

A Resource Toolkit for Establishing & Integrating Human Milk Bank Programs



A Training Curriculum Template for Hospital and Human Milk Bank Staff

Starting every life with mothers' milk

A Resource Toolkit for Establishing & Integrating Human Milk Bank Programs

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

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

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ABBREVIATIONS

ART	antiretroviral therapy	MOM	mother's own milk
CFU	colony-forming units	NEC	necrotizing enterocolitis
DHM	donor human milk	NICU	neonatal intensive care unit
HACCP	hazard analysis critical control points	SOP	standard operating procedure
НМВ	human milk bank	UNICEF	United Nations Children's Fund
ніν	human immunodeficiency virus	USAID	United States Agency for International
LBW	low-birthweight		Development
		WHO	World Health Organization



OBJ	IECTIVES OF THIS GUIDE	8
ABC	OUT THIS GUIDE	8
HOV	V TO USE THIS GUIDE	9
INTI	RODUCTION	10
MOE OVE	DULE 1: RVIEW OF BREASTFEEDING AS THE PREFERRED SOURCE OF INFANT NUTRITION	11
1.1	The importance of breastfeeding	12
1.2	Essential Newborn Care	15
1.3	Breastfeeding benefits and research	16
1.4	Nutrition recommendations	18
1.5	Special considerations for the HIV-positive mother	22
Moe Mat	DULE 2: ERNAL SUPPORT FOR BREASTFEEDING	23
2.1	Common breastfeeding challenges	24
2.2	Breastfeeding myths	24
2.3	Hospital support for breastfeeding	26
2.4	Community support for breastfeeding	29
2.5	Interpersonal and counseling skills	30
2.6	Expression of breast milk	33
2.7	Storage and handling of mother's own milk	37

MODULE 3:

OVE	RVIEW OF DONOR HUMAN MILK AND HUMAN MILK BANKING	39
3.1	Donor human milk and human milk banking	40
3.2	Appropriate use of donor human milk for the vulnerable baby	34
3.3	Risks of informal and commercialized milk sharing	46
3.4	Background of human milk banking in the local setting	47

MODULE 4:

DON	OR COUNSELING AND SCREENING	48
4.1	Mobilization for donor recruitment	49
4.2	Counseling for bereaved mothers	51
4.3	Qualifications of donors	52
4.4	Donor screening process	53
4.5	Counseling for mothers who are not eligible to donate	54
4.6	Donor education	55
4.7	Human milk expression and collection techniques	56

MODULE 5:

MILI	KHANDLING	58
5.1	Hygienic and safe handling of milk	59
5.2	Maintence of the cold chain	60
5.3	Hand hygiene as a safety mechanism	66

MODULE 6:

PAS	TEURIZATION OF DONOR HUMAN MILK	56
6.1	Processing donor human milk in preparation for pasteurization	69
6.2	Pasteurization Process	75
6.3	Post-pasteurization screening	77

MODULE 7:

DIST	RIBUTION OF DONOR HUMAN MILK	78
7.1	Prioritization of recipients	79
7.2	Outpatient recipients of donor human milk	80
7.3	Donor human milk distribution process	80
7.4	Donor human milk consent process	81
7.5	Review of hospital policy for handling donor human milk	82
7.6	Fortification of donor human milk	82
7.7	Ethical considerations for human milk banks	83

MODULE 8:

QUA	LITY AND SAFETY ASSURANCE	85
8.1	Systems for safety and quality	86
8.2	Your operational quality plan	87
8.3	Standard operating procedures	88
8.4	Good manufacturing practices and hazard analysis and critical control points	90
8.5	Auditing	92
8.6	Record keeping	92
8.7	Local guidelines	94
8.8	Supportive supervision	95

MODULE 9:

ADVOCACY	96
9.1 Advocacy in human milk banking	97
REFERENCES	98
APPENDIX 1.	
ADDITIONAL RESOURCES	104
APPENDIX 2.	
DONOR HUMAN MILK DECISION TREE	106
APPENDIX 3.	
SUPPLEMENTAL MODULE: BEREAVEMENT AND LACTATION SUPPORT	107

OBJECTIVES OF THIS TEMPLATE

- To facilitate the development of locally adapted training curriculum for hospital-based human milk banking systems.
- To ensure that hospital and human milk bank staff have the knowledge and skills to accurately and safely implement breastfeeding and human milk banking policies and procedures at their hospital.
- To guide hospital and human milk bank staff on effective methods to protect, promote, and support breastfeeding.
- To promote a culture of optimal infant feeding, prioritizing use of mother's own milk, and donor human milk when appropriate.

ABOUT THIS TEMPLATE

Comprehensive staff training for hospital and human milk bank (HMB) staff helps ensure that employees have the knowledge and skills to accurately and safely implement policies and procedures at their operation. This course is designed as an adaptable curriculum template, rather than a traditional training guide. Once local HMB guidelines are in place, this curriculum template can be adapted and implemented. Leaders in each country will need to modify and build out this training course before implementation. Not only does this ensure that training is relevant to the local context, but also increases the ownership and engagement with the materials.





HOW TO USE THIS TEMPLATE

This template is designed to help you, the "trainer," provide your hospital or HMB staff with the knowledge and skills necessary to carry out hospital and HMB procedures and policies as necessary.

The amount of time necessary to complete this training will depend on the amount of additional information added to this template. Appropriate hospital and HMB staff training is important for ensuring optimal infant feeding practices as well as promoting workplace productivity, and satisfaction. We encourage you to add as much additional information as is appropriate to this curriculum to ensure staff are well trained on the policies and procedures of your hospital and local HMB. To optimally benefit from this training, we recommend that participants attend the entire training. Reassure all participants that the answers they provide during this training will not impact the status of their employment. Estimated time to complete each module is listed at the beginning of each module.

To facilitate instruction and learning, this template is organized with different learning modes and colors. The learning modes used in this template are Explain and Activity.

Explain learning modes contain the bulk of the instructional content in this template. You should share the information in these sections with the class verbally, by reading or summarizing the content.

Activity learning modes are highlighted in **purple**, and contain activity-based questions and activities that facilitate learning the content within the Explain sections.

Text highlighted in **blue** is provided for your instruction and will prompt you to insert additional information specific to your hospital/ HMB and regional policies and guidelines. This text must be altered to finalize the training modules.

INTRODUCTION

A mother's breast milk is the optimal and most complete source of nutrition for an infant (i.e., a child under one year old), providing all the necessary nutrients and protective bioactive components needed for optimal growth and development.¹ Mothers of small or ill newborns face unique challenges in initiating lactation. Donor human milk (DHM) can provide vulnerable infants with a safer and more complete source of nutrition than formula, retaining many of the immune components that are lacking in formula and acting as a bridge to fully feeding of mother's own milk (MOM).² Compared to formula feeding, DHM-fed infants are less likely to develop necrotizing enterocolitis (NEC), feeding intolerance, and delayed gastric emptying.^{3,4} There is also evidence that retinopathy of prematurity and sepsis is decreased in infants that receive DHM compared to formula.⁵

Purpose

This course is designed to prepare hospital and human milk bank (HMB) staff to promote, protect, and support breastfeeding. It is developed from the foundation that MOM is irreplaceable, and DHM should be appropriately utilized to promote a culture of optimal infant feeding. DHM is not a replacement for MOM. Additionally, this course will discuss important strategies for promoting safety in the HMB. Beyond simply training staff to complete tasks, this course aims to guide learners through the various ways that safety can be fostered.

Prior to taking this course

Prior to presenting this curriculum guide, you will need to adapt the information and curriculum to the needs of your specific operation. Standard operating procedures (SOPs), quality assurance and control, and track and trace systems should be decided by HMB management prior to the introduction or adaption of this template.

- HMB management may have prerequisite education requirements for staff to take this course.
- Insert a list of prerequisite requirements for taking this course.
 - For example, WHO 20-hour Breastfeeding Training Course.⁶

MODULE 1: OVERVIEW OF BREASTFEEDING AS THE PREFERRED SOURCE OF INFANT NUTRITION

Objective:

- At the end of this module, participants should understand:
 - The importance of breastfeeding.
 - The importance of immediate skin-to-skin contact after birth.
 - The importance of timely initiation of breastfeeding to promote optimal infant nutrition and health.

Key Take-Away:

- Breastfeeding is an essential aspect of newborn care.
- Globally, exclusive breastfeeding for the first six months of life could prevent 823,000 infant deaths per year.¹

Lesson Topics:

- The importance of breastfeeding.
- Breastfeeding benefits and research.
- Nutrition recommendations.
- Special considerations for the HIV-positive mother.

Estimated Time: 3 hours

1.1 THE IMPORTANCE OF BREASTFEEDING

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- Start this module with a question and answer session to encourage active participation.
- The trainer can read questions, and have participants call out answers, or have participants discuss in small groups and then share answers with the larger class.
- Develop additional questions before leading the class.
- The guestions should focus on general infant care during the newborn period and should call attention to human milk and breastfeeding in your regional setting.
- Example questions:
 - Q: What are the basic needs of a baby at birth?
 - A: Ability to breathe, temperature regulation, human touch, and intake of human milk.
 - Q: How does human milk change with an infant's development?
 - A: The composition of human milk is dynamic and changes over time to fit the changing needs of the growing child.
 - Q: What are the main components of human milk?
 - A: Human milk contains carbohydrates, protein, fat, vitamins, minerals, digestive enzymes, immune cells, growth factors, and hormones.
 - Q: How does human milk uniquely support the maturation of the intestinal mucosa?
 - A: Probiotics, prebiotics, cytokines, antigens, antibodies, and growth factors found in human milk work to protect the development of a healthy gut.
 - Q: How does human milk support the maturation of an infant's immunity?
 - A: The components of human milk bind to pathogens, inhibit inflammation, regulate gut permeability, and help populate the infant gut with a healthy microbiota.
 - Q: How does human milk change during a single expression?
 - A: Milk expressed at the end of an expression can contain two to three times the amount of milk fat found in the milk initially expressed. This dynamic nature of breast milk is believed to impact appetite regulation in infants, improving the satiety responsiveness.



EXPLAIN

- Newborns have unique needs that must be addressed from the first moments of life.
- The ability to breathe, temperature regulation and human touch through skin-to-skin contact, and access to human milk are all necessary for infants to survive and thrive during their first days of life.7

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EXPLAIN

- In 2015, 4.5 million infants died worldwide.⁸ Complications from premature birth directly accounted for one million newborn deaths, and indirectly for one million more.⁹
- Exclusive breastfeeding for the first six months of life could save 823,000 infant lives every year.¹
- Globally, less than half (45 percent) of infants start breastfeeding within one hour of birth (Figure 1), and fewer still (43 percent) breastfeed exclusively for the first six months of life.

- Insert your national and regional statistics for:
 - Exclusive breastfeeding (first six months).
 - Continued breastfeeding (up to 2 years and beyond with complementary feeds).
- ▶ In-country sources, *Demographic and Health Surveys* from USAID and *Multiple Indicator Cluster Survey* from UNICEF are well-established sources of data.
- If available, insert a local case study or woman's story of successfully breastfeeding.

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Figure 1. Percentage of newborns put to the breast within the first hour of life. ¹⁰



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EXPLAIN

- Vulnerable babies, either those born prematurely at earlier than 37 weeks gestational age, those born small for gestational age (i.e., under 10th percentile birth weight for a particular gestational age and gender), as well as abandoned or orphaned infants are at highest risk for poor outcomes related to morbidity and mortality.
- Globally, more than 2 million at risk infants die each year from direct and indirect premature birth complications.¹⁰
- The care of vulnerable newborn babies is a priority for increasing overall neonatal survival rates.¹¹
- The premature and low-birthweight (LBW) baby is more likely to have complications such as retinopathy of prematurity, NEC and sepsis, and is more likely to have neurodevelopmental impairments and not attain genetic potential for height and body size.¹⁰

National and regional statistics

- If known, insert your national and regional statistics for:
 - LBW infants.
 - Very-low-birthweight infants.
 - Cause of LBW.
 - Preterm births.
 - Causes of preterm births.
 - Infant abandonment.
 - Orphaned infants.
 - Infant mortality.
 - Causes of infant mortality.

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1.2 ESSENTIAL NEWBORN CARE

EXPLAIN

Essential Newborn Care is a package of interventions that are proven to improve newborn survival rate.^{7,12}

- Essential Newborn Care includes:
 - Cleanliness: delivery and umbilical cord care.
 - Thermal control: including Kangaroo Mother Care.
 - Early and exclusive breastfeeding.
 - Other interventions for immediate post-birth period.
- Breastfeeding is a cornerstone of Essential Newborn Care; one that often goes overlooked, especially in the neonatal intensive care unit (NICU) population.
- Kangaroo Mother Care is a method of care for preterm infants that provides the benefits of an incubator and increases a mother's likelihood of exclusively breastfeeding her infant.
 - Kangaroo Mother Care involves infants being carried or held, usually by the mother, with extended periods of skin-to-skin contact.
- Vulnerable babies face a challenging early life course.
 - Adequate breathing and temperature control needs to be prioritized for the unstable NICU infant. Once those essential needs are met, nutrition is prioritized.
 - For the at-risk infant that does not have access to MOM, DHM from an HMB is the recommended alternative to formula.^{2,3}

Policy

• Review your national and regional policies related to feeding of the vulnerable baby, including premature and LBW neonates.

1.3 BREASTFEEDING BENEFITS AND RESEARCH

- Ask participants to list the disadvantages and increased risk, for both infants and mothers, associated with not breastfeeding. If possible write responses on a board or large piece of paper for participants to see.
- Once this is finished, have participants list the barriers to breastfeeding. These include social, maternal, or infant factors.
- If participants are knowledgeable about caring for premature and LBW infants, have them list both the additional disadvantages associated with not breastfeeding for vulnerable babies, as well as the unique challenges faced by this population.

Benefits to infant

- Breastfeeding is one of the most important and beneficial gifts a mother can provide her infant.
- Breastfeeding ensures her baby gets the optimal nutrition, immunity, and bonding needed to grow into a healthy adult (Table 1).
- Breast milk provides babies with the ideal blend of calories, nutrients, immune properties, growth factors, hormones, and enzymes that are unmatched by any commercial formula.¹
 - Premature and LBW babies are more likely to develop NEC if fed formula instead of breast milk.¹³
 - Studies have shown that premature and LBW infants who receive an exclusive human milk diet are more likely to survive and thrive than those who receive formula.^{11,14-16}
 - Healthy full-term infants who are fed formula are more likely to have ear infections, be hospitalized from diarrhea or acute respiratory infections in childhood, and even development of type 1 and 2 diabetes and obesity later in life.^{1,13,15}
- ▶ When MOM is unavailable, providing DHM from an HMB is recommended as the best alternative, in combination with breastfeeding support (Figure 2).^{2,3}
- In addition to offering optimal nutrition, breastfeeding also provides vital bonding time for the mother and her infant, providing skin-to-skin contact that can also help promote temperature regulation in the premature and LBW infant.

Benefits to the mother and community

- Mothers receive lifelong health benefits from breastfeeding as well, including a lower risk of breast cancer, cervical cancer, and type 2 diabetes.^{1,17}
- Mothers who exclusively breastfeed also benefit from lactational amenorrhea, which can increase the time between pregnancies and decrease unintended pregnancy rates.¹
- Purchasing formula involves both the individual's up-front cost, as well as the long-term economic cost associated with treating illnesses that are more likely to occur in formulafed infants and missed workdays as a result of caring for a sick infant.¹⁸
- Environmental costs associated with formula feeding include challenges in obtaining safe water, disposal of the non-compostable package, and the environmental impact of dairy farms and transporting formula.

Premature and low- birthweight infants ¹⁹	Healthy term infant ^{1,13}	Mother ¹	Community ²⁰
Î NEC	↓ IQ	Type 2 diabetes, metabolic, and cardiovascular disease	↑ Waste
1 Sepsis	1 Diarrhea	f Breast and ovarian cancer	↑ Cost (↓spending power)
Retinopathy of prematurity	1 Respiratory illness	Post-partum obesity	1 Illness in community
Bronchopulmonary Dysplasia	1 Ear infections	1 Cost of formula ²⁰	Î Environmental impact
Length of stay in the NICU	T Childhood obesity	Missed workdays resulting from a sick child	
	1 Sudden infant death		

Table 1. Direct and indirect risks of not breastfeeding.

 \uparrow Increased risk \downarrow Decreased risk

1.4 NUTRITION RECOMMENDATIONS

Figure 2. World Health Organization guidelines on optimal feeding of low-birthweight infants (2011).²¹

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



EXPLAIN

- Breast milk is the only food an infant needs for the first six months of life.²²
- Breastfeeding should start within an hour of birth, assuming mother and baby do not have other urgent medical needs.²²
- Immediate skin-to-skin contact increases successful breastfeeding and thermoregulation in the healthy newborn.²³
- > Drying, weighing, eye care, and other non-urgent medical procedures can safely be postponed for the first hour after birth to allow the mother and infant to bond skin-to-skin and breastfeed.^{23,24}
- Colostrum, the first milk a mother produces, is full of important immune components and protein, and is easy for the newborn baby to digest.

- As the infant grows, the composition of MOM will change from colostrum to mature milk.
- Breastfeeding education and support should ideally start in the antenatal period and continue until the infant is weaned at age two.
- In some countries, it is traditional to practice prelacteal feeding, or the custom of expressing and discarding colostrum and giving the infant alternative food (hot water, sugar-water, honey, mustard oil, tea, or goat/cow milk).
 - Prelacteal feeding can be harmful to infants by introducing infection, sensitizing the intestine to foreign proteins, and delaying the onset of lactation.²⁵
- It is vital to educate the mother and her family during antenatal care to prepare for breastfeeding.

Breastfeeding recommendations

- Mothers should be encouraged to let newborns breastfeed on demand, at least eight times per day.
- In cases where expressed breast milk will be used temporarily, as opposed to breastfeeding, avoid using bottles and teats as these may disrupt the transition to breastfeeding.
 - Alternative feeding methods include oro- or naso-gastric tube (in hospital or under medical supervision only), supplementary nursing systems (fine sterile tube coming from container of MOM taped to breast), and spoon and cup feeding. All require trained assistance to ensure safe use.
- Babies should get only breast milk until six months old, and do not normally need any extra formula, water, or other fluids before that age.
- After six months, babies should start complementary feeding.
- Infants should continue breastfeeding until at least two years of age, even as other foods and fluids are introduced.

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Modify and expand the general, evidence-based guideline below to represent your hospital's standard operating procedures for initiation and advancement of feeds for the premature or LBW infant.

Nutritional needs of the premature or LBW infant^{21,26}

As soon as the infant is medically stable, MOM should be given, either:

- Directly from mother's breast.
- From a cup or spoon, if expressed breast milk will be used temporarily.
- From a bottle if infant will not transition from expressed breast milk to breastfeeding.
- By orogastric or nasogastric tube.

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 Follow local hospital guidelines for initiation, advancement, and fortification of feeds for the at-risk baby.

 Modify and expand the general, evidence-based guideline below to represent your hospital's policy for the feeding of healthy infants.

Nutritional needs of the healthy newborn^{25,27,28}

The age and weight of the infant influence the feeding volumes required for the healthy infant.

- > The healthy newborn should breastfeed on demand.
- The premature and LBW baby requires a smaller quantity of breast milk than a healthy term infant.
- ▶ To guide feeding, the estimated daily energy requirements (kcal/day) are listed below:^{29,30}
 - kcal/day for 0–3 months = [89 kcal x (weight of infant in kg) 100] + 175.
 - kcal/day for 4–6 months = [89 kcal x (weight of infant in kg) 100] + 56.
 - Preterm infant = 110–150 kcal/kg.



An adequately fed newborn may be expected to:³¹

- ▶ Have 6-8 wet diapers a day.
- Lose no more than ten percent of birth weight.
- ▶ Sleep well between 2–3 hour feedings.
- Gain 15 grams each day after initial weight loss.
- > Steadily increase weight gain, aligning percentile on the growth chart.

Insert your hospital policies for feeding of healthy infants, based on weight.

Nutritional needs of the breastfeeding mother³²⁻³⁴

Exclusively breastfeeding mothers require a well-balanced diet with a variety of micronutrients to support not only their own nutrition but also that of their infants.

- Mothers should avoid restricting their diet unnecessarily in advance of their child's potential food allergies. Unless their infant reacts negatively toward a specific food, no foods should be absolutely avoided during breastfeeding.
- Breastfeeding women need to increase their normally balanced and varied diet by up to 500 calories per day to support milk production.
- Breastfeeding women require two liters of water per day.
- Once their child begins complementary feeds, a mother's caloric needs to decrease. However, infants may still predominantly obtain their nutritional needs from breast milk for at least several months after starting complementary foods.

Regional nutrition requirements

- Postpartum nutritional needs will vary by region.
- Insert information on local common:
 - Nutritional deficiencies.
 - Local foods that are high in these nutrients.
 - Locally available supplements.
- Micronutrient needs vary by region.
- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.

1.5 SPECIAL CONSIDERATIONS FOR THE HIV-POSITIVE MOTHER

• Ensure current global and local guidance is used in this section.



HIV

- For mothers living with HIV, messaging about breastfeeding can be complex. It is critical for health care workers, including HMB staff, to be knowledgeable about current national recommendations.
- As of 2016, WHO recommends exclusive breastfeeding in combination with antiretroviral therapy (ART) for mothers who are HIV-positive in settings where HIV is prevalent, and where diarrhea, pneumonia, and undernutrition are common causes of death for infants.³⁵
- Exclusive breastfeeding, even for HIV-exposed, negative infants, carries less risk than formula for two reasons:
 - In regions where water contamination is common, breast milk substitutes are a common source of infection.
 - Breast milk substitutes increase gut permeability, leading to an increased likelihood of seroconversion during breastfeeding.³⁶

MODULE 2: MATERNAL SUPPORT FOR BREASTFEEDING

Objective:

- At the end of this module, participants should understand:
 - The importance of continuous lactation support for all mothers.

Key Take-Away:

- Systems, support, education, and creating an enabling environment are essential for successful exclusive breastfeeding.
- Breastfeeding support should start immediately in the hospital, continue in the community, and include the entire family.

Lesson Topics:

- Common breastfeeding challenges.
- Breastfeeding myths.
- Hospital support for breastfeeding.
- Community support for breastfeeding.
- Interpersonal and counseling skills.
- Expression support.
- Storage and handling of mother's own milk.

Estimated Time: 2 hours

2.1 COMMON BREASTFEEDING CHALLENGES

EXPLAIN

- Optimal lactation support and strengthened newborn care systems can address breastfeeding challenges.
- Common breastfeeding challenges include:²⁶
 - Breast engorgement.
 - Blocked duct.
 - Mastitis.
 - Breast abscess.
 - Sore or fissured nipple.
 - Mastitis, abscess, and nipple fissure in an HIV-positive woman.
 - Candida infection (thrush) in mother and baby.
 - Inverted, flat, large, and long nipples.
 - Perceived insufficiency and low breast milk production.
 - Low breast milk intake caused by:
 - o Illness of the infant or mother.
 - o Poor latch caused by improper positioning or abnormality of the child (muscular weakness, tongue-tie, cleft lip and/or palate).
 - o Short or infrequent feeds.
 - o Delayed initiation.
 - Twins.
 - Separation of mother and baby.

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2.2 BREASTFEEDING MYTHS

Ι ΑCTIVITY

- Ask participants and, if possible, write responses on a board or large piece of paper for participants to see:
 - What common concerns about breastfeeding have you heard in your community?
 - What methods can be used to coach mothers and families with these concerns?

- Encourage group discussion.
- Create a list of common breastfeeding concerns and myths in your area.
 - Are these concerns evidenced-based?
 - If not, how likely are they to harm the infant or mother?
 - How can staff alleviate these concerns and support a mother's choice to breastfeed?
- Prepare responses for local breastfeeding myths and concerns.
 - For example, refer to WHO Breastfeeding Training for Health Care workers.⁶
- Utilize basic counseling skills including:
 - Asking open-ended questions.
 - Using positive nonverbal communication.
 - Praising the mother.

- Develop talking points that provide parents with easy-to-digest evidence highlighting the importance of breast milk.
- Consider ways to build off what your staff knows to empower them, while also bringing in scientific knowledge.

• Modify and expand the general list of breastfeeding myths below as appropriate for your community.

Local breastfeeding myths and concerns

- Colostrum isn't good for the baby and is "spoiled breast milk."
- If the milk changes color or is bloody, it should be discarded.
- Breastfeeding should always be "easy."
- If the baby has diarrhea, he/she should only receive water.
- Formula is as good as MOM or has more vitamins and nutrients than MOM.
- A mother needs to stop breastfeeding if she becomes pregnant or goes back to work.

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2.3 HOSPITAL SUPPORT FOR BREASTFEEDING



Hospital support

- Ensure that systems are in place for MOM to reach the infant, even when the mother is not present.
 - For example, when recovering from caesarean section on another unit, ensure the mother receives lactation support to express milk and that logistics are in place to transport MOM to her infant.
- ▶ New mothers need early support to coach them through the first hours and weeks of breastfeeding.³⁷
- > Although the natural way to feed infants, breastfeeding can be a challenge for new mothers.
- New mothers and their infants need help, education, and a supportive environment to successfully establish breastfeeding.
- As the foundation of the WHO/UNICEF Baby-friendly Hospital Initiative, the Ten Steps for Successful Breastfeeding summarize the maternity services that can protect, promote, and support breastfeeding (Figure 3).
- By following the *Ten Steps for Successful Breastfeeding*, hospitals can help support mothers during the first days of breastfeeding.
- ▶ Hospitals that routinely offer formula have lower breastfeeding rates.³⁸



Photo: PATH/Gabe Bienczycki









- Encourage group discussions; ask participants and, if possible, write responses on a board or large piece of paper for participants to see:
 - How does our hospital meet the Ten Steps for Successful Breastfeeding?
 - What changes could our hospital make to more closely align with these steps?
 - What changes has the hospital seen since implementing the *Ten Steps for Successful Breastfeeding*?



- Certified lactation consultants are essential for breastfeeding mothers and families.
- Certified lactation consultants support breastfeeding by:
 - Building confidence in the mother's ability to breastfeed her baby.
 - Assisting with basic infant positioning.
 - Providing prenatal counseling to discuss common lactation concerns.
 - Providing accurate clinical information to promote breastfeeding and lactation.
 - Addressing and preventing common breastfeeding challenges.
 - Providing strategies to help a mother continue breastfeeding and lactating after returning to work.

Local certified lactation consultants

- If your hospital has certified lactation consultants, insert their:
 - Contact information.
 - Available services.
 - Working hours.
 - Fees.

2.4 COMMUNITY SUPPORT FOR BREASTFEEDING

EXPLAIN

Importance of breastfeeding support

- Breastfeeding support that starts in the hospital and continues in the community is shown to be more effective than support in either setting alone.^{40,41}
- Coaching and support from a trusted family member, a community health worker, or community lactation consultant can be beneficial for a new mother.^{42,43}
- It is easier for a mother to successfully breastfeed if she feels happy and secure.
- Providing breastfeeding mothers with the support, encouragement, and community to feel empowered will help them to exclusively breastfeed.

Lactation support groups

- Parents of the premature or LBW baby can have unique challenges with lactation initiation, breastfeeding positions, and helping their new baby latch onto the nipple.
- Lactation support groups led by certified lactation consultants or nurses can provide parents with both clinical information and technical assistance with lactation, as well as camaraderie and support from fellow parents within the NICU.⁴⁴
- ▶ Where feasible and culturally appropriate, fathers should be integrated into support groups, as they can provide support for the new mother.⁴⁵⁻⁴⁸
- Lactation support groups should be adapted to the local context and can include breastfeeding peer counselors.
 - Peer counselors can support normal breastfeeding for new mothers and babies by providing support, encouragement, and accurate information.

Local lactation support groups

- List information on local lactation support groups in your hospital and community.
 - Contact information.
 - Group meeting times and locations.

- If your institution decides to include a breastfeeding peer counselor role, insert an overview of the qualifications and responsibilities of the breastfeeding peer counselor.
 - Relevant information might include:
 - o What training is required of breastfeeding peer counselor?
 - o Is it a volunteer or paid position?
 - o What is the time commitment?

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2.5 INTERPERSONAL AND COUNSELING SKILLS

EXPLAIN

Basic counseling skills review:22

- Praise, Inform, Suggest, Listen and Learn Actively support breastfeeding every time you
 interact with a breastfeeding mother.
 - Praise Compliment the mother for what she and her baby are doing right.
 - Inform Offer information.
 - Suggest Suggest something appropriate.
 - Listening and Learning Helps mothers tell you more.
- Nonverbal communication.
 - Nonverbal communication is how you communicate through posture and expressions.
 - Nonverbal expressions can show someone you're listening and make them feel you are interested in what they're saying.
- Ask open-ended questions.
 - Open-ended questions usually start with "How? What? When? Where? Why?"
 - Questions that start with "Did you...?" "Are you...?" will be answered with a yes/no response.
 - o Closed questions can be helpful but won't give you as much information.
- Use gestures and responses to show interest to the mother's answers.
- Reflect back what the mother says.
 - Repeat back what the mother has told you, so she knows you are listening.
- Empathize with the mother so she knows you understand her situation.

- Avoid "judging" words.
 - WHO's Infant and Young Child Feeding Counselling Course²² has a list of "judging" words in English, space to translate into the local language, and an activity where participants change the judgmental statement to an open sentence.
 - o "Judging" words such as properly, badly, right, wrong, and enough can make a mother feel as though she is not doing something correctly or something is wrong with her baby.



EXPLAIN

Tips for helping a mother to breastfeed:

- 1) Provide a quiet and calm environment.
- 2) Praise the mother for her hard work and efforts to breastfeed.
- 3) Ask the mother how she feels breastfeeding is going and discuss any concerns (see counseling skills section for more info).
- 4) Observe breastfeeding.
- 5) If needed, help the mother with the positioning of her baby.
- 6) Give the mother relevant information. Make sure the mother understands:
 - a) On-demand feeding.
 - b) Signs that baby is ready for feeding.
 - c) How milk consistency and volume of milk changes during the first few days and months of lactation.
- 7) Answer the mother's questions and provide follow-up care as needed.

••••••



- ▶ Break participants up into groups of 2–3 individuals, based on class size.
- Have one participant role-play the Breastfeeding Mother and the other participant roleplay the Counselor.
- Give the Breastfeeding Mother a common reason a new mother might be struggling to breastfeed. Examples can include:
 - "My baby won't latch."
 - "I'm not producing enough milk for my infant."
 - "My nipples hurt every time the baby nurses." •
 - "Breastfeeding is taking too much time out of my day."
 - "My husband wants to participate in feeding and wants me to switch to bottles." •
- The goal is for Counselors to encourage Breastfeeding Mothers by using praise, inform, suggest, listening, and learning, rather than telling mothers what to do.
- An optional third participant can be an observer and provide feedback to the Counselor.
- Participants should change roles so everyone has a chance to practice being the Counselor.





Photo: United States Breastfeeding Comittee

2.6 EXPRESSION OF BREAST MILK

EXPLAIN

- Special assistance is required for mothers in stressful situations, such as a preterm birth or caesarean section. The mother may not immediately express sufficient volumes of breast milk to meet her infant's needs.
- There are many reasons why an infant may have difficulty obtaining milk directly from the breast including:
 - Illness or infection:
 - o Jaundice.
 - o Thrush.
 - Infant frustration and difficulty with breastfeeding because of:
 - o Preference for a bottle.
 - o Difficulty attaching to a breast.
 - Fast-flowing milk especially at the beginning of a feed. The infant may find it difficult to swallow and breathe while ingesting so much milk.
 - Physical abnormalities:
 - o Cleft lip and or palate.
 - o Tongue-tie.
 - o Muscular weakness.
 - o Heart, kidney, or other abnormalities.
 - Premature or LBW baby:
 - o The infant may be too weak or too little to successfully nurse at the breast.
 - o The suck-swallow-breathe mechanism may not yet be developed.
 - \vartriangle This mechanism develops around 28 weeks' gestation and is fully developed at 34 weeks.
- If an infant is unable to breastfeed, a mother can express breast milk to be provided to her infant through a cup, spoon, supplementary nursing system, or nasogastric tube.
- Providers should always support a mother's infant feeding choice and provide adequate counseling, support services, and resources.



- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.
- Review Breast milk expression resources in Appendix 1.

Expressing milk by hand

- Supplies:
 - Clean container (e.g., spoon, cup, or jug).
 - o If mother collects milk into a spoon, a separate storage container should be cleaned.
 - Area for handwashing.
- Preparation:
 - Always wash hands and clean surfaces prior to handling any feeding equipment.
 - The container should be washed with soap and water.
 - Keep kettles, pans, and containers of boiling water away from the edge of surfaces and handle with extreme care.
 - Immediately before expressing, fill the cup or jug with boiling water and leave for a few minutes. If using a spoon, pour boiling water into another clean cup, and place the spoon into the boiling water for a few minutes.
 - o This process will kill most of the bacteria.
- Expression steps:
 - Wash hands.
 - A lactation consultant should show the mother where to position her fingers on the breast.
 - o Two fingers above and below the nipple.
 - o To help the mother, tape can be placed at the spots where she positions her fingers.
 - Push down (towards ribcage), not pinching out toward nipple, then squeeze.
 - o The first few attempts may not produce milk.
 - Collect the milk into the clean spoon or storage container.
 - Reassure the mother that during the first several days after giving birth, she may not produce much milk, but her infant is receiving all the nutrition they need.
 - Transfer the milk into clean storage container as needed.
 - Fasten the lid tightly and store sealed milk container appropriately.
 - Clean the supplies and let dry completely.

- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.
- If your operation uses a specific breast pump in the hospital, include instructions for that breast pump as appropriate.
- Review Breast milk expression resources in Appendix 1.

EXPLAIN

Expressing milk with a breast pump

- Refer to breast pump instructions for specific information.
- Supplies:
 - Breast pump. Wash all parts of the pump separately and according to manufacturer's instructions. Let dry completely before use.
 - Container for milk (see above for cleaning instructions).
- Expression steps:
 - Wash hands.
 - Assemble the breast pump according to manufacturer's instructions.
 - Place the flange around the nipple.
 - Apply suction, starting low and moving up as tolerated.
 - o Suction may be slightly uncomfortable but should never be painful.
 - o If painful, release the suction, and reassess placement of the flange and suction strength.
 - When the container is almost full, stop pumping (turn the switch to 'off' position, if using an electric pump), and insert one finger between the nipple and where the flange touches the skin.
 - Place the milk in the clean storage container, if using a syringe pump.
 - Fasten the lid tightly and store the sealed milk container appropriately.
 - Clean all parts of pump separately and let dry completely.
 - Store the pump in a clean and well-ventilated space.



How to support milk expression

- Create a quiet and comfortable space for the mother to express her milk.
- ▶ Help the mother feel comfortable, relaxed, and confident to encourage oxytocin release, which is necessary for milk letdown.
- Looking at and hearing the baby can help with oxytocin release. If the baby is not close, encourage the mother to think of her baby, look at a picture of her baby or smell a piece of the baby's clothing.
- Receiving a back massage or having the mother massage, stroke, and warm her breasts can also increase milk release.
- Explain to the mother that it can take up to 30 minutes to completely express her milk.
- Hand expression may be a preferred option in resource-limited settings, where cleaning of pumps may be difficult if a clean water supply is unavailable.
- Coach the mother on proper hand expression techniques, but do not express the milk for her, as this will limit her ability to independently hand express at home.
- The expression may be slightly uncomfortable but should never be painful. If expression hurts, check her technique or placement of the pump.



Photo: United States Breastfeeding Committee
2.7 STORAGE AND HANDLING OF MOTHER'S OWN MILK

 Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.

• Storage of MOM for home use has different requirements than for hospital or HMB use (Table 2).

Table 2. Requirements for home storage of mother's own milk.⁴⁹

Location	Maximum temperature	Duration	Comments
Room temp	< 25°C >	< 6-8 hours >	Containers should be covered and kept as cool as possible.
Insulated cooler bag	< 4°C >	< 24 hours >	Ice packs should be in contact with milk containers at all times. Limit opening of the bag.
Refrigerator	< 4°C >	< 5 days >	Store sealed containers in the back of the main compartment of refrigerator.
Freezer compartment of refrigerator	< -15°C >	< 2 weeks >	Keep sealed milk containers towards the back of the freezer. Milk is safe for longer periods, but lipids will break down.
Freezer compartment of the refrigerator with separate door	< -18°C >	< 3-6 months >	
Deep freezer	<-20°C>	< 6-12 months >	



 Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.



Using expressed MOM for mother's own infant

- To warm refrigerated milk:
 - Place sealed milk container in a bowl of warm water for several minutes.
 - Do not let container tip over in the water or let water touch the lid of the container.
- To thaw frozen milk:
 - Place the sealed milk container in the refrigerator overnight, under cool running water until it liquefies, or place in a bowl of warm water.
 - Do not let container tip over in the water or let water touch the lid of the container.
- Do not boil, place on stovetop, or microwave the milk.
 - This can destroy enzymes and immunoglobulins and can bring milk to unsafe temperatures for the infant.
- Once frozen milk is thawed, it can be kept in the refrigerator for 24 hours but cannot be refrozen.
- After feeding, any leftover milk should be discarded.

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Photo: PATH/Kimberly Mansen

MODULE 3: OVERVIEW OF DONOR HUMAN MILK AND HUMAN MILK BANKING

Objective:

- At the end of this module, participants should understand:
 - The role of human milk banking and DHM in newborn care.
 - How HMBs can be integrated into health care systems to support breastfeeding.

Key Take-Away:

- > DHM is an essential nutritional bridge for many neonates.
- HMBs are most impactful if they are a functional part of the larger health system.

Lesson Topics:

- Definition of donor human milk and human milk banking.
- Appropriate use of donor human milk for the vulnerable baby.
- Risks of informal milk sharing.
- Background of human milk banking in the local setting.

Estimated Time: 1 hour 30 minutes

3.1 DONOR HUMAN MILK AND HUMAN MILK BANKING

• Modify and expand the definitions below or include the definition as established by local and national guidelines or the local HMB.

DHM definition:

Donor human milk (DHM) is human breast milk in excess of an infant's current and future needs that is donated by a mother to an HMB for use by a recipient infant that is not the mother's own infant. DHM is offered voluntarily and without payment to the donor mother and is provided to the recipient infant based on clinical necessity. DHM is not an alternative to MOM but is instead used as an alternative to formula to serve as a bridge to ensure an exclusive human milk diet, as the mother is provided lactation support to build her milk supply for her own infant.^{50,51}

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



HMB definition:

- A human milk bank (HMB) is a service established to recruit breast milk donors, collect donated milk, and then process, screen, store, and distribute the milk to meet infants' specific needs for optimal health.
 - The mission of an HMB is to protect, promote, and support breastfeeding by providing safe, high-quality DHM to fill a gap for those who need mother's milk but cannot receive it.
 - To ensure quality and safety, HMBs should always be a functional part of the health care system, whether integrated within a hospital or operating independently (Figure 4).
 - An HMB can play a critical role in an integrated system for delivering optimal newborn care and serve as a centralized community hub for all mothers by (Figure 5):

Figure 5. Integrated systems for increased access to human milk.



- o Protecting, promoting, and supporting breastfeeding and Kangaroo Mother Care.
- o Recruiting donors, processing, and providing safe, pasteurized DHM when MOM is insufficient or not available.

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3.2 APPROPRIATE USE OF DONOR HUMAN MILK FOR THE VULNERABLE BABY

EXPLAIN

Use of human milk in the context of vulnerable infants

- Breast milk is the optimal and most complete source of nutrition for an infant.
- Only MOM provides all of the important nutrients and bioactive components newborns need for optimal growth and development.⁵²
- Breastfeeding is a natural act, but one that takes time and support to learn.
- Mothers of vulnerable babies may face special barriers when learning to breastfeed and express milk.
- The stress of worrying about one's newborn, being separated for medical care, and slower onset of milk production all make breastfeeding and breast milk expression particularly challenging for the new mother of a premature or LBW baby.



Benefits of DHM compared to formula

- When MOM is not available, DHM is recommended for vulnerable infants.
- DHM does not replace MOM but rather acts as a bridge to breastfeeding or fully receiving MOM.^{2,53}
 - In the absence of any MOM, DHM can be used as full or partial feeds.
 - Additionally, while a mother is building her milk supply, DHM can be used to supplement, if lactation support is provided along the way.
 - As the supply of MOM increases, the proportion of DHM should decrease, to avoid undermining breastfeeding.
- Compared to formula feeding, DHM-fed infants are less likely to develop NEC or bronchopulmonary dysplasia, or have feeding intolerance or delayed gastric emptying. This can contribute to a reduced length of stay in the NICU. There is also limited evidence that retinopathy of prematurity and sepsis are decreased in infants that receive DHM compared to formula, and there are cost benefits and neurodevelopmental benefits to providing DHM (Table 3).



Photo: PATH/Georgina Goodwin

Table 3. Studies demonstrating the impact of human milk and donor human milk on vulnerable infants.

NECROTIZING ENTEROCOLITIS (NEC)

▶ Human milk feedings, whether mother's own milk or donor milk, significantly reduce the incidence of any NEC.^{3,4,54-64}

BRONCHOPULMONARY DYSPLASIA (BPD)

▶ There is a positive effect of donor human milk (DHM) supplementation on BPD in very preterm and very low-birthweight infants.⁶⁴⁻⁶⁸

FEEDING TOLERANCE

► There is a higher incidence of diarrhea and feeding intolerance among formula-fed preterm and low-birthweight infants.^{2,3,5,57,58,69-71}

BREASTFEEDING RATES

► A single systematic review shows a significant positive impact on any breastfeeding on discharge after the introduction of DHM to neonatal units.^{56,61,72-74}

SEPSIS

► The meta-analyses of observational studies show nearly significant reduction in the incidence of long-term sepsis with an exclusive human milk diet.^{5,54,58,64,68,75}

RETINOPATHY OF PREMATURITY (ROP)

• Current meta-analyses show a potential protective effect of human milk feeding and exclusive human milk feeding in preventing any-stage ROP and severe ROP.^{5,54,66,68,76}

REDUCE LENGTH OF STAY IN NEONATAL INTENSIVE CARE UNIT (NICU)

Human milk feeding reduces the hospital length of stay.⁷⁷⁻⁷⁹ The cost of providing DHM to preterm infants is mitigated by a reduced risk of complications and shorter length of stay in NICU.^{60,70,80}

COST SAVING

 Increasing the use of human milk can provide cost savings through the reduction in NEC.^{57,60,70,80-83}

NEURODEVELOPMENTAL OUTCOMES AND LONG-TERM BENEFITS

Individual randomized control trials and observational studies show that preterm infants who receive human milk feedings have lower rates of metabolic syndrome, greater white matter, brain volumes, head circumference, and significantly higher scores for mental, motor and behavior ratings at later ages in childhood and adulthood.^{79,84-91}



Comparison of DHM and MOM

- MOM is the best source of nutrition for all infants.
- ▶ DHM is pasteurized to destroy disease-causing bacteria and viruses such as HIV. All forms of pasteurization reduce or eliminate some bioactive components that make human milk uniquely beneficial for human babies (Table 4).⁹²⁻⁹⁴
- Freezing DHM is usually necessary to reduce bacterial growth during transport and storage; however, it is known to reduce or destroy some of the bioactive components in DHM.⁹⁵
- Despite the impact of processing DHM, many of these bioactive components remain intact. Infant formula does not contain the complete protective and immune-boosting components.

Appropriate use of DHM

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- Emphasize that DHM is not a replacement for MOM but is rather a bridge to infants using MOM and thus an important part neonatal nutrition.
- > DHM is used as a temporary bridge to using MOM in cases where:
 - There is a delay in the mother's breast milk production.
 - The mother is ill.
 - There is a separation from the mother, when the infant or mother is transferred elsewhere.
 - The mother is taking medication that is contraindicated during breastfeeding.
- Depending on hospital criteria and HMB supply, DHM may also be used when an infant is abandoned, orphaned, or the mother is deceased.
- See Appendix 2 for more information on the prioritization of DHM and prevention of DHM overuse.



• Insert your hospital policy on the prioritization and criteria for the use of DHM.

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Component	Function	MOM (raw)	DHM (frozen/pasteurized)
Macronutrients (e.g., proteins, carbohydrate as lactose, lipids)	Source of energy Substrate for other components	Variable between mothers Protein and lipid higher in preterm birth	Lipids decreased with multiple freeze/thaw cycles Protein maintained Lactose maintained
Bioactive proteins (e.g., lactoferrin)	Anti-inflammatory Anti-infective Protects gut barrier	Highest in colostrum, decreases until one-month post- birth	Lower after pasteurization/ freezing Some components become inactive
Growth factors	Growth Maturation Protects gut barrier	Highest in very preterm colostrum, markedly decreased at one-month post- birth	Some reduced with pasteurization
Human milk oligosaccharides	Antimicrobial Prebiotic	Highest in preterm colostrum	No effect
Hormones (e.g., insulin, adiponectin)	Metabolic regulation	Highest in colostrum, higher in hindmilk	Reduced with pasteurization
Milk microbiome	Gut colonization	Highly specific to individual mothers	Destroyed with pasteurization

Table 4. Comparison of components in raw vs. processed human milk.⁹³⁻⁹⁵

* This list is a brief overview and is not meant to be exhaustive.

• Consider reviewing data in Table 3, and modify as necessary as new studies are published.

3.3 RISKS OF INFORMAL AND COMMERCIALIZED MILK SHARING

EXPLAIN

Risk of informal milk sharing and selling

- Mothers have been wet-nursing and milk sharing throughout history for at-risk infants or as a service to mothers.
- With advances in medical knowledge, we now better understand the risks of milk sharing without screening donor mothers and pasteurizing the donor milk.
- ▶ Many national HMB regulatory bodies discourage informal milk sharing.^{53,98-100}
- The robust screening process of a regulated HMB can provide infants with the benefits of human milk, without the risks of disease transmission or contamination.
- Milk that can be safely provided to the mother's own infant might not be safe to donate to a vulnerable infant, who can be uniquely susceptible to risk of infection, disease, and macro-and micronutrient deficiencies.
 - Unregulated donor milk can be unhygienic or contaminated with pathogens, chemicals, medications, and non-human milk, among others.¹⁰¹⁻¹⁰⁶
 - As human milk is dynamic and changes with the age of the infant, unregulated milk may not be age-appropriate for the vulnerable baby.¹⁰¹⁻¹⁰⁷
- ▶ The commercial buying and selling of human milk, in the absence of clinical oversight, is generally discouraged. This is partially to avoid incentivizing mothers resulting in a conflict of interest, potentially impacting the provision of her milk to her own infant (Table 5).¹⁰⁸

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Table 5. Types of milk sharing.

Donor human milk	Other types of milk sharing ⁵²
Expressed breast milk that has been pasteurized, tested, and handled—according to standard national guidelines—from a mother who has not received compensation for her time or milk.	Wet nursing: One woman directly breastfeeding another woman's infant for pay.
	Cross nursing: One woman directly breastfeeding another woman's infant (not for pay).
	Informal milk sharing: Expressed breast milk, not from an HMB, that is given to an infant.
	Informal milk purchasing: Expressed breast milk, not from an HMB, that the mother was paid to give.
	Formalized milk purchasing: Expressed breast milk provided to a for-profit business that the mother is paid to give.

3.4 BACKGROUND OF HUMAN MILK BANKING IN THE LOCAL SETTING

EXPLAIN

History of the local HMB

- ▶ Insert a brief overview of how your hospital/region decided to create an HMB.
- Relevant information might include:
 - Initial key stakeholders.
 - Regional involvement in your HMB.
 - Funders/donors, etc.

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- Relevant statistics about the HMB, after it has been open for more than six months.
 - o Example statistic: "As of today, our HMB has provided ____ infants with more than ____ liters of DHM."
- When available, public statements from the minister of health and other leaders about the importance of building an HMB.



Photo: PATH/Tom Furtwangler

MODULE 4: DONOR COUNSELING AND SCREENING

Objective:

- At the end of this module, participants should understand:
 - Locally appropriate donor recruitment strategies.
 - Screening required for potential donors.
 - Safe milk expression and collection techniques.

Key Take-Away:

- Donor mobilization and support is critical for supplying the HMB with DHM.
- Appropriate screening strategies and hygienic milk expression and collection can improve the safety of DHM.

Lesson Topics:

- Mobilization for donor recruitment.
- Counseling for bereaved mothers.
- Qualifications of donors.
- Donor screening process.
- Counseling for mothers who are not eligible to donate.
- Donor education.
- Human milk expression and collection techniques.

Estimated Time: 1 hour 30 minutes

SEE TOOL #6

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

SEE TOOL #7

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—<u>A Counseling Guide for Engaging Bereaved Mothers</u>.

4.1 MOBILIZATION FOR DONOR RECRUITMENT

- Breastfeeding is the first step to ensuring optimal neonatal nutrition.
- Mobilizing donors is key for the sustainability and success of the HMB.
- Donors can be recruited through multiple communication channels to meet the HMB's need for DHM including:
 - Mass media channels:
 - This includes print media, such as informational pamphlets left in antenatal clinics, hospitals, places of work, daycare centers, family practice facilities, postnatal wards, maternity shops, children's centers, and other areas. Other promotional media include online sources, television, and radio—all of which can reach a large, broad audience. Celebrities, sports stars, or other influential people can serve as powerful community advocates both in the media and within the community.
 - Interpersonal channels:
 - o Antenatal staff, physicians, midwives, nurses, NICU staff, lactation consultants, maternity wards, and nutritionists can promote breastfeeding, and refer and recommend donation to the HMB.
 - Community-oriented channels:
 - o This includes word of mouth in social networks such as families, peer support groups, and community. Donors themselves often serve as the best recruiting tool as they talk to friends and family.
- Promotional methods for donor recruitment should target ethical and appropriate donation of DHM.
- Donors can be actively mobilized using direct referrals, community engagement, and the media.
- Recruitment materials and messages should be clear, easy to read, and suitable for all reading levels, avoiding technical language.
- All donor recruitment activities and materials should include ongoing breastfeeding education and lactation support to ensure the mother has or is expressing sufficient milk for her infant.
- HMBs have an important duty to ensure all milk donations are in the best interest of both the mother and the infant.
 - Mothers should be counseled on the importance of an exclusive human milk diet for their own infants; only if they have excess milk supply should donation be considered.
 - Mothers who are donating excessive quantities of milk on an ongoing basis, beyond what is healthy for her, should be offered counseling on reducing their lactation to manageable levels.

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- Examples where additional counseling may be needed:
 - o A mother who donates her milk that she pumps when at work, while her child receives prepared formula or other feeds elsewhere.
 - o A mother who donates all of her frozen milk stock and does not keep any in case of emergency.
 - A mother who was recruited during a time of breast engorgement and may be donating a larger quantity of milk than is healthy.

- Brainstorm ideas for recruitment in the media, hospital, and community, using Figure 6 as an example.
 - Have participants identify local strategies and locations for donor recruitment.
 - Identify ways HMB/NICU/hospital staff could facilitate the recruitment of donors.
 - o Examples of facilitation:
 - △ Initial awareness should take place at routine antenatal care, for both potential recipients and donors.
 - △ NICU nurses and lactation consultants can provide information on donating milk during breast milk expression support.
 - △ Lactation consultants and peer mentors can discuss milk donation during lactation support meetings.
 - △ Medical providers can discuss donation during well-baby check-ups.
 - △ Medical providers can discuss donation during medical visits with bereaved mothers.
 - △ Hospital staff may also serve as donors.

⁻⁻⁻⁻⁻⁻

Figure 6. Strategies and locations for donor recruitment.

HOSPITAL

Examples:

Direct referrals and recommendations from:

- Current and previous donors
- Staff at neonatal units
- Pediatricians
- Healthcare professionals providing postpartum care
- Childbirth educators

MEDIA

Examples: TV Radio Newspapers Magazines Social media

COMMUNITY Examples:

• Pamphlets and flyers to be left in antenatal clinics and postnatal wards; maternity and childbirth centers; children's and maternity shops; childcare centers; and organized community events for infants and their caregivers.

Community events.

• Direct referals and recommendations from organizers and attendees of antenatal and post-partum classes; breastfeeding mothers' support groups and organizations; and high-visibility advocates.

Photo: © 2011 Danny Victoriano, Courtesy of Photoshare

4.2 COUNSELING FOR BEREAVED MOTHERS



- Some mothers who have experienced the loss of their infant may find it therapeutic to donate expressed breast milk that they had already pumped for their own infant.
 - Mothers may decide to continue pumping as part of the grieving process.
 - Mothers who have a miscarriage or a stillbirth may choose to begin pumping and gradually suppress their milk supply, rather than aim to cease lactating immediately.
 - This has been described as helping bereaved mothers feel more connected to motherhood and the infant they lost. It may also have health benefits for the mother.
- When screening potential donor mothers, it is best to ask broad questions such as:
 - "How did you end up with extra breast milk to donate?" as opposed to "How old is your baby?"
- Mothers may need additional support during this period, so be prepared to refer mothers to local bereavement support groups, printed materials, and bereavement websites.

• For a more detailed training module on counseling bereaved mothers, please review Appendix 3: Bereavement and lactation support.

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4.3 QUALIFICATIONS OF DONORS

- Criteria for the eligibility of donation and temporary discontinuation of donation can vary according to resources, disease risks, and cultural considerations of a region.
- Expand the general, evidence-based criteria below to meet hospital protocols. Explain why your protocols may differ from the included criteria listed under either the "Example screening criteria for eligible donors" or "Example temporary exclusion criteria."

- A robust donor screening process is the first step to ensuring the safety of DHM.
- The reasons for screening and testing should be explained to all interested donors.
- Potential donors should be advised that depending on their answers to screening questions, they may not be eligible to donate milk, but their own milk is still safe for their own infants and they should continue to breastfeed.
- Screening needs to be designed to exclude all mothers whose milk could create a risk for vulnerable infants, balancing risks and resources to meet the needs of the local setting.

Who can donate?

- Healthy women with more than enough breast milk to feed their own infants.
- Women who are screened to ensure safety for donors and recipients.

Example exclusion criteria for donors:

- Tobacco or nicotine user.
- Excessive alcohol consumption < x units of alcohol per day >.
- Illicit/recreational drug use.
- Mentally unfit.
- Underage minor, per the local setting.
- Infant older than < x months >.
- Increased risk for Creutzfeld-Jakob disease.

- Positive test results for any of the following:
 - HIV (type 1 or 2).
 - Syphilis.
 - Human T-lymphotropic virus type I or II.
 - Hepatitis B or C.

Example temporary exclusion criteria:

- Local breast disease.
- Receiving medication or medical treatment contraindicated during breastfeeding.
- High-risk behavior including: recent tattoo, body piercing, acupuncture, IV drug use, recipient of organ or tissue transplant, recipient of blood transfusion, and accidental needle sticks occurring in the medical field.
- Significant environmental or chemical exposure.
- Poor nutritional intake or supplemented (Vitamin B12) vegan diets.
- If donating would compromise nutrition and health of own infant.

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4.4 DONOR SCREENING PROCESS

EXPLAIN

- All potential donors need to undergo a screening process, which includes an oral and written screening and a serological blood test for infectious diseases.
- The donor screening process is a unique process and may change throughout time, based on local needs.
- Donor screening should focus on the disease risk of the region served by the HMB.

- Insert your hospital and HMB policies and procedures for screening potential donors, as established by local guidelines.
- Your policies and procedures should at minimum describe:
 - Screening tools and procedures used to evaluate and select potential donors, including serologic testing.
 - Exclusion criteria.
 - Temporary exclusion.
 - Informed consent.
 - Procedures for approving donors.
 - Procedure for rescreening women donating over extended periods.
 - Methods for confirming that the infant's own health is not compromised.

4.5 COUNSELING FOR MOTHERS WHO ARE NOT ELIGIBLE TO DONATE

 Modify and expand the recommendations below to meet hospital and HMB policies and procedures.

- Mothers who do not meet the screening criteria for human milk donation are typically still able to breastfeed their own infants, and may require careful counseling.
 - Mothers may be concerned that because they are ineligible to donate, they should no longer breastfeed their own infant.
 - Unpasteurized MOM has unique qualities that are beneficial for her own infant.
 - Staff should reassure mothers that it is safe to continue breastfeeding per their physician's recommendation.
 - Mothers should be encouraged to continue breastfeeding and be provided with support services to ensure they continue breastfeeding their own infants.
 - Mothers with a limited volume of milk to donate should be informed of the high cost to screen mothers, and the HMB has limited ability to screen and accept milk in small volumes.

Counseling of mothers who are ineligible due to contaminated donor milk

- If donated milk tests positive for bacteria < above x colony-forming units (CFU) /mL > for total viable microorganisms before pasteurization, HMB staff should discuss hygienic and safe expression and storage practices with the donor.
 - Identify and help the mother address any barriers to optimal expression and storage.
 - Identify any knowledge gaps that the mother may have.
- Ensure the mother is thoroughly cleaning her pump, both for donation and also her own infant. (See **Module 2: Maternal Support** for pump cleaning information.)

4.6 DONOR EDUCATION

- The content and level of material included in donor education will vary according to resources and cultural considerations of the region.
- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.



Donor education includes:

- Lactation support for breastfeeding and establishing an optimal milk supply.
- Emotional support for all mothers, including bereaved mothers.
- Counseling on HMB guidelines for a healthy diet, including food safety and alcohol limitations.
- Coaching on procedures for maintaining safety and quality of the milk donated, including safe collection and storage of milk.
- Understanding that the satiety needs of mother's own infant come before donation.
- Understanding the need to discuss suspension and discontinuation of milk donation if:
 - The mother develops a fever or infection or is exposed to disease.
 - The mother begins taking a new, potentially contraindicated medication.
- Support on procedures for pick-up and delivery of donated milk for the HMB.



Photo: Brazilian National Network of Human Milk Banks

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4.7 HUMAN MILK EXPRESSION AND COLLECTION TECHNIQUES

- Techniques for milk collection will vary according to resources and cultural considerations of the region.
- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.



- Hygienic and proper collection of breast milk by the donor mothers is essential to DHM safety.
- HMB staff should educate and empower donor mothers on the process of expressing breast milk for HMB donation.

Milk expression and collection

For optimal milk expression and collection, mothers should:

- Wash hands before breast milk expression and handling.
- Choose if hand or pump expression is best.
 - Hand expression may be preferred to pump expression, due to the following considerations:
 - o Improperly cleaned pumps are frequent sources of contamination.
 - o Pumps are difficult to clean properly, with many small parts and areas where bacteria can grow.
- Collect expressed milk rather than drip milk.
- Add freshly expressed milk to its own container; fresh milk should not be added to containers holding previously frozen milk.
- Learn how to prevent contamination.
- Store expressed breast milk in < containers approved by your HMB >.
 - Containers should be filled about < volume approved for your HMB >.
 - Containers should be completely sealed with airtight lids.
- These steps ensure that breast milk does not leak during thawing and is not contaminated.
- Label containers with:
 - Mother's name or donor ID.
 - Date of expression.

- Place expressed breast milk immediately in a freezer.
 - Expressed milk that is initially placed in the refrigerator is stored in the freezer within < 24 hours >.
- Clean all parts of pump separately and let dry completely.
- Send milk for donation to the HMB by <x days/months>.
 - Hand-expressed or pumped breast milk for mother's own infant may be safely stored longer at home than breast milk that is sent to the HMB for donation.
 - Shelf life and storage of DHM in the HMB is covered in **Module 8: Storage**.

- ▶ Break participants up into groups of 2–3 individuals, based on class size.
- Have one participant role-play the Donor Mother and the other participant role-play the Hospital Staff.
- The Donor Mother will have a script telling her why she's donating breast milk, how old her baby is, and if she has any health problems.
- An optional third participant can be an observer and provide feedback to the Hospital Staff participant.
- Participants should change roles, so everyone has a chance to practice being the Hospital Staff.
- The participants will role-play through the entire screening process. The Hospital Staff participant will be responsible for identifying any issues that might prevent the Donor Mother participant from donating.
 - Example scenarios to role-play:
 - o Counseling a mother who is ineligible to donate.
 - △ Allow Hospital Staff participants to practice counseling mothers on the importance of continuing breastfeeding their own infant even if they cannot donate.
 - o Counseling a bereaved mother seeking information about donation.
 - △ Allow Hospital Staff to practice counseling mothers that have suffered a loss.

MODULE 5: MILK HANDLING

Objective:

- At the end of this module, participants should understand:
 - The importance of safe and hygienic handling of milk.
 - The importance of maintaining the cold chain.
 - The importance of hand hygiene.

Key Take-Away:

- Safety is the most critical service a hospital or HMB can provide patients.
- As bacteria thrive in warm nutrient-rich environments, the cold chain is necessary to ensure proper temperatures are maintained at each stage of processing.
- Hand hygiene is a critical aspect of safety and the most effective technique for preventing communicable diseases.

Lesson Topics:

- Hygienic and safe handling of milk.
- Maintenance of the cold chain.
- Hand hygiene as a safety mechanism.

Estimated Time: 1 hour 40 minutes

5.1 HYGIENIC AND SAFE HANDLING OF MILK

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 Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.

- Hygienic and safe handling of DHM helps to decrease the possibility of contamination.
- Hygienic and safe handling of milk includes:
 - Safe collection of milk.
 - Proper hand and personal hygiene.
 - Wearing gloves whenever handling DHM.
 - Wearing a hairnet and mask when processing DHM.
 - Maintenance of the cold chain and safe storage.

ΑCTIVITY

- Ask participants and, if possible write responses on a board or large piece of paper for participants to see:
 - What might prevent clinical staff or mothers from using safe handling practices?
- Answers might include:

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- Being too busy at work to take time for handwashing.
- Having stock-outs, and not having gloves to wear.
- No one else in the facility does it.
- Mothers are under stress or don't have access to handwashing stations.
- Ask participants to create a verbal contract with each other that each staff member will:
 - Maintain safe handling of DHM.
 - Be receptive if a peer or manager notes non-compliance.
 - Raise issues with peers if they notice non-compliance.
 - Encourage and show mothers best hand-hygiene practices with lactation and handling milk.

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5.2 MAINTENANCE OF THE COLD CHAIN

Maintenance of the cold chain for DHM

- An infant's immune system and intestinal microbiome are not yet fully developed, leaving the infant at an increased risk of developing an illness.¹⁰⁷
- Premature and LBW infants in the NICU are especially vulnerable and are more likely to be in danger of getting seriously ill if their milk is contaminated.¹⁰⁸
- After proper hand hygiene, temperature control is the next most important safety mechanism for preventing DHM contamination.
- The cold chain is a process that ensures continuous maintenance of optimal temperatures at each stage of processing.
 - HMB staff need to be attentive to maintaining the cold chain for DHM.^{51,96,109,110}
 - Bacteria thrive in warm, nutrient-rich environments, and improper maintenance of the cold chain can create unacceptable levels of bacteria.¹¹¹
- ► Food safety principles are important to follow when handling and preparing food for all infants.¹⁰⁸

- Ask participants and if possible write responses on a board or large piece of paper for participants to see:
 - When is DHM not in the cold chain?
- Examples include:
 - During expression.

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- Immediately after expression.
- While being processed in the milk bank (e.g., pooling and testing).
- Ask participants to identify how DHM can enter the cold chain as soon as possible.
- Examples include:
 - After expression, immediately transfer milk container to the refrigerator or freezer.
 - While processing donor milk, take care to be efficient and not leave milk out of the refrigerator or freezer for longer than it needs to be.
 - Taking ownership and responsibility to be aware of and limit the time that milk is outside of the refrigerator. Avoid distractions while processing milk.



- Specific procedures and policies for the storage of DHM in the home setting can vary according to the resources and logistics of the local area.
- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.

EXPLAIN

Storage of DHM at home

- The storage requirements of DHM in the home setting can be more stringent than requirements for storage of MOM for her own infant (Table 6).
- Storage guidelines can vary between countries, highlighting the need for evidence-based recommendations.
- Human milk expressed at home and intended for donation to the HMB should be placed in the freezer within < x hours >.

Location	Maximum temperature	Duration	Comments
Refrigerator	<+2-+8°C>	<24 hours>	< Milk intended for donation should be stored in a freezer within < 24 hours >.
Freezer compartment of combined refrigerator unit	< -15°C >	< 2 weeks from date of expression >	< Keep milk towards back of the freezer compartment. Milk is safe for longer periods when frozen, but lipids will begin to break down >.
Freezer compartment of combined refrigerator unit with separate door for the freezer	< -18°C >	< 3–6 months from date of expression >	
Deep freezer	< -20°C >	< 6–12 months from date of expression >	

Table 6. Requirements for donor human milk storage in the home setting.

- Insert your hospital and HMB policies and procedures for storing DHM at home as established by local guidelines.
- Your policies and procedures should at minimum describe:
 - Temperature and time regulation and verification.
 - Hand hygiene.



Transportation of DHM at home to the HMB

- A temperature-controlled supply chain or cold chain system is required for transporting milk expressed at home to the HMB.
- Maintaining DHM in the cold chain ensures that the milk stays frozen with minimal bacterial content and maximal nutritional content.
- Specific procedures for transporting DHM to the HMB will vary by local concerns, resources, and hospital and HMB policies and guidelines.
 - In Brazil, DHM is transported to the HMB by volunteer firefighters and paramedics using designated vehicles with refrigerated storage that ensure the breast milk arrives at the HMB as soon as possible.
 - In the United States, breast milk is often packed with ice and shipped via mail systems.
 - In the United Kingdom, volunteer trained 'Blood Bikers' courier blood, donor milk, hospital notes, pharmaceuticals, and other emergency consignments in support of the National Health Services and local hospitals.

- Insert your hospital and HMB policies and procedures for transporting DHM to the HMB, and for corrective action if the policy is not followed.
- Your policies and procedures should at minimum describe:
 - How the DHM gets to the HMB from the donor's home.
 - How the cold chain is maintained.
 - What types of containers are used to transport milk.
 - How the milk is packed into containers.
 - Which staff member is responsible for logging the DHM into the record/tracking system.

- How your operation verifies that the DHM has not thawed or been tampered with during transport.
- How records of transportation are maintained.
- What the corrective actions are (such as disposal), if cold chain is not compromised.

ΑCTIVITY

- Give participants examples of local challenges with collection and transportation of DHM from a donor's home to the HMB.
- Have participants identify methods to address or mitigate these issues.
- Examples scenarios below:

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- Raw DHM tests positive for unacceptable levels of bacteria.
 - o Properly dispose of contaminated DHM. Counsel donor mother on cleaning breast pump (if applicable), washing hands before expressing, and using only clean containers for milk collection.
- Raw DHM has foreign particles contamination (hair, food crumbs, etc.).
 - o Counsel mother on how to keep expressed breast milk safely sealed from foreign particles.
- Raw DHM arrives at HMB completely thawed.
 - o Staff should discard the DHM and identify the reason for thawing:
 - △ Is transportation delayed?
 - △ Is DHM improperly shipped or packaged?
- A donor mother has expressed breast milk but has no way to get it to the HMB.
 - o Counsel mother on available local resources to help transport her breast milk to the HMB.



- Specific procedures and policies for the storage of DHM in the HMB and NICU settings can vary according to the resources and disease risk in the region.
- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.

EXPLAIN

Storage of DHM in the HMB and NICU settings

- Maximum storage temperature and duration within the HMB and NICU settings can differ (Tables 7 and 8).
- > DHM in the HMB should be stored and labeled separately:
 - Unpasteurized DHM.
 - Pasteurized DHM awaiting microbial screening results.
 - Pasteurized DHM that is cleared for release to NICU/infants.

Location	Maximum temperature	Duration
Room temperature	< 18-22°C >	< For processing raw milk: x hours from time removed from refrigerator >.
Refrigerator	< +2 - +8°C >	< Prior to freezing if expressed at HMB: x hours from time of expression >. < For thawing: x hours from date removed from freezer >.
Hospital-grade freezer	<-20°C>	< Unpasteurized DHM: x months after date of expression >. < Pasteurized milk: x months after date of pasteurization >.

Table 7. Maximum donor human milk storage guidelines in the human milk bank setting.

Table 8. Maximum donor human milk storage guidelines in the neonatal intensive care unit setting.

Location	Maximum temperature	Duration
Room temperature	< 18-22°C >	< Before immediate use of pasteurized milk: x hours from time removed from refrigerator >.
Refrigerator	< +2 - +8°C >	< For thawing prior to use: x hours from time removed from freezer >.
Hospital-grade freezer	<-20°C>	< Pasteurized milk: x months after date of pasteurization >.

- Insert your hospital and HMB policies and procedures for storing DHM at the HMB and NICU settings.
- Your policies and procedures should at minimum describe:
 - Temperature and time regulation and verification.
 - Hand hygiene.
 - Procedures for verifying labels.

5.3 HAND HYGIENE AS A SAFETY MECHANISM

- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.
- The information in this section does not need to be included if it is part of another training.

Importance of hand hygiene

- Hand hygiene is the most effective technique for preventing the spread of person-toperson infections.
- Health care workers often contaminate their hands unknowingly, which puts their patients at an increased risk for infection.
- Proper handwashing is especially critical for health care workers who are caring for vulnerable infants in the NICU.
 - Premature and LBW infants in the NICU have an immature immune system and are more likely to get severe infections than healthy infants.
- HMB staff who handle and process DHM need to adhere to strict hand hygiene protocols to ensure that DHM does not become contaminated and a route for infection.

When to wash your hands¹¹²⁻¹¹⁴

- At the start of your shift.
- When hands are visibly soiled.
- Before and after eating, or feeding someone else.
- After blowing your nose, sneezing, or touching your face or hair.
- After using the toilet.
- Before starting a medical procedure (i.e., inserting a nasogastric tube; handling DHM).
- Before putting on gloves.

Proper handwashing steps¹¹²⁻¹¹⁴

- 1. Prepare a clean towel to dry your hands, if available.
- 2. Wet your hands together under clean and warm running water.
- 3. Apply antimicrobial soap to your hands.
- 4. Rub your hands vigorously for at least 15 seconds.
 - Wash and rub the entire hand up to wrists, rubbing under fingernails.

- Include a common song that lasts about 15 seconds.
- Popular English songs are "The A-B-C song" and "Happy Birthday."
- 5. Rinse hands with fingers pointing down.
- 6. Dry hands with a clean towel. If there is no towel, allow hands to air dry.
 - Towels should be disposable paper or single-use, if fabric. Fabric towels should be rewashed in hot water and air dried.



- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.
- Remove this section if hand sanitizer is not typically used or available in your facility.



Hand sanitizer¹¹⁴

- Hand sanitizer inactivates many microbes but does not work for all types of infectious agents and does not remove dirt or grease from hands.
- Hand sanitizer can be appropriate:
 - When hands are not visibly soiled.
 - Before putting on gloves.
 - Before starting a medical procedure (i.e., inserting a nasogastric tube; handling raw and pasteurized DHM).

Proper steps for using hand sanitizer¹¹⁴

- 1. Apply recommended amount to one palm.
- 2. Rub hands together, applying the product to all surfaces of hands and fingers.
- 3. Rub hands together vigorously until dry.

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MODULE 6: PASTEURIZATION OF DONOR HUMAN MILK

Objective:

- At the end of this module, participants should understand:
 - The steps necessary to process DHM in preparation for pasteurization.
 - The steps necessary for pasteurization of DHM.
 - Safety considerations during pasteurization.

Key Take-Away:

- Handling and processing DHM includes more than pasteurization and is critical to providing safe quality DHM.
- > Pasteurization reduces the bacterial count and viral load in DHM.
- Pasteurization is an important step in ensuring milk safety as it eliminates potentially pathogenic bacteria.

Lesson Topics:

- Processing donor human milk in preparation for pasteurization:
 - Thaw DHM.
 - Pre-pasteurization microbiological testing (HMB guideline dependent).
 - Analysis of nutritional content.
 - Pooling of DHM.
 - Homogenization.
 - Aliquoting DHM and sealing containers.
- Pasteurization process.
- > Post-pasteurization screening (HMB guideline dependent).

Estimated Time: 3 hours

SEE TOOL #2d

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—<u>Establishing Quality Assurance: An Audit Template, Appendix 1. Verification protocol for a Holder</u> <u>pasteurization device</u>.

6.1 PROCESSING DONOR HUMAN MILK IN PREPARATION FOR PASTEURIZATION

 Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.

- Frozen, raw DHM must be properly prepared before pasteurization.
- Throughout the following steps, ensure that DHM is handled hygienically.
- All personnel handling DHM at minimum should:
 - Use strict hand hygiene.
 - Wear gloves.
 - Wear hair net.
 - Wear a mask that covers the mouth and nose.
 - Wear clean protective clothing < may include a lab coat or apron >.
- > DHM containers should remain sealed unless they are being processed.





Photo: PATH/Will Boase



- Specific procedures and policies for thawing milk in preparation for pasteurization can vary according to resources of the region.
- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines, including SOPs related to labelling DHM.

Thawing DHM

- To reduce the risk of bacterial growth, specific evidence procedures should be in place for thawing milk (Table 9).
- A refrigerator and thermometer are needed for safe thawing.

Procedures

- Thaw milk with refrigeration when possible.
- Carefully inspect containers before placing in refrigerator or freezer.
- Wipe off any visible debris from outside of the container.
- > Properly discard any containers that are damaged or leaking.

Table 9. Requirements for thawing donor human milk in a human milk bank and neonatal intensive care unit setting.

Product	Maximum temperature	Duration	Comments
Room temperature	< 18-22°C >	< Check DHM temperature at least hourly until target temperature is reached >.	< This is a more labor- intensive method for rapid thawing of DHM with the goal to immediately pasteurize >.
Hospital-grade refrigerator	< 4°C >	< 24 hours >	This is the preferred method for safely thawing DHM. Place in refrigerator overnight and pasteurize within < 24 hours >.



- Specific procedures and policies for pooling DHM can vary according to hospital and HMB policies and procedures.
- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.



Pooling DHM

- Pooling procedures differ around the world and are determined by hospital and HMB policies and procedures.
- < Define local criteria for pooling DHM. Remove section if not applicable >.

Procedure

Thawed milk from a <single (or potentially multiple) donor(s)> is pooled together into a large container with thawed milk from other mothers.

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Photo: PATH/Jared Wilmoth



- Specific procedures and policies for pre-pasteurization microbial screening DHM can vary according to resources of the region.
- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.

Pre-pasteurization microbiological screening

- Control Con
 - Definition should at minimum include:
 - o Microorganisms tested.
 - o Method used for testing (culture media used and length of time used to test).
- Pre-pasteurization microbiological screening is needed for testing total viable microbial content, or/and Enterobacteriaceae, or/and Staphylococcus aureus, or/and other pathogens and contaminants.

Procedure

- From thawed DHM, remove a < x mL > sample and send to a laboratory for testing.
 - To ensure the sample is representative of all the milk being tested, milk should be constantly stirred or well stirred immediately prior to taking the sample.
- Discard milk if samples contain:
 - More than < insert local cut-off point in CFU/mL > for total viable microorganisms.

More than < insert local cut-off point in CFU/mL > for Enterobacteriaceae.

More than < insert local cut-off point in CFU/mL > for Staphylococcus aureus.

▶ If screening DHM reveals bacterial contamination, counsel mother on handwashing, expression, hygiene, and storage practices, as well as continued breastfeeding.


- Specific procedures and policies for analyzing the nutritional content of DHM can vary according to resources of the region.
- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.

Analysis of nutritional content

- The nutritional content of breast milk can vary significantly between mothers and expression sessions throughout the day.
- When possible, gestational age (or prematurity) of DHM should be matched to the recipient's gestational age to most closely meet their nutritional needs.
- DHM may be tested for nutritional content using a nutrient content analyzer, depending on the local hospital and HMB's resources, policies, and procedures.
- < Define local criteria for analyzing the nutritional content of DHM. Remove section if not applicable >.

Procedure

- From pre-pasteurized screening DHM, remove a < x mL > sample and send to laboratory for nutritional analysis.
 - To ensure the sample is representative of all the DHM being tested, DHM should be constantly stirred or well stirred immediately prior to taking the sample.
- Discard the sample after analysis is completed.



- Specific procedures and policies for homogenizing DHM can vary according to resources of the region.
- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.



Homogenization

- Homogenization ensures equal distribution of fat in DHM.
- > < Define local criteria for homogenizing DHM. Remove section if not applicable >.

Procedure:

• Before pasteurization, DHM is processed using a homogenizer.



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- Specific procedures and policies for aliquoting DHM and sealing containers can vary according to resources of the region.
- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.

Aliquoting DHM and sealing containers

- Before pasteurization, DHM is transferred into < x mL > containers to help ensure even temperature distribution during pasteurization.
- These small containers also help ensure that DHM used in the NICU does not go to waste.
 - Premature and LBW infants only need small quantities of milk; the milk needs to be used or discarded once a container is opened.
- Improperly sealed DHM containers pose a contamination hazard.
- Once DHM is pasteurized, container lids should not be opened. If the lids are opened for any reason, the entire contents of the container should be discarded.

Procedure

- Before pasteurization, DHM is separated into smaller containers.
- > DHM needs to be safely sealed with airtight lids according to the HMB instructions.
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6.2 PASTEURIZATION PROCESS

EXPLAIN

- To provide safe DHM while also maintaining the maximum amount of bioactive substances, DHM needs to be heated to the appropriate temperatures for the appropriate amount of time.
- Pasteurization is the process of heating a liquid to inactivate infectious agents, such as bacteria and viruses.
- Under- or over-heating poses risks to the quality of the DHM.
- The process of pasteurization causes the degradation of some bioactive components; however, the concentration of bioactive components remains superior to formula.

- Specific procedures and policies for pasteurization of DHM can vary according to resources and disease risk in the region.
- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.

Holder pasteurization93

- Most common and well-established form of milk pasteurization.
- DHM is typically pasteurized using a shaking water bath or specialized human milk pasteurization equipment that has inbuilt cooling and agitates bottles throughout temperature cycles.
- ▶ DHM is heated to 62.5°C for 30 minutes.
- ▶ Following the heat phase, to optimize the end quality of the milk, DHM needs to be immediately and rapidly cooled to 4°C using an ice bath, chilled water, or processing equipment designed to cool milk.
- With a water bath pasteurizer, special precautions must be taken to ensure the lid of the bottle is not submerged.
 - Advantages:
 - o Is a well-established method.
 - o Included in all major HMB guidelines.
 - Disadvantages:
 - o Requires rigorous quality control to ensure proper temperature curves are met.93

- Insert your hospital and HMB policies and procedures for pasteurization, based on the pasteurization method and pasteurizer you use and as established by local guidelines.
- Your policies and procedures should at minimum include:
 - Frequently asked questions or troubleshooting information that is listed in your pasteurizer's user manual.
 - A description of how milk is rapidly cooled to 4°C after Holder pasteurization.
 - A description of how records of pasteurization and contamination are maintained.

- Have participants identify potential hazards that can occur during pasteurization of DHM.
- Review each step independently for hazards.
- Ask participants:
 - 1. What do you do if you notice something going wrong in the thawing process?
 - 2. What do you do if the pasteurizer gets too hot?
 - 3. What do you do if the pasteurizer did not get hot enough?
 - 4. What do you if there is a critical failure of the electrical system?
 - 5. What do you do if DHM comes back positive for contamination?
 - 6. How do you maintain records of contamination?
 - 7. How do you maintain records of pasteurization?
 - 8. How do you verify the safety of the DHM?

6.3 POST-PASTEURIZATION SCREENING

- Modify and expand the general, evidence-based guideline below to meet hospital protocols and local HMB guidelines.
- If pre-pasteurization is prioritized, post-pasteurization testing may not be routinely practice, or may be used as an additional screening method.



Post-pasteurization screening

- Post-pasteurization screening monitors for failed pasteurization, as well as potential contamination introduced during or directly after pasteurization.
- < Insert frequency of post-pasteurization testing at your operation (every batch, x tests per x batches) > of pasteurized DHM undergoes microbial screening.
- To guarantee the safety of DHM for recipients, pasteurized milk is discarded if any microbial content (< 0 CFU/mL >) is found after pasteurization.

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Photo: PATH/Kimberly Manser

MODULE 7: DISTRIBUTION OF DONOR HUMAN MILK

Objective:

- At the end of this module, participants should understand:
 - How DHM is safely distributed from the HMB to the infant.
 - The shelf life of thawed, pasteurized DHM.
 - The DHM prescription/authorization and consent process.
 - How to prioritize recipients if the demand for DHM is greater than the supply.

Key Take-Away:

 Quality, safety, and equity of DHM are maintained through appropriate distribution processes.

Lesson Topics:

- Prioritization of recipients.
- Outpatient recipients of donor human milk.
- Donor human milk distribution process.
- > Donor human milk consent process.
- Review of hospital policy for handling donor human milk.
- Fortification of donor human milk.
- Ethical considerations for human milk banks.

Estimated Time: 1 hour 30 minutes

7.1 PRIORITIZATION OF RECIPIENTS

Prioritization

- In most settings, availability of DHM will be limited; therefore, the local hospital and HMB policies and procedures should reflect the prioritization criteria.
- Donation, processing, and transport of DHM can all act as bottlenecks in the process of transferring DHM to vulnerable infants in the NICU.
- When DHM availability is limited, HMBs and health care facilities should prioritize allocation to high-priority infants; typically, this includes the following, and should be adapted per local supply and need:
 - Preterm newborns.
 - LBW newborns.
 - Infants with a history of NEC.
 - Infants with infection.
 - Infants taking enteral nutrition.
 - Infants without access to their MOM or when MOM is contraindicated (contraindicated medication, sickness, etc.).
- HMBs and health care facilities should always prioritize the use of MOM, when available.
- Health care facilities need to set clear guidelines on the usage of DHM.

• Insert your hospital and HMB policies and procedures for the use of DHM and prioritizing recipients of DHM.

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7.2 OUTPATIENT RECIPIENTS OF DONOR HUMAN MILK

- Infants who experience maternal abandonment or are orphans who will need long-term, safe sources of nutrition.
- Human milk remains the optimal source of infant nutrition.
- Policies, supply, and prioritization of DHM will dictate if it is appropriate for this population.

• Insert your hospital and HMB policies and procedures for providing DHM to the outpatient population.

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7.3 DONOR HUMAN MILK DISTRIBUTION PROCESS

EXPLAIN

- The prescription/authorization process for providing DHM is often beyond the scope of traditional HMBs; however, HMBs often work closely with physicians in determining how to best use the DHM that is in stock.
- DHM should never undermine breastfeeding, and careful consideration should be taken to ensure that all infants receive their own mother's milk prior to being considered for DHM. Use of the Donor Human Milk Decision Tree (Appendix 2), may be a helpful tool to avoid overor misuse of DHM.
- When DHM is transported to the hospital, the cold chain must always be maintained.
- DHM should only be supplied to health care facilities that agree to comply with all HMB described tracking and tracing procedures for milk.

- Specific processes and policies for distributing DHM vary according to resources and local concerns in the region.
- Insert your hospital and HMB policies and procedures for distributing DHM, as established by local guidelines.
- Your policies and procedures should at minimum describe:
 - The DHM prescription process at your operation.
 - Who is responsible for prescribing, ordering, and distributing DHM.
 - o In some settings, it is the neonatologist/physician; in some settings it is the pharmacist, etc.

- When DHM should be ordered.
- How DHM is transported to the hospital.

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EXPLAIN

- Prescription orders for DHM typically include information on:
 - The patient's diagnosis and their specific reason for needing DHM.
 - The amount of DHM required.
 - The estimated duration for DHM usage.

- Insert a copy of your operation's DHM prescription or order form.
- ▶ If common issues with orders have been identified, please describe them.

ΑCTIVITY

- ▶ Together with the participants, walk through the Donor Human Milk Decision Tree (Appendix 2).
- Using a case study from the NICU, walk through the *Donor Human Milk Decision Tree* to determine optimal steps for safe provision of DHM, if needed.

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7.4 DONOR HUMAN MILK CONSENT PROCESS

EXPLAIN

- Consent for any medical intervention should be based on adequate information.ⁱ
- Medical providers are responsible for educating their patients on the benefits and risks of interventions.
- Evidence suggests that DHM is better for vulnerable infants than formula, although it does not carry the same benefits as MOM and should not undermine breastfeeding.
- Although HMBs take many steps to ensure the safety of DHM, any biologic substance carries some risk, which parents should be informed about.



• Insert a copy of the hospital or HMB DHM recipient consent form.

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Universal Declaration of Bioethics and Human Rights: Article 6 - Consent

i. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

7.5 REVIEW OF HOSPITAL POLICY FOR HANDLING DONOR HUMAN MILK

EXPLAIN

• A clear hospital policy that outlines the proper storage, handling, and disposal of DHM is essential to maintaining DHM safety.

- ▶ Insert your hospital and HMB policies and procedures on handling DHM.
- The policies and procedures should at minimum describe:
 - The procedure for receiving DHM.
 - How DHM is labeled.
 - How DHM is stored.

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- How DHM is distributed to specific infants with prescriptions.
- Criteria for disposing DHM.
- How unused DHM is safely disposed.

7.6 FORTIFICATION OF DONOR HUMAN MILK

EXPLAIN

- The need for DHM fortification is a clinical decision made by the attending physicians and clinical staff, based on hospital policy.
- Premature and LBW babies may need fortification of their feeds to increase their growth velocity.
- DHM is often fortified to increase the macro- and micronutrient content based on the individual needs of an infant.

• Insert your hospital and HMB policies and procedures on DHM fortification.

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7.7 ETHICAL CONSIDERATIONS FOR HUMAN MILK BANKS

- Women who are donating breast milk need to support their own infant's needs prior to donating.
- HMBs should always support breastfeeding and ensure the availability of DHM does not undermine access to MOM.
 - DHM should be used as a bridge, only when MOM is not available, to ensure an exclusive human milk diet.
- > Parents should not be pressured or coerced into donating or receiving DHM.
- ▶ All infants should have equitable access to DHM—regardless of gender, race, social class, income, religion, or their ability to pay.

- Review the following case studies that present potential ethical dilemmas for which there may not be a single correct answer.
- There is value in discussing and thinking about ethical dilemmas, as this process can help identify one's own beliefs, biases, and values.

Scenario 1

- Two vulnerable babies need DHM, yet there is not enough DHM in your HMB for both infants. One mother can pay for the DHM and another mother cannot.
 - Which infant will you give DHM to? Why?

Scenario 2

- A mother comes into your HMB with breast milk for donation. She mentions that this is the last time she'll be donating, as a company is offering her money to donate her excess breast milk to them instead.
 - How do you respond to this mother?
 - What concerns would you have about her receiving payment for her breast milk?
 - What further steps can you take to ensure women in your community are supported to breastfeed their own babies?

Scenario 3

- A vulnerable baby is soon to be discharged from the NICU. Her mother has expressed more than enough breast milk for the baby's needs, and there is a large amount of her frozen milk in your NICU freezer.
 - What rights does the mother have to her own milk?
 - Should mothers with an excess of breast milk be compelled to donate it for vulnerable infants?
 - What are the benefits for compelling a mother to donate?
 - What are the risks if she is compelled by HMB staff to donate all of her milk?

Scenario 4

- A vulnerable baby is identified as needing DHM by the NICU staff. The parents refuse to consent for it, as they have concerns about its safety.
 - How would you respond to these parents?
 - If you've provided parents with evidence of DHM safety and they still refuse, what would you do?
 - What would you do if the parents in this scenario became unreachable or deceased since stating these concerns?

- Potential ethical concerns and considerations vary due to cultural differences and local settings.
- Insert additional scenarios focusing on local ethical concerns.
- Include potential additional ethical concerns in the local setting, including any commercialization, selling, or informal sharing of human milk.

MODULE 8: SAFETY AND QUALITY ASSURANCE

Objective:

- At the end of this module, participants should understand:
 - Quality assurance strategies for ensuring DHM safety throughout screening, collection, processing, and distribution.

Key Take-Away:

- Safety is the most important service a hospital or HMB can provide patients.
- Quality assurance strategies and supportive supervision enable staff members to raise safety and quality concerns.

Lesson Topics:

- Systems for safety and quality.
- Your operational quality plan.
- Standard operating procedures.
- Good manufacturing practices and hazard analysis and critical control points.
- Auditing.
- Record keeping.
- Local guidelines.
- Supportive supervision.

Estimated Time: 2 hours

SEE TOOLS #2a and #2b

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—<u>Establishing Quality Assurance: A Workshop for Developing a Hazard Analysis Critical Control</u> <u>Points Plan (Trainee Workbook)</u> and (<u>Trainer Guide</u>).

SEE TOOL #2d

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

SEE TOOL #5

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Program—<u>A Guide for Track and Trace Documentation</u>.

8.1 SYSTEMS FOR SAFETY AND QUALITY



Systems for safety and quality

- Each HMB needs to decide how to best utilize available resources to meet the needs of their community and help guarantee the safety and quality of their DHM.
- Systems for ensuring safety and quality of DHM can vary due to the diversity of local needs, resources, disease risks, and cultures.
- There are currently no global SOPs for safely collecting, processing, and distributing DHM. Local guidelines are not always enforced at the local level, and HMBs need to self-regulate as an independent body or network.
- Local HMB guidelines should adhere to the highest standard of practice possible for the local context.
- Local HMB guidelines should align with newborn care and infant and young child nutrition guidelines.
- ► Adopting quality assurance and quality control measures into milk banking is a strategy to manage safety and quality requirements of new and existing HMBs.¹¹⁵
- ▶ The Seven Principles of Quality Management¹¹⁶ include:
 - Customer focus
 - Leadership
 - Engagement of people
 - Process approach
 - Improvement
 - Evidence-based decision-making
 - Relationship management

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• Discuss how the Seven Principles of Quality Management apply to the HMB process.

8.2 YOUR OPERATIONAL QUALITY PLAN



Flow diagram

- Every HMB performs numerous and complex procedures that help ensure the safety and quality of the DHM they collect, process, and distribute.
- A flow diagram can be used to organize the complex system of practices in human milk banking (Figure 7).
- The process steps organized in a flow diagram of HMB practices begin with recruitment of donors, include the handling and processing of DHM within the HMB, and finishing with the allocation of the DHM to the recipient.

- Flow diagrams of HMB facilities can vary due to resources, disease rates, and cultural considerations of the region.
- Insert your hospital or HMB flow diagram for DHM.

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Figure 7. Flow diagram of process practices in human milk banking.





- Break participants into three or four equal groups and distribute the different steps in your flow diagram evenly. Each group receives a step (or a few steps) and identifies potential hazards that could make DHM unsafe for infant consumption.
- ▶ This list is not exhaustive but should include steps where hazards (bacterial, chemical, physical) could occur, where record keeping could fail, etc.
 - Relevant hazards could include:
 - o Bacterial contamination.
 - o DHM that does not meet criteria set by HMB. (See **Module 5: Donation and collection** for complete discussion on aspects of donation and donor counseling.)
 - o Improperly pasteurized DHM. (See **Module 7: Pasteurization** for a complete discussion of pasteurization.)
 - o Unpasteurized and pasteurized DHM being mixed up due to improper labeling.
- Ask participants to list ideas of how to prevent, mitigate, or address these hazards. Strategies should include preventative steps, such as maintaining the cold chain, as well as corrective action such as raising concerns with the supervisor and disposing of contaminated milk.
- If your operation has had issues with a particular hazard, this is a good opportunity to discuss both the issue and the steps your operation is taking to mitigate that risk.
- The example below describes the hazard present in one HMB and how that hazard was mitigated.
 - One HMB had an issue with high pre-pasteurization bacterial contamination. Eventually, this was traced to the breast pumps being improperly cleaned between donor mothers.
 - o Hazard bacterial contamination.
 - o Mitigation proper pump cleaning.

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8.3 STANDARD OPERATING PROCEDURES

Standard operating procedures

- SOPs are the detailed written instructions that specify how a process is to be performed.
- ▶ SOPs describe the "standard" approved procedures that are routinely carried out.¹¹⁷
- SOP documentation is an important part of a quality and safety assurance system.

It provides the chance to do the correct action the first (and every) time.

- ► SOPs are to be developed based on local guidance of good manufacturing practices and hazard analysis and critical control point (HACCP) principles.¹¹⁸
- Usually the initial draft of an SOP is written by the person performing the procedure or by someone who knows the procedure well. It must be written including the details and the time needed for the tasks.
- The basic template of an SOP should be:
 - Purpose: Why is this procedure written; why is it being performed.
 - Scope: When this procedure needs to be performed, and where this procedure applies.
 - Responsibility: Who performs the procedure, and who is responsible to see it is performed correctly.
 - Materials and equipment: What is needed to perform the procedure.
 - Procedure: How the procedure should be performed.
 - Reporting: Where the result should be recorded, and what to do if there are deviations during procedure.
 - Reference document.
 - Forms/annexes.
- SOPs for all steps of HMB operations should be developed and approved by appropriate supervisory staff. In addition to HMB operational protocols, the following procedures should be included in the SOP packages for an HMB:
 - Personal hygiene.
 - Equipment/tools cleaning and sterilization.
 - Equipment operation, maintenance, and calibration.
 - Facility cleaning and maintenance, including water supply/sewage system.
 - Staff training, refresher training, and updates.

- ▶ Insert your list of HMB SOPs.
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8.4 GOOD MANUFACTURING PRACTICES AND HAZARD ANALYSIS AND CRITICAL CONTROL POINTS

- One effective approach to help develop a quality control system is implementation of a HACCP process (Figure 8).
- ► HACCP is a rigorous food safety management system originally designed to address food safety—from the production of products through consumption.
- HACCP can be used to assess and mitigate potential risks in individual settings by mapping out the process steps and identifying points of potential hazards, contamination, or mishandling of DHM.
- HACCP is important to consider during the very early stages of HMB development. With this approach, HMB teams conduct a unique HACCP assessment of their operation, which can be used to guide operations and ensure the operation is adequately equipped to provide optimal quality and safety of DHM.
- A critical control point is any step, point, or procedure in the food production process at which a food safety hazard can be prevented, eliminated, or reduced to an acceptable level.
 - Identifying critical control points helps identify steps in the HMB process where teams should pay particular attention to risks, as failure to follow the SOPs could result in unsafe milk and harm to infants.
 - Critical control points often have clearly defined, quantifiable critical limits set by temperature and time, and they differ from other steps in the HMB process because they have a subsequent step in the process that can reduce the hazard to an acceptable level.
- HACCP plans also help identify good manufacturing practices or HMB processes that need to be monitored but do not have a quantifiable critical limit or risk level as high as a hazard.
 - Good manufacturing practices are the minimum sanitary and processing requirements necessary to ensure the production of safe, high-quality foods.
 - Good manufacturing practices include procedures such as staff training and equipment disinfection.

• If applicable, insert your operational HACCP plan, as established by local guidelines.





8.5 AUDITING



- Evaluation of SOPs in HMBs is essential to ensuring the safety and quality of DHM. Both internal and external auditing should take place regardless of local or national enforcement.
- Auditing is a means of continuous assessment and improvement for HMBs by evaluating operational performance and triggering and prioritizing an improvement process.
- The auditing should cover the entire milk banking process from donor recruitment, donor screening, milk expression, handling, processing, and prioritization in the distribution to the recipients, and staff training—as well as staffing needs, infrastructure, equipment, record keeping, and documentation recommendations.

- Auditing procedures can vary based on local guidelines and resources.
- Insert your hospital and HMB policies and procedures for internal and external auditing, as established by local guidelines.

8.6 RECORD KEEPING

Record keeping

- Accurate records are essential to ensuring DHM safety and quality.
- Records can help HMB and NICU staff identify early-on potential trends that signal a system-wide problem.
 - For example, some HMBs track monthly positive DHM post-pasteurization screening results. This can help staff and leadership identify if there is a consistent problem with contamination of DHM.
- Another important reason to keep accurate and complete records is to ensure that if DHM is found to be contaminated, recipient infants could be rapidly identified, screened, and treated appropriately.

- Insert example copies of your hospital and HMB track and trace documentation/records including:
 - Forms to be filled out by HMB staff, such as verification records of process steps.
 - The labels placed on DHM bottles.
 - Logs and registers tracking donors, DHM donations, pasteurization, microbial screening, and distribution.
 - Orders/requests/prescriptions for DHM.
 - Consent forms to be filled out by the donor and recipient parents.
- The forms will be reviewed in detail in further sections and according to the participant's job functions.

ΑCTIVITY

- Review the flow diagram with participants.
- Have participants identify which steps require record keeping.
- Allow participants time to think of steps and coach them through any important missed record-keeping moments.
- At the end of the activity, show participants the flow diagram again with the record-keeping moments highlighted.

8.7 LOCAL GUIDELINES

EXPLAIN

Local systems for safety and quality

- Systems for safety and quality can vary based on the local resources, disease risk, and cultural considerations.
- Insert policies and procedures used at your operation that have not previously been described, which guarantee safety and quality in DHM collection, processing, and distribution.
- Your policies and procedures should at minimum describe:
 - Who is responsible for quality management?
 - How do staff members bring safety concerns, observations, or suggestions to management?
 - Additional guidelines used at your operation to guarantee safety and quality of DHM.
- Review Quality control resources in Appendix 1.
- If your HMB does not have a quality and safety training, operational leadership should consider spending some time identifying or integrating quality management and supportive supervision strategies into the operational overall strategic plan.

EXPLAIN

Beyond the HMB-record-keeping impacts downstream

- ▶ Insert information about how your HMB will interface with your local health authority.
- If your HMB makes records available to local health authorities, these records should at minimum include:
 - Periodic reports of donations.
 - Quality control test results.

- Total volume of milk collected.
- Total number of DHM recipients.

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8.8 SUPPORTIVE SUPERVISION

- Supportive supervision is an approach utilized by operational leadership to encourage staff empowerment for independently identifying and solving problems.
- Traditional management strategies involve a top-down approach, but a more collaborative approach can foster ownership and enable better and quicker problem solving.

• Review Supportive supervision resources in Appendix 1; add any instructions here that are relevant to your setting.

ΑCTIVITY

- Have participants act out two different management scenes:
 - Scene 1
 - 1. Have two volunteer participants come to the front of the room.
 - 2. One volunteer is the Difficult Manager who tells the other volunteer, the Employee, what to do and points blame for quality issues that arise.
 - 3. The Employee can choose how to respond, but the Difficult Manager will stick to the script of blaming and lecturing the Employee.
 - 4. Once the scene ends, the remaining participants will provide feedback on how well the quality issue was resolved by the Difficult Manager.
 - Scene 2
 - 1. Have two volunteer participants come to the front of the room.
 - 2. One volunteer is the Supportive Supervisor who solicits feedback and trouble shoots with the other volunteer, the Employee, when a quality issue arises.
 - 3. The Employee can choose how to respond, but the Supportive Supervisor will stick to the script of soliciting feedback and troubleshooting with the Employee.
 - 4. Once the scene ends, the remaining participants will provide feedback on how well the quality issue was resolved by the Supportive Supervisor.
 - 5. Ask the group:
 - △ "How did the interaction go this time?"
 - △ "What was different from the first scene?"
 - △ "How realistic would this type of interaction be?"
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MODULE 9: ADVOCACY

Objective:

- At the end of this module, participants should understand:
 - The role of advocacy in the promotion of an exclusive human milk diet and the role of an HMB.
 - How to develop advocacy programs for health care providers, community, and policymakers.

Key Take-Away:

- Advocacy is an important facet of the health care system.
- Learning how to be an advocate is the first step in promoting the best health for the vulnerable infants that HMBs support.
- Advocacy can be used to support and empower breastfeeding women.

Lesson Topics:

• Advocacy in human milk banking.

Estimated Time: 1 hour

SEE TOOL #6

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

9.1 ADVOCACY IN HUMAN MILK BANKING

- Advocacy strategies can help increase public knowledge and promote positive perception of human milk and of HMBs.
- Increasing public support for HMBs can improve breastfeeding rates, as well as create more demand for and supply of DHM.
- Advocates support, promote, and push for change. To promote the culture of breastfeeding, there needs to be a change in behavior of health care providers, community, and policymakers.
- Health care providers can help raise awareness about the benefits of human milk by involving community members who will be key in supporting or noticing the change in behavior.
- Educate policymakers who can potentially support policies that promote breastfeeding and the use of DHM.
- Create support programs that empower women to breastfeed and learn about the value of their breast milk, particularly for vulnerable infants do not have access to MOM.

- Insert advocacy strategies for your operation, including information on community and outreach events to recruit donors and inform the public.
- Review Advocacy training resources in Appendix 1.

ΑCTIVITY

- Parents, community members, and new staff may not have heard of human milk banking before. This activity will help your staff develop an advocacy plan.
 - Have staff break into groups of 3–5 people and brainstorm about who is a potential advocate; have them make a list and discuss it as a group.
 - Discuss knowledge and perceptions of these potential advocates, regarding the importance of breastfeeding and how HMBs can support it.
 - Ask participants to list ideas of communications channels (radio, TV, newspapers, social media) that could be used to convey information to the community.

- Insert common questions about human milk banking and DHM that are relevant for your local area.
- Goal of this training is for staff to identify factual, respectful ways to address potential parent/community member concerns and identify avenues for advocacy.

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APPENDIX 1. ADDITIONAL RESOURCES

Breastfeeding statistics

- ▶ USAID. Demographic and Heath Surveys; <u>https://dhsprogram.com/</u>.
- ▶ UNICIEF. Multiple Indicator Cluster Survey; <u>http://mics.unicef.org/</u>.

Breastfeeding support resources

- UNICEF, Hand Expression Video <u>https://www.unicef.org.uk/babyfriendly/baby-friendly-resources/video/hand-expression/.</u>
- Stanford Medicine, Hand Expression of Breastmilk (video) <u>https://med.stanford.edu/newborns/professional-education/breastfeeding/hand-expressing-milk.html</u>.
- American Academy of Pediatrics. Essential Care for Small Babies <u>https://shop.aap.org/essential-care-for-small-babies-ecsb-provider-guide/</u>.
- Global Health Media's Breastfeeding series, Helping a Breastfeeding Mother <u>https://globalhealthmedia.org/portfolio-items/helping-a-breastfeeding-mother/?portfolioID=5623</u>.
- Global Health Media, Expressing the First Milk (video) <u>https://globalhealthmedia.org/</u> portfolio-items/expressing-the-first-milk/?portfolioID=5623.
- US Food and Drug Administration, Using a Breast Pump (video) <u>https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BreastPumps/ucm061944.htm</u>.
- CDC, Cleaning a Breast Pump; <u>https://www.fda.gov/MedicalDevices/</u> <u>ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/</u> <u>BreastPumps/ucm061950.htm</u>.

Supportive supervision resource

 USAID, Making Supervision Supportive and Sustainable: New Approaches to Old Problems; <u>http://pdf.usaid.gov/pdf_docs/Pnacs924.pdf</u>.

Quality control resources

- ► ISO-9000; <u>http://asq.org/learn-about-quality/iso-9000/overview/overview.html</u>.
- ► IHI PDSA; <u>http://www.ihi.org/resources/Pages/Tools/PlanDoStudyActWorksheet.aspx</u>.
- WHO http://www.who.int/maternal_child_adolescent/topics/quality-of-care/webinars/en/.
- http://www.who.int/maternal_child_adolescent/topics/quality-of-care/N_Livesley_ppt_ webinar2903.pdf?ua=1.
- WHO, Training for Midlevel Managers; <u>http://www.who.int/immunization/documents/MLM_module4.pdf</u>.

Advocacy training resources

- USAID Advocacy Training Guide: <u>http://pdf.usaid.gov/pdf_docs/pnabz919.pdf</u>.
- CDC Action guides for nurses <u>https://www.cdc.gov/breastfeeding/pdf/actionguides/</u> <u>nurses_in_action.pdf</u>.
- CDC Action guides for doctors <u>https://www.cdc.gov/breastfeeding/pdf/actionguides/</u> <u>doctors_in_action.pdf</u>.

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

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

APPENDIX 2. DONOR HUMAN MILK DECISION TREE



APPENDIX 3. SUPPLEMENTAL MODULE: BEREAVEMENT AND LACTATION SUPPORT

Objective:

- At the end of this module, participants will identify:
 - The role of the healthcare worker during bereavement.
 - How to provide lactation support during bereavement.

Key Take-Aways:

- When working with bereaved mothers, it is a priority to recognize, honor, and respect the mother's grieving prior to discussing lactation.
- > It is always the choice of the mother what to do with her milk.
- Lactation education should be presented in a non-biased and sensitive way.

Lesson Plan:

- What is bereavement?
- What is grief?
- What to expect at onset of bereavement.
- The role of the health care worker during bereavement.
- Helping a mother with her options in lactation during bereavement.
- Supporting mothers in their decision.
- Healthcare workers practicing self-care.

SEE TOOL #7

Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs—<u>A Counseling Guide for Engaging Bereaved Mothers</u>.

WHAT IS BEREAVEMENT?

EXPLAIN

- Bereavement is the state and experience of loss after a loved one has died.
- The loss of a baby can occur at any stage of pregnancy or any time after birth.

There are different types of perinatal loss:

- Miscarriage (early or late).
- Stillbirth.
- Neonatal death.
- Infant death.

Figure 1. Perinatal loss during pregnancy.



Figure 2. Loss after birth.


STRENGTHENING HUMAN MILK BANKING

WHAT IS GRIEF?

- Grief is a natural and normal response to loss and a means of healing after the loss of a loved one.¹
- ▶ Everyone experiences grief differently.^{2,3}
- > Parents may need different things to help them begin the grieving process, such as:
 - The opportunity to "parent" their baby (e.g., holding the baby, spending time alone with baby, expressing breast milk).
 - The opportunity to create memories with their baby (e.g., taking photos, creating footprints/handprints, collecting locks of hair, spending time alone with baby, storing breast milk).

WHAT TO EXPECT AT THE ONSET OF BEREAVEMENT?

• There are many emotions that bereaved parents might feel after the loss of their baby, and each parent will have a different response.

- Ask the participants "What are some possible reactions that a bereaved mother/parent might have?"
 - Possible reactions may include:
 - o Difficulty accepting loss
 - o Guilt
 - o Shock
 - o Anger
 - o Disbelief
 - o Difficulty making decisions
 - o Desire to know why baby died
 - o Apathy
 - o Disinterest
 - o Depression
 - o Physical symptoms

A GUIDE FOR CURRICULUM TRAINING

THE ROLE OF THE HEALTH CARE WORKER DURING BEREAVEMENT

Five general ways to support bereaved parents

- Empathy and sensitivity
 - Show the family that you care about their baby.
 - Individualize treatment for mothers and families.
 - Sensitively acknowledge their loss.
- Time and space
 - Give parents time and space to process loss.
 - Do not rush decision-making, time spent with baby, or the time you spend with mother and family.
- Practical help
 - Answer questions.
 - Provide resources.
 - Support decision-making.
- Communication
 - Be forthcoming with information.
 - Use the same terminology the mother uses to refer to her loss (e.g., "death", "loss") and her baby (e.g., "baby", "infant", "fetus", or name of the baby).
- Continuing support
 - The grieving process continues after parents leave your care.
 - Offer resources.
 - Help create follow-up appointments when appropriate.

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HELPING A MOTHER WITH HER OPTIONS IN LACTATION DURING BEREAVEMENT

- Ask the participants "Why is it important to provide individualized care for bereaved mothers?"
- Encourage trainees to put themselves in the place of a bereaved mother and understand their feelings.
- Remind trainees: "The goal is to provide mothers with support, and information so they can make their own decisions."



Lactation support during bereavement

- Regardless of the birth outcome, milk will be produced if the pregnancy has reached 16 weeks (or earlier in some cases).
- Counsel mothers differently, depending on the type of pregnancy loss.
 - Miscarriage or stillbirth.
 - o Mothers might not have much or any knowledge about lactation.
 - o Inform mothers about what to expect during milk production.
 - Neonatal death or infant death.
 - o Mothers may have milk already stored in the freezer in the neonatal intensive care unit.
 - △ Give mothers the choice to: 1) take their milk home with them, 2) have hospital staff dispose of it, or 3) get screened to donate the milk.
- All mothers should be given the option to do nothing about their milk supply, to suppress their milk supply, or to express their milk.
 - Mothers who want to do nothing.
 - o Explain engorgement and techniques to manage engorgement, including:
 - \vartriangle Hot showers to release small amounts of milk.
 - \triangle Supportive bras.
 - △ Cold compresses.
 - \triangle Crushed cabbage leaves as breast pads.
 - △ Over-the-counter, anti-inflammatory medication.
 - Mothers who want to suppress their milk.

A GUIDE FOR CURRICULUM TRAINING

- o Explain that gradually reducing (both the frequency and length of time) hand expression or expression with a pump will signal body to make less and less milk over time.
- o Mothers who want to express their milk.
- o Explain that they can decide how much and how often to express their milk.
- o Mothers can then choose what to do with their milk.
- Some mothers may wish to donate their milk.
 - Let mothers know that they can donate their milk to a human milk bank; provide information on the applicable screening process and how to donate.

SUPPORTING MOTHERS IN THEIR DECISION

- Once a mother has decided how she wants to address lactation, she will need to have continued support in her decision.
 - Staff should provide mothers with appropriate resources for additional bereavement counseling and lactation support.

HEALTH CARE WORKERS PRACTICING SELF-CARE

- Remind health care workers that when working with bereaved mothers, it is completely normal to feel overwhelmed and occasionally feel stressed.
- It is important for health care workers to take time for themselves to process their emotions.

- Ask health care workers to describe some ways they can practice self-care.
- Refer to the table "Ways for health care workers to practice self-care" in A Counseling Guide for Engaging Bereaved Mothers for suggestions to share.
- Answers may include:
 - Get adequate rest and sleep.
 - Go for a walk or spend time in nature.
 - Read a book.

STRENGTHENING HUMAN MILK BANKING

- Practice relaxation techniques.
- Seek support from co-workers or supervisors.
- Check in with yourself regularly to identify sources of stress early.
- Remember that you aren't expected to have all the answers.
- Seek the help of a counselor if serious mental challenges arise.



Photo: PATH/Andrew Berends

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



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

Scaling up breastfeeding to a near-universal level could prevent an estimated 823,000 deaths in children under the age of five worldwide every year. It's especially lifesaving in resource-limited settings, where a non-breastfed child's risk of death is six times that of a breastfed child. Integrating human milk banks into newborn and nutrition programs ensures that all infants have access to human milk, including vulnerable, preterm, and low-birthweight infants who lack sufficient mother's own milk. This toolkit of templates and resources serves as a systems strengthening guide for integrating human milk banking, making available safe and quality donor human milk for vulnerable infants, with a goal to ensure optimal lactation support and breastfeeding practices.

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