

6. To establish the potential effectiveness of the integrated HMB model on neonatal outcomes (morbidity, hospital case fatality rate and length of hospital stay) for premature, low-birthweight, very low-birthweight, and sick neonates.

Baseline and endline assessments would utilize a pre-post study design on two independent samples (before/after), involving both quantitative and qualitative data collection methods. This type of implementation science research study is conducted in three distinctive and interrelated phases:

▸ Pre-intervention (baseline) phase.

▸ Implementation or intervention phase.

▸ Post-intervention (endline) phase.

Baseline data collection should take place just prior to the initiation of any of the intervention activities to capture practices just before changes begin. The intervention process, including the comprehensive activities for supporting lactation and provision of mother's own milk, in addition to launching the HMB and establishing and stabilizing systems for providing safe DHM, should be fully operational for at least three months and ideally for nine months or more to adequately measure change. Endline data collection should take place immediately following the intervention phase.

This section provides guidance, templates, and examples for conducting qualitative and quantitative baseline and endline research, consisting of focus group discussions, in-depth interviews, key informant interviews, medical record reviews, and facility costs reviews.

The following resources are included in Appendix 3 as templates and examples:

▸ A template to aid researchers in the development of a research protocol for conducting baseline and endline assessments for human milk banking.

  • This template includes comprehensive information for both qualitative and quantitative methodology as a guide for preparing rigorous and comprehensive research protocols. This resource contains instructions throughout to guide the input of locally appropriate text, in blue.

▸ Examples of data collection tools.

  • Qualitative tools.

    o In-depth interview guides targeting mothers, fathers, community members, policy leaders, and health care workers.

    o Focus group discussion guides targeting mothers, fathers, community members, and health care workers.

  • Quantitative tools.

    o In-depth interview tools with mothers/caregivers to assess current feeding and lactation practices and support.

    o Prospective data collection for neonatal health and infant feeding.

APPENDIX 1.
EXAMPLE OF COMPREHENSIVE MONITORING AND EVALUATION PLAN
FOR AN INTEGRATED NEWBORN NUTRITION HUMAN MILK BANKING PROGRAM

Level of measurement	Indicators	Category	Definition	Potential data source	Frequency of measurement
Goal: 100% of infants in target facility receive optimal feeding as a part of early and essential newborn care during stay at facility, resulting in improved newborn health outcomes.	NEC incidence rate Neonatal sepsis incidence rate Length of stay in NICU	Impact			Baseline/Endline surveys
Objective 1. Increase human milk feeding.					
Outcome 1.1 Increased use of MOM	Early initiation of breastfeeding rate (infant was put to the breast or received MOM within 1 hour of birth)	Outcome	Number of infants that receive MOM within 1 hour of birth	Daily Feeding & Neonate Care Log	Annually
	Exclusive breastfeeding (MOM) rate	Outcome	Numerator: Number of infants feeding with MOM only within first 6 months either through breast or feeding Denominator: Total number of infants eligible	Daily Feeding & Neonate Care Log	Annually
	Proportion of breastfed infants that are supplemented with formula, glucose water, water, or other during NICU stay	Outcome	Numerator: Total number of breastfed infants receiving supplementation during NICU stay Denominator: Total number of breastfed infants eligible for supplementation	Daily Feeding & Neonate Care Log	Monthly
	Percentage of feedings consisting of HM	Output	Total % of infant diet of MOM (volume). Daily percentage of enteral feedings consisting of (MOM) human milk	Daily Feeding & Neonate Care Log	Monthly

(HM: human milk; MOM: mother's own milk; NEC: necrotizing enterocolitis; NICU: neonatal intensive care unit)

Level of measurement	Indicators	Category	Definition	Potential data source	Frequency of measurement
Goal: 100% of infants in target facility receive optimal feeding as a part of early and essential newborn care during stay at facility, resulting in improved newborn health outcomes.	NEC incidence rate Neonatal sepsis incidence rate Length of stay in NICU	Impact			Baseline/ Endline surveys
Outcome 1.2 Increased access to DHM for those infants without access to MOM	Proportion of eligible infants who ever received DHM	Outcome	Numerator: Number of infants who receive DHM Denominator: Total number of infants eligible for DHM (eligibility is not having access to MOM)	Daily Feeding & Neonate Care Log	Monthly
	Proportion of eligible infants in NICU receiving perscribed volume DHM from HMB at day 1, day 2, day 7, day 14, entire NICU stay	Outcome	Numerator: Number of infants in NICU receiving perscribed volume DHM dissaggregated by day Denominator: Total number of infants in NICU eligible to receive DHM	HMB Reporting Form	Monthly
	Proportion of infants in NICU who receive formula in entire NICU stay	Output	Numerator: Number of infants in NICU received formula Denominator: Total number of infants in NICU	Daily Feeding & Neonate Care Log	Monthly
	Number of breast milk donors	Output	Total number of people who donate breast milk	HMB Reporting Form	Monthly
	Average volume of breast milk donated	Output	Numerator: Volume of breast milk by month Denominator: Total donation instances	HMB Reporting Form	Monthly

(DHM: donor human milk; HM: human milk; HMB: human milk bank; MOM: mother's own milk; NEC: necrotizing enterocolitis; NICU: neonatal intensive care unit)

Level of measurement	Indicators	Category	Definition	Potential data source	Frequency of measurement
Goal: 100% of infants in target facility receive optimal feeding as a part of early and essential newborn care during stay at facility, resulting in improved newborn health outcomes.	**NEC incidence rate** **Neonatal sepsis incidence rate** **Length of stay in NICU**	**Impact**			**Baseline/ Endline surveys**
Objective 2. Integrate HMB with essential newborn care programming					
Outcome 2.1 Enhanced provision of optimal newborn care	Proportion of mother/infant dyads that adhered to 10 steps to successful breastfeeding	Outcome	Numerator: Number of mother/infant dyads that adhered to all 10 steps Denominator: Total mother/infant dyads	Certification for baby friendly facility	Annually
	Proportion of mother/infant dyads that practiced KMC within NICU	Outcome	Numerator: Number of mother/infant dyads that practice KMC Denominator: Total number of mother/infant dyads in NICU	Daily Feeding & Neonate Care Log	Monthly
	Mean duration in hours of KMC	Output	Numerator: Total number of hours of KMC Denominator: Total mother/infant dyads in NICU	Daily Feeding & Neonate Care Log	Monthly
	Proportion of full-term infants initiate breastfeeding within one hour	Output	Numerator: Number of full-term breastfed infants initiate breastfeeding within 1 hour Denominator: Total number of eligible infants	Sick neonate form	Monthly
	Mean age in hours of life of infants at first HM feeding	Output	Numerator: Total of ages in hours of infants at first HM feeding (disaggregated by source: MOM, DHM) Denominator: Total number of infants who received HM	Daily Feeding & Neonate Care Log	Monthly
	Mean age in hours of life of infants at initiation of breastfeeding	Output	Numerator: Total of ages in hours of infants at initiation of breastfeeding Denominator: Total number of infants who initiated breastfeeding	Sick neonate form	Monthly
	Proportion of mothers receiving lactation support by trained lactation staff	Output	Numerator: Number of mothers receiving lactation guidance Denominator: Total mother/infant dyads	Daily Feeding & Neonate Care Log	Monthly
	Number of staff trained on 10 Steps to Successful Breastfeeding as part of HMB curriculum	Output	Total number of staff trained disaggregated by cadre	Training records	Annually

(DHM: donor human milk; HM: human milk; HMB: human milk bank; KMC: Kangaroo Mother Care; MOM: mother's own milk; NEC: necrotizing enterocolitis; NICU: neonatal intensive care unit)

Level of measurement	Indicators	Category	Definition	Potential data source	Frequency of measurement
Goal: 100% of infants in target facility receive optimal feeding as a part of early and essential newborn care during stay at facility, resulting in improved newborn health outcomes.	**NEC incidence rate** **Neonatal sepsis incidence rate** **Length of stay in NICU**	**Impact**			**Baseline/Endline surveys**
Outcome 2.2 Improved institutionalization of HMB with nutrition and newborn programming	Average monthly number of donor referrals from facility with which HMB is integrated	Outcome	Total number of donor referrals monthly/Total number of months	Initial screening forms	Monthly
	Incorporation of HMB into hospital's/facility's budget	Output	In budget line (yes/no)	Facility financial records	Annually
	Policies and procedures aligned with facility functions	Output	HMB SOPs available	KMC facility policies	Annually
	Integration of HM facility into hospital	Output	HMB SOPs available	Facility-level policies	Annually
	Linkages to KMC and existing lactation support structures	Output	Total number of staff cross-trained (KMC, lactation, HMB)	Training records	Annually
Objective 3. Facilitate quality, safety, and efficiency of HMB and hospital staff					
Outcome 3.1 Improved staff lactation support competency through training and compliance	Proportion of trained staff receiving improved test scores (between pre–post)	Outcome	Numerator: Number of staff with improved test scores Denominator: Total number of staff trained	Training records	Annually
	Proportion of mothers who received breastfeeding counseling or support at least once during postnatal period	Output	Numerator: Number of mothers receiving counseling/support Denominator: Total number of women eligible during postnatal period	Medical records	Annually
	Total number of mothers advised on storing/pumping techniques	Output-optional	Number of mothers receiving advice	Medical records	Annually
Outcome 3.2 Improved quality control and routine monitoring of HMB	Facility successfully passed system audit	Outcome	Passed audit (yes/no)	Audit records	Annually
	HMB Track and Trace monitoring system utilized	Output	Forms completed accurately (yes/no)	HMB Track and Trace system records	Monthly

(HMB: human milk bank; KMC: Kangaroo Mother Care; NEC: necrotizing enterocolitis; NICU: neonatal intensive care unit; SOP: standard operating procedure)

Level of measurement	Indicators	Category	Definition	Potential data source	Frequency of measurement
Goal: 100% of infants in target facility receive optimal feeding as part of early and essential newborn care during stay at facility, resulting in improved newborn health outcomes.	NEC incidence rate Neonatal sepsis incidence rate Length of stay in NICU	Impact			Baseline/ Endline surveys
Objective 4. Facilitate enabling environment and expand global evidence base of HMB					
Outcome 4.1 Increased evidence base of HMB	Data collection initiated for routine monitoring for rigorous measurement of HMB activities	Outcome	Data collection system established	Facility records	At start of HMB
	Number of research studies conducted	Outcome	# of research studies	Facility records	Annually
	Number of disseminations (dissaggregated by type)	Output	# of reports submitted	Facility records	Annually
		Output	# of presentations completed	Facility records	Annually
		Output	# of peer-reviewed publications published	Facility records	Annually
		Output	# of disseminations completed	Facility records	Annually
Outcome 4.2 Improved perceptions and knowledge of HM and DHM/HMB	Proportion of mothers who report belief in myths related to HMB	Outcome	Numerator: Number of mothers who report beliefs in myths Denomintor: Total number of mothers surveyed	Survey results	Annually
	Proportion of mothers who report willing to donate their excess breast milk to HMB	Output	Numerator: Number of mothers who report willingness to donate breast milk Denominator: Total number of mothers surveyed	Survey results	Annually
	Proportion of mothers who report willing to accept DHM for their infant from HMB, if necessary	Output	Numerator: Number of mothers who report willingness to accept DHM Denominator: Total number of mothers surveyed	Survey results	Annually
Outcome 4.3 Guidelines aligned with national level policies	Total number of facility-level guidelines aligned with national level policies on BFHI, pre-term/LBW care and IYCN.	Output	Number of facility-level guidelines in alignment with national-level policies	Facility guidelines	Annually

(BFHI: Baby-friendly Hospital Initiative; DHM: donor human milk; HM: human milk; HMB: human milk bank; IYCN: infant & young child nutrition; LBW: low-birthweigth; MOM: mother's own milk; NEC: necrotizing enterocolitis; NICU: neonatal intensive care unit)

APPENDIX 2A.
FORMATIVE ASSESSMENT PROTOCOL TEMPLATE

This Formative Assessment Research Protocol document is designed to aid researchers in the development of a formative assessment research protocol for human milk banking. It contains instructions throughout, in blue. Please delete these instructions after completion of the document.

See External Appendices for Appendix 2B. Formative Assessment Data Collection Tool Examples.

Title Page: Title of Protocol, Sponsor, Version Number and Date

Choose a clear, concise title that accurately describes your study. Be consistent with your title throughout the document and dissemination efforts.

SUGGESTION: Establishing Potential Feasibility of an Integrated Human Milk Banking Initiative for Vulnerable Neonates in [insert country name].

Table of Contents

Complete this section last. List sections and corresponding page numbers.

List of Abbreviations

List commonly used acronyms and abbreviations for purposes of removing repetition and unnecessary space.

SUGGESTION:
DHM donor human milk

Contact Information

Principal investigator:
Co-investigators:
Research team and contact information:
Study site:
Funder and funding source:

1.0   BACKGROUND AND RATIONALE FOR THE STUDY

This section is based on your research question. Begin with a brief introduction to describe the importance of this study. Answer these questions in this section: why is this research question important? What benefit does this study offer? Review relevant studies and reference accordingly. State the main purpose of the study and summarize all information provided in this background section. Make sure to state how the study will contribute to the knowledge base of the topic being studied.

The following are suggestions of headers/sections to include in your introduction/rationale section:

Current state of breastfeeding and infant health globally

▸ Discuss infant health status, progress, and challenges.

▸ Discuss the main barriers/challenges to breastfeeding.

Benefits of the consumption of human milk in infants

▸ Discuss infant outcomes related to exclusive breastfeeding.

- Necrotizing enterocolitis (NEC), sepsis, etc.

▸ Discuss downsides to formula use.

- Gut health, inflammation, etc.

Why donor human milk (DHM) is needed

▸ Describe situations in which the infant does not have access to mother's own milk (MOM).

▸ Describe the importance of human milk for vulnerable infants.

- Low birth weight, preterm, etc.

Human milk bank (HMB) overview

▸ Describe the current status of human milk banking.

▸ Describe the benefits of an HMB.

▸ Provide a brief overview of HMB processes.

Larger breastfeeding promotion program overview and rationale

▸ Describe how an HMB fits in with larger breastfeeding promotion programs.

▸ Describe the promotion of the Ten Steps to Successful Breastfeeding.

- ▸ Describe the integration of an HMB with the facility.
- ▸ Describe the provision of support and counselling for mothers.

Why this study is important/needed

- ▸ Describe the gap in data that this study will fill and potential impact on local policies.

2.0   STUDY OBJECTIVES

This section describes the objectives to be achieved and/or questions to be answered. Objectives define the study and dictate how it will be conducted. The objectives should be clear and measurable. They will vary greatly by location and should therefore be adapted by researchers to match local context.

Primary Objective

Clearly state the primary objective. The primary objective is the main objective of the study that dictates study design, data collection strategy, and data analysis.

SUGGESTION: The primary objective of this research study is to assess the perceptions and acceptability of DHM and investigate the current state of breastfeeding practices, particularly for vulnerable infants.

Secondary Objective(s)

Clearly state any secondary objectives, if applicable. Secondary objectives are other objectives that would be valuable to achieve/reach, but do not take precedence and will not affect the overall design or success of the study.

Research Question(s)

Clearly state the specific questions that will be answered/addressed through this study. These should be more specific than the objectives and should reflect what the researchers are interested in assessing.

The following research questions will be addressed:
Question 1:
Question 2:
Question 3:
Question 4:
Question 5:

SUGGESTIONS:

‣ What are the general attitudes and perceptions of breastfeeding and formula/breast milk substitute among mothers and caregivers of young children?

‣ What are the general feeding practices for vulnerable children among mothers/caregivers of young children and among health care workers (at the facility level)?

‣ What are the general attitudes and perceptions of DHM among:

  • Mothers and caregivers of young children.

  • Community members.

  • Health professionals.

  • Policymakers.

‣ What are the potential barriers of and benefits to the establishment of HMBs?

‣ What are the general perceptions on the establishment of an HMB among:

  • Mothers and caregivers of young children.

  • Community members.

  • Health professionals.

  • Policymakers.

3.0 STUDY DESIGN, SAMPLING, AND RECRUITMENT

Study Design

Indicate the type of study design (e.g., cross-sectional versus longitudinal; multicenter; controlled; randomized). Provide justification for the study design to be used.

Many researchers performing formative research on HMBs have used a cross-sectional survey design, administered at the facility- and community-level.

Briefly state the data collection methods, but do not elaborate as there is a separate section below for this. The study may contain both qualitative and quantitative data collection methods, but should include quantitative data for purposes of analysis. Make sure to specify why both methods are necessary, if so, and the utility of each method.

**If using mixed-methods, be sure to distinguish between the two methods in each of the subsequent sections.

This section should include the following information:

Study Location

▸ Provide the exact location(s) where the survey will be administered.
▸ Describe the background of the location(s): include relevant location history, culture, tradition, etc.
▸ Provide a rationale for selecting this location(s).

Study Population

▸ Give a demographic overview of the population targeted.
▸ Give a rationale for targeting this population.

Inclusion Criteria

▸ State specific characteristics, demographics, etc. that would warrant inclusion in the study.
▸ SUGGESTIONS: mothers, key decision makers, policymakers, health care workers.

Exclusion Criteria

▸ State specific characteristics, demographics, etc. that would warrant exclusion from the study.
▸ SUGGESTIONS: physical or mental health impairments, communication challenges, any characteristic that would hinder care of neonatal intensive care unit (NICU) infants and/or their mothers, or other specific factors that would cause out-of-the-ordinary breastfeeding behavior.

Sampling and Recruitment

This section should describe the sampling and recruitment methods used.

Sample Size

First and foremost, it is highly advised that sample size calculation not be performed without the expert guidance of an epidemiologist/biostatistician/researcher. An expert will bring strategic guidance that will help avoid costly miscalculations or unreliable study results.

In this section, provide detailed information as to the sample size calculations and strategies that were used to estimate sample size and differentiate between quantitative and qualitative methods.

Quantitative Sample Size:

For detailed instructions for calculation of sample size for a cross-sectional survey, please see Appendix 8.1.

Resources for Quantitative Sample Size Calculations:

OpenEpi is an open source software for epidemiologic statistics. It can be used in both an online or downloadable manner.

Qualitative Sample Size:

For qualitative sample size, provide detailed estimates of the quantity of each interview, based on assumption. Denote whether each interview is an individual or group interview, as well as the type of person interviewed. For qualitative research, one-on-one interviews may return the most credible, honest, and extensive responses, but focus groups may be more feasible due to shortage of resources. One may choose to take a data-driven approach where data is collected until no new information is provided, or a pragmatic approach where sample size is determined by resources.

Table X. Example table of study populations and sample sizes.

Interview type	Participant	Number of interviews	Number of participants in each interview	Total
Key informant interviews	Mothers, health care workers, policymakers, etc.	X	X	X
Focus groups		X	X	X
Total		X	X	X

Recruitment and Sampling Procedures

For both quantitative and qualitative methods, describe in detail how participants will be identified and recruited. Include:

▸ How participants will be identified.
▸ Where participants will be recruited (in their homes, at a clinic, at work).
▸ Who will recruit participants and how.

Explain how the recruitment plan is feasible given the sample size, inclusion/exclusion criteria, and other study logistics.

Specify which sampling method you will be using. As a reminder, random sampling means that chance alone determines who will be included in the sample. Convenience sampling means that the sample is determined by which members of the source population are easiest to obtain.

When considering sampling strategies, be sure to think through validity of your sample. The below diagram represents the different sampling levels of a cross-sectional study.

Figure X. Sampling levels for cross-sectional studies.

Target population

⬇

Source population

⬇

Sample / Eligible population

⬇

Study Participants

Target population = population that the results of the study will be generalized to

Source population = catchment population that you can actually get access to

Sample / Eligible population = the intended study population that you can access all of

Study Participants = participants that are actually enrolled in your study

External validity should be the ultimate goal when considering sampling strategy. External validity is the generalizability of the study, or the extent to which we can generalize to the target population. If study participants are entirely representative of the target population, then this would have very high external validity.

As appendices to the protocol, attach any recruitment materials to be used—for example, recruitment scripts, public announcements, and/or flyers.

4.0   DATA COLLECTION AND MANAGEMENT

Data Collection

Restate the study design and specify precise data collection methods used to obtain both quantitative and qualitative data.

Quantitative Data Collection:
Specify the data collection method and who will be targeted (make this brief since it was already covered in study population). Also, state the exact locations where the data collection will take place, who will collect which data, and whether data collection will be paper-based, electronic, Electronic Medical Record-based, etc. Specify which data are collected to answer which research question.

Qualitative Data Collection:
Specify which methods of qualitative data collection will be used (key informant interviews, focus groups, etc.), where they will take place, who will be targeted (again, make this brief since it was already covered), who will conduct the interview, who will be present to help facilitate the interview, who will take notes, how notes will be taken (paper, computer, tape-recorded), and which research questions this data will be used to answer. For procedures conducted in groups or in pairs, explain how privacy and confidentiality will be protected. If research participants are being recorded, describe what type of recording will be used and how the recordings will be labeled, stored, and secured to protect confidentiality.

Note the language of the data collection tools and any necessary translation.

For both qualitative and quantitative data collection, state how investigators plan to validate the data.

Data Management and Analysis

State how data will be stored, cleaned, and analyzed.

Quantitative Data Management and Analysis:
Specify which data management software and which data analysis software will be used. State who will manage the data and analysis.

For data analysis, specify the calculations, statistical tests, statistical methods (linear, logistic regression, etc.), if applicable. For a cross-sectional survey, this would likely involve calculating proportions for each question and possibly using logistic regression to investigate how these proportions change based on a variety of explanatory variables (e.g., socioeconomic status, education level, geographic location). If stratification was used, specify how analysis will be done within strata.

SUGGESTIONS:
A researcher could investigate the association between socioeconomic status and whether or not a mother is willing to donate her breast milk to an HMB through logistic regression. Socioeconomic status would be a categorical independent variable (in quintiles, for example), and the dependent variable would be a binary "yes/no" variable. A logistic regression analysis could be performed to show differences in probabilities of being willing to donate by each socioeconomic strata. A p-value should be calculated to indicate statistical significance of association. Odds ratios can be calculated to compare relative odds of being willing to donate between socioeconomic strata.

Qualitative Data Management and Analysis:
Clarify how qualitative data will be managed by stating how data will be transcribed and stored. Specify the qualitative data analysis method for coding and analysis and which software will be used.

For both qualitative and quantitative data, indicate where data will be stored, how it is secured, and how access to the data is managed. Indicate how the key to the study code is maintained. Indicate others (besides the research study team) who reserve the right to access research data (e.g., sponsors, regulatory or government officials, institutional review boards [IRBs]/ research ethics committees [RECs], study monitors, data safety and monitoring boards [DSMBs]).

Identify if data collected in the research will be disclosed (e.g., reported to health officials, entered into the medical record of participants, reported to supervisors).
Describe plans for retention of data. Describe how long the research data, including specimens, will be retained and any plans for destroying the linking code or the data.

5.0   ETHICAL CONSIDERATIONS, CONSENT PROCESS, BENEFITS

Risks

State potential risks for study subjects. All studies should be evaluated by an IRB in country. Restate confidentiality measures that will be taken throughout data collection and analysis phases. Possible risks include:

▸ *Physical risks:* Not likely for this type of study but, if applicable, estimate the probability that a given harm may occur and state its potential reversibility.
▸ *Psychological risks* (e.g. distress, embarrassment, deception): Possible for this type of study.
▸ *Social risk* (e.g., harm to reputation, stigma, harm to relationships): Possible for this type of study.
▸ *Economic risk* (e.g, financial standing, employability, insurability): Not likely for this type of study.

If a potential risk is identified, state what measures will be taken to mitigate it. Potential risks from a study of this nature would be loss of time, discomfort answering questions, fear of breach of confidentiality, etc. Recommendations for how to mitigate these risks include assuring the participants of confidentiality measures described above, requesting that they keep their own and others' responses private, etc.

Despite the low risk involved with a study of this nature, it is important to nevertheless declare adherence to ethical considerations of local/national research institutions or review boards.

Describe the consent process. Make sure to include when and where consent will occur, who will secure consent, and who is providing consent. With regard to minimizing risks, be sure to describe the steps taken to train persons obtaining consent in human subjects protections and ensuring the privacy and confidentiality of participants. It is important to document the type of consent (writing, thumbprint, oral, etc.) and whether any witnesses should be present or necessary, in addition to what changes will be made for those who cannot provide the desired level of consent (illiterate, not able to speak, etc.). Finally, be sure to describe any benefits that participants will receive for participation. Due to ethical issues, payment to participants should not be listed as a benefit; however, participants may receive benefits such as transportation assistance, etc.

Study and Safety Monitoring

Be sure to outline the plan for monitoring the safety and wellbeing of study participants, including steps, frequency, persons responsible, whether there will be a board for ensuring safety, and policies and procedures for monitoring.

6.0   TIMELINE AND INVESTIGATOR RESPONSIBILITIES

Provide a timeline of proposed activities and completion dates, to the best of your ability. Below is an example from a different study. This example is not meant to give a suggestion for timing, but rather format. Adjust timeline as appropriate.

Figure X. Example timeline of proposed activities.

Key Deliverabies and Timelines- Formative Assessment																					
	YEAR 1												YEAR 2								
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S
Preparation/contracting	█	█																			
Study design and tools development	█	█																			
Ethical clearance		█	█	█																	
Community mobilization and sensitization				█																	
Qualitative data collection					█	█															
Qualitative data management (transcription, coding, and analysis)					█	█	█														
Dissemination								█													
Quantitative data collection									█	█											
Quantitative data management and analysis										█	█	█									
Report writing (formative assessment)													█	█	█						
Further analysis and paper writing													█	█	█	█	█	█	█	█	█
Participation in other project activities (e.g., stakeholder meetings, design of guidelines, learning exchanges, etc.)		█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█

List the individual investigators' responsibilities in conducting and managing this study (e.g., training, documentation, oversight, reporting).

7.0   EXPECTED APPLICATION OF THE RESULTS AND DISSEMINATION

This protocol template should guide next steps in the development of an implementation plan and/or tool for all stakeholders involved. Results and conclusions gleaned from this formative study will directly inform communication strategies for advocacy and for the establishment of an HMB.

In this section, describe where and how results will be applied. List dissemination events and documents.

SUGGESTIONS:
▸ A technical report on best implementation of HMBs in the respective country/location.
▸ A scientific publication from the data collected by the end of the project.
▸ A dissemination workshop with policymakers in the ministry of health and other key stakeholders.

8.0   APPENDICES

Provide separate attachments to any additional documents. These should be referenced throughout the prior sections of the protocol clearly so that the reader knows which appendix corresponds with which section. Please attach:
▸ Data collection forms (e.g., surveys, questionnaires, interview and focus group guides, eligibility checklists, adverse event report forms, case report forms).
▸ Consent form(s) and assent form(s).
▸ Recruitment materials.
▸ Study flow diagrams.
▸ Study products' documentation

Sample size calculation for a cross-sectional survey

For a cross-sectional survey measuring a single proportion, sample size can be calculated using the following formula:

$$n = \frac{(z^2 \times p(1-p))}{d^2}$$

Where:

n = sample size

z = The value of z from the standard normal variate tables. If the values are normally distributed (which they should be in a cross-sectional survey) then the value of z is 1.96, because 95% of the values will fall within two standard errors of the mean.

p = prevalence/proportion of the condition. In this case, this will be based off of prior studies that have assessed perceptions of breastfeeding, breastfeeding practices, etc. If no prevalence is known, 50% should be used to return the maximal sample size, as this proportion is symmetric around its maximum of 50%. However, this will result in a larger sample size than likely necessary.

d = precision of the estimate, which is half of the desired confidence interval width. This is determined by the researcher/investigator. A precision of 0.05 is standard. Note that increasing the precision value (e.g., using 0.1 instead of 0.05) will decrease the sample size, which may be helpful for budget or resource constraints, but will increase the confidence interval, and therefore will decrease the precision.

Example:

To calculate a sample size for the proportion of women willing to donate breastmilk, the investigator would review other studies. If this proportion is found to be 60%, then p=0.60. Then, 1.96 can be used for z and 0.05 can be used for d. Therefore, the calculation can be written as follows:

$$369 = \frac{(1.96^2 \times 0.6(1-0.6))}{0.05^2}$$

Note: Non-response should be considered. The estimated non-response proportion should be added to the total sample size to ensure adequate sampling (e.g., if 10% are expected to not respond, take 10% of the calculated sample size and add to this estimate to calculate a revised sample size).

Note: If known differences exist between some specific demographic strata, consider calculating sample sizes for each strata to ensure representation (e.g., if willingness to donate breastmilk differs by socioeconomic status or education level).

9.0   REFERENCES

Add relevant references here.

APPENDIX 3A.
BASELINE-ENDLINE ASSESSMENT PROTOCOL TEMPLATE

This Baseline-Endline Assessment Protocol document is designed to aid researchers in the development of a baseline and endline research protocol for human milk banking. It contains instructions throughout, in blue italics. Please delete these instructions after completion of the document.
See **External Appendices** for Appendix 3B. Baseline-Endline Assessment Data Collection Tool Examples.

Title Page: Title of Protocol, Sponsor, Version Number, and Date

Choose a clear, concise title that accurately describes your study. Be consistent with your title throughout the document and dissemination efforts.

SUGGESTION: A Baseline-Endline Impact Assessment of a Human Milk Banking and Breastfeeding Promotion Program on Infant Feeding Practices and Neonatal Health Outcomes.

Table of Contents

Complete this section last. List sections and corresponding page numbers.

List of Abbreviations

List commonly used acronyms and abbreviations for purposes of removing repetition and unnecessary space.

SUGGESTION:
DHM   donor human milk

Contact Information

Principal investigator:
Co-investigators:
Research team and contact information:
Study site:
Funder and funding source:

1.0 BACKGROUND AND RATIONALE FOR THE STUDY

This section is based on your research question and is used to describe the importance of this study. Answer these questions in this section: why is this research question important? What benefit does this study offer? Review relevant studies and reference accordingly. State the main purpose of the study and summarize all information provided in this background section. Make sure to state how the study will contribute to the knowledge base of the topic being studied.

The following are suggestions of headers/sections to include in your introduction/rationale section:

Current state of breastfeeding and infant health globally

▸ Discuss infant health status, progress, and challenges.

▸ Discuss the main barriers/challenges to breastfeeding.

Benefits of the consumption of human milk in infants

▸ Discuss infant outcomes related to exclusive breastfeeding.

- Necrotizing enterocolitis (NEC), sepsis, etc.

▸ Discuss downsides to formula use.

- Gut health, inflammation, etc.

Why donor human milk (DHM) is needed

▸ Describe situations in which the infant does not have access to mother's own milk (MOM).

▸ Describe the importance of human milk for vulnerable infants.

- Low birth weight, preterm, etc.

Human milk bank (HMB) overview

▸ Describe the current status of human milk banking.

▸ Describe the benefits of an HMB.

- Provide a brief overview of HMB processes.

Larger breastfeeding promotion program overview and rationale

▸ Describe how an HMB fits in with larger breastfeeding promotion programs.

- ▸ Describe the promotion of Ten Steps to Successful Breastfeeding.
- ▸ Describe the integration of an HMB with the facility.
- ▸ Describe the provision of support and counseling for mothers.

Why this study is important/needed

- ▸ Describe the gap in data that this study will fill and potential impact on local policies.

2.0   STUDY OBJECTIVES

This section describes the objectives to be achieved and/or questions to be answered. Objectives define the study and dictate how it will be conducted. The objectives should be clear and measurable. They will vary greatly by location and should therefore be adapted by researchers to match local context.

Primary Objective

Clearly state the primary objective. The primary objective is the main objective of the study that dictates study design, data collection strategy, and data analysis.

SUGGESTION: The main objective of this research study is to evaluate efficacy of the human milk banking/lactation promotion program as compared to routine lactation support and milk bank services in improving utilization of human milk (MOM or DHM) for feeding of neonates admitted in secondary and tertiary care hospitals.

Secondary Objective(s)

Clearly state any secondary objectives, if applicable. Secondary objectives are other objectives that would be valuable to achieve/reach, but do not take precedence and will not affect the overall design or success of the study.

SUGGESTION: The secondary objective of this research study is to evaluate efficacy of the human milk banking/lactation promotion program as compared to routine lactation support and milk bank services in improving infant outcomes (including survival without systematic sepsis, NEC, neonatal sepsis) among very low-birthweight (VLBW) neonates admitted in secondary and tertiary care hospitals.

3.0 INTERVENTION

Description of the Intervention

Give a detailed description of the purpose of the intervention, specific components of the intervention, and what will be changed/implemented.

SUGGESTIONS for description of the components of the intervention:

‣ Human milk banking procedures to be implemented.

‣ Lactation management and support programs.

Baseline period

‣ Define the baseline period. Provide time series.

Endline period

‣ Define the endline period.

4.0 OUTCOMES OF INTEREST

Primary Objective

Primary Outcome Measure

State the outcome measure for the primary objective that is the main outcome of interest and why this was chosen as the primary outcome for this objective.

SUGGESTION:

The primary outcome measure is difference between before- and after-period of the study in proportion of neonates who are on exclusive human milk feeding at the time of disposition from hospital. A neonate will be classified to be exclusive human milk fed if he/she has received only DHM or MOM for feeding and has not been fed any other type of non-human milk during the hospital stay. We have chosen exclusive human milk feeding at discharge as the primary outcome as this most accurately reflects the efficacy of all the components of the model in improving utilization of human milk for feeding of admitted neonates.

Secondary Outcome Measures

List the secondary outcome measures. Bullet format is acceptable for secondary outcome measures.

SUGGESTIONS:

▸ Difference in proportion of neonates who receive MOM or DHM for first feed.

▸ Difference in mean age in hours at initiation of breastfeeding. Age breastfeeding initiation will be taken as the age when baby is first put to breast with intent to attach on nipple and start sucking on the breast.

▸ Difference in mean of percent of volume of total feeds given as human milk (MOM and DHM).

Secondary Objective(s)

Repeat the above for any secondary objectives.

5.0   STUDY DESIGN, SAMPLING, AND RECRUITMENT

Study Design

Indicate the type of study design and provide justification. For a baseline-endline assessment, multiple study design options exist:

▸ A randomized study design would be the most reliable and valid, but a lack of resources for such an involved design commonly inhibits the ability to use this design.

▸ Instead, researchers can use a quasi-experimental study design, which would involve comparing baseline and endline between an intervention group and a control group.

▸ If this is still too resource-heavy to involve a control group, researchers can choose to use a non-experimental time-series study design to look for changes and trends over time within the intervention group.

▸ Other designs exist. Be sure to consult with an expert to determine the best study design for your objectives.

Briefly state the data collection methods, but do not elaborate, as there is a separate section for this below. State whether the study will use only quantitative methods or mixed-methods.

The study may contain both qualitative and quantitative data collection methods but should include quantitative data for purposes of analysis. Make sure to specify why both methods are useful, if so, and the utility of each method.

**If using mixed-methods, be sure to distinguish between the two methods in each of the subsequent sections.

This section should include the following information:

Study Location

▸ Provide the exact location(s) where the survey will be administered.

▸ Describe the background of location(s): include relevant location history, culture, tradition, etc.

▸ Provide a rationale for selecting this location(s)

Study Population

▸ Give a demographic overview of the population targeted.

▸ Give a rationale for targeting this population.

▸ State whether the study will enroll neonates, mothers, or neonate-mother pairs.

Inclusion Criteria

▸ State specific characteristics, demographics, etc. that would warrant inclusion in the study.

▸ SUGGESTIONS: all born neonates admitted in the hospital, who have a mother to provide consent, would be eligible for enrollment. Parents must be over the age of 18 to provide consent.

Exclusion Criteria

▸ State specific characteristics, demographics, etc. that would warrant exclusion from the study.

▸ SUGGESTIONS: physical or mental health impairments, medical contraindication to human milk, communication challenges of the mother, any characteristic that would hinder care of neonatal intensive care unit (NICU) infants and/or their mothers, major congenital malformation (define major), or neonates without a mother to provide consent.

Sampling and Recruitment

This section should describe the sampling and recruitment methods used.

Sample Size

First and foremost, it is highly advised that sample size calculation not be performed without the expert guidance of an epidemiologist/biostatistician/researcher. An expert will bring technical guidance that will help avoid costly miscalculations or unreliable study results. Below is an overview of sample size strategy.

In this section, provide detailed information as to the sample size calculations that were used to estimate sample size and differentiate between quantitative and qualitative methods.

Quantitative Sample Size:

State the sample size calculation methods and formulas in detail. The formula will depend on the study design chosen. The following resources may be useful in calculating sample size:

▸ Quasi-Experimental Design and Methods by UNICEF.[1]

▸ How Do We Know if a Program Made a Difference? A Guide to Statistical Methods for Program Impact Evaluation by MEASURE Evaluation.[2]

Qualitative Sample Size:

For qualitative sample size, provide detailed estimates of the quantity of each interview, based on assumption. Denote whether each interview is an individual or group interview, as well as the type of person interviewed. For qualitative research, one-on-one interviews may return the most credible, honest, and extensive responses, but focus groups may be more feasible due to shortage of resources. One may choose to take a data-driven approach where data is collected until no new information is provided, or a pragmatic approach where sample size is determined by resources.

Table X. Example table of study populations and sample sizes.

Interview type	Participant	Number of interviews	Number of participants in each interview	Total
Key informant interviews	Mothers, health care workers, policymakers, etc.	X	X	X
Focus groups		X	X	X
Total		X	X	X

[1] White H, Sabarwal S. *Quasi-Experimental Design and Methods*. Florence: UNICEF Office of Research; 2014. Available at https://www.unicef-irc.org/KM/IE/img/downloads/Quasi-Experimental_Design_and_Methods_ENG.pdf.

[2] Lance P, Guilkey D, Hattori A, Angeles G. *How Do We Know if a Program Made a Difference? A Guide to Statistical Methods for Program Impact Evaluation*. Chapel Hill: MEASURE Evaluation; 2014. Available at https://www.measureevaluation.org/resources/publications/ms-14-87-en.

Recruitment and Sampling Procedures

For both quantitative and qualitative methods, describe in detail how participants will be identified and recruited. Include:
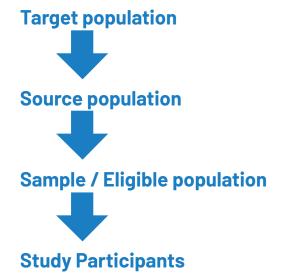
- ▸ How participants will be identified.
- ▸ Where participants will be recruited (in their homes, at a clinic, at work).
- ▸ Who will recruit participants and how.

Explain how the recruitment plan is feasible given the sample size, inclusion/exclusion criteria, and other study logistics.

Specify which sampling method you will be using. As a reminder, random sampling means that chance alone determines who will be included in the sample. Convenience sampling means that the sample is determined by which members of the source population are easiest to obtain.

When considering sampling strategies, be sure to think through the validity of your sample. The diagram in Figure X represents the different sampling levels of a cross-sectional study.

Figure X. Sampling levels for cross-sectional studies.

Target population

⬇

Source population

⬇

Sample / Eligible population

⬇

Study Participants

Target population = population that the results of the study will be generalized to

Source population = catchment population that you can actually get access to

Sample / Eligible population = the intended study population that you can access all of

Study Participants = participants that are actually enrolled in your study

External validity should be the ultimate goal when considering sampling strategy. External validity is the generalizability of the study, or the extent to which we can generalize to the target population. If study participants are entirely representative of the target population, then this would have very high external validity.

As appendices to the protocol, attach any recruitment materials to be used—for example, recruitment scripts, public announcements, and/or flyers.

6.0   DATA COLLECTION AND MANAGEMENT

Data Collection

Restate the study design and specify precise data collection methods used to obtain both quantitative and qualitative data.

Quantitative Data Collection:
For a baseline-endline assessment, state the data collection procedures that will occur in both phases. Also state the exact locations where the data collection will take place, who will collect which data, and whether data collection will be paper-based, electronic, Electronic Medical Record-based, etc. Be sure to specify which data are collected for which objective. The following is an example of a table to be included in the protocol that outlines the plan for outcome measurement.

Table X: Outcome measurement plan.

Outcome	Definition	Outcome measurement
Related to specific objective 1		
Primary		
Exclusive human milk feeding during hospital stay	Proportion of neonates discharged to home without receiving any feed with non-human milk during hospital stay	Research personnel will review the nursing charts of the enrolled neonates daily to count total feed received and type of feeds received, classifying in one of the following categories: ▸ Own mother's milk. ▸ Unprocessed donor human milk. ▸ Processed (as per SOPs of HMB) donor human milk. ▸ Formula milk/ cow's milk. Source documents (nursing charts) will be reviewed and, if needed, modified so that this information is collected routinely.

Outcome	Definition	Outcome measurement
Related to specific objective 1		
Secondary		
Use of human milk for first feed	Proportion of neonates who receive first feed as human milk	Research personnel will review the nursing charts of the enrolled neonates daily to count total feed received and type of feeds received, classifying in one of the following categories: ▶ Own mother's milk. ▶ Unprocessed donor human milk. ▶ Processed (as per SOPs of HMB) donor human milk. ▶ Formula milk/ cow's milk. Source documents (nursing charts) will be reviewed and, if needed, modified so that this information is collected routinely.
Age at initiation of breastfeeding	Age when baby is first put to breast with intent to attach on nipple and start sucking on the breast (hours).	Research personnel will review the nursing charts of the enrolled neonates to note time at which neonate receive first human milk feed. Source documents (nursing charts) will be reviewed and, if needed, modified so that this information is collected routinely.
Proportion of total feeds given as human milk	Proportion of total feeds given as human milk during hospital stay	Research personnel will review the nursing charts of the enrolled neonates daily to count total feed received and type of feeds received classifying in one of the following categories: ▶ Own mother's milk. ▶ Unprocessed donor human milk. ▶ Processed (as per SOPs of HMB) donor human milk. ▶ Formula milk/ cow's milk. Source documents (nursing charts) will be reviewed and, if needed, modified so that this information is collected routinely.

(HMB: human milk bank; SOP: standard operating procedure)

Qualitative Data Collection:
Specify which methods of qualitative data collection will be used (key informant interviews, focus groups, etc.), where they will take place, who will be targeted (make this brief since it was already covered), who will conduct the interview, who will be present to help facilitate the interview, who will take notes, how notes will be taken (paper, computer, tape-recorded), and which research questions this data will be used to answer. For procedures conducted in groups or in pairs, explain how privacy and confidentiality will be protected. If research participants are being recorded, describe what type of recording will be used and how the recordings will be labeled, stored, and secured to protect confidentiality.

Note the language of the data collection tools and any necessary translation.

For both qualitative and quantitative data collection, state how investigators plan to validate the data.

Data Management and Analysis

State how data will be stored, cleaned, and analyzed.

Quantitative Data Management and Analysis:

Specify which data management software and which data analysis software will be used. State who will manage the data and analysis.

For data analysis, specify the calculations, statistical tests, statistical methods (linear, logistic regression, etc.), if applicable. For a baseline-endline assessment, this will largely include tests for equal proportions, including Chi-square and Fisher's exact (for a small sample size).

Provide a table of tests for each outcome of interest. An example is given below. Please remove and replace cells with your study's information.

Table X. Example table of tests for study outcomes.

Outcome	Hypothesis	Methods of analysis
Primary analysis (for all neonates)		
Exclusive human milk feeding at discharge	Improvement as increase	Chi-square or Fisher exact test
Primary analysis (for VLBW neonates)		
Survival without late-onset sepsis or NEC (≥stage 2A)	Improvement as increase	Chi-square or Fisher exact test
Secondary analysis (for all neonates)		
Use of human milk for first feed	Improvement as increase	Chi-square or Fisher exact test
Age at initiation of breastfeeding	Improvement as decrease	T-test or Mann-Whitney test

(NEC: necrotizing enterocolitis; VLBW: very low-birthweight)

Qualitative Data Management and Analysis:

Clarify how qualitative data will be managed by stating how data will be transcribed and stored. Specify the qualitative data analysis method for coding and analysis and which software will be used.

For both qualitative and quantitative data, indicate where data will be stored, how it is secured, and how access to the data is managed. Indicate how the key to the study code is maintained. Indicate others (besides the research study team) who reserve the right to access research data (e.g., sponsors, regulatory or government officials, institutional review boards [IRBs]/research ethics committees [RECs], study monitors, data safety and monitoring boards [DSMBs]).

Identify if data collected in the research will be disclosed (e.g., reported to health officials, entered into the medical record of participants, reported to supervisors). Describe plans for retention of data. Describe how long the research data, including specimens, will be retained and any plans for destroying the linking code or the data.

7.0 ETHICAL CONSIDERATIONS, CONSENT PROCESS, AND BENEFITS

Risks

State potential risks for study subjects. All studies should be evaluated by an IRB in country. Restate the recommendation for DHM by international agencies and ministry of health (if applicable) to reinforce the safety and benefit of the HMB. Restate confidentiality measures that will be taken throughout data collection and analysis phases.

Possible risks include:

▸ Physical risks: Not likely for this type of study but, if applicable, estimate the probability that a given harm may occur and state its potential reversibility.

▸ Psychological risks (e.g., distress, embarrassment, deception): Possible for this type of study.

▸ Social risks (e.g., harm to reputation, stigma, harm to relationships): Possible for this type of study.

▸ Economic risks (e.g., financial standing, employability, insurability): Not likely for this type of study.

If a potential risk is identified, state what measures will be taken to mitigate it. Potential risks from a study of this nature would be loss of time if interviews are conducted, discomfort answering questions, fear of breach of confidentiality, etc. Recommendations for how to mitigate these risks include assuring the participants of confidentiality measures described above, requesting that they keep their own and others' responses private, etc.

Despite the low risk involved with a study of this nature, it is important to nevertheless declare adherence to ethical considerations of local/national research institutions or review boards.

Describe the consent process. Make sure to include when and where consent will occur, who will secure consent, and who is providing consent. With regard to minimizing risks, be sure to describe the steps taken to train persons obtaining consent in human subjects protections and ensuring the privacy and confidentiality of participants. It is important to document the type of consent (writing, thumbprint, oral, etc.) and whether any witnesses should be present or necessary, in addition to what changes will be made for those who cannot provide the desired level of consent (illiterate, not able to speak, etc.). Finally, be sure to describe any benefits that participants will receive for participation. Participants may receive benefits such as transportation assistance, etc.
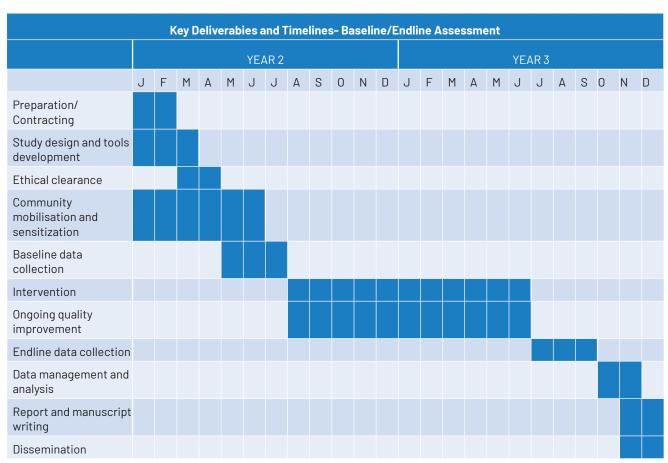
Study and Safety Monitoring

Be sure to outline the plan for monitoring the safety and wellbeing of study participants, including steps, frequency, persons responsible, whether there will be a board for ensuring safety, and policies and procedures for monitoring.

8.0 TIMELINE AND INVESTIGATOR RESPONSIBILITIES

Provide a timeline of proposed activities and completion dates, to the best of your ability. Below is an example from a different study. This example is not meant to give a suggestion for timing, but rather format. Adjust timeline as appropriate.

Figure X. Example timeline of proposed activities.

Key Deliverabies and Timelines– Baseline/Endline Assessment																								
	YEAR 2												YEAR 3											
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
Preparation/ Contracting	█	█																						
Study design and tools development	█	█	█																					
Ethical clearance			█	█																				
Community mobilisation and sensitization	█	█	█	█	█	█	█																	
Baseline data collection					█	█	█																	
Intervention								█	█	█	█	█	█	█	█	█	█	█						
Ongoing quality improvement								█	█	█	█	█	█	█	█	█	█	█						
Endline data collection																			█	█	█			
Data management and analysis																					█	█		
Report and manuscript writing																							█	█
Dissemination																							█	█

List the individual investigators' responsibilities in conducting and managing this study (e.g., training, documentation, oversight, reporting).

9.0   EXPECTED APPLICATION OF THE RESULTS AND DISSEMINATION

This protocol template should guide next steps in the development of an implementation plan and/or tool for all stakeholders involved. Results and conclusions gleaned from this study will directly inform best practices and quality improvement strategies.

In this section, describe where and how results will be applied. List dissemination events and documents.

SUGGESTIONS:

▸ A technical report on the benefit of human milk banking in the respective country/location.

▸ A scientific publication from the data collected by the end of the project.

▸ A dissemination workshop with policymakers in the ministry of health and other key stakeholders.

10.0   APPENDICES

All appendices should be referenced throughout the prior sections of the protocol clearly so that the reader knows which appendix corresponds with which section.

11.0   REFERENCES

Add relevant references here.

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**

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