TRAINEE WORKBOOK

A workshop for developing a

Hazard Analysis Critical Control Points plan

for your human milk bank

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ABOUT THIS WORKBOOK

Hazard analysis critical control points (HACCP) planning is a critical step in ensuring the safety and quality of any food product, including donated and processed human milk. HACCP planning is useful and is possible for any human milk bank (HMB) program, regardless of size, resources, or location.

This workbook was developed to help staff and stakeholders in HMBs become trained in HACCP. As participants in the workshop for developing a HACCP plan for your HMB, this workbook was designed to be used with the trainer's manual and the presentation used for instructing the workshop.

This workbook WILL:

- Guide HACCP workshops at new and existing HMBs.
- Help trainers and participants work together to create HACCP plans that are specific to their sites and that address local needs.

This workbook will NOT:

- Provide global guidance in employing a HACCP plan. Because local needs and resources vary, each HACCP plan developed with the help of this guide will be different.

WHAT IS HACCP?

HACCP is an internationally recognized system used in the food industry to identify and reduce hazards during food processing. The objective of HACCP is to identify and prevent, eliminate, or reduce to acceptable levels any biological, chemical, or physical hazard that would be likely to occur in a food production or distribution environment.[1,2]

Through HACCP, food safety is addressed at every phase of the process including procurement, handling, distribution, processing, and consumption.

OBJECTIVES OF THIS WORKSHOP

By the end of each HACCP workshop, you will be able to:

- Understand the importance of using HACCP in human milk banking.
- Understand and identify each of the 12 steps used in creating a HACCP plan.
- Identify appropriate reference manuals for applying HACCP and develop a site-specific HACCP plan and quality control system to ensure the safety of donor human milk.

HOW TO USE THIS WORKBOOK:

This trainee workbook is designed to help you, the "participant," and staff at your HMB, create a site-specific HACCP plan with the help of the workshop "facilitator."

This trainee workbook is organized into four different sections:

- **Section A** introduces the workshop.
- **Section B** is the main learning section in this workshop and is divided into 12 different steps, each representing the 12 steps of HACCP. Each step contains a learning segment and an activity segment.
- **Section C** closes the workshop.
- **Section D** contains the appendices with examples of each of the 12 steps in a HACCP plan.

About 12 hours is needed to complete this workshop. Estimated time to complete each section or step is listed in the objectives at the beginning of each section and step.

To facilitate instruction and learning, this workbook is organized around learning modes: **Understand, Example,** and **Action**. Text inside these segments is contained in the trainer's guide. A description of each of these learning modes follows.

UNDERSTAND

Understand learning modes contain the bulk of the informational content in this workbook and will help you understand the basic steps and principles of HACCP.

EXAMPLE

Example learning modes present illustrations of different steps of the process by highlighting forms and procedures used in other HMBs. As a reminder, these examples are a guide only. They are provided to help you develop your own site-specific plans.

ACTION

Action learning modes contain questions that you should answer in full and in writing. *Action* learning modes contain activity-based questions that facilitate accurate and full completion of each activity in each step.

CONTENTS

ACRONYMS

CCP	critical control point
CJD	Creutzfeldt—Jakob disease
CVM	cytomegalovirus
DHM	donor human milk
GMP	good manufacturing practice
HACCP	hazard analysis critical control points
HIV	human immunodeficiency virus
HMB	human milk bank
HTLV	human T-lymphotropic virus type-1

Section A:
Introduction to the workshop on HACCP and human milk banking

OBJECTIVES

By the end of the section, you will be able to:

- Understand the objectives of the hazard analysis critical control points (HACCP) workshop.
- Understand and identify why HACCP is important for human milk banking.

LESSON PLAN

- Welcome

Learning

- HACCP explained

Welcome

UNDERSTAND

Goal of workshop

- This workshop is intended for staff at new and existing human milk banks (HMBs).
- **It will:** help you gain a better understanding of HACCP and give you the skills to develop your own HACCP plan that aligns with the needs and resources of your facility. Every HACCP plan is unique.
- **It will not:** tell you exactly what to include in your HACCP plan or how to plan.

Organization of workshop

- The main learning section in this workshop is Section B.
- Each step of Section B represents the 12 steps of HACCP.
- Each step is divided into a learning section and an activity section.
- This is a learning course—nothing has to be perfect. Sometimes you might not have all the people or all the information you need. That is okay. You will do each activity to the best of your ability, and work together as a team.

LESSON PLAN: **LEARNING**

HACCP explained

✓ **UNDERSTAND**

- A HACCP is an internationally recognized system used in the food industry to identify and reduce hazards during food processing.
- The objective of HACCP is to identify and prevent, eliminate, or reduce to acceptable levels, any biological, chemical, or physical hazard that would be likely to occur in a food production or distribution environment.[1,2]
- Through HACCP, food safety is addressed at every phase of the process including procurement, handling, distribution, processing, and consumption.

✓ **UNDERSTAND**

- **Why HACCP is needed:**
  - Human milk banking currently has no global standard safety procedure, but it is still critical to manage safety and quality. Adopting HACCP into milk banking is a strategy to manage safety and quality requirements of new and existing HMBs.[3]
  - HMB processes involve many steps where contamination can occur and also where alteration of nutritional or immunological properties may take place. HACCP provides a solution for balancing the priorities of safety and quality within each location's own needs and limitations.
  - The verifiable system of standard safety procedures and the transparency offered by its systematic documentation has been identified as helping to build confidence and support from recipients, clinicians, and regulators.[4]
- **HACCP offers an adaptable framework:** This means *it must be customized to each individual HMB.* Just as there is not, and cannot be, a single global model for milk banking, no single HACCP plan is best.
- Instead, the framework empowers leaders at each site to customize their own plan, based on existing plans.

Section B:
Implementing HACCP

OBJECTIVES

By the end of the section, participants will be able to:

- Define the seven principles and 12 steps of HACCP.
- Provide knowledge, tools, and examples of existing guidelines to help develop an individualized HACCP plan.

PLEASE NOTE

Steps 1 to 5 constitute more preliminary measures and may not take much of your time. Steps 6 to 12 should account for more of your time. Much of the information that will be discussed in Steps 1 to 5 may be reaffirming information covered in previous trainings, established by local sites, or established by international teams. Steps 6 to 12 will require more collaboration and action to customize and establish standards for your individual site. Estimated time to complete each step is provided on the first page of that step.

PATH

STEP 1

STEP 1

Assemble a multidisciplinary HACCP team.

OBJECTIVES

By the end of the step, you will be able to:

- Identify qualified and relevant professionals for HACCP plan development.

METHODS OF INSTRUCTION

- Lecture
- PowerPoint presentation
- Trainee activity

LESSON PLAN

Learning

- Recruiting appropriate candidates for your HACCP team.
- Training and responsibilities of HACCP team members.

Activity 1

- Identify your team

LESSON PLAN: **LEARNING**

Recruiting appropriate candidates for your HACCP team

UNDERSTAND

HACCP team

- HACCP teams should represent a diverse base of onsite professionals.
- Some HMBs may also consult additional experts for advice on HACCP plan development.
- It may be valuable to consult with HACCP-trained professionals with experience in the food service industry for help with administration of this process.
- It is very important to include HMB personnel. They have expertise in human milk banking. They are also more familiar with the variability and limitations of the operation. They must implement and support the plan.[3]
- All members of the team play a part in ensuring the highest quality, safety, and ethical practices in donor milk collection, treatments, and provision.
- HACCP teams may, however, consist of a smaller group of representatives from the larger group of the HMB team.
- A diverse range of expertise fosters valuable brainstorming and supports effective decision-making.[1]

EXAMPLE

A HACCP HMB team may include people from the following disciplines[3]

- Microbiology
- Lactation
- Nutrition support
- Midwives
- Nurses
- Nurse Practitioner
- Medicine
- Neonatology
- Pediatrics
- Infection control
- Management/administration
- Community relations
- Advisory committee members
- Support staff

LESSON PLAN: **LEARNING**

Training and responsibilities of HACCP team members

UNDERSTAND

Responsibilities of the HACCP team

- Members of the HACCP team will be trained on HACCP protocols.
- This will ensure that the HACCP plan continues to be managed.
- It will also ensure that the team is prepared to adjust the plan as necessary, noting the changes that pertain to their particular department.
- Once the HACCP plan is in place, HACCP team members will provide comprehensive training for all other staff (as appropriate to their role).
    - Appendix 1 provides an example of a HACCP team.

LESSON PLAN: **ACTIVITY 1**

Identify your team

UNDERSTAND

- The objective of Activity 1 is to establish your personalized HACCP team. Ideally, your HACCP team is with you taking this HACCP workshop. If your HACCP team is not here, then you may consider this a "training of trainers." In other words, you may use what you learn here to train other HACCP team members at your HMB when you are able.
- For this activity, please work as a team to complete the table in Activity 1, found in your workbook. Please refer to Appendix 13 for recommended resources.
    - The table should contain information on the current position and skills of each member of your HACCP team and the specific role they will play in carrying out your HACCP plan.
- Begin by having a discussion with the individuals at this workshop about the roles and responsibilities of each member of a HACCP team.
- Next, as time permits, review key components of existing HMB guidelines and published recommendations reviewing roles and requirements for HACCP teams. Please refer to Appendix 1 for an example of a HACCP team.

ACTION

Answer the following questions to complete the activity

- What are the skills of the different members of your HMB team?
- Who will carry out the HACCP plan on an ongoing basis?
- Who will oversee the HACCP process?
- Can you justify why each person on your team is qualified to carry out his or her role?
- How will each person on the HACCP team secure adequate time to dedicate to the HACCP plan?

ACTIVITY 1 TABLE: HACCP TEAM.

HMB ROLE	SKILLS/STAFF	CREDENTIALS

Queen Charlotte's and Chelsea Hospital Milk Bank, London, United Kingdom)

STEP 2

STEP 2

Describe the product/process.

OBJECTIVES

By the end of this step, you will be able to:

- Define the specifications the team will use to describe the product in its acceptable state.

METHODS OF INSTRUCTION

- Lecture
- PowerPoint presentation
- Trainee activity

LESSON PLAN

Learning

- Review the risks
- Donor human milk (DHM) specifications and distribution for safety

Activity 2

- Individualized product and process specifications

LESSON PLAN: **LEARNING**

Review the risks

UNDERSTAND

Product risks

Each newly formed HACCP team has to begin with a few key steps.

- First, they must complete a description of their product, DHM,[1] so that they can identify all the possible hazards in the milk. This product description should include information on the composition of the human milk, its potential to support dangerous microbial growth, and brief details on the production process.[5]
- To effectively complete this step, the HACCP team must consider processes that mitigate or exacerbate risks. For example:
  - Suboptimal collection, storage, and transportation could result in contamination by pathogenic bacteria.
  - Unknown viral infections in the mother may be transmitted through milk without proper selection and processing.
  - Other contaminants such as medications the donor is taking could pose risks.
- HMBs should work to manage these risks. They must also balance the time and cost associated with managing these risks with the risks of not providing DHM at all.
- HMBs must set and uphold strict safety regulations.[3,6]

LESSON PLAN: **LEARNING**

Specifications and distribution

UNDERSTAND

Milk specifications and distribution

- HMB practices and methods differ worldwide. Examples include having donors express milk at home (versus in a hospital), pooling practices, pasteurization methods, established "shelf-life," and more. Different modes are acceptable, provided there is sufficient research and the HACCP plan accounts for them.[3]
- HACCP plans often include specification sheets. These include a brief description of a product's color, microbiological profile, and storage container and conditions.[5]
- The specifications written for DHM in the HACCP plan will depend on specific processing at each HMB. For example, specifications may include descriptions of DHM in the liquid and frozen state, if the HMB accepts fresh milk in addition to frozen.
- Later HACCP steps will prompt your HACCP team to develop a more detailed description of its processing and practices. The goal of this step is to briefly categorize the ideal state of the DHM.

LESSON PLAN: **ACTIVITY 2**

Individualized product and process specifications

UNDERSTAND

- The objective of Activity 2 is to identify product and process specifications for your facility.
- For this activity, please work as a team to complete Activity 2 table found in your workbook. Please refer to Appendix 13 for recommended resources.
  - This table should contain specific requirements that define safe human milk. Your HACCP team should add additional descriptors to this table as needed.
- Begin by having a discussion with your HACCP team about your product and process specifications.
- Next, start to review recognized guidelines and published recommendations regarding the qualities of safe donor milk. Please refer to Appendix 2 for an example of a completed product description table.

ACTION

Answer the following questions to complete the activity

- Is the milk at your HMB donated frozen or fresh?
- Is the milk at your HMB packaged in food-safe bottles?
- How is the milk transported to and from the HMB?
- Is the milk pooled between a single, or multiple, donors prior to dissemination?
- What microorganisms are of concern in raw milk?
- Is your product description different from that in Appendix 2?
- Can you justify the specific descriptions of your product?
- How does your product description differ from that in Appendix 2?
- Can you justify the specific descriptions of your product?

ACTIVITY 1 TABLE: HACCP TEAM.

PRODUCT NAME	
PHYSICAL STATE (frozen solid, liquid)	
COLOR	
CONTAINER	
PACKAGING IN TRANSPORT	
SHELF LIFE	
LABELING ON STORAGE CONTAINER	
BACTERIOLOGICAL CHARACTERISTICS	

Brazilian National Network of Human Milk Banks

STEP 3

STEP 3

Identify the intended use/ consumer.

OBJECTIVES

By the end of this step, you will be able to:

- Define the specifications the team will use to describe the product in its acceptable state.

METHODS OF INSTRUCTION

- Lecture
- PowerPoint presentation
- Trainee activity

LESSON PLAN

Learning

- Define consumers and consider risks

Activity 3

- Defining your consumers and risks

LESSON PLAN: **LEARNING**

Define consumers and consider risks

UNDERSTAND

DHM consumer

- The population intended to receive DHM has been well defined by different organizations involved in human milk banking. In order to guide the allocation of this resource and define the associated risks, each HMB must define or adopt existing recommendations indicating the populations they will supply and how they will prioritize who receives the DHM, especially if the volumes available are low.[3]

UNDERSTAND

Factors to be considered in prioritization[7]

- Recipient: age, projected length of need, medical condition, prognosis, prevention of problems, research, ability to pay (may be considered if medical need is not evident).
- Maternal: insufficient milk supply, medical contraindication to breastfeeding, adoption, choice.
- Other: length of use, preventive treatment, benefit to community and individual.

EXAMPLE

Standards of practice: prioritization for allocation of DHM[7]

1. (First priority) Premature infants who are sick.
2. Premature infants who are well.
3. Infants 0 to less than 12 months old with medical conditions likely to respond to DHM therapy.
4. Children older than 12 months with medical conditions likely to respond to DHM therapy.
5. Research contracts for clinical use in well-designed studies.
6. Children older than 12 months with chronic medical conditions and high-normal functioning and low-dose need to DHM therapy.
7. Children older than 12 months with chronic medical conditions and high-normal functioning and high-dose need to DHM therapy.
8. Children older than 12 months with chronic medical conditions and low-level functioning and low-dose need to DHM therapy.
9. Children older than 12 months with chronic medical conditions and low-level functioning and high-dose need to DHM therapy.
10. Infants for short-term use, no specific medical condition.
11. Laboratory research (milk that cannot be used for human consumption due to contamination).

LESSON PLAN: **ACTIVITY 3**

Defining your consumers and risks

UNDERSTAND

- The objective of Activity 3 is to identify the target recipients of DHM considering any specific safety concerns for this identified population, and begin to establish the prioritization that will be used for dispensing DHM.
- For this activity, please work as a team to complete Activity 3 Table found in your workbook. Please refer to Appendix 13 for recommended resources.
  - This table should contain information for the prioritization of DHM used at your HMB.
- Begin by having a discussion with your HACCP team about the recipients of DHM from your HMB and discuss any current standards of practice in place for infant feeding.
- Next, start to review national guidelines and published recommendations reviewing typical prioritization of DHM. Please refer to Appendix 3 for an example of a completed DHM prioritization table.

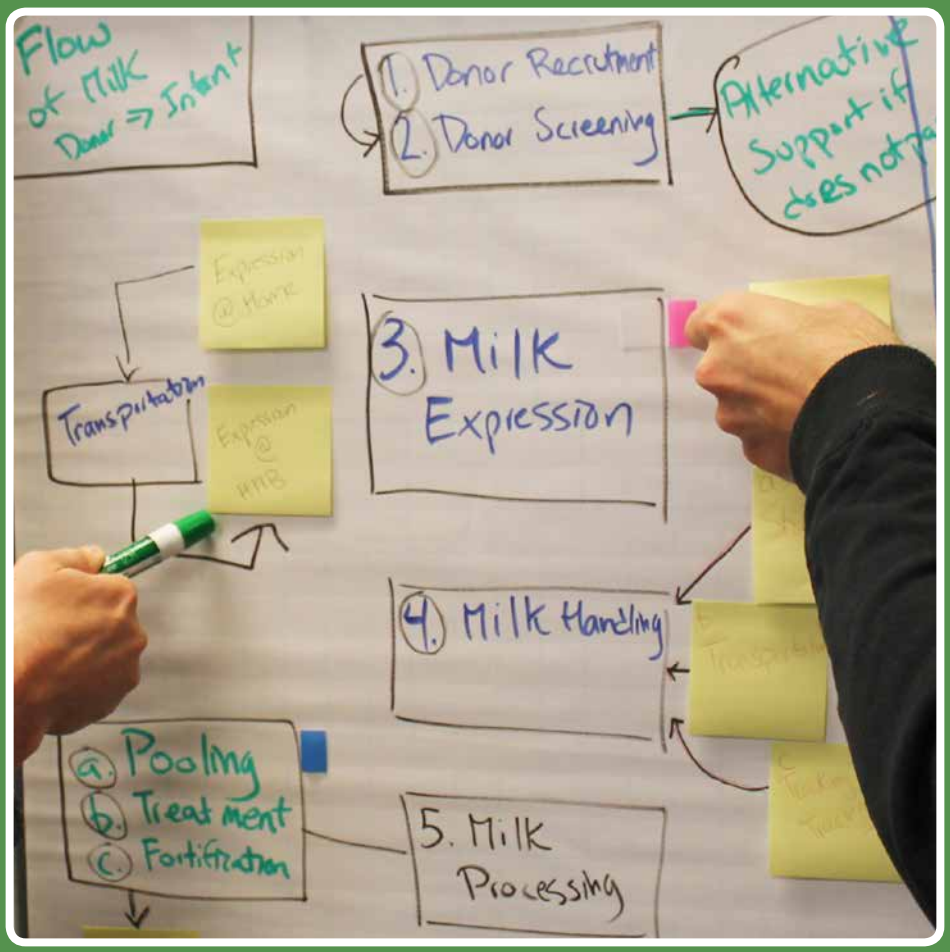
ACTION

Answer the following questions to complete the activity

- What are infants in the neonatal intensive care unit currently being fed?
- What is the current need for DHM?
- Which populations will be given priority in providing DHM?
- What criteria will you use in deciding priority?
- Which populations have already been identified as high risk by other standard operating procedures?
- What are their specific safety concerns?
- In what setting is the milk allocated?
- Is your list of priority recipients different than those in Appendix 3.
- What evidence is there to justify this prioritization of the recipient population?

ACTIVITY 3 TABLE. DEFINITION OF CONSUMER: INDICATIONS FOR DONOR HUMAN MILK (DHM) AND PRIORITIZATION.[7]

WEIGHT	
GESTATIONAL AGE	
DISEASE STATE/CONDITION	
OTHER INDICATORS	
PRIORITIZATION FOR ALLOCATION OF DHM	


Flow of Milk
Donor => Intent
1. Donor Recruitment
2. Donor Screening
Alternative
Support if
does not
Expression @ Home
3. Milk Expression
Transportation
Expression @ HMB
4. Milk Handling
a. Pooling
b. Treat ment
c. Fortification
5. Milk Processing

PATH

STEP 4

STEP 4

Construct a flow diagram of the process.

OBJECTIVES

By the end of this step, you will be able to:

- Adopt, adapt, or create a flow diagram that tracks the DHM through all steps of the HMB procedure.

METHODS OF INSTRUCTION

- Lecture
- PowerPoint presentation
- Trainee activity

LESSON PLAN

Learning

- Flow diagram

Activity 4

- Establishing a customized flow diagram

LESSON PLAN: **LEARNING**

Flow diagram

UNDERSTAND

Flow diagram[5]

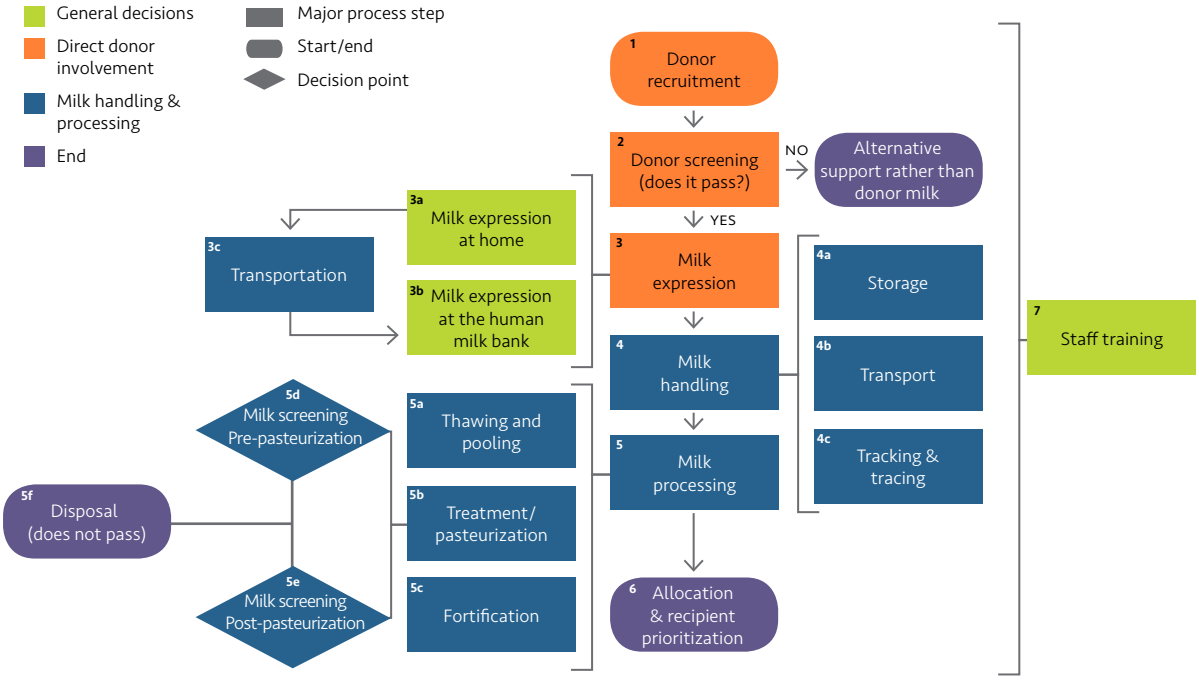
- Flow diagrams are used in HACCP to identify procedural steps involved in processing of each product.
- People create and use flow diagrams to identify potential paths (routes) of contamination, suggest methods of control, and facilitate discussion of these routes among the HACCP team.
- Flow diagrams are created using interviews, blueprints, guidelines, observation of operations, and other sources of information.
- Your flow diagram should contain enough detail to distinguish between different procedural steps, but not so much as to overwhelm the clarity of the schematic.
- All steps, from donor recruitment to pasteurization and milk allocation, should be included.

EXAMPLE

Flow diagram

- Figure 1 below presents a flow diagram of HMB processing, which is a compilation of the procedural steps involved in current HMB practices used worldwide. Individual sites may adapt this flow diagram. The goal is to catalog the flow of the DHM from donor recruitment to recipient, so that potential hazards may be identified.

FIGURE 1. FLOW DIAGRAM OF PROCESS PRACTICES IN HUMAN MILK BANKING



LESSON PLAN: **ACTIVITY 4**

Establishing a customized flow diagram.

UNDERSTAND

- The objective of Activity 4 is for your HACCP team to develop a flow diagram specific to your HMB site.
- For this activity, please work as a team to complete the Activity 4 Table found in your workbook. Please refer to Appendix 13 for recommended resources.
- This table should list each process step in the processing of DHM, from donor recruitment to milk allocation.
- Begin by having a discussion with your HACCP team about each process step at your HMB.
- Next, start to review national guidelines and published recommendations, reviewing typical process steps at HMBs. Please refer to Appendix 4 for an example of a completed flow diagram.

ACTION

Answer the following questions to complete the activity

- Does your flow diagram capture each step in DHM processing?
- Are there steps that can be broken down into two parts to better detail what happens at your HMB?
- Is your flow diagram different than that presented in Appendix 4?
- Can you justify differences in your flow diagram?
- Does your HMB have intentions to make changes to your processing plan?

ACTIVITY 4 TABLE. FLOW DIAGRAM.

	PROCESS STEPS
1	
2	
3	
4	
5	
6	
7	
8	
9	

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STEP 5

STEP 5

Verify the flow diagram onsite.

OBJECTIVES

By the end of this step, you will be able to:

- Confirm the processing operation against the flow diagram during all stages of operation, and amend the diagram where appropriate.

METHODS OF INSTRUCTION

- Lecture
- PowerPoint presentation
- Trainee activity

LESSON PLAN

Learning

- Verifying the flow diagram

Activity 5

- Verifying your flow diagram

LESSON PLAN: **LEARNING**

Verifying the flow diagram

UNDERSTAND

Verifying the flow diagram[2,5]

- The flow chart drafted in Step 4 should now be verified.
- To complete this step, the HACCP team must look at those processes identified and documented in the flow chart, and confirm them through physical observation. This means onsite confirmation that the assumptions are correct and steps are being carried out as the graphic implies.
- Although the HACCP team should already be familiar with the processing steps in human milk banking, it is important for the team to observe the HMB operations long enough to be confident that their flow diagram lists all processing steps in chronological order.
- **Your team should:**
  - Observe employees executing each processing step.
  - Observe hygienic practices while noting all potential hazards.
  - Observe and analyze process steps that destroy microorganisms.
- It might also be necessary to take measurements of important processing parameters to confirm existing operating conditions.

EXAMPLE

Products and processing steps to measure

- Bacterial content measurements.
- Medical evaluations including serological testing from the mother.
- Temperatures including heat processing and cooling or chilling operation.
- Time for pasteurization, cooling, and storing.

LESSON PLAN: **ACTIVITY 5**

Verifying your flow diagram

UNDERSTAND

- The objective of Activity 5 is either to verify your flow diagram OR establish the importance of doing so (once operational).
- In the list below, please choose option A or B, depending on the circumstances of your HMB site.
- For both options, use the diagram developed in Activity 4 to verify your flow diagram. Use Appendix 5 Table in your workbook as a verification checklist.

- If your HMB is operational (that is, already processing donor milk) you may now go track the entire process of the DHM along its course at the HMB, comparing the steps to those listed on the flow chart.
- If your HMB is still being established, your team may verify verbally, and then must revisit this step as soon as possible once operations begin.

ACTION

Answer the following questions to complete the activity

- Is your flow chart accurate and comprehensive?
- Are steps carried out the same way and by the same staff member every time?
  - If any deviations are observed, amend the original flow diagram for accuracy.

ACTIVITY 5 TABLE. VERIFICATION CHECKLIST.

PROCESS TYPE	PRESENT IN FLOW DIAGRAM (Y/N)
Step(s) for recruiting donors	
Step(s) for screening donors	
Step(s) for milk expression	
Step(s) for milk handling	
Step(s) for milk processing	
Step(s) for milk allocation and recipient prioritization	

PATH

STEP 6

STEP 6 List potential hazards, conduct a hazard analysis, and determine control measures.

OBJECTIVES

By the end of this step, you will be able to:

- Identify and list all potential hazards associated with each processing step and consider any measures to control identified hazards.

METHODS OF INSTRUCTION

- Lecture
- PowerPoint presentation
- Trainee activity

LESSON PLAN

Learning

- Definition of hazard and hazard analysis
- How to identify potential hazards
- How to conduct a hazard analysis

Activity 6

- Performing a hazard analysis

LESSON PLAN: **LEARNING**

Definition of hazard and hazard analysis

UNDERSTAND

Hazard analysis[5]

- People conduct a hazard analysis to look for potential hazards that are reasonably likely to occur in an operation to decide which hazards are significant and must be addressed in the HACCP plan.
- The hazard analysis is the first principle of developing a HACCP plan.
- In the hazard analysis, the HACCP team must identify the hazards associated with each step in the HMB process, from donor recruitment and selection to the allocation to the recipient.
- A thorough hazard analysis is the key to a successful HACCP program. If a hazard is not correctly identified, risks to HMB milk safety increase significantly.

EXAMPLE

Reasons why hazards may vary at different HMBs

- Prevalence of chemical exposures among potential donors.
- Prevalence of infectious diseases among potential donors.
- Equipment used in milk processing.
- Storage conditions.
- Duration of processing.
- Knowledge and experience of staff.

LESSON PLAN: **LEARNING**

How to identify potential hazards

UNDERSTAND

Potential hazards[8]

- A hazard can be a "biological, chemical, or physical vehicle in, or condition of, a food that creates the potential to cause an adverse health effect."

EXAMPLE

Potential biological, chemical, and physical hazards[3,5,9,10]

- The following list can be used as a guide to identify potential hazards at your HMB.

TYPE OF HAZARD	DESCRIPTION OF HAZARD	EXAMPLE HAZARDS IN HUMAN MILK
Biological	Biological hazards in human milk banking include microbiological organisms such as bacteria, viruses, and fungi. Most biological hazards are killed or inactivated through pasteurization and further minimized by proper handling and storage practices (hygiene, temperature, and time) of milk. Many biological hazards can also be minimized through prudent donor selection to exclude potential donors with infectious diseases.	• Enterobacteriaceae • Staphylococcus aureus • Pseudomonas aeruginosa • Human immunodeficiency virus • Mycobacterium tuberculosis • Bacillus cereus • Cytomegalovirus
Chemical	Chemical hazards of concern in human milk include trace elements that pass through human milk as a result of maternal exposure and can cause potential harm to the infant. Chemical hazards in human milk can include those from recreational drugs, medications or medical interventions, and workplace exposures.	• Tobacco or nicotine • Alcohol • Amphetamines • Cocaine • Heroin • Marijuana • Antidepressants • Cytotoxic medication • Pharmacologically active herbal products • Diagnostic radioactive isotopes • Other local drugs that present a hazard to human milk safety
Physical	Physical hazards include hard foreign objects, which can result from poor milk handling procedures. Physical hazards are typically less of a concern in human milk banking.	• Glass • Plastic • Metal • Wood • Hair • Insects

LESSON PLAN: **LEARNING**

How to conduct a hazard analysis

UNDERSTAND

Conducting a hazard analysis[8]

- This guide breaks the hazard analysis procedure into three steps. Applying these steps sequentially can ensure hazards are not omitted.
- The information collected during the hazard analysis can be used to review and verify:
  - Potential hazards at each process step.
  - The stages or steps of the plan at which control can be used to prevent, eliminate, or reduce the risk of hazards to an acceptable level.
  - The severity and the likelihood of each hazard occurring and the amount of risk associated with that hazard.

EXAMPLE

Identifying potential hazards[5]

- **Step 1: The first part of conducting a hazard analysis is listing each step of the collection, processing, storage, and distribution of human milk and identifying all the hazards (biological, chemical, or physical) reasonably expected at each step. Typical process steps and their associated hazards have been identified in Appendix 6.**
- The following questions can help your HACCP team determine whether a hazard exists at the HMB:
  - Could the raw material (raw human milk from potential and existing donors) contain pathogenic microorganisms, toxins, chemicals, or physical hazards? To answer this question, you might evaluate the transmission of microorganisms, infections, toxins, and chemical hazards from a mother to her milk.
  - Could contaminants reach the product during the step? To answer, you might evaluate personal hygiene, contaminated equipment or material, and potential cross-contamination from raw materials.
  - During the step, could a microorganism of concern multiply to a level where it is considered a hazard? To answer, you might consider temperature and time.

UNDERSTAND

Identifying the origin of the hazard[5]

- **Step 2: The second step in the hazard analysis is identifying the origin of the hazard as well as the acceptable level of the hazard in human milk.**
- When thinking of the origin of the hazard, it is also important to begin outlining potential methods and procedures to prevent, eliminate, or control hazards to an acceptable level. This information is crucial to monitoring and controlling all critical control points (CCPs).
- There may be more than one method to control a specific hazard. Some hazards may require multiple methods for optimal control.

EXAMPLE

Methods for controlling biological, chemical, and physical hazards[5,7,9,10]	
Methods for controlling biological hazards	• Donor screening including interviews and serological testing. • Thermal processing (heating) to eliminate the organism. For example pasteurizing milk for 30 minutes at 62.5°C. • Temperature/time control (refrigeration and storage time) to minimize the proliferation of the organisms. • Packaging conditions (vacuum packaging) to inhibit microorganism contamination and proliferation. • Staff and mother training on proper hygiene methods for milk expression and storage. • Proper labeling and separation of all expressed and stored milk to prevent cross-contamination of raw and pasteurized milk.
Methods for controlling chemical hazards	• Donor screening including interviews and serological testing. • Proper separation of all chemicals present in processing area from raw and processed human milk. • Staff training to control possible contamination from chemicals (water, sanitation chemicals). • Proper labeling of all chemical hazards in processing area.
Methods for controlling physical hazards	• Proper separation of all physical hazards from raw and processed human milk. • Staff training on proper handling of all glass milk containers. • Environmental control measure to ensure no physical contamination from building, facilities, work surfaces, or equipment.

UNDERSTAND

Assessing the risk of the hazard[5]

- **Step 3: The third and final step in the hazard analysis is to assess the risk of the hazard. This is accomplished by evaluating both the severity of the hazard and the likelihood that it will occur.**
- To assess of the risk of each hazard, your HACCP team must use a combination of experience, epidemiological data, and technical literature.
- Note that even among experts in the field of human milk banking, there can be differences of opinion in the level of risk of each hazard.

UNDERSTAND

Severity of hazard[5]

- *Severity* is how serious the consequences of a hazard are. Severity can be used to categorize the magnitude of harm that results when a hazard exists.
  - *High-severity* hazards are life threatening.
  - *Moderate-severity* hazards are severe or chronic.
  - *Low-severity* hazards are moderate or mild.

UNDERSTAND

Likelihood of hazard[5]

- The *likelihood* of a hazard is the probability that the hazard will contaminate the human milk. It can be calculated at each step of the milk banking process (that is, likelihood may be higher in one step than in another).
- The likelihood of a hazard occurring can be categorized as *high, moderate, or low.*
- The likelihood of a hazard can vary between regions. Thus, each individual HMB should be evaluated onsite.

UNDERSTAND

Risk of hazard[5]

- The *risk* of a hazard is a function of the *likelihood* and the *severity* on the safety of the human milk.
- All steps at which there is a justified hazard must be considered as possible CCPs using the CCP decision tree described in Step 7.
- Teams should assess their list of hazards closely to be sure that all are worth prioritizing. To be included, a hazard must be risky enough that preventing it, eliminating it, or reducing it to acceptable levels is necessary and essential to producing safe human milk.

EXAMPLE

Severity and likelihood table

- A common method of assessing the true risk of a hazard is to use a tool, such as Figure 2 below. Once users have completed the tool for each hazard, they can use it to assess risk. All hazards labeled *high/high, high/moderate,* or *moderate/high risk* are considered significant (justified). They should remain on the list.

FIGURE 2. SEVERITY AND LIKELIHOOD TABLE

		SEVERITY OF HAZARD		
		HIGH	**MEDIUM**	**LOW**
LIKELIHOOD OF HAZARD	**HIGH**	H / H	H / M	H / L
	MEDIUM	M / H	M / M	M / L
	LOW	L / H	L / M	L / L

UNDERSTAND

Good manufacturing practices[5]

- When a hazard has a low likelihood of occurrence as well as a low severity, it should be addressed through good manufacturing practices (GMPs) rather than under the HACCP plan. GMPs will be explained in Step 7.

LESSON PLAN: **ACTIVITY 6**

Performing a hazard analysis

UNDERSTAND

- The objective of Activity 6 is for your HACCP team to create a hazard analysis adapted for operating an HMB in your region or facility.
- For this activity, please work as a team to complete Activity 6 Table found in your workbook. Please refer to Appendix 13 for additional resources.
- Your table should list each process step identified in Activity 4. You should record possible hazards at every step, the origin of the hazard, acceptable levels of the hazard in DHM, how the hazard is controlled or prevented, and whether the hazard is justifiable.
- Begin by having a discussion with your team about hazards at each process step.
- Next, review available guidelines and published recommendations for addressing potential hazards at HMBs. Please refer to Appendix 6 for an example of a completed hazard analysis table.

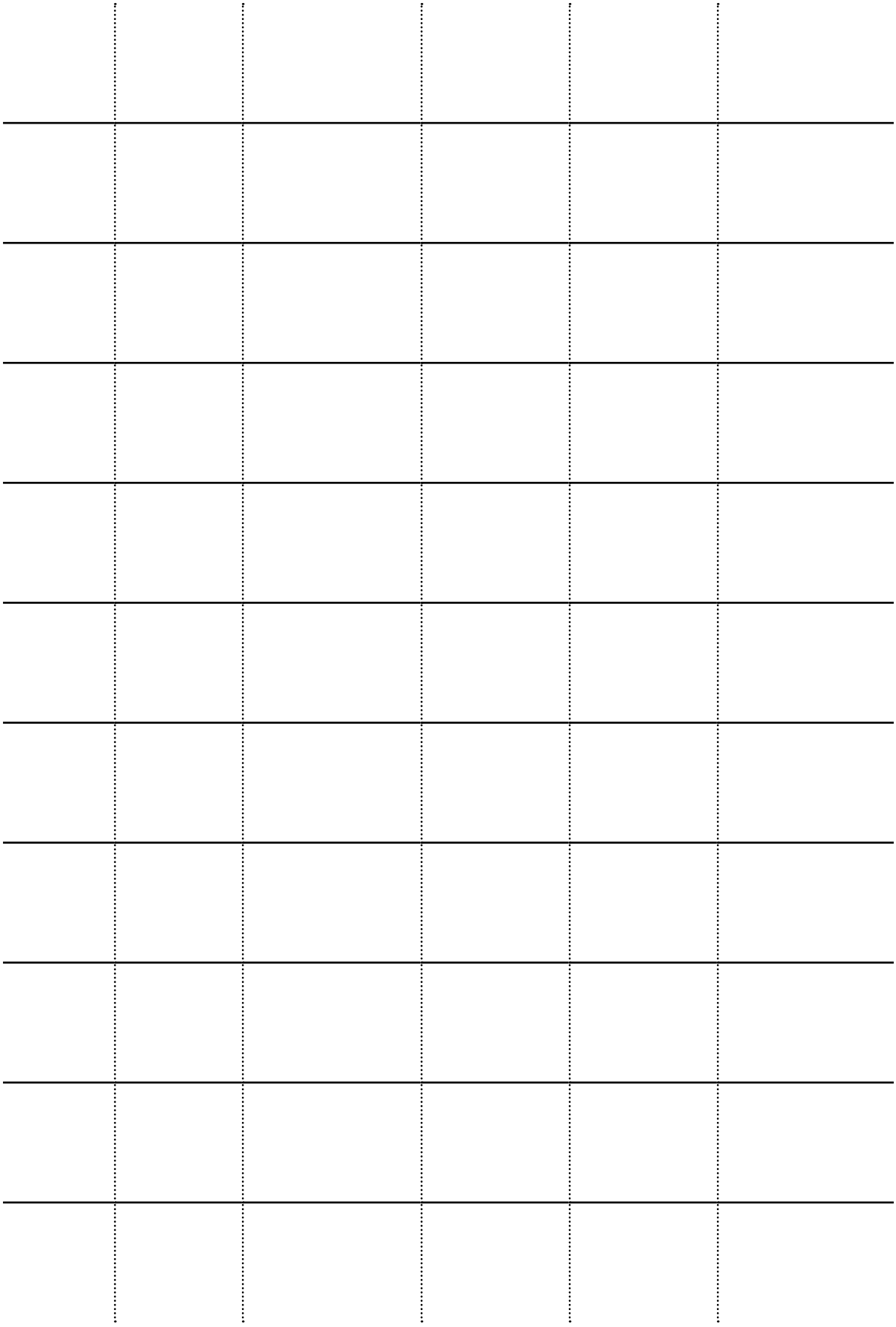
ACTION

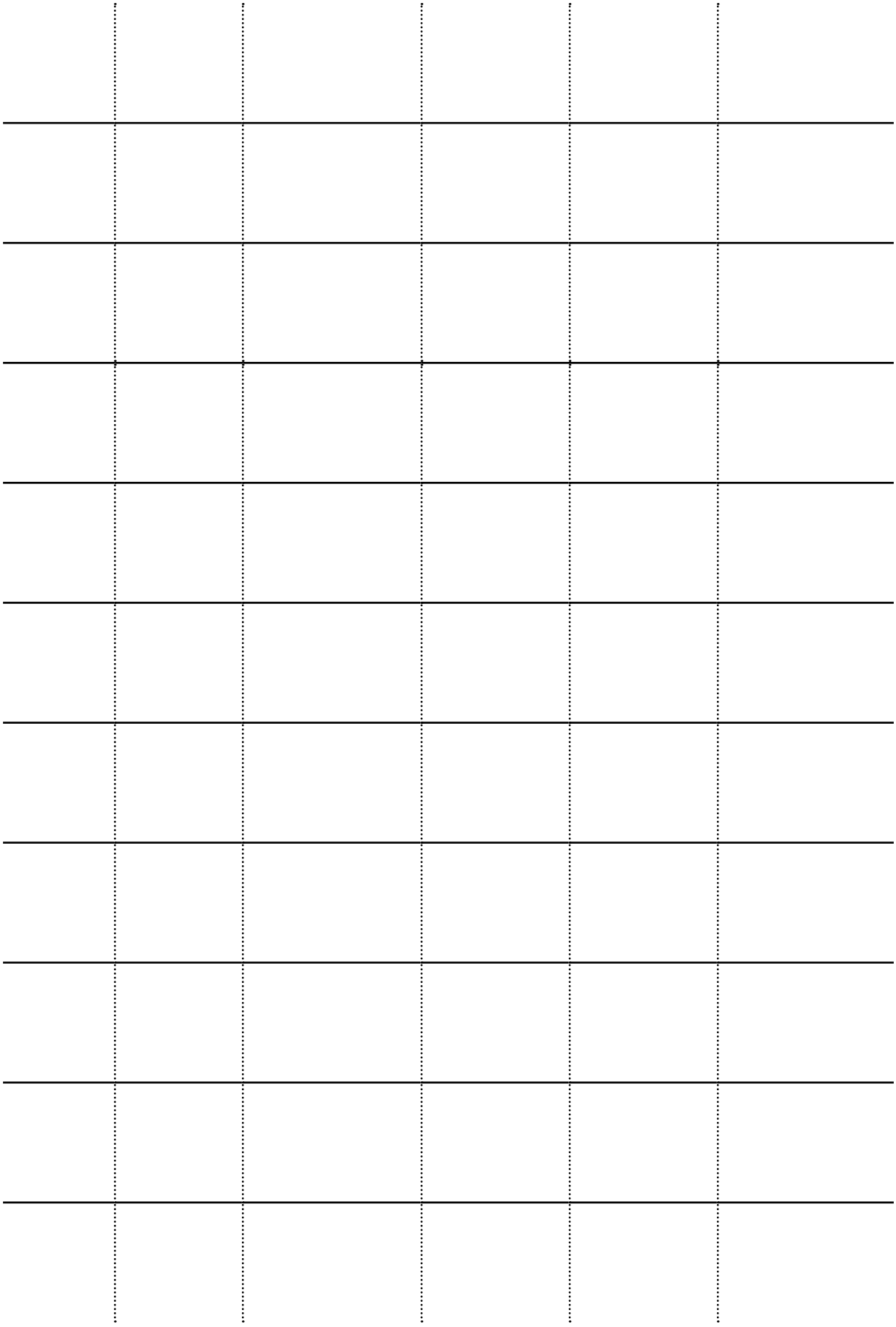
Answer the following questions to complete the activity

- Which process steps have potential hazards?
- What is the origin of each hazard?
- What is the acceptable level of each hazard in human milk?
- What is the severity of each hazard?
- What is the likelihood that each hazard will occur?
- What is the risk of each hazard?
- Is the seriousness of each hazard less severe or more severe in your setting as compared with the example in Appendix 6?
- Is the likelihood of a hazard less likely or more likely in your setting as compared with the example in Appendix 6?
- How does your hazard analysis otherwise compare to the example in Appendix 6?
- Can you provide evidence to support your decisions in identifying justified hazards (i.e., published literature, case reports)?

ACTIVITY 6 TABLE. HAZARD ANALYSIS.

PROCESS STEP	**HAZARD**	**ORIGIN OF** (HAZARD PRESENT, INTRODUCED, GROWTH OR SURVIVAL)	**ACCEPTABLE LEVEL IN MILK**	**CONTROL/ PREVENTION**	**LIKELIHOOD X SEVERITY** **JUSTIFIED HAZARD=YES/ NO**





Cheshire and North Wales Human Milk Bank

STEP 7

STEP 7

Determine CCPs.

OBJECTIVES

By the end of this step, you will be able to:

- Provide all trainees with the necessary skills and knowledge to identify CCPs in the HACCP system.

METHODS OF INSTRUCTION

- Lecture
- PowerPoint presentation
- Trainee activity

LESSON PLAN

Learning

- Definition of CCPs
- Review of identified hazards
- How to identify CCPs
- The CCP decision tree
- Recording CCPs

Activity 7

- CCP identification

LESSON PLAN: **LEARNING**

Definition of CCPs

UNDERSTAND

CCPs[1,5,8]

- **A CCP 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. At these CCPs, failure to follow the standard operating procedures could result in unsafe milk and harm to infants.**
- Identifying CCPs is the second principle of HACCP and the seventh step in the process.
- Identifying CCPs helps identify steps in the HMB process where teams should pay particular attention to risks. These steps often have clearly defined, quantifiable critical limits set by temperature and time.
- CCPs differ from other steps in the HMB process because **a CCP does not have a subsequent step in the process that is able to reduce the hazard to an acceptable level.** In other words, a CCP is the **last step** in the process that can control the hazard.
- Based on local needs and resources, each HMB will have unique process points and corrective measures. CCPs in different settings may focus on diseases with a higher prevalence in the area served by the HMB.

UNDERSTAND

Good manufacturing practices[5]

- HACCP plans also identify steps in the HMB process that need to be monitored but do not have quantifiable critical limits. They may not have a risk level as high as justifiable hazards. These steps are referred to as GMPs. GMPs are the minimum sanitary and processing requirements necessary to ensure the production of safe, high-quality foods. GMPs include practices such as staff training and equipment disinfection. These practices reduce hazards to an acceptable level when followed appropriately.

LESSON PLAN: **LEARNING**

Review of identified hazards

UNDERSTAND

Verifying control by GMPs[5]

- Before identifying CCPs, the HACCP team should review all the hazards identified in the hazard analysis and verify whether any are fully controlled by GMPs. If a justified hazard in a process step is not fully controlled by a GMP, that process step must be assessed and reviewed to determine if it is a CCP.

LESSON PLAN: **LEARNING**

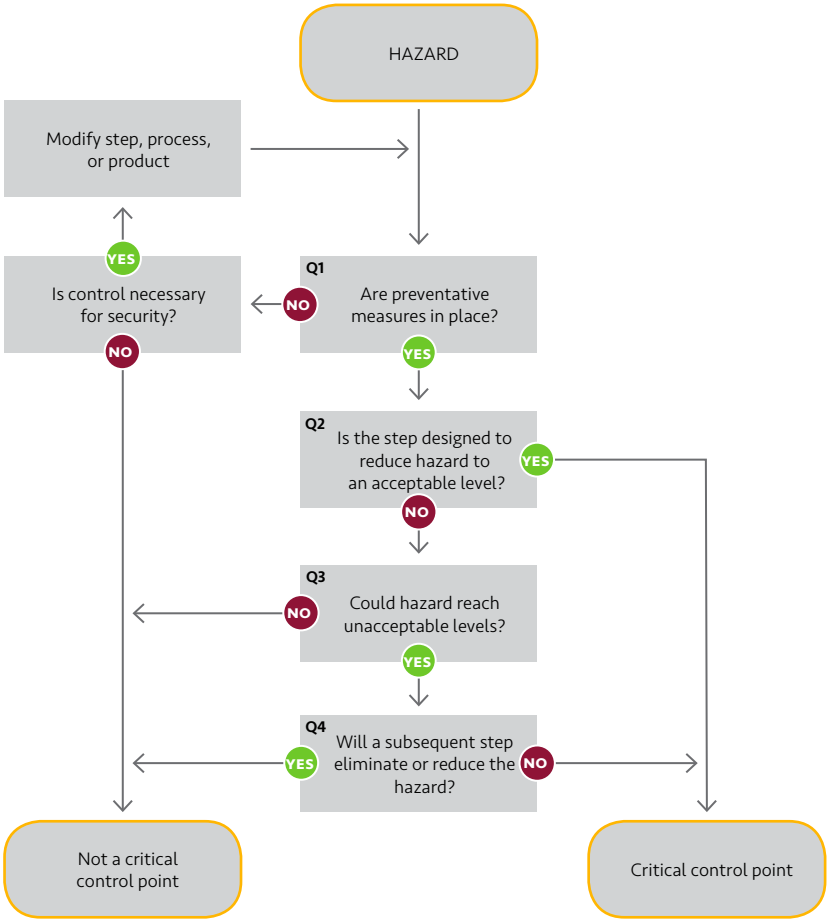
How to identify CCPs

UNDERSTAND

CCP decision tree[3,5,10]

- A decision tree is a tool that teams can use to assist in identifying the CCPs in the processing plan. It uses four questions to help teams objectively assess whether an identified hazard must be controlled with a CCP.
- Figure 3 presents an example of a decision tree used to determine CCPs in the process flow.

FIGURE 3: DECISION TREE FOR IDENTIFYING PROCESS STEPS AS CRITICAL CONTROL POINTS



LESSON PLAN: **LEARNING**

The CCP decision tree questions

UNDERSTAND

CCP decision tree questions were designed to facilitate identification of CCPs. Your HACCP team will review each of these questions in detail in Activity 7.

Question 1: Are preventive measures in place?[5]

- Question 1 is asking whether HMB staff could use an existing control measure in the HMB process to control the hazard. Examples include a temperature control measure or a bacterial count assessment.
- If the response is "no" (that is, no control measure exists), then you must indicate how the hazard is controlled before or after this processing step. For example, bacterial content in raw human milk is controlled by pasteurization.

Question 2: Is the step designed to reduce the hazard to an acceptable level?[5]

- Question 2 is referring to specific procedures or operations in HMB process steps that are specifically designed to reduce hazards to an acceptable level. These may include:
  - Pasteurization.
  - Sanitation procedures needed to prevent contamination after pasteurization.
  - Proper storage of pasteurized human milk.
  - Proper separation of pasteurized human milk from raw milk.
  - Adequate screening of potential and existing donors to exclude donors with infectious diseases.
- If the operation at this process step is specifically designed to eliminate or reduce the hazard to an acceptable level, you must answer "yes" to Question 2. Following the decision tree, a step that is specifically designed to eliminate or reduce the hazard becomes a CCP.

Question 3: Could the hazard reach unacceptable levels?[5]

- Question 3 is asking whether it is likely that the hazard could approach unacceptable levels at future process steps. This question is specifically referring to both the potential severity and the likelihood of the hazard.
- If the hazard is not known to reach unacceptable levels, you should answer “no.” This process step not a CCP and you can continue to evaluate the next identified hazard in the process step.

Question 4: Will a subsequent step eliminate or reduce the hazard?[5]

- This question is used to identify hazards that are known to be a threat to human health or that could increase to unacceptable levels, which will be controlled in subsequent steps in the operation.
- You should answer “no” to this question if no subsequent step will control the identified hazard. This process step should be identified as a CCP.
- You should answer “yes” to this question if a subsequent step exists to control the identified hazard. This process step is not a CCP and you can proceed to evaluating the next identified hazard.

UNDERSTAND

Examining hazards not controlled by the HMB[5]

- If a specific hazard is not controlled by the HMB, it should be reexamined to determine whether a control measure should be established at the HMB.
  - For example, your HMB may not control biological hazards associated with contamination of milk in the allocation steps of the HMB process. If your HMB does not have control over hazards in future process steps, you should indicate how these hazards could be addressed outside your HMB processing procedure. If your re-examination determines that a control measure should be established at the HMB, then appropriate control measures should be identified and reviewed accordingly.

LESSON PLAN: **LEARNING**

Recording CCPs

UNDERSTAND

Recording CCPs[5]

- A specific identification protocol is used to record CCPs. This protocol facilitates quick and simple identification of a CCP, independent of process operation numbering, and indicates which type(s) of hazards need to be controlled for a particular CCP operation.
  - CCPs are identified both numerically and with a category qualifier (B=Biological; C=Chemical; P=Physical).
  - For example, if the first CCP identified in your protocol is a biological hazard, the CCP should be recorded as "CCP-1 (B)." If the third CCP identified in your protocol is chemical, the CCP should be recorded as "CCP-3 (C)."
  - Hazards that are fully controlled by good manufacturing principles should be recorded as "GMP."
  - Please refer to Appendix 7 for additional examples.

LESSON PLAN: **ACTIVITY 7**

Identification

UNDERSTAND

- The objective of Activity 7 is to identify the CCPs at your HMB facility.
- For this activity, please work as a team to complete Activity 7 table found in your workbook. Please refer to Appendix 13 for additional resources.
  - Have your team go through the CCP decision tree for each justified hazard you identified in Activity 6.
  - Using this table creates a reference for re-evaluating why certain process steps were or were not designated as a CCP.
  - Discuss each question with your HACCP team and review national guidelines and published recommendations for best practices in HMBs.
  - Please refer to Appendix 7 for an example of a completed CCPs table.

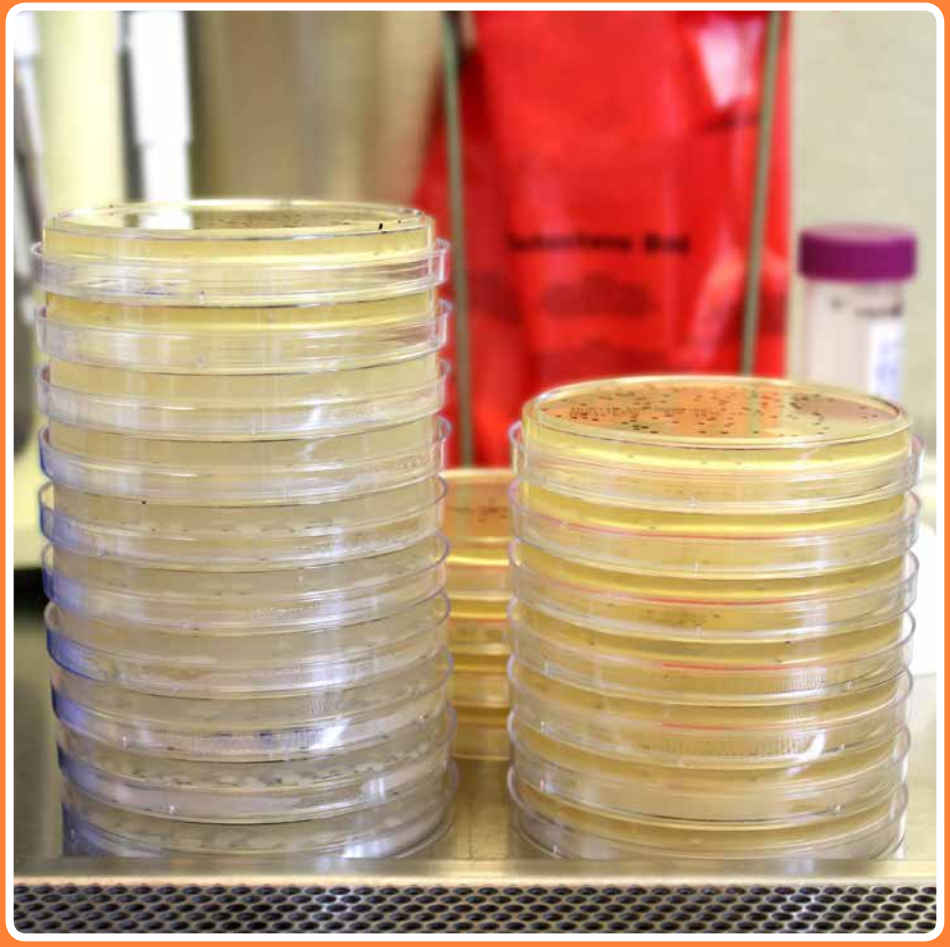
ACTION

Answer the following questions to complete the activity

- How are your answers to the decision tree questions different from those in Appendix 7?
- Did you identify additional CCPs?
- Do recognized guidelines exist that identify the same CCPs?
- If time permits, have a discussion among your HACCP team and answer the following questions:
  - Can you provide evidence to support your answers to the decision tree questions?
  - Can you justify your decision to evaluate a process step as a CCP rather than a GMP?

ACTIVITY 7 TABLE. CCP IDENTIFICATION USING THE CCP DECISION TREE.

PROCESS STEP	HAZARD	CCP DECISION TREE				
		Q1	Q2	Q3	Q4	CCP



PATH

STEP 8

STEP 8

Establish critical limits for each CCP.

OBJECTIVES

By the end of this step, you will be able to:

- Identify critical limits for each CCP in their HACCP plan.

METHODS OF INSTRUCTION

- Lecture
- PowerPoint presentation
- Trainee activity

LESSON PLAN

Learning

- Definition of critical limits
- Operating limits

Activity 8

- Setting critical limits

LESSON PLAN: **LEARNING**

Definition of critical limits

UNDERSTAND

Critical limits[1,5]

- Critical limits are the specific values used to separate acceptable levels of identified hazards from unacceptable levels of hazards. A critical limit sets the boundaries to ensure your HMB is producing safe milk.
- Establishing critical limits is the third principle of HACCP and the eighth step in the process.
- Critical limits must be established and specified at each CCP.
- Depending on the CCPs set by your HMB, critical limits can be set for factors such as temperature, time, bacterial concentration before or after pasteurization, and serological blood levels of infectious diseases.
- There may be situations in which one CCP can be controlled by more than one critical limit.

EXAMPLE

Sources of information for setting critical limits

- Recognized HMB guidelines (Human Milk Banking Association of North America, Italian Association of Human Milk Banks, UK National Institute for Health and Care Excellence).
- Scientific data and publications.
- Information from experts (infectious disease experts, neonatologists, pediatricians, academics).

UNDERSTAND

Setting critical limits[3,5]

- When data and information for establishing a reliable critical limit are not available, conservative values should be utilized.
- All references and rationale for setting critical limits should be recorded and saved at the HMB as part of the supporting documentation for the HACCP plan.
- Depending on the needs and capacity of regions, critical limits can vary. For example, the critical limit for microbial content in milk post-pasteurization is 10 CFU/µL in the United Kingdom, while the critical limit is 0 CFU/µL bacterial content in Canada, Brazil, Italy, Norway, France, Switzerland, and the United States.

LESSON PLAN: **LEARNING**

Operating limits

UNDERSTAND

- Operating limits are used to prevent a deviation from critical limits and can help staff take action to prevent loss of control before a critical limit is exceeded.
- Operating limits are often set at a level that would be reached before the critical limit is violated.
- Current national guidelines for human milk banking have not set operating limits. However, choosing to operate your HMB at a more conservative limit may facilitate taking corrective action when required.

LESSON PLAN: **ACTIVITY 8**

Setting critical limits

UNDERSTAND

- The objective of Activity 8 is to identify the critical limits appropriate for your setting.
- For this activity, please work as a team to complete Activity 8 table found in your workbook. Please refer to Appendix 13 for additional resources.
- This table should provide information on the specific critical limits appropriate for controlling each of the CCP identified in Activity 7.
- Begin by having a discussion with your team about appropriate limits for each CCP.
- Next, start to review national guidelines and published recommendations for best practices in HMBs. Please refer to Appendix 8 for an example of a completed critical limits table.

ACTION

Answer the following questions to complete the activity

- Where did you find evidence to support your critical limits?
- Do other countries have similar critical limits in their guidelines?
- How do your critical limits differ from those in Appendix 8?
- How do you justify having critical limits more or less conservative than those listed in Appendix 8?

ACTIVITY 8 TABLE. CRITICAL LIMITS FOR CCPS.

PROCESS STEP	CCP	HAZARD	CRITICAL LIMITS

PATH

STEP 9

STEP 9

Establish a monitoring system for each CCP.

OBJECTIVES

By the end of this step, you will be able to:

- Identify a monitoring system for each CCP in their HACCP plan.

METHODS OF INSTRUCTION

- Lecture
- PowerPoint presentation
- Trainee activity

LESSON PLAN

Learning

- Definition of a monitoring system
- Design of an effective monitoring system

Activity 9

- A monitoring system

LESSON PLAN: **LEARNING**

Definition of a monitoring system

UNDERSTAND

Monitoring procedures[1,5]

- **A monitoring procedure is a planned sequence of measurements and observations used to assess if a CCP is under control.**
- Establishing monitoring procedures is the fourth principle of HACCP and the ninth step in the process.
- As monitoring procedures are designed to detect loss of control at the CCP, each monitoring procedure must be a scheduled measurement or observation of the critical limits for each.
- An effective monitoring system will specify how, when, and by whom monitoring steps will be performed. The purpose of a monitoring system includes:
  - Measuring and establishing records to trend the performance of the HMB at each CCP and to ensure that the HMB complies with its HACCP plan.
  - Determining when the HMB is performing at a level that would result in a loss of control at the CCP, such that there is deviation from a critical limit.
- The manager of an HMB can use the monitoring process to show that the operation and conditions of the HMB are in compliance with the HACCP plan. To prevent loss of control at the CCPs, an effective monitoring system will provide information on critical limits with adequate time to allow for any adjustments to the process.

UNDERSTAND

Types of monitoring[5]

- As with other steps in the HACCP plan, there are many ways to effectively monitor the critical limits of a CCP. Each HMB must choose the method that corresponds to their needs and resources.
- For some CCPs in the HMB process, monitoring can be performed on a batch basis or on a continuous (100%) basis.
  - When feasible, continuous monitoring should always be performed, as it is more reliable and can detect shifts around target levels (e.g., bacterial counts).
  - When monitoring is performed on random samples or batches, the frequency and amount of monitoring must be high enough to provide assurance that the CCP is being controlled.
- All monitoring procedures performed during the HMB process should result in written documentation, which serves as a record of all operating procedures and conditions. In the event of a loss of control, monitoring records are also essential for permitting corrective action as well as for adjusting process steps if there is a trend toward a loss of control.
- The final step of the monitoring process is evaluation of the monitoring records by a designated person(s) with the authority, knowledge, and skills to carry out corrective actions when indicated.

- For a monitoring system to be effective, the person responsible for the monitoring procedure must be clearly defined. In addition, all individuals carrying out monitoring procedures must be adequately trained in the procedures for the CCP for which they are responsible. All responsible individuals must have timely access to monitoring information, must have no bias in monitoring, and must accurately report all monitoring activity.

LESSON PLAN: **LEARNING**

Design of an effective monitoring system

UNDERSTAND

The four questions that monitoring systems answer[5]

- Monitoring procedures determine if the control measures discussed in Step 6 are being implemented to control the hazards at the CCP and ensure that critical limits are not exceeded. Appendix 9 contains an example monitoring system for an HMB. Monitoring specifications for each CCP should answer the following questions:
- What is being monitored?
- What are the procedures for monitoring?
- How should monitoring be performed?
- Who is responsible for monitoring?

UNDERSTAND

What is being monitored?[5]

- Many different components of the HMB process can and should be monitored to determine compliance with a critical limit.
- Monitoring systems can include measurements and observations of temperature and time of a thermal process, temperature and time of cold storage, visual examination of a storage container or pasteurization process, serological screening, and microbiological testing.

UNDERSTAND

What are the procedures for monitoring?[3,5,7]

- Deviations from critical limits must be detected as soon as possible to permit adequate time for corrective action to be taken and to limit the amount of affected milk.
- When possible, monitoring procedures should provide real-time results and should avoid lengthy analysis procedures. To effectively monitor the CCPs identified at your HMB, measuring equipment must be properly selected and calibrated.
- The monitoring equipment used at your HMB will depend on your facility's capacity and methods of screening donors and treating donated milk. For example, some HMBs use microbiological cultures, phosphate tests, and titratable acidity to monitor milk post-pasteurization, while others use the bright green bile 2% lactose test.

EXAMPLE

Monitoring equipment[3,9]

- Timer
- Microbiological cultures
- Serological tests
- Phosphate tests
- Titratable acidity tests
- Bright green bile 2% lactose test

UNDERSTAND

How should monitoring be performed?[5,8]

- When possible, continuous monitoring is preferred over noncontinuous monitoring. Continuous monitoring is only effective when the monitoring results are regularly reviewed and corrective action is taken when necessary.
- When noncontinuous monitoring is utilized, the frequency of monitoring must be determined by knowledge of the HMB process and scientific data. If problems are detected in the HMB process, the frequency of monitoring may need to be increased.
- Guidelines vary worldwide for monitoring human milk post-pasteurization, with some HMBs monitoring every batch and others conducting monitoring procedures for this step randomly, or at least once per a month or every ten cycles, whichever comes first.[3]

EXAMPLE

Types of continuous monitoring[3]

- Measurements of time and temperature of pasteurization.
- Monitoring container closures.
- Monitoring microbiological activity of all pasteurized milk.
- Monitoring the serological tests of all potential and current donors.

UNDERSTAND

Who is responsible for the monitoring?[1,5,8]

- Responsibility for monitoring is an important consideration when developing the HACCP plan. Variability in HMB settings and staff can dictate who is responsible for monitoring the CCP.
- Individuals responsible for monitoring the CCPs must:
  - Have adequate training in the CCP monitoring techniques.
  - Understand the importance of monitoring the CCP.
  - Have access to all monitoring activity.
  - Accurately report all activity being monitored, including all unusual deviations from critical limits and usual milk processing.

  - Have the authority, knowledge, and skills to take necessary action as outlined in the HACCP plan.
  - Rapidly report deviations from critical limits.
- All monitoring reports must be signed by the individual responsible for CCP monitoring as well as one or more individuals responsible for reviewing official documents of the HMB.

EXAMPLE

Types of individuals assigned to monitor CCPs[3]

- Equipment operators
- Supervisors
- Maintenance personnel
- Quality assurance personnel
- Nurses
- Lactation consultants
- Microbiologists
- Infectious disease specialists

LESSON PLAN: **ACTIVITY 9**

A monitoring system

UNDERSTAND

- The objective of Activity 9 is to identify the monitoring systems appropriate for your setting.
- For this activity, please work as a team to complete Activity 9 table found in your workbook. Please refer to Appendix 13 for additional resources.
  - This table should contain a detailed plan of your monitoring procedure, frequency, and responsible personnel.
- Begin by having a discussion with your team about appropriate monitoring procedures.
- Next, start to review national guidelines and published recommendations for best practices in HMBs. Please refer to Appendix 9 for an example of a completed monitoring procedures table.

ACTION

Answer the following questions to complete the activity

- Where did you find evidence to support your monitoring procedures?
- Do other countries have similar monitoring procedures in their guidelines?
- How do your monitoring procedures, frequencies, and responsibilities differ from those in Appendix 9?
- How can you justify the safety of your monitoring system?

ACTIVITY 9 TABLE. MONITORING SYSTEM FOR CCPS.

PROCESS STEP	CCP	HAZARD	MONITORING: PROCEDURE, FREQUENCY, RESPONSIBILITY

PATH

STEP 10

STEP 10 Establish corrective actions for deviations from critical limits.

OBJECTIVES

By the end of this step, you will be able to:

- Identify and establish corrective actions appropriate for controlling each CCP.

METHODS OF INSTRUCTION

- Lecture
- PowerPoint presentation
- Trainee activity

LESSON PLAN

Learning

- Corrective actions

Activity 10

- Development of a corrective action plan

LESSON PLAN: **LEARNING**

Corrective actions

UNDERSTAND

Corrective actions[1,2,5,8]

- Once critical limits are identified for each CCP and monitoring methods are in place, corrective actions must be established to account for any deviances.
- **Corrective actions are predetermined steps that are necessary to take if critical limits are exceeded. This step of HACCP ensures that HMBs have a plan to address possible deviations identified during the monitoring of critical limits.**
- Establishing corrective actions is the fifth principle of HACCP and the tenth step in the process.
- Defined corrective action procedures are needed to determine the cause of the deviation and to take action to prevent a recurrence. Monitoring and reassessment of the deviation is required to ensure that the corrective action taken is effective. Corrective actions should address the root cause of the deviation; otherwise, the deviation could recur.
- Corrective action procedures can differ depending on your setting and resources.
- Corrective actions should:
  - Identify person(s) responsible for implementing corrective action.
  - Investigate the root cause of problems.
  - Describe the means by which the observed deviation will be corrected (i.e., will another sample be cultured?).
  - Describe the action to be taken with the product processed during the period when the process was out of control (i.e., what will be done with the contaminated milk?).
  - Provide written record of measures taken, indicating all relevant information (e.g., date, time, type of action, actor, and subsequent verification check).

EXAMPLE

Information that should be recorded in deviation and corrective action records[5]

- Date
- Time
- Type of action taken
- Signature of staff responsible for action and evaluation
- Results of evaluation: nature of deviation
- Cause of deviation identified
- Reassessment of effectiveness of corrective action
- Disposal of product if appropriate
- Authorization for disposal

UNDERSTAND

Preventative actions[1,2]

- If corrective actions for the same procedure have to be implemented repeatedly, preventative measures may need to be put in place.
- Identification of the root cause of a problem that was established during corrective action procedures should be helpful in guiding this process. Documentation should also be taken here to measure effectiveness.

EXAMPLE

An example of corrective action[3]

- *Scenario:* Microbial content is determined to be consistently high (exceeding the critical limit) in milk donations from a single donor.
- *Corrective action:* Make contact with that donor, offer support, and review hygiene measures. Continued contamination may result in a second contact for educational content and support, or in a discontinuation, depending on the corrective action protocol established by each HMB. The protocol established pre-emptively for this instance is an example of establishing corrective action.
- An example of preventative action may be implementing more thorough initial support and education of new donors.

LESSON PLAN: **ACTIVITY 10**

Development of a corrective action plan

UNDERSTAND

- The objective of Activity 10 is to write a corrective action plan appropriate for your setting.
- For this activity, please work as a team to complete Activity 10 table found in your workbook. Refer to Appendix 13 for additional resources.
  - This table should contain a detailed plan of the corrective action that will be taken when critical limits are reached.
- Begin by having a discussion with your team about appropriate corrective actions.
- Next, start to review national guidelines and published recommendations for best practices in HMBs. Please refer to Appendix 10 for an example of a completed corrective action table.

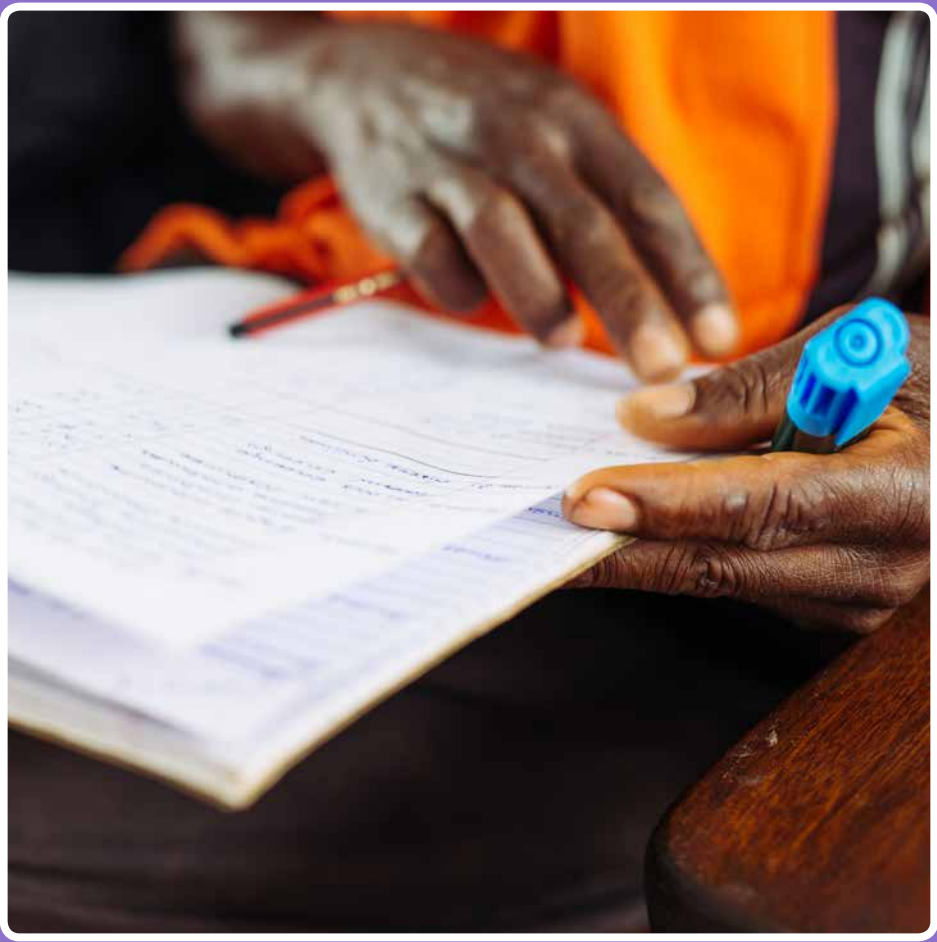
ACTION

Answer the following questions to complete the activity

- What corrective actions will you apply to each CCP where critical limits are reached?
- Are there any opportunities for rejected milk to be used in research?
- How do your corrective actions compare to those of other milk banks?
- What evidence is there to justify the safety and/or usefulness of your corrective actions?

ACTIVITY 10 TABLE. CORRECTIVE ACTION PLAN.

PROCESS STEP	CCP	HAZARD	CRITICAL LIMIT	CORRECTIVE ACTIONS



PATH

STEP 11

STEP 11

Establish verification procedures.

OBJECTIVES

By the end of this step, you will be able to:

- Establish and identify verification procedures for their HACCP plan.

METHODS OF INSTRUCTION

- Lecture
- PowerPoint presentation
- Trainee activity

LESSON PLAN

Learning

- Verification procedures

Activity 11

- Verification procedures

LESSON PLAN: **LEARNING**

Verification procedures

UNDERSTAND

Verification procedures[5]

- Once the HACCP plan is implemented, it is necessary to evaluate its effectiveness. Similar to the concept introduced in Step 5, the methodologies established in previous steps must now be verified.
- The purpose of verification is to ensure that the plan is working to control quality and ensure safety.
- Establishing verification procedures is the sixth principle of HACCP and the eleventh step in the process.
- This step should be carried out initially upon implementation and then any time there are significant changes in the operation, in order to confirm the plan's continued effectiveness.

EXAMPLE

Types of verification[2]

- Verification procedures may be thought of as an internal audit of HACCP procedures. There are three types of verification: validation, ongoing verification, and reassessment.
  - **Validation:** This is the initial phase in which the theoretical plan is actually conducted. The decisions that have been made while formulating a HACCP plan must now be tested to ensure that they are effective and appropriate for the specific HMB.
  - **Ongoing verification:** This is done periodically or randomly to ensure the plan is carried out and effective on a day-to-day basis.
  - **Reassessment:** This is applied when any changes are made to the operation that could affect HACCP plan functioning or there are any breaches of quality. Like validation, it looks at the plan effectiveness in general.

UNDERSTAND

Standardized verification[9]

- Verification may start with reviewing existing research and best practices for controlling hazards in an HMB. Ultimately, milk banks must verify that their methods, procedures, tests, and equipment are optimal for their location.
- For example, there are no internationally standardized screening tools or guidelines for screening donors. There is consensus among the guidelines for donor screening that screening must be performed, yet the procedures and tests differ according to the local prevalence of infectious disease and support resources available to the HMB. Considering this variation, milk banks that are being established can use research and expert opinion to adapt screening tools from existing HMBs. However, these tools must be validated by evaluating their effectiveness in the new setting.

EXAMPLE

Verification procedures[1,5]

- Inspection of physical operations, including storage, transport, and processing.
- Observation of personnel involved in different stages of processing.
- Review of records and analysis of deviations.
- Confirmation that CCPs are kept within critical limits.
- Validation of critical limits.
- Calibration of instruments used for monitoring.
- Validation of screening tools.
- Review of corrective action effectiveness.
- Review of consumer complaints.

LESSON PLAN: **ACTIVITY 11**

Verification procedures

UNDERSTAND

- The objective of Activity 11 is to write the verification procedures that will be used in your setting and then use that procedure to verify your HACCP plan.
- For this activity, please work as a team to complete Activity 11 table found in your workbook. Refer to Appendix 13 for additional resources.
- The verification flow sheet should identify the type of verification, responsibilities of HACCP team members, and frequency of verification.
- Begin by considering each CCP, identifying the various tools and methods used to control the hazard, then establish how these tools and methods can be verified.
- Have a discussion with your team about appropriate verification procedures, then begin to review national guidelines and published recommendations for best practices in HMBs. Please refer to Appendix 11 for an example verification procedure table.
- As is possible, begin the process of carrying out these written verification procedures, depending on the operational capacity of your site.

ACTION

Answer the following questions to complete the activity

- Which parts of your HACCP plan need verifying? How will you verify them?
- Are there any parts that cannot be verified at this time? What is your plan for their verification?
- What will be the frequency of these verification procedures?
- Whose responsibility is it to carry out each of these verification procedures?

ACTIVITY 11 TABLE. VERIFICATION PROCEDURES.

PROCESS STEP	CCP	HAZARD	VERIFICATION: TYPE, FREQUENCY, RESPONSIBILITY

Queen Charlotte's and Chelsea Hospital Milk Bank, London, United Kingdom)

STEP 12

STEP 12

Establish a record-keeping and documentation process.

OBJECTIVES

By the end of this step, you will be able to:

- Establish efficient and accurate record-keeping systems.

METHODS OF INSTRUCTION

- Lecture
- PowerPoint presentation
- Trainee activity

LESSON PLAN

Learning

- The importance of record keeping and documentation
- Systems for tracking and tracing
- Record-keeping practices and recommendations

Activity 12

- Record keeping and documentation

LESSON PLAN: **LEARNING**

The importance of record keeping and documentation

UNDERSTAND

Importance of record keeping and documentation[2,5]

- To properly demonstrate your HMB's adherence to the HACCP plan, complete HACCP records are needed. Records provide documentation of control at CCPs and can make managers and operators aware of CCPs that are approaching critical limits.
- Establishing record-keeping and documentation procedures is the seventh and last principle of HACCP and the twelfth step in the process.
- Record keeping is applicable to high- and low-resource settings and can include both manual and digital systems of documentation.
- Without proper records and documentation, it is not possible to identify trends toward critical limits that would enable you to make operational adjustments and to take timely corrective action.

LESSON PLAN: **LEARNING**

Systems of tracking and tracing

UNDERSTAND

Systems of tracking and tracing[1-3,9]

- Each HMB is responsible for clinical and quality control, which requires administrative systems of record keeping.
- There is currently no evidence supporting the most effective and efficient tracking and tracing systems, but there is consensus that tracking and tracing of the collection and administration of donations are needed to guarantee the safety of DHM. This means that all donor milk fed to an infant must be traced back to its treatment record and the expression from the original donor mother.
- Software systems developed and used by HMBs can facilitate tracking and tracing, but there are many appropriate methods and procedures. When deciding upon a system for tracking and tracing, the milk bank should consider available resources, such as staff time and money. Implementing effective tracking and tracing methods in HMBs may address safety concerns that create barriers for the expansion of human milk banking and thus potentially increase the use of donor milk.
- Some milk banks make records available to local health authorities. This may include periodic reports of donations, quality control test results, total volume of milk collected, and/or total number of recipients.
- HMBs should, at minimum, be able to produce the necessary documentation when a deviation of critical limits must be evaluated or their organization is being audited. Certain locations have routine sample-location "drills" to ensure the functioning of their tracking and tracing system and to maintain staff training on record recall.

LESSON PLAN: **LEARNING**

Record-keeping practices and recommendations

EXAMPLE

Types of record keeping and documentation[2]

- HACCP plan development and utilization:
  - CCP critical limits
  - Monitoring data and time
  - Monitoring observations and measurements
  - Operator's signature or initials
  - Identification of deviation, if applicable
    - Amount of affected milk in deviation
    - Nature of deviation
    - Description of corrective action taken
  - Reviewer's signature or initials
  - Date of review
  - Results of verification activities
    - Equipment testing and evaluation
    - Date of verification

UNDERSTAND

Tracking from milk donor to infant recipient[6,7,9]

- Donor milk containers should be labeled clearly for identification at all stages. Local authorities should determine the length of time needed to keep records that are critical to the safety and quality of DHM. These records should be confidential and held in a secure place.
- Donated milk must be tracked from the donor through to the recipient hospital. Once milk has been delivered to the hospital or neonatal intensive care unit, record-keeping responsibilities continue with the hospital's medical record. Inappropriately labeled milk cannot be accepted. It is crucial that HMBs only use locations that comply with tracking procedures outlined by the milk bank.

EXAMPLE

Records kept by the hospital or neonatal intensive care unit for each bottle of DHM[9]

- Name of the recipient
- Date of birth of recipient
- Date of administration
- Batch number
- Condition of the donor milk on arrival following transport
- Storage conditions

- When possible, the health outcome of the recipient.
- Additional monitoring may include records of:
  - Refrigerator and freezer temperatures
  - Pasteurization processes (heat treatment, time)
  - Stock control
  - Bacteriological test results by batch

EXAMPLE

Records kept by the HMB for each batch of donor milk[9]

- The donor:
  - Donor ID
  - Consent
  - Donor screening forms with relevant medical history and results of serological tests
- The container, pre-pasteurization:
  - Donor ID
  - Date of expression
  - A testing log, including the tests undertaken and their results
- The container, post-pasteurization:
  - Samples making up the batch
  - Batch number
  - A testing log, including the tests undertaken and their results
  - Pasteurization details, including date of the pasteurization
  - Instructions to keep frozen and use within 24 hours (if defrosted)
  - An expiry date (no later than six months from expression)

LESSON PLAN: **ACTIVITY 12**

Record keeping and documentation

UNDERSTAND

- The objective of this activity is to identify what record-keeping procedures and documentation will be used in your HMB to appropriately catalog HACCP plan utilization.
- For each process step, consider the documentation that will be necessary to accurately track and trace donor milk from collection at your HMB to allocation to infants in the hospital. Please refer to Appendix 13 for recommended resources. Your HACCP team will have to create these documents or find examples of record-keeping documents found at other HMBs and adapt them to your own needs.

- Begin by having a discussion about record keeping with your HACCP team.
- Next, review national guidelines and published recommendations for best practices in HMBs. Please refer to Appendix 12 for an example of documentation required for recording information at each CCP as well as example labeling forms for DHM.

ACTION

Answer the following questions to complete the activity:

- Does your milk bank have access to automated tracking software? What other systems are available?
- How will your milk bank track information specific to CCPs?
- What information will be placed directly on bottle labels and what information will be filed away?
- What is the most appropriate location to keep each document?
- Who will create these documents?
- How will your HMB coordinate with the hospital in managing records?
- Who will be responsible for maintaining these records? How will this person be accountable?

ACTIVITY 12 TABLE. DOCUMENTATION AND RECORD KEEPING.

PROCESS STEP	CCP	HAZARD	REQUIRED DOCUMENTATION

Section C:
Review of the HACCP workshop

OBJECTIVES

By the end of the section, you will be able to:

- Feel prepared to implement your HACCP plan in your setting.
- Understand the next steps you should take in implementing your HACCP plan.

LESSON PLAN

Learning

- HACCP explained

Closing remarks

Implementing your HACCP plan

UNDERSTAND

Next steps for your HMB

- Now that you have finished the workshop and have a better understanding of HACCP, it is up to you to be a valued HACCP team member.
- By applying the HACCP principles learned in this training workshop and using the site-specific HACCP training plan created during each activity, your HACCP team can help improve and ensure systems of safety and quality at your HMB.
- As you begin to implement your HACCP plan, remember to review and adjust your plan as necessary. Adjustments are needed in your HACCP plan when there is:
  - Loss of control in a CCP.
  - Changes have been made in the HMB processing plan.
  - New equipment is introduced in your facility.
  - New individuals join your HACCP team.

Closing remarks

UNDERSTAND

Summary of workshop

- This workshop was intended for new and existing HMBs to gain a better understanding of HACCP and to facilitate the development of a site-specific HACCP plan that will meet local needs.
- We hope that the instruction and examples provided you the necessary tools and knowledge to complete each activity and leave this workshop with a finalized HACCP plan specific to the needs of your HMB.

Section D: Appendices

APPENDIX 1. EXAMPLE HACCP TEAM.

HUMAN MILK BANK ROLE	SKILLS/STAFF	CREDENTIALS
HACCP leader	Head neonatologist	M.D.
Milk safety specialist	Microbiologist	M.S.
Pasteurization technician	Nursing	R.N.

APPENDIX 2. EXAMPLE OF PRODUCT DESCRIPTION.

PRODUCT NAME	DONOR HUMAN BREAST MILK
Physical state (frozen solid, liquid)	Frozen on arrival, thawed to liquid according to procedures (in refrigerator no longer than 4–8 days)
Color	White to yellowish cream
Container	Food-grade plastic bottles with sealed lids
Packaging in transport	Insulated, rigid container; dry ice allowable
Shelf life	Raw: 12 months Pasteurized, frozen: 12 months Pasteurized, defrosted: 24 hours
Labeling on storage container	Name of donor, date of collection, pasteurization, date of pasteurization, donor's number, identification of bank, date of freezing, batch number
Bacteriological characteristics	Pre-pasteurization: No Enterobacteriaceae or Staphylococcus aureus; Post-pasteurization: 0 CFU/µL

APPENDIX 3. DEFINITION OF CONSUMER: INDICATIONS FOR DHM AND PRIORITIZATION.[7]

Weight	Less than 1,500 g (very low birth weight)
Gestational age	Less than 37 completed weeks of gestation
Disease state/condition	History of necrotizing enterocolitis, feeding intolerance, etc.
Other indicators	Physician order, infants without access to mother's own milk, infants with mothers who have a contraindication to breastfeeding (medication, illness), infants taking enteral nutrition
Prioritization for allocation of DHM	1. (First priority) Premature infants who are sick. 2. Premature infants who are well. 3. Infants 0 to 12 months old with medical conditions likely to respond to DHM therapy. 4. Children older than 12 months with medical conditions likely to respond to DHM therapy. 5. Research contracts for clinical use in well-designed studies. 6. Children older than 12 months with chronic medical conditions and high normal functioning and low-dose need to DHM therapy. 7. Children older than 12 months with chronic medical conditions and high-normal functioning and high-dose need to DHM therapy. 8. Children older than 12 months with chronic medical conditions and low-level functioning and low-dose need to DHM therapy. 9. Children older than 12 months with chronic medical conditions and low-level functioning and high-dose need to DHM therapy. 10. Infants for short-term use, no specific medical condition. 11. Laboratory research (milk that cannot be used for human consumption due to contamination).

APPENDIX 4. EXAMPLE FLOW DIAGRAM.

Process Step

1. Donor recruitment
2. Donor screening
3. Milk expression
    - Milk expression at home
    - Milk expression at the HMB
    - Transportation
4. Milk handling
    - Storage
    - Transportation
    - Tracking and tracing
5. Milk processing
    - Thawing and pooling
    - Milk screening: pre-pasteurization
    - Treatment and pasteurization
    - Milk screening: post-pasteurization
    - Fortification
    - Disposal
6. Allocation and recipient prioritization

APPENDIX 5. VERIFICATION CHECKLIST.

PROCESS TYPE	PRESENT IN FLOW DIAGRAM (Y/N)
Step(s) for recruiting donors	
Step(s) for screening donors	
Step(s) for milk expression	
Step(s) for milk handling	
Step(s) for milk processing	
Step(s) for milk allocation and recipient prioritization	

APPENDIX 6. EXAMPLE COMPLETE HAZARD ASSESSMENT.

PROCESS STEP	HAZARD	ORIGIN OF HAZARD (present, introduced, growth, or survival)	ACCEPTABLE LEVEL IN MILK	CONTROL/ PREVENTION	LIKELIHOOD * SEVERITY JUSTIFIED HAZARD= YES/NO
1 and 2. Donor recruitment / selection	Physical: none.				
	Chemical: mother is a smoker or using nicotine replacement therapy.[6,9,11-19]	Present: from mother.	None.	Donor screening: written or telephone questionnaire,[20-22] serologic testing, informed written consent, knowledge from individual conducting screening of donors.[7]	Medium * Medium No
	Chemical: mother regularly uses excessive amounts of alcohol.[9,14,19,23-32]	Present: from mother.	None.	Donor screening: written or telephone questionnaire,[20-22] serologic testing, informed written consent, knowledge from individual conducting screening of donors.[7]	Medium * Medium No
	Chemical: mother uses recreational or habit-forming drugs.[9,14,19,33-38]	Present: from mother.	None.	Donor screening: written or telephone questionnaire,[20-22] serologic testing, informed written consent, knowledge from individual conducting screening of donors.[7]	Low * Medium No
	Chemical: mother is receiving medication or a medical intervention that is contraindicated during breastfeeding, including antidepressants, cytotoxic medication, pharmacologically active herbal products, and exposure to diagnostic radioactive isotopes.[9,10,19,39-55]	Present: from mother.	None.	Donor screening: written or telephone questionnaire,[20-22] serologic testing, informed written consent, knowledge from individual conducting screening of donors.[7]	Low * High No
	Microbiological: mother has a sepsis postsurgery or infant with sepsis postdelivery.[9,56]	Present: from mother.	None.	Donor screening: written or telephone questionnaire,[20-22] serologic testing, informed written consent, knowledge from individual conducting screening of donors.[7]	Low * High No

	Microbiological: mother has tested positive for HIV, CMV, hepatitis B or C, HTLV type I or II, or syphilis.[9,19,56-66]	Present: from mother.	None.	Donor screening[56,61-65]: written or telephone questionnaire,[20-22] serologic testing, informed written consent, knowledge from individual conducting screening of donors.[7]	Medium * High Yes
	Microbiological: mother has a local breast disease such as infective or non-infective mastitis or candida.[9,56]	Present: from mother.	None.	Donor screening: written or telephone questionnaire,[20-22] serologic testing, informed written consent, knowledge from individual conducting screening of donors.[7]	Low * High No
3a. Milk expression at home	Physical: none.				
	Chemical: use of paraffin skin creams unsuitable for ingestion that may contaminate the milk.[67,68]	Introduced: poor hygiene.	None.	Mothers are trained on hygienic expressing of milk,[69-73] including: education on paraffin products that can contaminate milk.[67,68]	Low * High No
	Microbiological: pathogens (E. coli and Staph aureus) introduced through poor hand-washing.[74,75]	Introduced: poor hygiene.	No *E.coli* and *Staph aureus.*	Mothers are trained on hygienic expressing of milk,[69-73] including: general food safety,[76,77] hand-washing,[78-81] use of alcohol rubs.[80,82]	Low * High No
	Microbiological: breast pump that has not been adequately sterilized or used without the appropriate barrier device to prevent exposure to aerosols of milk or water. Example: Staph aureus.[74,75,83-85]	Growth and introduction: poor hygiene practice.	No *E.coli* and *Staph aureus.*	Mothers are trained on hygienic expressing of milk,[69-73] including: general food safety,[76,77] hand-washing,[78-81] use of alcohol rubs,[80,82] use of clean pump kits and bottles and proper cleaning of pump kits,[72,81,86,87] and proper storage of milk.[88-90]	Low * High No
	Microbiological: containers that are not sterilized or become contaminated.[72,74,75]	Growth and introduction: poor hygiene practice.	No *E.coli* and *Staph aureus.*	Mothers are trained on hygienic expressing of milk,[69-73] including: general food safety,[76,77] hand-washing,[78-81] use of alcohol rubs,[80,82] use of clean pump kits and bottles and proper cleaning of pump kits,[72,81,86,87] and proper storage of milk.[88-90]	Low * High No
	Microbiological: expressed milk not refrigerated or stored correctly.[91-93] (Spoilage bacteria)	Growth and introduction: poor storage practice.	Limited amount of spoilage bacteria.	Mothers are trained on hygienic expressing of milk. Freezer and refrigerator temperatures are monitored.[90,94-100]	Medium * Medium No

	Microbiological: bottle not sealed properly.[101,102] (Spoilage bacteria)	Growth and introduction: poor storage practice.	Limited amount of spoilage bacteria.	Mothers are trained on hygienic expressing of milk.[101,102]	Medium * Medium No
	Chemical and Microbiological: incorrect label placed on the bottle.[103] No date available=milk stored for too long. No mother's details=unable to withdraw if a problem is reported by the mother. (Disease, virus, alcohol, smoking, etc.)	Growth and introduction: poor storage practice.	Limited amount of spoilage bacteria.	Mothers are trained on hygienic expressing of milk, including proper labeling of all expressed and stored milk.[10,103]	Medium * Medium No
3b. Milk expression at the HMB	Physical: none.				
	Chemical: none.				
	Microbiological: pathogens (E. coli and Staph aureus) introduced through poor hand-washing.[74,75]	Introduced: poor hygiene.	No *E.coli* and *Staph aureus.*	Mothers are trained on hygienic expressing of milk,[69-73] including: general food safety,[76,77] hand-washing,[78-81,104,105] use of alcohol rubs.[80,82]	Low * High No
	Microbiological: breast pump that has not been adequately sterilized or used without the appropriate barrier device to prevent exposure to aerosols of milk or water. Example: Staph aureus.[74,75,83-85]	Growth and introduction: poor hygiene practice.	No *E.coli* and *Staph aureus.*	Mothers are trained on hygienic expressing of milk,[69-73] including: general food safety,[76,77] hand-washing,[78-81] use of alcohol rubs,[80,82] use of clean pump kits and bottles and proper cleaning of pump kits,[72,81,86,87] and proper storage of milk.[88-90]	Low * High No
	Microbiological: containers that are not sterilized or become contaminated.[72,74,75]	Growth and introduction: poor hygiene practice.	No *E.coli* and *Staph aureus.*	Mothers are trained on hygienic expressing of milk,[69-73] including: general food safety,[76,77] hand-washing,[78-81] use of alcohol rubs,[80,82] use of clean pump kits and bottles and proper cleaning of pump kits,[72,81,86,87] and proper storage of milk.[88-90]	Low * High No
	Microbiological: expressed milk not refrigerated or stored correctly.[91-93] (Spoilage bacteria)	Growth and introduction: poor storage practice.	Limited amount of spoilage bacteria.	Mothers are trained on hygienic expressing of milk. Freezer and refrigerator temperatures are monitored.[90,94-100]	Medium * Medium No
	Microbiological: bottle not sealed properly.[101,102] (Spoilage bacteria)	Growth and introduction: poor storage practice.	Limited amount of spoilage bacteria.	Mothers are trained on hygienic expressing of milk.	Medium * Medium No

	Chemical and microbiological: incorrect label placed on the bottle.[103] No date available=milk stored for too long. No mother's details=unable to withdraw if a problem is reported by the mother. (Disease, virus, alcohol, smoking, etc.)	Growth and introduction: poor storage practice.		Mothers are trained on hygienic expressing of milk, including proper labeling of all expressed and stored milk.[10,103]	Medium * Medium No
3c. Transportation (home to milk bank)	Physical: glass from a cracked glass container.	Introduced: poor handling.	No foreign body contamination.	Mothers are trained on the correct handling and use of milk containers.[106,107]	Low * Medium No
	Chemical: none.				
	Microbiological: milk thaws due to not being properly frozen prior to transport.	Growth: poor temperature control.	Limited amount of spoilage bacteria.	Mothers are trained on correct handling of milk, including proper storage.[78,79,88-90,100]	Medium * Medium No
4a. Milk handling: storage	Physical: none.				
	Chemical: none.				
	Microbiological: expressed milk not refrigerated or stored correctly.[91-93] (Spoilage bacteria)	Growth and introduction: poor storage practice.	Limited amount of spoilage bacteria.	Mothers are trained on hygienic expressing of milk. Freezer and refrigerator temperatures are monitored.[90,94-100]	Medium * Medium No
	Microbiological: incorrect separation of pasteurized and non-pasteurized milk. Possible pathogen or spoilage bacteria presence.	Introduced: incorrect storage practices.	No pathogens and limited amount of spoilage bacteria.	Milk bank staff are trained on correct storage, identification, and separation of pretreated and post-treated milk.[108]	Low * High No
4b. Milk handling: transport	Physical: glass from a cracked glass container.	Introduced: poor handling.	No foreign body contamination.	Mothers and milk bank staff are trained on the correct handling and use of milk containers.[106,107]	Low * High No
	Chemical: none.				
	Microbiological: milk thaws due to not being properly frozen prior to transport.	Growth: poor temperature control.	Limited amount of spoilage bacteria.	Mothers and milk bank staff are trained on correct handling of milk including proper storage.[78,79,88-90,100] Control of temperature is handled through storing in a temperature-controlled container (ice box) and time monitoring.[88,99,100]	Medium * Medium No

4c. Milk handling: tracking and tracing	Physical: none.				
	Chemical: none.				
	Chemical and Microbiological: no label placed on the bottle.[103] No date available=milk stored for too long. No mother's details=unable to withdraw if a problem is reported by the mother. (Disease, virus, alcohol, smoking, etc.)	Growth and Introduction: poor storage practice.	Limited amount of spoilage bacteria.	Milk bank staff are trained on hygienic expressing of milk, including proper labeling of all expressed and stored milk.[10,103]	Medium * Medium No
5a. Thawing and pooling	Physical: none.				
	Chemical: none.				
	Microbiological: poor thawing process (no temperature and time control) leading to bacteria growth (Spoilage bacteria)[101,102,109,110]	Growth and Introduction: poor storage practice.	Limited amount of spoilage bacteria.	Milk bank staff are trained on the correct thawing process.[10]	Medium * Medium No
	Microbiological: poor thawing process where milk container falls over in hot water bath leading to bacteria-containing water (E. coli) contaminating the milk. (Virus)[101,102,110,111]	Growth and Introduction: poor handing practice.	No pathogens.	Milk bank staff are trained on the correct thawing process.	Low * High No
	Chemical and Microbiological: no label placed on the bottle.[103] No date available=milk stored for too long. No mother's details=unable to withdraw if a problem is reported by the mother. (Disease, virus, alcohol, smoking, etc.)	Growth and Introduction: poor labeling / traceability.	Limited amount of spoilage bacteria.	Milk bank staff are trained on hygienic expressing of milk, including proper labeling of all expressed and stored milk.[10,103]	Medium * Medium No
	Microbiological: pathogens (E.coli and Staph aureus) introduced through poor hand-washing.[74,75]	Growth and Introduction: poor hygiene	No *E.coli* and *Staph aureus.*	Milk bank staff are trained on hygienic handling of milk, including proper hand-washing.[78-81,104,105] use of alcohol rubs,[80,82] and use of gloves.[112-114]	Low * High No
5b. Treatment / pasteurization (includes cooling)	Physical: none.[115,116]				
	Chemical: none.				
	Microbiological: pathogens and spoilage bacteria present in milk from prior mishandling of the milk.[102]	Present: in the milk.	No pathogens and limited spoilage bacteria.	The milk is pasteurized / treated to eliminate or reduce the bacteria to an acceptable level.[7,9,10,56,93,110,117-119]	Medium * High Yes
	Microbiological: spoilage bacteria growth due to poor cooling of the milk.[101]	Growth: in the milk.	Limited amount of spoilage bacteria.	The milk bank staff are trained on the correct cooling process.[9,19 2,15,33]	Medium * Medium No

5c. Fortification	(Not applicable to all sites.)				
5d: Milk screening pre-pasteurization	(Not applicable to all sites.)				
5e. Milk screening post-pasteurization (microbiological testing)	Physical: none.				
	Chemical: none.				
	Microbiological: presence of pathogens (Staph aureus and E. coli) due to incorrect or poor pasteurization.	Growth: poor processing.	No pathogens.	The milk is screened to check that the pasteurization process was effective.[7,9,10,56]	Low * High No
5f. Disposal	Physical: none.				
	Chemical: none.				
	Microbiological: none.				
6. Allocation and recipient prioritization (issue of milk)	Physical: glass from a cracked glass container.	Introduced: poor handling.	No foreign body contamination.	Milk bank staff are trained on the correct handling and use of milk containers.[7,9,10,106,107]	Low * High No
	Chemical: none.				
	Chemical and microbiological: no label placed on the bottle.[103] No date available=milk stored for too long. No mother's details=unable to withdraw if a problem is reported by the mother. (Disease, virus, alcohol, smoking, etc.)	Growth and introduction: poor labeling / traceability.	Limited amount of spoilage bacteria.	Milk bank staff are trained on hygienic expressing of milk, including proper labeling of all expressed and stored milk.[7,9,10,103]	Medium * Medium No
	Microbiological: milk is exposed to excessive temperature due to not being properly handled (chilled) prior to transport.	Growth: poor temperature control.	Limited amount of spoilage bacteria.	Milk bank staff are trained on correct handling of milk. Including proper storage.[78,79,88-90,100] Control of temperature is handled through storing in a temperature-controlled container (ice box) and time monitoring.[88,99,100]	Medium * Medium No

APPENDIX 7. EXAMPLE OF CCP IDENTIFICATION USING THE CCP DECISION TREE.

PROCESS STEP	HAZARD	CRITICAL CONTROL POINT (CCP) DECISION TREE				
		Q1	Q2	Q3	Q4	CCP
1 and 2. Donor recruitment / selection	Microbiological: mother has tested positive for HIV, CMV, hepatitis B or C, HTLV type I or II, or syphilis.[2,10,50-60]	Yes: donor screening and serological testing are both used as preventative measures.	Yes: this step in the process is designed to reduce the hazard to an acceptable level.			CCP-1 (B)
5c. Treatment / pasteurization (includes cooling)	Microbiological: pathogens and spoilage bacteria present in milk from prior mishandling of the milk.[96, 102]	Yes: pasteurization is used to eliminate or reduce the bacteria to an acceptable level.	Yes: this step in the process is designed to reduce the hazard to an acceptable level.			CCP-2 (B)

APPENDIX 8. EXAMPLE OF CRITICAL LIMITS FOR CCPs.

PROCESS STEP	CCP	HAZARD	CRITICAL LIMITS
1 and 2. Donor recruitment / selection	CCP-1 (B)	Microbiological: mother has tested positive for HIV, CMV, hepatitis B or C, HTLV type I or II, or syphilis.[9,19,56-66]	No acceptable level of infectious disease by serological testing or as determined by high-risk behaviors.[9,10,120]
5c. Treatment / pasteurization (includes cooling)	CCP-2 (B)	Microbiological: pathogens and spoilage bacteria present in milk from prior mishandling of the milk.[96, 102]	0 CFUs/100 µL[7,10]

APPENDIX 9. EXAMPLE OF MONITORING SYSTEM.

PROCESS STEP	CCP	HAZARD	MONITORING: PROCEDURE, FREQUENCY, RESPONSIBILITY
1 and 2. Donor recruitment / selection	CCP-1 (B)	**Microbiological:** mother has tested positive for HIV, CMV, hepatitis B or C, HTLV type I or II, or syphilis.[9,19,56-66]	**Procedure:** Review of medical records from different health care professionals (primary care providers and pediatricians). Telephone or in-person interview conducted by milk bank staff (milk bank coordinator or the milk bank nurse). Potential donors are asked about:[9,11,13,16-18] • General health and medical history of mother and infant (acute/chronic infections, recent vaccinations, and/or blood transfusions). • Exposure to HIV, toxoplasmosis, tuberculosis, syphilis, hepatitis, rubella, herpes, CMV, and Creutzfeldt–Jakob disease (CJD). • Risky behaviors excluding donors include: ▸ Piercing or tattooing without a throw-away, single-use instrument, or acupuncture not practiced by an authorized medical doctor and without the use of throw-away needles within the six months preceding the donation.[17] ▸ Traveling to the endemic zones for tropical diseases within the three months preceding the milk donation.[17] ▸ Receiving blood products, blood transfusion, or organ transplants within the six months preceding the donation.[17] ▸ In the United States, milk donations are not accepted from women who were in the United Kingdom for more than three months or in Europe for more than five years between 1980 and 1996 due to higher risk of CJD exposure.[9] ▸ Receiving a cornea or dura mater transplant and using human pituitary-derived growth hormone are excluded permanently because of the risk of CJD.[17] • Surgeries and diagnostic or therapeutic interventions must be evaluated for underlying pathology and the presence of blood transfusions.[17] **Frequency:** Potential donors will be screened and tested before milk is accepted by milk bank. Existing donors will be re-screened every three months if they continue to donate. **Responsibility:** A designated nurse in the HMB will collect and review all interview and medical information on potential and current donors. This designated nurse will record the levels at each CCP and determine if the mother is eligible to donate. The HMB supervisor will review all records and confirm the assessment performed by the designated nurse.

5c. Treatment / pasteurization (includes cooling)	CCP-2 (B)	**Microbiological:** pathogens and spoilage bacteria present in milk from prior mishandling of the milk.[96, 102]	**Procedure:** 1. A 200 µL sample of pasteurized milk from each batch is cultured on 5% horse blood and Cystine-lactose-electrolyte deficient agar. 2. Sample is incubated at 35°C in 5% CO2 overnight (18-24 hours). 3. Bacterial growth is identified by standard microbiological techniques and colony growth is also quantified.[6] 4. Milk is discarded when there is any bacterial growth. 5. Pasteurized milk cannot be used until culture results are known.[10] **Frequency:** Post-pasteurization monitoring of milk must occur for every batch of milk.[6,9] **Responsibility:** The microbiology technician will carry out all monitoring procedures and will record all monitoring results. The HMB supervisor will review all records and confirm the assessment performed by the microbiology technician.

APPENDIX 10. EXAMPLE OF CORRECTIVE ACTION PLAN.

PROCESS STEP	CCP	HAZARD	CRITICAL LIMIT	CORRECTIVE ACTIONS
1 and 2. Donor recruitment / selection	CCP-1 (B)	Microbiological: mother has tested positive for HIV, CMV, hepatitis B or C, HTLV type I or II, or syphilis.[9,19,56-66]	No acceptable level of infectious disease by serological testing or as determined by high-risk behaviors	Any positive results on serological tests indicating infectious disease should result in the disposal of any milk from this donor, and the patient should be deferred indefinitely.[7,9,10] Sufficient support should be offered to this donor, including a referral to a health care provider of the woman's choice for confirmatory diagnostic testing and counseling. An investigation should be made into possible inadequacy of the screening tool or services.

5c. Treatment / pasteurization (includes cooling)	CCP-2 (B)	Microbiological: pathogens and spoilage bacteria present in milk from prior mishandling of the milk.[96,102]	0 CFUs/100 µL	1. If culture shows that pasteurized milk contains less than 0 CFU/100 µL:[6,7,9,10] • Label milk ACCEPTABLE and advance (keep records of analysis). 2. If culture shows that pasteurized milk contains 1-5 CFU/100 µL:[6,7,9,10] • Label milk INDETERMINATE and retest two more samples from batch. ▸ If both retests show pasteurized milk contains less than 0 CFU/100 µL: o Label milk ACCEPTABLE and advance (keep records of secondary analysis). ▸ If one or more retests show pasteurized milk contains greater than 0 CFU/100 µL: o Label milk UNACCEPTABLE and dispose of or use in research as applicable (keep records of secondary analysis) 3. If culture shows that pasteurized milk contains greater than 5 CFU/100 µL:[6,7,9,10] • Label milk UNACCEPTABLE and dispose of or use in research as applicable (keep records of secondary analysis).

APPENDIX 11. EXAMPLE OF VERIFICATION PROCEDURES.

PROCESS STEP	CCP	HAZARD	VERIFICATION: TYPE, FREQUENCY, RESPONSIBILITY
1 and 2. Donor recruitment / selection	CCP-1 (B)	**Microbiological:** mother has tested positive for HIV, CMV, hepatitis B or C, HTLV type I or II, or syphilis.[9,19,56-66]	**Type:** Validate screening methods. Review updated donor screening forms used at other HMBs or provided by local regulatory associations. Visually observe staff conducting screening to confirm they are using tools as intended and that possible barriers, such as language, are overcome. Compare information gathered throughout screening with information gathered with serological testing, evaluating inconsistencies. **Frequency:** After the initial validation of screening methods, re-verify any time corrective action is taken or if there are any concerns that the screening tool is ineffective or could be improved. **Responsibility:** Intake staff
5c. Treatment / pasteurization (includes cooling)	CCP-2 (B)	**Microbiological:** pathogens and spoilage bacteria present in milk from prior mishandling of the milk.[96,102]	**Type:** Calibrate equipment used in processing and record this. Ensure lab is correctly conducting bacterial culturing techniques through visual inspection. Do sample testing: compare pre-pasteurization with post-pasteurization microbiological results, noting inconsistencies. Review deviation reports, compare over time. Ensure monitoring records are being filled out completely and at time of observation.[9] **Frequency:** Initial validation, with ongoing verification when CCPs change, equipment changes, there are changes in the process or personnel, or after a system failure. **Responsibility:** Lab manager

APPENDIX 12A. EXAMPLES OF LABELING FORMS.[7]

Donor number: _____	Use before: _____
Expressing date: _____	Freeze date: _____
Pasteurisation date: _____	Batch no: _____

Recipient name: _____

Number: _____

Thawing date: _____ Time of thawing: _____ h _____

Expiry date: _____ Expiry time: _____ h _____

Store for less than 24 hours after thawing

APPENDIX 12B. EXAMPLE OF DOCUMENTATION AND RECORD KEEPING

PROCESS STEP	CCP	HAZARD	REQUIRED DOCUMENTATION
1 and 2. Donor recruitment / selection	CCP-1 (B)	Microbiological: mother has tested positive for HIV, CMV, hepatitis B or C, HTLV type I or II, or syphilis.[9,19,56-66]	Screening form: administrative files. Consent form: administrative files. Donor mothers registration: administrative files.
5b. Treatment / pasteurization (includes cooling)	CCP-2 (B)	Microbiological: pathogens and spoilage bacteria present in milk from prior mishandling of the milk.[102]	Pasteurization lab: lab notebook. Freezer temperature: on outside of freezer.

APPENDIX 13. CONTACTS AND RESOURCES.

REGIONAL ASSOCIATION	COUNTRY	REFERENCE GUIDELINE
Human Milk Banking Association of North America (HMBANA) https://www.hmbana.org/	United States and Canada	Human Milk Banking Association of North America (HMBANA). "Guidelines for the Establishment and Operation of a Donor Human Milk Bank." 2015.
https://www.hmbana.org/publications		
European Milk Banking Association (EMBA) http://www.europeanmilkbanking.com/	United Kingdom	Centre for Clinical Practice at NICE (UK). "Donor breast milk banks: The operation of donor milk bank services." 2010. https://www.nice.org.uk/guidance/cg93
	Italy	Arslanoglu S, Bertino E, et al. Guidelines for the establishment and operation of a donor human milk bank. Italian Association of Human Milk Banks (Associazione Italiana Banche del Latte Umano Donato). The Journal of Maternal-Fetal & Neonatal Medicine. 2010; 23(S2):1–20.
	France	Marimbert J. The Director General of the French health care products safety agency: considering the public health code and especially article L.2323-1, L. 5311-1 (8) and R. 2323-1, 2, 3, 4 Decrees. December 2007.

	Switzerland	Frishknecht K, Walchli C, Annen V, Fuhrer T, Gianoli P, Stocker M. Recommendations pour l'organisation et le fonctionnement d'une banque de lait en Suisse. Paediatrica. 2010; 21(4): 24–28.
	Sweden	Polberger S, Bonn S, Domelloff M, et al. Guidelines for use of human milk and milk handling in Sweden. Milknet, version 2.0; 2001. English Translation: 2013.
	Norway	Study on the operation and organization of human milk banks. Utredning om drift og Organisering av morsmelkbanker. IK-2760. Oslo: January 2002.
Programa Iberoamericano de Bancos de Leche Humana (Ibero-American Network of Human Milk Banks) http://www.iberblh.icict.fiocruz.br/	Brazil, national and regional guidance for outreach countries	Banco de leite humano: funciona-mento, prevancao e controle de riscos/Angencia National de Vigiancia Sanitaria. -Brasilia, Anvisa; 2008.
South Africa	South Africa	Human Milk Banking Association of South Africa (HMBASA). Guidelines for the operation of the donor human milk bank in South Africa. Best practice for the collection, storage and handling of human milk. Compiled 2008, updated 2011.
	South Africa	Milk Matters. South Africa. Operational guidelines: the operation of donor milk bank services. Developed by the Management Committee of Milk Matters. Updated 2014.

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