THE TECHNICAL GUIDELINE

FOR ESTABLISHING AND OPERATING HUMAN MILK BANKS

VIETNAM, 2021

Ministry of Health

_____

No: 2394/QĐ-BYT

Socialist Republic of Viet Nam

Independence - Freedom - Happiness

Ha Noi, May 14, 2021

DECISION

Approval of "The technical guideline for establishing and operating Human Milk Banks"

_____

THE HEALTH MINISTER

Pursuant to the Government's Decree No.75/2017/ND-CP dated June 20, 2017, defining the functions, tasks, responsibilities, and organizational structure of the Ministry of Health.

Pursuant to the Government's Decree No. 100/2014/ND-CP dated November 06, 2014, regulating the trading and use of nutrition products for infants, feeding containers and teats.

Pursuant to the Circular No.38/2016/TT-BYT dated October 31, 2016, of the Health Minister regulating measures for breastfeeding promotion at health facilities.

At the request of Director of Department of Maternal and Child Health, Ministry of Health.

DECIDES

Article 1. To approve "The technical guideline for establishing and operating Human Milk Banks" attached to this Decision.

Article 2. The document "The technical guideline for establishing and operating Human Milk Banks" is the basis for the implementation of health facilities providing maternity and newborn services.

Article 3. The Decision takes effect from the date of signing, promulgating.

Article 4. The Chief of the Ministry Office, Director of the Department of Maternal and Child Health, Director of the Medical Services Administration, Director of related Departments of the Ministry of Health, Directors of Provincial Departments of Health, Heads of related agencies are responsible for implementing the Decision./.

Recipients*:*
- As per Article 4.
- The Health Minister (for reporting).
- The Deputy Ministers (for cooperating direction).
- The Website of the Ministry of Health.
- Hospitals providing maternal and newborn care under line management of the Ministry of Health
- Saved at: Admin, Maternal and Child Health Department

On behalf of The Health Minister

Deputy Health Minister

Nguyen Truong Son

List of Abbreviation

MOH	Ministry of Health
CFU	Colony-forming unit
EENC	Early essential newborn care
HACCP	Hazard Analysis and Critical Control Points
HTLV	Human T-lymphotropic virus
KMC	Kangaroo mother care
HMB	Human milk bank
NICU	Neonatal intensive care unit
DHM	Donor human milk
PDHM	Pasteurized donor human milk
SOP	Standard operating procedure
DOH	Department of Health
CDC	Center of Disease Control and Prevention
WHO	World Health Organization

Table of Contents

PART I: Overview of a Human Milk Bank

- Human milk provides optimal nutrition for infants and child development. The World Health Organization (WHO) estimates that human milk is a solution to prevent more than 800,000 deaths per year (13% of all deaths) among children under five years old. However, many infants are unable to receive their mother's own milk. Infants who cannot access breastmilk are more vulnerable, especially when they are preterm, underweight, orphaned or severely malnourished.
- For vulnerable infants, many benefits of donor human milk (DHM) have been proven, namely reducing the risk of sepsis, and necrotizing enterocolitis, increasing absorption and digestion, reducing the length of stay in the neonatal intensive care unit (NICU) with significant savings in costs and human resources for the public health system. Given the benefits of DHM to infants, WHO recommends that the best source of nutrition for infants when mother's own milk is not available is pasteurized donor human milk (PDHM) from human milk banks (HMB) where accessible.
- The first HMB in the world was established in 1909 in Austria. Currently, there are more than 700 HMBs worldwide. Brazil is considered a pioneer with more than 220 HMBs of various scales.

I. Definitions

1. Human Milk Bank

A Human Milk Bank is established in the health facilities providing maternal and newborn care to mobilize human milk donation from nursing mothers, screen donors, collect and pasteurize the raw DHM, then distribute and manage the use of PDHM. This process ensures all newborns are able to access human milk for their optimal health.

2. Satellite Human Milk Bank

- A satellite human milk bank is established in the health facilities connecting to a HMB to mobilize human milk donation form nursing mothers, screen donors and collect and deliver raw DHM to a HMB for pasteurizing. After receiving PDHM which meets all screening criteria (qualified) from HMBs, the satellite HMB distributes for use.
- A satellite HMB does not pasteurize DHM.

3. Human milk donor

- A human milk donor is a nursing mother who voluntarily donates her breast milk to the HMB after being screened and recruited. Donors receive no payment or compensation.

4. **Donor human milk**

- Human milk is expressed to donate, stored according to HMB regulations and distributed to other mothers' children.
- Fresh-raw milk: Human milk expressed within 24 hours, stored in a refrigerator at 7°C or below.
- Fresh-frozen milk: Unpasteurized human milk frozen at -20°C or below, not exceeding three months from the date of expression.
- Pasteurized donor human milk: After being pasteurized at 62.5°C for 30 minutes, the human milk is rapidly cooled to 4°C then stored in a freezer at -20°C or below.
- Pooled milk: Human milk from multiple donations of the same donor can be pooled together. Human milk of multiple mothers must not be pooled.
- A pool of donor milk: A pool of donor milk is human milk from multiple donations of the same mother in the same pasteurization batch.
- A batch of milk pools: A batch of milk pools is the whole milk batch including pools of multiple mothers for pasteurization.

5. **Donor human milk depot**

- The area is fully equipped with clean breast pumps, milk containers and a refrigerator exclusively devoted to DHM storage purpose.

6. **Pasteurized donor human milk receiving unit**

- PDHM receiving units in the hospital are in charge of receiving and distributing PDHM for newborns and commit to comply with the principles of management, storage and use of PDHM. PDHM receiving units in the hospital include Neonatal department, Neonatal intensive care unit, postpartum departments, etc.

7. **Informal human milk sharing**

II. Informal human milk sharing is breast milk shared from one mother to another mother's children without the safety and control of the HMB process.Goals of a Human Milk Bank

- A HMB supports and promotes breastfeeding by providing safe screened pasteurized human milk for infants who need breast milk and whose mothers are unable to provide it or cannot provide enough.

III. Human Milk Bank Operation Principles

1. The establishment and operation of HMBs are for humanitarian purposes. HMBs

charge a fee to sufficiently cover the costs of establishing and operating the HMB/Satellite HMB but are not for profit.

2. Ensure safety and quality standards.
3. Ensure breastfeeding support which is the foundation of the HMB operation.
4. Ensure human milk voluntary donations.
5. Ensure confidentiality for human milk donors and recipients.
6. Applies Hazard Analysis and Critical Control Points process (HACCP) in all quality control processes.
7. PDHM can be used when microbial culture results meet the requirements of the Guideline.
8. PDHM is only used for purposes including medical staff criteria, training and for conducting scientific research.
9. In order to ensure all information is accurately traced and available when required, the HMB is responsible for the documenting and archiving of all tracking records from donor to recipient.

IV. Human Milk Bank Network Planning

- In order to develop, efficient functioning of the HMB network, and ensure breastfeeding promotion through HMB activities, provincial DOHs could, based on local demands, capability and resources propose the efficient and safe establishment of a HMB. Other hospitals in the region can establish a satellite HMB if the requirements in section VI are met.

V. Preconditions for a Human Milk Bank

1. The hospital is designated as a “Center of Excellence for Breastfeeding” according to Decision No. 3451/QĐ-BYT on August 6, 2019.
2. The hospital implements uninterrupted KMC for at least 80% of preterm and low birth weight infants < 2000g.
3. The hospital commits to allocating financial and human resources to the HMB, including infrastructure, staffing, start up and operating costs.
4. The hospital attains at least Grade 4 in the hospital quality standard, according to Decision No. 6858/QĐ-BYT dated November 18, 2016.
5. All HMB staff must be fully trained and competent in HMB procedures and updated on any change to the HAACP, standards on food safety, standards of practice (SOP) and counselling skills to provide support for human milk donors.
6. The number of high-risk infants in the Neonatal Department of the hospital is over 2000 every year.

VI. Preconditions for a Satellite Human Milk Bank

1. The hospital fully attains Criteria 1-5 (Section V).
2. There are less than 2000 high-risk infants.

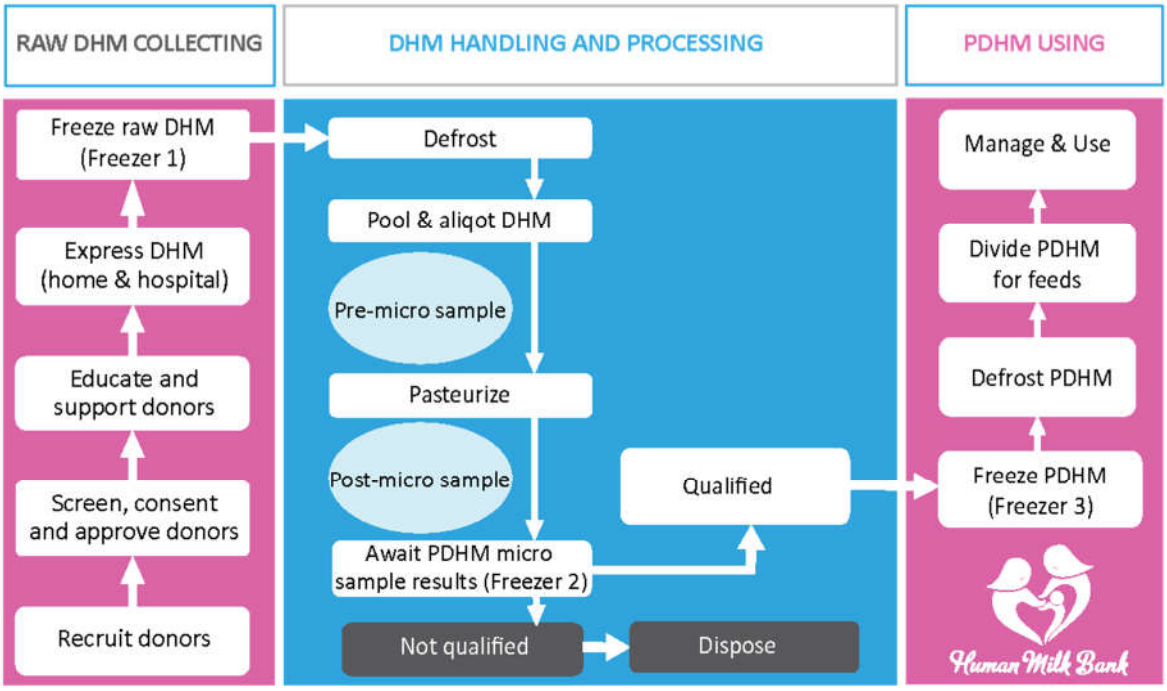
PART II: Human Milk Bank Standard Operating Procedures

- The following diagram shows that the HMB standard operating procedures (SOPs) are divided into three groups:

1. Screening donors and collecting raw DHM
2. Handling and processing DHM
3. Distributing and managing the use of PDHM

- A satellite HMB only implements procedures related to group 1 and 3.

Diagram 1. Human Milk Bank operation procedure



DHM: Donor human milk ▮ PDHM: Pasteurized donor human milk

I. Screening donors and collecting raw donor human milk

Screening to recruit human milk donors is a multi-step process to ensure safety and voluntary participation as a source of DHM for recipients. The process is implemented through the four steps demonstrated in Diagram 2.

1. Mobilizing human milk donors

a. Target groups for human milk donation mobilization

- The priority group for donation mobilization includes:
- Breastfeeding mothers of premature infants' applying KMC in the Neonatal Department where a DHM depot is available.
- Female staff breastfeeding and working for the hospital where the DHM depot is located.
- Breastfeeding mothers with children under 12 months old.
- Mothers giving birth at the hospital with the potential to donate milk.
- As DHM recipients are mainly preterm, low-birthweight or sick infants, breastfeeding mothers with premature infants are in the priority group for mobilizing DHM. Mothers in this category may have a better quality of breast milk which is a similar stage to recipeints and the donors will have had education on human milk expressing, storing and maintaining hygiene .

b. Human milk donation mobilization

- HMB staff or health care workers are trained in mobilizing potential human milk donors.
- Staff of the Department of Social Work or members of Youth Union coordinates with the HMB staff to mobilize human milk donors from the community through media and social networks.

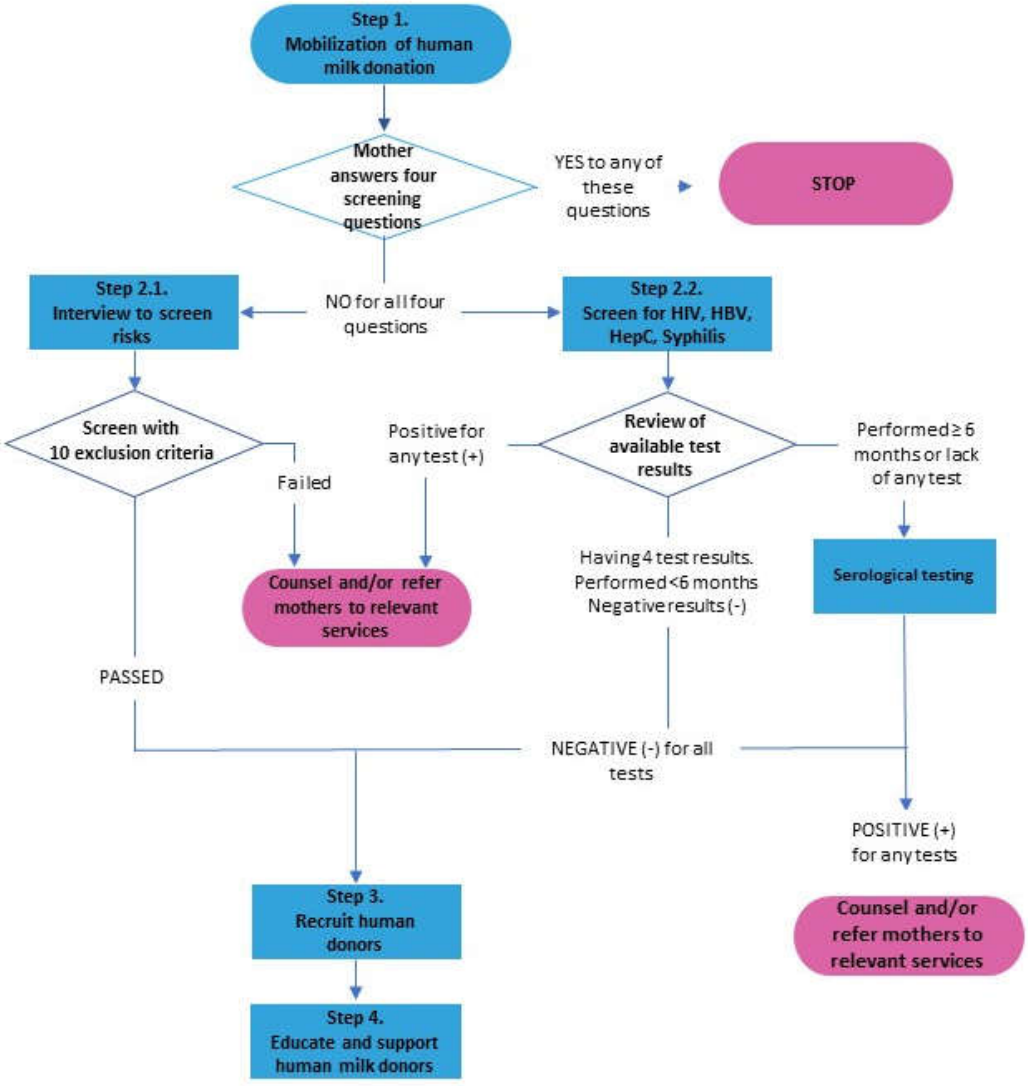
c. Contents of human milk donation mobilization

- Meaning of human milk donation
- Benefits of breastfeeding and importance of DHM for preterm, low-birthweight or sick infants.
- Mechanisms of lactation and maintenance of breast milk supply.
- Relative risks of informal milk sharing without screening and pasteurizing.
- Screening process for human milk donors.
- Safety and quality of PDHM: procedures for handling, storage, and usage.

d. Implementation

- Depending on the target groups, the mobilization of human milk donation may be conducted at health facilities, in the community through face-to-face meetings, group discussions, workshops, webinars, and events or online through Facebook, websites or other mobile apps. The messages for mobilizing human milk donation will be shared via materials including leaflets, videos and posters.

Diagram 2. Steps to screen and recruit human milk donors



2. Screening and recruiting human milk donors

a. First screening for mothers who enroll for donation

- Mothers aged 18 or over and voluntarily enrolling to donate human milk are required to answer four screening questions:
  - Do you smoke/use nicotine replacement therapy?
  - Do you currently drink alcohol including beer?
  - Have you been using drugs or addictive substances?
  - Have you ever tested positive for HIV, hepatitis B, hepatitis C or syphilis?
- Mother is not able to donate milk if she answers "yes" to any of the above questions.

- Mother continues to the second screening if she answers "no" to questions above.

b. Second screening

- The second screening includes the 10 exclusion criteria below (through the Screening Form – BM2, Appendix 4):

i. Have you received blood transfusions, blood products (eg: red blood cells, platelets, plasma, serum ...) or organs transplant (e.g., liver, kidneys, skin, breasts ...) within the past six months?

ii. Have you had a history of treatment for hepatitis B, C, tuberculosis or cancer?

iii. Have you currently used any kind of medication, traditional medicine, addictive substances, chemicals, or been exposed to radiation?

iv. Have you ever tested positive for HIV or hepatitis B or hepatitis C or syphilis?

v. Have you been vaccinated with rubella or MMR (mumps, measles, and rubella) over the last 4 weeks?

vi. Do you currently smoke or use nicotine replacement therapy (gum, transdermal patch, nasal spray, inhaler, sublingual tablets/lozenges, electronic cigarettes…)?

vii. Do you drink more than two units of alcohol per week? An alcoholic unit is equivalent to 1/2 cup of liquor (25ml, 40%), or a small glass of wine (100ml, 12%), or a cup of beer (200ml, 5%).

viii. Have you used any illicit drugs such as opium, marijuana, cocaine, heroin, marijuana, narcotics, ecstasy…?

ix. Over the last six months, have you had unsafe sex (did not use a condoms or other barrier method) with anyone at risk of HIV, hepatitis B, hepatitis C or syphilis infection?

x. Over the last six months, have you had any permanent tattoos?

Mother is not eligible to donate human milk if she answers "**YES**" to any of the above questions.

Mother is eligible to donate human milk if she answers "**NO**" to all above questions.

c. Steps for recruiting human milk donors

- After the second screening, mothers' HIV, hepatitis B, hepatitis C and syphilis test results under 6 months old are reviewed. If the serological test results are ≥ 6 months or missing, complete blood screening for donors.
- When all above blood tests are negative and within the last 6 months, the HMB staff will collect the complete records of the human milk donors, including:
  - Results of the screening questionnaire.

- Results of serological test, including HIV, hepatitis B, hepatitis C, and syphilis.

- Reviewing and selecting human milk donors: The HMB manager will review the results and select the human milk donors based on the selection and exclusion criteria: Signing the donation consent form: After selection, human milk donors, the HMB staff contacts and schedules the donor to sign the consent form for voluntary milk donation and education to support the hygiene practices for milk expression and storage, and maintenance of sufficient milk supply for their own child as well as HMB recipients.
- Recording and maintaining documents of a human milk donor: HMB staff must enter human milk donor information into logbooks, complete and archive the records of donors according to the regulation of DHM tracking.
- Updating maternal health status to inform decisions for suspending or stopping milk donation: During the milk donation period, HMB staff are responsible for discussing with the mothers every three months any concerns, current health status, drug use, and risks identified via Screening Form (BM2, Appendix 4). The HMB manager's decision for suspending/ stopping milk donation is based on the HMB exclusion criteria:
  - Answers "yes" to any of the questions in the Screening Form.
  - Has a positive result for any of the blood screening tests - HIV, hepatitis B, hepatitis C, and syphilis tests.
  - Uses any of the medicines that are contraindications for breastfeeding mothers according to Appendix 1.
  - Has mastitis or abnormalities in or around the breast.
  - Infant is discharged from the hospital and mother is unable to donate her human milk
  - Does not want to continue donating milk for any reason.
- Counsel for mothers who are not eligible for milk donation to:
  - Continue breastfeeding if there are no contraindications.
  - Refer them to the health facilities relevant to the mother's health status.

3. Educating human milk donors

a. Educators

Educators are HMB staff or trained health workers.

b. Contents

Contents for the educating first-time human milk donors:

- Basic knowledge about the importance of breastfeeding and optimal breastfeeding practices.

- Knowledge about the mechanism of human milk production and how to maintain human milk supply.
- Common breastfeeding problems and solutions.
- Support for infant feeding, especially breastfeeding.
- Hand and equipment hygiene practices for human milk expression and storage.
- Instruction for DHM expression and storage at home or at the DHM depots.
- What situations or challenges need to be discussed with health workers/HMB staff during the milk donation period.

4. Expressing, collecting and transporting donor human milk

4.1. Principles

a. Hygiene practices

- All HMB and Satellite HMB staff and health workers perform suitable handwashing and wear appropriate personal protective equipment (medical gowns, hairnets, masks, gloves) before handling DHM.
- Donors are advised to perform adequate hand and equipment hygiene practices for prior to human milk expression and storage.
- All equipment and instruments for handling DHM must be sterilized. Surfaces at the DHM depots, the milk handling room and the milk receiving units must be disinfected and cleaned as part of infection control regulations.

b. Optimal conditions for DHM storage

Place of storage	Storage temperature	Optimal storage time		Note
		Raw DHM	PDHM	
Room temperature	16 - 30°C	Should be stored in the refrigerator/ freezer straight after expression	3-4 hours	Counted from start of storing
Domestic refrigerator	8-15°C	12 hours	12 hours	
Domestic freezer	≤ -4°C	2 weeks	2 weeks	
Refrigerator at the HMB	≤ 4°C	Pasteurize or freeze within 24 hours	Thaw and aliquot within 24 hours	

Freezer at the HMB	≤ -20°C	Pasteurize within 3 months after expression	Use within 6 months after expression	Counted from earliest expressing date

4.2. Storage of fresh raw human milk at the DHM depots

a. Principles

- DHM can be expressed by hand or breast pump.
- Donors should collect expressed breast milk for donation rather than 'drip' milk which is passively collected from one breast while the infant feeds at the other. Breast milk expressed for donation should be refrigerated or frozen as soon as possible to maintain the nutritional and microbial quality. When pooling milk, donors must maintain the temperature of raw pooled milk.
- HMB only accepts raw DHM stored in containers provided by the HMB. Each container should contain maximum 3/4 of the total volume to allow for expansion of the milk when frozen.
- Raw DHM and PDHM must be stored in a different freezer or refrigerator, especially at DHM depots and DHM receiving units.

b. Responsibilities

- HMB or Satellite HMB is responsible for:
  - Providing clean containers for human milk donors at DHM depots or donors' homes.
  - Checking temperature records of refrigerator/freezer on a daily basis at the HMB depots or every two weeks at donors' homes.
  - Ensuring enough breast pumps and clean equipment for donors use.
- Departments/units/health facilities with DHM depots are responsible for:
  - Monitoring and recording the refrigerator temperature as outlined in the SOPs.
  - Providing donors with clean containers for expressing.
  - Instructing donors on the labeling of DHM containers as outlined in the SOPs.
  - Educating and monitoring donors on suitable handwashing, cleaning of breast pumps and DHM containers for collecting human milk for donation.
  - Collecting raw DHM and checking the status of containers as outlined in the SOP before storing in the refrigerators.

- Ensuring the safe delivery of the raw DHM to HMB staff.

4.3. Collecting and transporting DHM to HMB

a. Implementer

HMB/ Satellite HMB staff or trained health workers, volunteers.

b. Principles of implementation

- In hospitals, raw DHM is collected and transported to the HMB daily. The transporting time of raw DHM to HMB is agreed between the HMB and the departments/units within 24 hours from expressing to freezing.
- Outside hospital, 100% of raw DHM must have remained in a frozen state and checked upon arriving at the HMB as outlined in the SOP.
- Raw DHM is transported in insulated boxes.

II. Handling and Processing Human Milk at a Human Milk Bank

After delivering to the HMB, raw DHM is stored in a deep freezer at - 20°C or below.

HMB staff should be trained and competent in processes required and outlined in the SOPs.

1. Thawing

- Slowly thawing milk for 24 hours in the refrigerator at ≤ 4°C.
- Thawed milk is stored in the refrigerator at < 8°C for ≤ 24 hours.
- Do not refreeze thawed milk.
- Do not use microwave to thaw milk.
- Frozen raw DHM should be pasteurized within three months from the date of earliest expression.

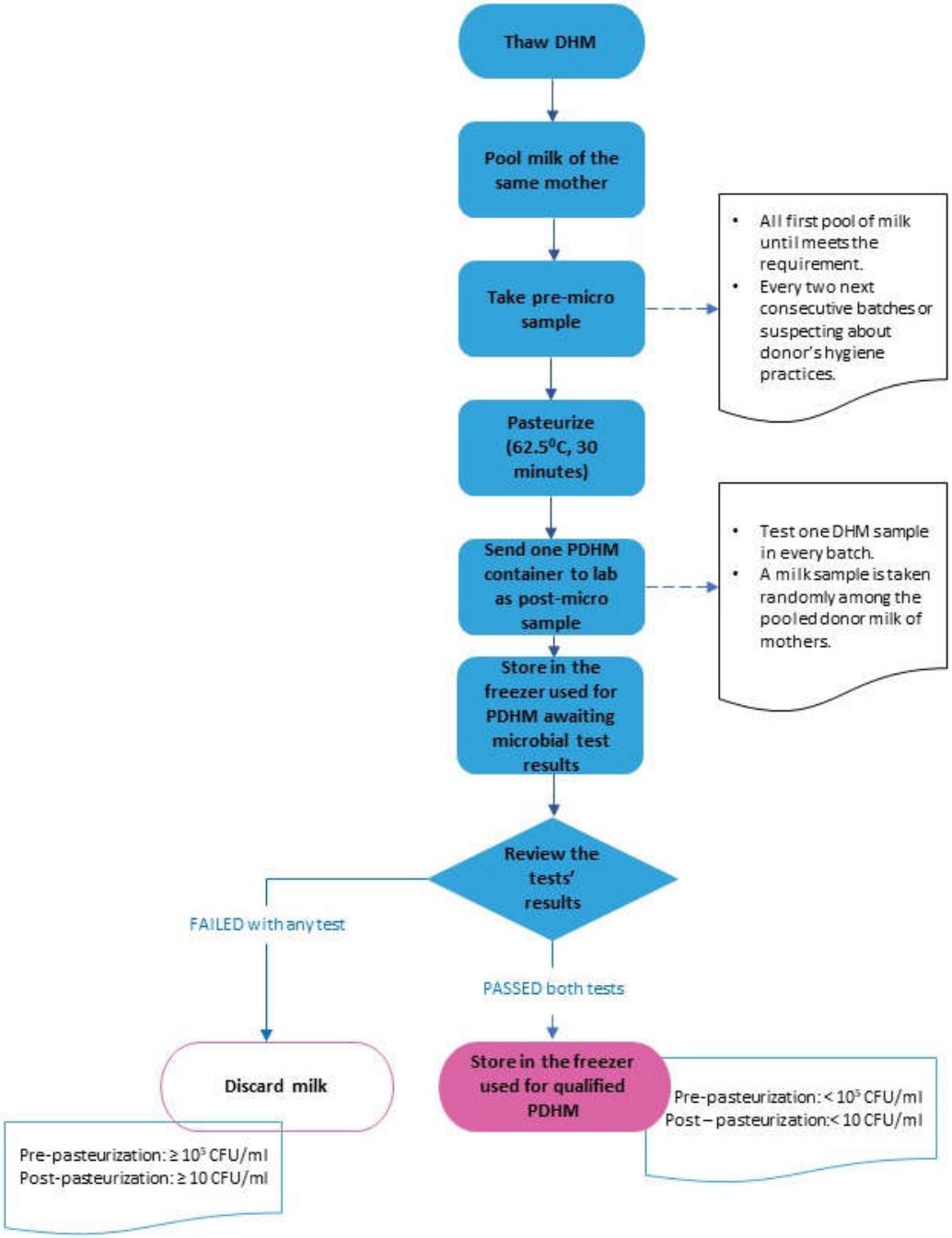
2. Pooling

- Pooling thoroughly thawed milk in a large container with a filter and gently stirring to ensure milk whey completely dissolved.
- Use a biological safety cabinet and apply sterilazation techniques to pool milk .
- Only pool thawed raw DHM from the same donor. It is safe to pasteurize separate milk pools from different mothers in the same batch if clearly identifiable.

3. Pasteurizing

- Milk is heat treated at 62.5°C for 30 minutes then quickly cooled down to 4◦C and frozen. This is the most common method to ensure the microbial safety and retain the immunity quality of DHM.
- A pasteurization batch may consist of milk pools from one or many mothers, depending on the amount of human milk donated by each donor and the need of DHM receiving units. All batches must be clearly identifiable from each other.
- Size and volume of milk containers in a pasteurization batch should be consistent.
- The container temperature during the pasteurization process should be monitored and recorded. A thermometer connected to a probe is secured in a container storing an equivalent amount of water to the largest volume of DHM being pasteurized. This should be placed in the center of the pasteurizer.
- The pasteurization time is counted from the time the milk reaching 62.5°C (+/-0,5^{o}C).

Diagram 3. Steps of handling and processing donor human milk



4. Screening milk

a. Screening DHM before pasteurization

- Apply to the first pool of every donor until qualified. Test a sample after every three pasteurization runs or if there are concerns about the donor's hygiene practices.
- In a pasteurization batch consisting of various pools from different donors, make sure that each pool of donor milk is tested separately.
- Test a pre-pasteurization sample for microbial contamination and discard if samples exceed a count of:
  - 10^5 colony-forming units (CFU)/ml for total viable microorganisms or
  - 10^4 CFU/ml for Enterobacteriaceae or
  - 10^4 CFU/ml for Staphylococcus aureus.
  - Fungi found.

b. Screening DHM after pasteurization:

- Test a post-pasteurization sample per batch.
- Randomly select a milk container from a pasteurization batch.
- Discard all PDHM from the batch if the results of the microbial test are ≥ 10 CFU/mL (according to NICE Guideline 93 of the United Kingdom).
- Label the PDHM container as being used for microbial test and discard the container after receiving results.

III. Distributing and Managing the Use of PDHM

1. Transporting and delivering

- Identify and summarize orders for PDHM.
- Orders for PDHM are sent via e-mail, by phone calls or written forms from PDHM receiving units to HMB. The time and frequency are agreed between HMB and PDHM receiving units (including Satellite HMBs).
- After receiving orders from PDHM receiving units, HMB staff are responsible for:
  - Summarizing PDHM orders.
  - Reviewing the amount of PDHM available in the HMB and informing delivery time to PDHM receiving units.

- Recording in the logbooks and transferring to PDHM receiving units.

- PDHM is delivered to the receiving unit in insulated cold boxes for PDHM only, separated with boxes for raw DHM. PDHM containers are tightly packed with ice gels while transported in a trolley to minimize vibration. When transporting PDHM to PDHM receiving units, the cold box temperature is monitored by thermometer during delivery period. At satellite HMBs, containers must be checked and 100% frozen upon arrival and promptly transferred to the freezer ≤ -18°C.
- When delivering, HMB staff and nurses/midwives of the receiving unit are responsible for checking the milk quality by ensuring the containers have closed caps and are labeled with the recipient child's name, room/bed number, milk volume and expiry date.

2. Thawing

PDHM must be thawed within six months from the date of expression.

Methods for thawing PDHM:

- Slow thawing the frozen PDHM at ≤4°C for 24 hours in the refrigerator at the HMB until PDHM thoroughly thawed for aliquoting. After aliquoting, slowly thawed PDHM is stored at ≤ 4°C in the refrigerator and should be used within 24 hours. After 24 hours from time of aliquoting, thawed unused PDHM must be discarded according to HMB regulations.
- Rapid thawing using boiled water at ≤37°C until PDHM is thoroughly thawed. Rapidly thawed milk is stored at ≤ 4°C in the refrigerator and should be used within four hours since thoroughly thawed. After 4 hours, thawed PDHM must be discarded according to HMB regulations.
- At room temperature, thawed PDHM should be used within 2-3 hours for sick infants in the Neonatal Department and within 3-4 hours for healthy infants.

3. Aliquoting

- PDHM is aliquoted in a biological safety cabinet according to orders and in compliance with the hygiene practice SOPs of HMB. Infant feeding equipment should be handled according to the hospitals' regulations.
- PDHM can be administered by health workers or mothers/caregivers who have receive training in hygiene practices and PDHM use.

4. Indications for the use of PDHM

- Trained doctors, nurses, or midwives in charge of the infant care will prescribe the use of PDHM.

- The use of PDHM is limited to the period when mothers may not have enough milk for their infants. The use of PDHM should stop when the mother's own milk is available or when the HMB runs out of milk.
- The priority for receiving PDHM is as follows:
  - Preterm infants at <32 weeks or infants <1,500 gram in weight.
  - Newborns with complex congenital heart conditions.
  - Newborns with severe illness/after surgery, especially due to gastrointestinal infection.
  - Well preterm or low-birthweight newborns.
  - Full-term newborns whose mothers are human milk donors.
  - Well full-term newborns.
  - Infants under six months old with special medical conditions (cancer, immunodeficiency, heart diseases, gastrointestinal diseases, etc.).
- Where mothers' own breastmilk is unavailable:
  - Mother is absent due to health issues or death.
  - Mother is under treatment with drugs that are contraindications to breastfeeding.
  - Mother is too weak to express milk for her infant.

5. Instructions on the use of PDHM

a. Implementer

Health workers working in PDHM receiving units who are trained in breastfeeding, storage and usage of PDHM.

b. Instruction content

- Risks and preventative measure for feeding infants with PDHM.
- Handwashing practices.
- Practices for safe sterilization of feeding equipment.
- Spoon and cup feeding.
- PDHM storage.
- Circumstances where support from a health workers may be required
- Breastfeeding, mechanisms of human milk production and relactation, including feeding cues and supportive breastfeeding positions before using PDHM.

PART III: Quality Management, Monitoring, Supervising and Reporting Procedures

I. Quality Management

1. Principles

- Ensure all donor information is well documented and archived to allow tracking and traceability of DHM from donors to recipients.
- Apply HACCP principles to all procedures.
- A SOP for each step is developed, approved, and complied by all staff. (Appendix 2: List of HMB SOPs).
- Equipment for milk expression, storage, transportation, handling, and usage should be:
  - Cleaned/disinfected and stored according to hospital regulations.
  - Regularly maintained.
  - Operated as per manufacturers manuals.
  - Checked as per manufacturer's recommendations, especially temperature and limit warning.
- Provide continuous training for all HMB and related staff; training activities should be documented.
- Monitoring compliance of all SOPs and periodic quality control.

2. Tracking and tracing DHM

a. Principles

- Tracking and tracing DHM from donors to recipients.
- Tracing information includes freezer temperature, pasteurization process and expiration date of DHM.
- At all stages, DHM containers should be labeled to identify at what stage they are within the milk bank process (raw DHM, PDHM awaiting microbial test results, ready-to-use PDHM).

- Records are kept at the HMB, Satellite HMB or hospital storage according to medical records requirements regulated by the Ministry of Health. The same principle is applied to digital records.

b. Information Required on DHM labels at each stage

	Information required on the label
Label on raw DHM containers Code: Maa-bbb Expression date: …/…/….	- Unique identifiers of the human milk donor. - Milk status: refrigerated/ frozen, raw, not in use. - Expression date. aa: the last two digits of the year when the mother was approved as human milk donor. bbb: serial number of the approved human milk donor in the year. Ex: A mother who is approved as human milk donor in 2019 will have code M19-001.
Label on PDHM containers (final product of the HMB) SMTT - Đ [ ]; K [ ] *Exp: …/…/…* Maa-bbb-c-dd-eee-gg Thaw at: …h…., …/…/…	- Code of milk container. - Testing results: qualified. - Milk status: frozen, pasteurized and ready-for-use. - Expiration date. c: serial number of the sterilizer. dd: last two digits of the year of the pasteurization batch. eee: the number of pasteurization batch in the year gg: the number of containers of the pasteurization batch. For example: M19-001 is the 15th pasteurization batch in 2021 on pasteurizer number 1. The container code is: M19-001-1-21-15-gg (gg is from 01 to 35, depending on the capacity of the pasteurizer).
Label on thawed PDHM containers Maa-bbb-c-dd-eee-gg Thaw at: ….h, …. /…/… Exp: ….h, …. /…./….	- Code of milk container. - Milk status: thawed, pasteurized and ready-to-use. - Time of thawing start, method of thawing. - Expiration date.
Label on DHM cup/container after aliquoting	- Unique identifier of the recipient (name, department, floor). - Code of milk container.

	Information required on the label
Name of recipients: … Department: … Floor: … Maa-bbb-c-dd-eee-gg Aliquot: ...h, .../.../... Exp: ...h, .../.../... No of ml: ... No of bottle: ...	- Testing results: qualified. - Milk status: thawed, pasteurized and ready-to-use. - Expiration date and time. - Amount of ml in each cup/bottle after aliquoting.

c. Regulations on recording

At the HMB, the following records should be archived for 10 years:

Records	Information to be archived
1. Human milk donor records	- Personal information of the human milk donor. - A signed consent form for voluntary donation. - Results of screening questionnaires. - Results of serological tests.
2. Records for each pasteurization batch	- Information of pooled DHM containers: ID codes of the human milk donors. - Serial number of DHM containers that are pooled for pasteurization. - Number of pasteurization batch. - Results of microbial tests before and after pasteurization (if any). - Information of pasteurization batch, including pasteurization time and temperature (automatically recorded by the pasteurizer). - Discarded DHM due to disqualification.

The units receiving DHM, records of the recipient child should be archived, specifically:

- Recipients' name, date of birth, date of hospitalization.
- Indications for DHM usage.
- Consent form for the use of DHM in Appendix 4.
- Code of DHM containers, quantity and date of usage are documented in the medical records of the recipient.

- PDHM conditions when received from the HMB.
- PDHM storage conditions at the DHM receiving unit.

In the Satellite HMB, records of human milk donors and DHM recipients must be archived. These documents are associated and shared with the main HMB to support track and trace for future reference.

3. HACCP for the operation of a Human Milk Bank

a. Goal

HACCP aims to identify, prevent, eliminate, or mitigate biological, chemical or physical hazards that can happen in the process of milk expression, collection, transportation, storage, handling and distribution, and ensure food hygiene and safety standards.

b. Implementer

Members of the HACCP team will include doctors, nurses, midwives, quality management, microbiology, and infection control personnel.

c. Responsibilities

- Develop HACCP action plan for the HMB and review annually or upon SOP changes.
- Monitor the implementation of HACCP.
- Regularly monitor and verify and the critical control points.
- Assess the effectiveness of corrective actions when the critical control points are outside of agreed control limits.
- Assess the effectiveness of HACCP in preventing hazards.

II. Monitoring

1. Monitoring by the hospital

- Periodic monitoring is conducted in compliance with Ministry of Health's quality control regulations.
- Compliance audit is conducted by each unit on a weekly basis. Where an incident is identified with collection, storage, handling and use of DHM, a daily audit is put in place until compliance and competency is achieved. The audit is conducted by the head of units or assigned staff.
- Quality control audit is conducted monthly by the HACCP team under the direction of the quality control department. Where incidents are identified, this will be more frequently until compliance and competency is achieved.

2. Monitoring by the Provincial Department Ministry of Health

The provincial Department of Health is responsible for an annual inspection of activities within the HMB, including donor screening, DHM storing and pasteurizing, PDHM screening; managing the use of PDHM; storage of records of HMB activities (the quality control checklist in Appendix 3).

3. Monitoring by the Ministry of Health and technical assistance organizations

The Ministry of Health and technical assistance organizations (e.g., FHI 360/ Alive & Thrive…) conduct periodic monitoring/ad-hoc monitoring.

III. Supervising and Reporting

1. Objectives

- Provide routine data and optimize the HMB operation.
- Ensure the safety of HMB operation and compliance with SOPs.
- Ensure the traceability for each DHM sample.
- Provide data for research.

2. Data collecting and reporting

- HMB staff and departments/units collect data with the support of HMB managers.
- HMB staff prepare a monthly report.

3. Lists of forms and reporting criteria

a. Monitoring and surveillance systems consist of 11 forms (Table 2): 01 form for general reporting (BC 1); 03 forms for human milk donors (BM 1 – BM 3), 03 forms for HMB operation (NH 1 – HN 3), and 04 forms for related departments and recipients (KH 1 – KH 4). Details on the contents and instructions for completing the forms are presented in Appendix 4.

HMBs and Satellite HMBs should use the electronic software and ensure these are prevented:

- Issuing a donor's code without valid screening tests and consent forms.
- Pasteurizing raw DHM greater than three months since expression date.
- Using PDHM missing or failing microbial results before and after pasteurization.
- Thawing of PDHM over six months since the expression date.
- Using slowly thawed PDHM out with the 24 hours period of use.

- HMB staff generate monthly data by using template BC1, Appendix 4.

b. HMB quarterly reports to the Department of Medical affairs, annually to the provincial Department of Health and Ministry of Health with the following indicators:

1. Amount of collected raw DHM.
2. Number of human milk donors.
3. Amount of PDHM disqualified due to microbial test before pasteurization.
4. Amount of PDHM disqualified due to microbial test after pasteurization.
5. Amount of PDHM discarded due to disqualification of microbial standards.
6. Amount of qualified PDHM.
7. Amount of used qualified PDHM.
8. Number of infants receiving PDHM.
9. Number of infants with adverse health outcomes after using PDHM.

Satellite HMB has responsibility for reporting indicators 1, 2, 7, 8, 9 to the main HMB.

List of forms

List of forms	Management unit	Related HMB Process / Purpose
BC 1. Monthly report	HMB	Report Information for BC 1 is extracted from BM 1 & 4; NH 1; and KH 2 & 3.
BM 1. Donation mobilization book	Departments & HMB	Mobilize mothers to donate
BM 2. Human milk donor profile logbook	HMB	Screening, consent, approval, education, and health status of human milk donor
BM 3. Logbook of milk donation activities	HMB	Mother's milk donation
NH 1. Milk tracking logbook at pasteurization room	HMB	Collecting, storing, thawing, pasteurization, distribution, discarding, and tracking the amount of DHM at different stages of HMB process

NH 2. Pasteurization batch record	HMB	Thawing, pooling, testing, pasteurizing, and approving PDHM
NH 3. Logbook for milk delivery from HMB	HMB	Transportation and delivery of PDHM
KH 1. Consent form for PDHM use	Department	Use of PDHM in the department
KH 2. Summary sheet of information related to PDHM recipient	Units using DHM & HMB	PDHM use in the departments: summing amount of PDHM needed, recording feeding methods and PDHM fee in recipients' medical records.
KH 3. Logbook of each PDHM container received at the department	Units using DHM	PDHM use in the departments: Monitoring SOP compliance, the amount of milk used, and the recipients.
KH 4. Monitoring the PDHM use in the department	Units using DHM	PDHM use in the departments: Support for nurses calculating the amount of PDHM needed for each feed.

PART IV: Facility, Equipment and Human Resources

I. Facility

1. Location of the Human Milk Bank

- HMB should be located a convenient distance between related departments (pediatrics and neonatology, postpartum, infection control, laboratory), for media and mobilizing activities, and breastfeeding promotion. Where possible, the HMB location should be close to the Neonatal Department.
- HMB area should be sufficient for operational rooms which are well-ventilated and away from infection sources such as the canteen, restrooms and departments with high infection.

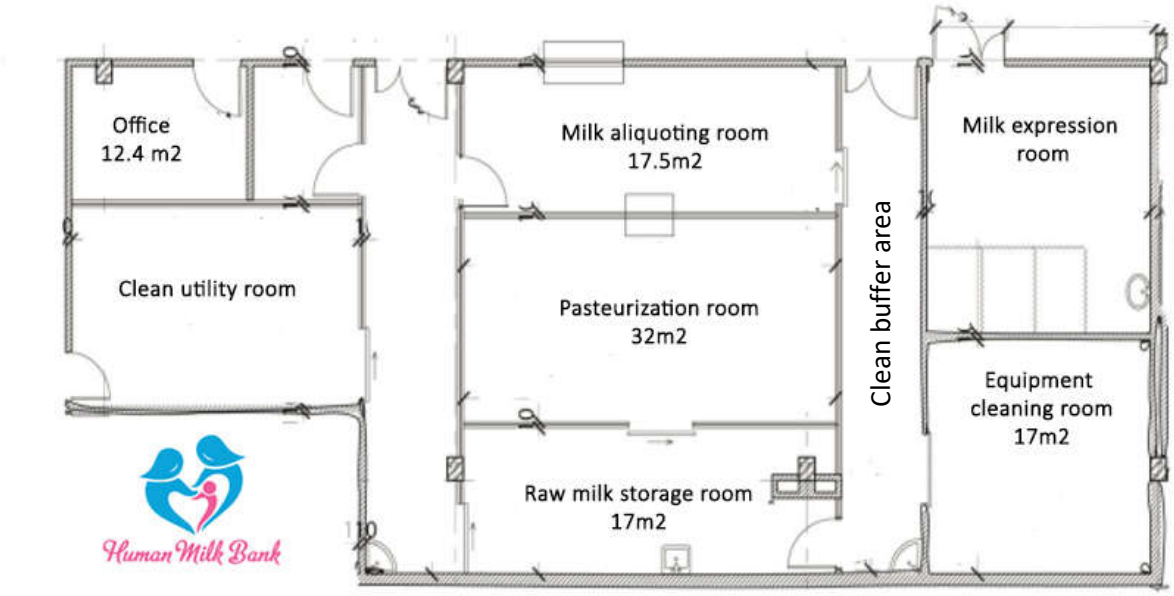
2. Requirements for the operational rooms

- The counseling and milk expressing room is a clean area to conduct breastfeeding counselling, mobilize human milk donation, and express breast milk.
- The room for raw DHM storage, is a clean area to store frozen and thawed raw DHM before pasteurization. There is at least one freezer for frozen raw DHM and one refrigerator for thawed raw DHM.
- The pasteurization room is a sterilized area to handle DHM with a temperature below 25°C. It should be well-ventilated, ideally has both hot and cold-water sources with enough pressure to support a pasteurizer. Surfaces should be made of an easy-to-clean material which are easily maintained and have a handwashing sink and a hatch for delivering clean equipment. The area must be sufficient to contain at least one pasteurizer, two freezers to store DHM awaiting test results and ready-to-use PDHM, one refrigerator for thawed ready-to-use PDHM and one biological safety cabinet for DHM pooling.
- The PDHM aliquoting room is a clean area to aliquot qualified PDHM into containers to deliver to PDHM receiving units. This room must be sufficient to contain one biological safety cabinet and one refrigerator for thawed ready-to-use PDHM.
- The equipment cleaning room is for disinfecting all equipment before transferring and to be sterilized at the Department of Infection Control. The drainage tunnel must be kept clear.
- The clean utility room is for storing equipment and consumable items. There should be a separate entrance to receive clean utilities.

- Clean buffer area: This area is designed to to restrict unnecessary entrance and prevent cross infection within the operational areas where DHM is processed.
- Arrange the operational rooms, entrance, windows to ensure a one-way workflow in the clean and dirty buffer areas. Limit unnecessary entrance to the pasteurization room and clean utility room.

A satellite HMB needs at least two rooms: One for counseling and milk expression and another to store raw DHM, PDHM and to aliquot.

Diagram 4. Sample Floor Plan of a Human Milk Bank



II. Equipment

1. Equipment for storing and handling milk at a Human Milk Bank

a. Deep freezers

- Minimum: 03 deep freezers (01 for frozen raw DHM, 01 for PDHM awaiting microbial test results and 01 for ready-to-use PDHM).
- Minimum technical requirements: Temperature is set to -20° or below, (ideally from -25°C to -30°C). To prevent thermal loss and to monitor the temperature, there should be a thermometer outside of the freezer and an audible temperature alarm.
- Optimal technical requirements: locks, glass windows to prevent unnecessary opening, no sharp edges for easy cleaning.

b. Refrigerators

- Minimum: 02 (01 for thawing frozen raw DHM for pasteurization, and 01 for thawing PDHM before using).
- Minimum technical requirements: Ensure temperature ranges from 2°C to 4°C. To prevent thermal loss and monitor the temperature, there should be a thermometer outside the refrizerator and an audible temperature alarm.
- Optimal technical requirements: locks, glass window to prevent unnecessary opening, no sharp edges for easy cleaning.

c. Pasteurizer

- Minimum: 01, optimal 02 pasteurizers to alternate use in case of incidents.
- Minimum technical requirements: pasteurization capacity of about nine liters per batch. Holder pasteurizer by heating milk at 62.5°C (+/- 0.5°C) for 30 minutes (+5 minutes), then rapid cooling to 4°C (+0.5°C). The pasteurizer must be able to record temperature and be connected to a computer in order to archive pasteurization information. Electricity supply of 220-240V/50Hz.

d. Biological safety cabinet: to prevent human milk from being contaminated from airborne microorganisms when milk is exposed (during pooling, aliquoting and testing before/after pasteurization).

- Minimum: 01, optimal 02 cabinets (01 for pooling milk before pasteurization, 01 for aliquoting milk after pasteurization).
- Minimum technical requirements: Vertical laminar flow hood with low-noise and energy-saving engines. Filter is qualified according to EN-1822 (H14), Europe. Microprocessor control system displays all information on one screen. Stainless steel operating chamber designed with chemical corrosion resistance, easy cleaning and the outside surface covered with antibacterial paint. Electricity supply of 220-240V/50Hz.

e. Electrical supply: HMB needs to have a priority 24/24 electrical supply.

2. Equipment for storing and handling milk at a Satellite Human Milk Bank

Satellite HMB needs at least: 02 deep freezers (01 for raw DHM and 01 for ready-to-use PDHM), 01 refrigerator (for thawing PDHM to aliquot into containers). Ideally all satellite HMB's should have one biological safty cabinet (for aliquoting PDHM into containers).

3. Equipment for expressing raw DHM

- Hospital grade breast pumps: Available in the milk expressing area.
- Individual breast pumps: Human milk donors can borrow individual breast pumps if they do not have one.

4. **Utility washing machine and dryer**

- Utility washing machine: sterilize reusable equipment e.g., inox container for pooling milk, whisks and milk containers, breast pumps parts prior to delivering to Department of Infection Control. A minimum technical requirement: operates at 66-74°C and rinses at 82-91°C.
- Dryer: quickly dries equipment. Minimum requirement: 01.

5. **Equipment for admin work and education/ communication activities**

- Computers, printers, professional label printers to ensure label quality during pasteurization process.
- Television, video, educational leaflets.
- Tables, chairs, shelves.

6. **Other consumables**

- Cleaning detergents and tools to clean surfaces in the operational rooms.
- Handwashing soap.
- Insulated cold boxes and ice gel bags for transporting raw DHM and PDHM. Minimum requirements: 02 separate boxes, one for raw DHM and one for PDHM.
- Milk containers: 130ml and 250ml, thermal-resistant; single-use or reusable.

III. Human Resources

Depending on Human Milk Bank capacity and staffing, the minimum requirements are:

1. **Human Milk Bank manager**

Expertise in maternal, newborn care and breastfeeding and responsible for HMB operation:

- Planning, developing, and participating in HMB activities.
- Monitoring and evaluating HMB procedures and SOP compliance.
- Providing clinical guidelance and coordinate with other departments in the hospital.
- Approve decisions relating to donor screening and recruiting, DHM screening and PDHM use.

2. **Human Milk Bank coordinator**

Equipped with knowledge and skills relating to HMB operational procedures:

- Managing daily tasks relating to the operation of the HMB.
- Directly supervising the HMB SOP compliance.
- Recruiting donors.
- Reporting to HMB manager.

3. Human Milk Bank staff in charge of human milk donors

Performing the following tasks:

- Counseling donors and supporting breastfeeding in the counseling and media room.
- Mobilizing, screening, and recruiting donors.
- Monitoring all procedures relating to donors: Educating and supporting donors in hygiene practices, expressing milk, storing milk and cleaning equipment.
- Collecting and delivering raw DHM to HMB.
- Recording data relating to raw DHM.
- Monthly, quarterly, annual reporting of data to hospitals, Department of Heath, and related agencies.

4. Human Milk Bank staff in charge of handling and processing DHM

Performing the following tasks:

- Thawing, pooling, pasteurizing DHM.
- Transferring pre- and post-pasteurized milk samples for microbial test and monitoring the results.
- Correctly storing PDHM.
- Discarding unqualified PDHM.
- Managing the use of consumables.
- Counseling and supporting breastfeeding mothers
- Documenting, reporting and archiving.

5. Human Milk Bank staff in charge of distributing PDHM

Performing the following tasks:

- Thawing and aliquoting PDHM.
- Monitoring PDHM receiving units.
- Managing PDHM recipients.
- Transporting and delivering PDHM to receiving units and instructing on the correct storage method.

- Counseling and supporting breastfeeding mothers

6. Human Milk Bank assistant

Responsibility for cleaning rooms (if professional cleaning service is not available), disinfecting equipment, sterilizing milk containersand delivering screening tests for donors and DHM.

PART V: Implementation Organizations

I. Ministry of Health

Department of Maternal and Child Health is the focal point to implement and coordinate with the Medical Services Administration on:

1. Chair or collaborate to develop and amend supplemental legal documents in relation to human milk banking; develop technical guideline on human milk banking, submit to the Health Minister or related authorities to approve.
2. Chair or coordinate to evaluate the applications of new advanced technology in HMB in compliance with law.
3. Evaluate the HMB operation in compliance with law.
4. Host the professional committee on technical issues and lead international cooperation and scientific research related to human milk banking.
5. Direct, instruct and build the capacity of HMB staff to ensure professional management and competency.
6. Direct and instruct the implementation of information technology, data analysis and database management in HMB operation.

II. Provincial Department of Health

1. Direct, implement, manage, monitor and evaluate the HMB activities within the province.
2. Estimate annual demand for PHDM in the province based on information from local health facilities; collaborate with related agencies to mobilize human milk donation to ensure adequate PDHM supply for health facilities.
3. Propose, amend, update regulations, instruct and support management team to address challenges experienced by HMB.
4. Produce, analyze, and report data on HMB and satellite HMB operation in the province to the Department of Maternal and Child Health and the Ministry of Health.

III. Health Facilities with a Human Milk Bank

1. Strictly follow Decree 100/2014/ND-CP dated November 6, 2014, on trading and use of nutritioun products for infants, feeding containers and teats; Implement EENC and KMC;

Promote breastfeeding by providing safe and quality PDHM to at-risk infants; Maintain "Center of Excellence for Breastfeeding" designation.

2. Arrange facility and human resources to ensure HMB sustainability.
3. Mobilize human milk donors; provide information on donation, ensure confidentiality of clinical screenings and tests; notify human milk donors of their screenings and test results upon their request.
4. Implement and monitor the practices of HMB technical guidelines and SOPs.
5. Implement quality control for HMB activities.
6. Produce, analyze, report data, and result of HMB to the Ministry of Health, Department of Health.
7. Collaborate with satellite HMBs to:
   a. Provide, transport and storeDHM safely, according to the demands of the satellite HMBs and HMB receiving units.
   b. Provide information about adverse health outcomes by DHM recipients.
   c. Investigate incidents of adverse health outcomes by DHM recipients.
   d. Develop training documents and conduct training on the proper use of DHM as a clinical treatment.
8. Advise authorities about legal framework revision to address concerns raised during HMB operation.

IV. Health Facilities with a Satellite HMB

1. Mobilize human milk donors; provide information on donation, ensure confidentiality of clinical screenings and tests; notify human milk donors of their screening and test results upon their request.
2. Summarize the number of orders and plan PDHM use in line with orders. Also take into consideration the safe transportation of raw DHM to the HMB.
3. Direct and develop regulations, SOPs and guidelines on the use of PDHM in health facilities; organize training for related staff including the use of PDHM according to the approved regulation; monitor the compliance of regulations, SOPs, guidelines in health facilities.
4. Advise authorities about required revision to the legal framework to address concerns raised during satellite HMB operation.

List of Appendixes

Appendix 1. List of donor medication for consideration when donating

Appendix 2. List of standard operating procedures (SOP)

Appendix 3. Quality monitoring checklists

Appendix 4. Monitoring and reporting system

Appendix 1. List of medicines to consider using when donating human milk

Group of drugs	Human milk donation	Breastfeeding
1. Cancer treatment drugs 2. The drug contains radioactive substances	Not suitable	Contraindicated
3. Certain psychiatric and anticonvulsant drugs	Not suitable	Observe recipient child for drowsiness
4. Chloramphenicol, tetracyclines, metronidazole, quinolone (ciprofloxacin) antibiotics	Not suitable	Find alternative medication
5. Sulfonamides, dapsone, sulfamethoxazole + trimethoprim (cotromoxazole), sulfadoxine + pyrimethamine (fansidar) antibiotics	Not suitable	Observe for side effects of jaundice in recipient child
6. Estrogens (including oral contraceptive pills estrogen) 7. Thiazide diuretics, drugs that stimulate uterine contractions		Find an alternative medication as it imay inhibit lactation
8. Most common drugs used as recommended by the manufacturer.		Safe for breastfeeding. High doses should be used with caution.

Please see the details in Appendix 3. Use of medications during breastfeeding. Vietnam National Pharmacopoeia for grassroots-level health facilities published in 2007.

Based on WHO Breastfeeding and Maternal Medication, 2002 documents http://apps.who.int/iris/bitstream/10665/62435/1/55732.pdf

Appendix 2. List of standard operating proedures (SOP)

No.	Standard operating procedures (SOP)	Scope of application
1.	Recording and archiving	HMB, DHM receiving unit
2.	Label regulation	HMB, satellite HMB
3.	Donor mobilization and screening	HMB, satellite HMB
4.	Donor recruitment	HMB, satellite HMB
5.	Hand washing	HMB, Milk expression area, PDHM receiving unit
6.	Preparing and handing empty containers for human milk donors	HMB, satellite HMB, milk expressing area
7.	Milk expression at hospital and at home	Milk expressing area, HMB, PDHM receiving unit
8.	Transporting raw milk from hospital/ community to HMB	HMB, PDHM receiving unit
9.	Thawing milk before pasteurization	HMB
10.	Pooling milk and pasteurization	HMB
11.	Screening milk	HMB
12.	Microbial testing of DHM and PDHM	Scientific laboratory
13.	Microbial testing of DHM	HMB
14.	Indications for PDHM use	HMB
15.	Thawing and pooling PDHM	HMB
16.	Transporting PDHM to receiving units	HMB
17.	Managing the use of PDHM	Satellite HMB, PDHM receiving unit
18.	Equipment cleaning and sterilizing	DHM receiving unit HMB Department of Infection Control
19.	Facilities and equipment maintenance	HMB Department of Infection Control Equipment department
20.	Cleaning functional rooms	HMB Department of Infection Control

No.	Standard operating procedures (SOP)	Scope of application
		Cleaning services company
21.	Internal quality control	HACCP and Quality Control Department
22.	Discarding milk	HMB
23.	Problem detection and solution	HMB, PDHM receiving unit, HACCP team, Quality control department
24.	Pasteurizer operation and maintenance	HMB, Equipment department
25.	Freezer operation and maintenance	HMB, Equipment department
26.	Refrigerator operation and maintenance	HMB, Equipment department
27.	Biological safety cabinet operation and maintenance	HMB, Equipment department
28.	Equipment washing machine and dryer operation and maintenance	HMB, Equipment department
29.	Mini sterilizer operation and maintenance	PDHM receiving unit
30.	Breast pumps operation and maintenance	Milk expression area; PDHM receiving unit, HMB, Equipment department
31.	HMB staff training	HMB, PDHM receiving unit
32.	Transporting raw DHM and PDHM between hospitals	Satellite HMB, HMB

Appendix 3. Quality control checklists

Quality control checklist

Monitoring date (DD/MM/YYYY) ……. /……./…….

Supervisor (*write your full name and sign*) …….

Unit: *Human Milk Bank*

No.	Content	Yes	No	NA	Comment
1	***Facilities/Human resource***				
1.1	Clean functional room with neatly arranged equipment:				
	Pasteurization room				
	Milk aliquoting room (if any)				
	Internal hallway				
	Clean utility room				
	Breastfeeding counseling room				
	Equipment washing room				
1.2	Surfaces for DHM handling are clean, waste is handled as regulated				
1.3	Sufficient quantity of clean and sterile utensils and equipment				
	Milk containers and container caps				
	Appropriate clothes for use in sterile room (gowns)				
	Appropriate footwear				

	Washcloths for working surfaces				
	Set of milk containers, whisks and jugs				
1.4	Equipment is maintained as per schedule and records retained				
	Pasteurizer				
	Biological safety cabinet				
	Refrigerator				
	Freezer				
	Air-conditioner in a sterile room				
1.5	HMB staff when working in the DHM handling room				
	Hand hygiene as per regulations				
	Appropriate protective clothing as per regulations				
1.6	HMB staff				
	Sufficient staffing level to undertake the HMB workload (no pending tasks due to staff shortage)				
	Trained and competent in performing their assigned tasks				
1.7	HMB documents/records are updated and maintained according to regulations				
	Donor record				
	Pasteurization record				

	PDHM recipient tracking book				
	Periodic report				
1.8	Updated guidelines/SOPs are archived for convenient use and reference				
2	***Screening human milk donor records (randomly select three records based on Human milk donor Logbook)***				
2.1	Records contain all the mandatory documents approved by HMB manager				
	Valid test results (6 months from the latest expression date)				
	Screening questionnaires				
	Signed consent form for blood test if required				
	Signed consent form for voluntary milk donation				
	Receipt of raw DHM collection (from home) with complete documentation of freezer temperature, maternal health status and process for transporting DHM				
2.2	Donor selection follows the selection criteria as regulated				
2.3	Donor is trained as required in the regulations and records retained in the donor profile; if meeting face to face, audit training by asking the donor to describe the steps below.				
	Hand hygiene as per regulations				

	Cleaning, sterilizing equipment procedure				
	Milk expression procedure				
	Milk storage procedure				
2.4	Raw DHM quality: where DHM is disqualified, donors are provided further training on hygiene practices for expressing and storing milk.	a			
2.5	Screening questionnaires are updated every three months				
3	***DHM collection, transportation, and storage***				
3.1	HMB staff wash hands as regulated before handling DHM or touching clean equipment				
3.2	DHM is stored in sterilized and labeled containers as regulated				
3.3	Refrigerator/freezer: DHM at different stages are stored separately (raw/pasteurized milk awaiting test results /ready-to-use pasteurized milk).				
3.4	Refrigerator/freezer displays the temperature within the specified range (4 to 6°C for the refrigerator and -20°C to -18°C for the freezer) and has a temperature monitoring logbook (record 2 times/day, 7 days/week and check temperature is displayed as per regulation).				
3.5	Raw DHM/PDHM is transported in a separate cold storage box with a thermometer.				

3.6	Randomly check 3 containers of milk in the refrigerator/freezer and compare with the log books to ensure there is no expired raw DHM and/or PDHM: • In the refrigerator: raw DHM and PDHM are no more than 24 hours. • In the freezer: raw DHM is within 3 months and PDHM is within 6 months from expression date.				
4	**Pasteurization procedure*: (randomly check records of 3 pasteurization batches)***				
	Fully documented, updated and signed for approval				
	Temperature chart shows the qualified temperature during the pasteurization process (62.5^{o}C for 30 minutes then rapid cooling to 25^{o}C within 10 minutes, then cooling to 4^{o}C)				
	Pool milk from one donor for one milk pool (a pasteurization batch can consist of one or more separate pools of milk from many donors)				
	Passed microbial test results - before pasteurization: less than 10^5 CFU/mL				
	Passed microbial test results - after pasteurization: less than 10 CFU/ mL				
	Frequency of microbial tests before pasteurization as regulated (for the first batch of each donor until qualified; then, test every three times of pasteurization).				

	Frequency of microbial tests after pasteurization as regulated (one milk container for one pasteurization batch)				
	Repeat microbial tests as regulated				
5	***Monitoring SOP compliance***				
5.1	Clearly assign SOP compliance monitoring tasks. Assigned staff are well-trained and competent.				
5.2	Regularly monitor SOP compliance				
5.3	Meeting minutes and summary of agreed solutions and improvement plan at least every quarter				

Quality control checklist
Monitoring date (DD/MM/YYYY): ……. / ……./…….
Supervisor (*write your full name and sign*): …….

Unit: *Raw DHM receiving unit*

No.	Content	Yes	No	NA	Comment
1	**DHM hygiene and storage conditions**				
1.1	Clean DHM collection area and keep equipment well-arranged and accessible				
1.2	Sufficient facilities for handwashing. Milk expression and storage containers are sterilized according to regulations				
1.3	Refrigerator/freezer displays the temperature within the regulated range (≤7°C for the refrigerator and ≤-15°C for the freezer) and has a temperature monitoring table				
1.4	Staff in charge of collecting DHM are trained on HMB SOPs				
1.5	Logbook for collecting and delivering DHM is updated as regulated				
2	**DHM expression and storage**				
2.1	Donor is instructed on, hygiene practices for hand washing, milk expression and for storage equipment				

2.2	Audit donors by asking the mother/family member to describe the instructions for procedures below				
	Handwashing				
	Milk expressing and equipment sterilizing				
	Milk expression methods				
	DHM storage				
2.3	*Store DHM and use within regulated time (no more than 24 hours in the refrigerator, no more than two weeks in the freezer. Randomly check three milk containers in the refrigerator/freezer).*				
3	***Monitoring SOP compliance (applied at DHM receiving unit of health facilities)***				
3.1	Clearly assign SOP compliance monitoring tasks. Assigned staff are well-trained and competent.				
3.2	Regular SOP compliance monitoring				
3.3	Meeting minutes and summary of agreed solutions and implementation plan at least every quarter				

In Satellite HMB/PDHM receiving unit

FOLLOW-UP ACTION PLAN AFTER MONITORING

Recommendations for improvement *(Two copies: at the HMB and at Quality Control Department)*

Monitoring date (DD/MM/YYYY): ……. /……./…….

Supervisor (*write your full name and sign*): …….

No	**Priority issues**	**Solutions**	**Person in charge**	**Deadline**	**Progress** (To review at next monitoring)	**Supervisor** (sign)

Quality control checklist

Monitoring date (DD/MM/YYYY): ……. /……./…….

Supervisor (*write your full name and sign*): …….

Unit: *DHM receiving unit*

No.	Content	Yes	No	NA	Comment
1	***Facilities/Human resource***				
1.1	Clean functional room with well-arranged equipment				
1.2	Surfaces for milk handling are clean, waste is handled as regulated				
1.3	Clean and sterilized equipment				
1.4	*Refrigerator/freezer displays the temperature within the regulated range (≤7° C for the refrigerator and ≤-15°C for the freezer) and has a temperature monitoring tracking table (track 3 times/day, 7 days/week and display temperature as regulated)*				
1.5	*Randomly check 3 bottles of milk in the refrigerator/freezer and compare with the tracking books:* *Investigate expired PDHM not used as per regulation* *Used within 24h for slowly thawed PDHM or within 3h for rapidly thawed PDHM.*				

No.	Content	Yes	No	NA	Comment
	Frozen PDHM stored in the freezer is not expired – no more than 3 months from the pasteurization date.				
1.6	Staff wear appropriate protective clothing as regulated in milk handling room (if any)				
1.7	Staff are trained in HMB SOPs				
1.8	Donor milk recipient logbook is updated as regulated				
1.9	Milk aliquoting logbook is updated correctly				
1.0	Updated guidelines/SOPs are stored in an accessible and convenient area for users				
1.11	Randomly check three donor milk recipient records:				
	Check indications for PDHM use in medical records meet regulations and order of priority				
	Completed consent to use PDHM				
	Completed record that allows tracing from donor to recipient				
2	***For recipients (observing clinical practices)***				
2.1	Equipment for infant feeding is cleaned as regulated				
2.2	Mother of PDHM recipient is counselled on breastfeeding and milk expression				

No.	Content	Yes	No	NA	Comment
2.3	Mother/family member of PDHM recipient is instructed on procedures below:				
	Handwashing, feeding preparation				
	Methods for feeding infants with PDHM				
	Cleaning equipment after feeding PDHM				
	Storing PDHM				
3	***Monitoring SOP compliance***				
3.1	Clearly assign SOP compliance monitoring tasks. Assigned staff are appropriately trained and competent.				
3.2	Regularly monitor SOP compliance				
3.3	Meeting minutes and summary of agreed solutions and improvement plan at least every quarter				

Quality control checklist

Monitoring date (DD/MM/YYYY): ……. /……./…….

Supervisor (write your full name and sign): …….

Unit: Microbial laboratory for DHM

No.	Content	Yes	No	NA	Comment
I.	***Facilities/Human resource***				
1.1	Clean operating room with well-arranged equipment				
1.2	Surfaces for milk handling are clean, waste is handled as regulated				
1.3	Sufficient quantity of clean and sterile utensils and equipment				
	Bacterial culture kits				
	Appropriate protective clothing when culturing milk samples				
	Appropriate protective footwear				
	Washcloth for working surfaces				
1.3	Environment is appropriate and meets qualification for the culturing of milk sample according to the department regulations.				
1.4	Equipment is maintained as per manufacturer's instructions and maintenance records retained				

No.	Content	Yes	No	NA	Comment
	Refrigerator				
	Laminar flow hood/ Biological safety cabinet				
	Biological incubator, biological culture cabinet				
1.5	Staff dressed in appropriate protective clothing as regulated when culturing milk sample				
1.6	Staff conducting milk sample culture				
	Adequate staff to undertake the workload of the unit (no pending tasks due to staff shortage)				
	Staff are trained in the principles required for culturing milk sample including hygiene and sterile conditions				
1.7	Documents/records are updated according to regulations				
1.8	Updated guidelines/SOPs are stored in a convenient and accessible area for users				
2	***Performing milk sample culturing (observe procedure to ensure compliance***				
2.1	Preparation: perform all hygiene practices according to the regulations of the department				
	Hand hygiene following all steps				

No.	Content	Yes	No	NA	Comment
	Thoroughly clean biological safety cabinet with a sterile towel				
	Ensure culture utensils and equipment are properly cleaned prior to use				
	Prepared petri dish, distilled water and necessary utensils				
	Record the milk sample number on petri dish				
	Turn on UV following regulations				
2.2	Perform milk sample culturing				
	Hand hygiene following all steps				
	Wear appropriate protective clothing and – sterile gloves				
	Proceed following the correct order: culture pasteurized sample => culture raw milk sample => cultured negative temperature coefficient				
2.3	Clean utensils equipment and biological safety cabinet after culturing				
2.4	No violation of the sterile principles followed in the process of milk sample culturing				
	Ensure good hygiene practice when moving between areas being careful not to transfer dirt or contaminates				

No.	Content	Yes	No	NA	Comment
	from one area to another while cleaning working surfaces				
	Do not handle clean equipment without following hand hygiene/wearing gloves				
	After hand hygiene, do not handle “dirty” tools and equipment				
	When wearing protective clothing do not: touch the outside of the clothing				
	Sterile utensils should not come in to contact with non-sterile equipment				
	Do not touch areas of risk e.g., the top of the container or container cap during milk culture which may cross contaminate the culture				
3	***Monitoring SOP compliance***				
3.1	Clearly assign SOP compliance monitoring tasks. Ensure assigned staff are appropriately trained and competent.				
3.2	Regular SOP compliance monitoring				
3.3	Meeting minutes and summary of agreed solutions and implementation plan at least every quarter				

At Infection Control Department

Quality control checklist

Monitoring date (DD/MM/YYYY): ……. /……./…….

Supervisor (*write your full name and sign*): …….

Unit: Sterilization of utensils and fabrics

No.	Content	Yes	No	NA	Comment
I.	***Facilities/Human resource***				
1.1	Clean operating room with well-arranged and accessible equipment				
1.2	Equipment is maintained as per manufacturer's instructions and maintenance records retained				
	Autoclave machine (Sterilization by steam)				
	Low-temperature sterilizer				
1.2	Staff wear appropriate clothing as per regulations				
1.3	Staff involved in the utensil sterilization				
	Adequate staff to undertake the workload of the unit (no pending tasks due to staff shortages)				
	Staff are trained and competent as regulated				
1.4	Documents/records are updated according to regulations				

1.5	Updated guidelines/SOPs are stored in a convenient and accessible area for users				
2	***Perform relevant procedures***				
2.1	Check cleaned equipment and feedback to relevant departments				
2.2	Package in accordance with the needs of the department				
2.3	Perform sterilization properly as outlined in the SOP				
2.4	Sterilization quality record book				
	Oven test				
	Packaging quality test				
	Delivery of sterilized utensils				
2.5	Monitoring of compliance of expiry date of sterilized utensils in departments (tracking book)				
3	***Monitoring SOP compliance***				
3.1	Clearly assign SOP compliance monitoring tasks. Assigned staff are appropriately trained and competent				
3.2	Regular SOP compliance monitoring				

3.3	Meeting minutes and summary of agreed solutions and implementation plan at least every quarter				

Appendix 4. Monitoring and reporting system

1. Purpose of monitoring, monitoring, and reporting systems

- Provide routine data and to optimize the operation of the HMB.
- Ensure the safety of HMB operation complying with SOPs.
- Ensure two-dimensional traceability for each milk sample.
- Provide data for research (e.g., efficiency, cost…).

2. Overview

- The monitoring system includes 11 forms (**Table 1**): 01 general report form (BC 1), 03 forms related to the donors (BM 1 - BM 3), 03 forms related to HMB operation (NH 1 - NH 3), and 04 forms related to faculties and customers (KH 1 – KH 4).
- Information will be collected, managed, and used by HMB staff and departments with the support of the HMB manager.
- Every month, HMB staff will synthesize monthly reports and send them to the HMB manager.

Table 1. List of forms

List of forms	Update	Management unit	Related HMB Process / Purpose
BC 1. Monthly report	Automatic	HMB	Report Information for BC 1 is extracted from BM 1 & 4; NH 1; and KH 2 & 3.
BM 1. Donation mobilization logbook	Upon activities	Departments & HMB	Mobilize mothers to donate
BM 2. Human milk donor profile logbook	Upon changes	HMB	Screening, consent, approval, education, and health status of human milk donor
BM 3. Logbook of milk donation activities	Upon activities	HMB	Mother's milk donation

NH 1. Milk tracking logbook in pasteurization room	Automatic	HMB	Collecting, storing, thawing, pasteurization, distribution, discarding, and tracking the amount of DHM at different stages of HMB process
NH 2. Pasteurization batch record	Upon changes	HMB	Thawing, pooling, testing, pasteurizing, and approving PDHM
NH 3. Logbook for milk delivery from HMB	Upon changes	HMB	Transportation and delivery of PDHM
KH 1. Consent form of PDHM use	Upon activities	Units using SMHT	Use of PDHM in the department
KH 2. Summary sheet of information related to PDHM recipient	Upon changes and hospital discharge	Units using DHM & HMB	PDHM use in the departments: totalling amount of PDHM needed, recording feeding methods and PDHM fee in recipients' medical records.
KH 3. Logbook of each PDHM container at the department	Upon changes	Units using DHM	PDHM use in the departments: Monitoring SOP compliance, the amount of milk used, and the recipients.
KH 4. Monitoring the PDHM use in the department	Upon changes	Units using DHM	PDHM use in the departments: Supporting nurses to calculatethe amount of PDHM needed at each feed.

BC 1. Monthly report

Human Milk Bank ……Month …… Year 20…

Indicators	Form	Calculation method
0. General information from the hospital:		
0.1. Number of vaginal births		
0.2. Number of cesarean births		
0.3. Number of low-birthweight infants (<2500 g)		
0.4. Number of pre-term infants (<37 weeks)		
0.5. Number of infants in neonatal intensive care unit (NICU). Can be divided into groups of causes (if available).		
0.6. Number of infants born by mothers with HIV/AIDS		
0.7. Number of orphans or abandoned infants		
1. Recruit, screen, and manage donors		
1.1. Number of group meetings	BM 1	Count column 8
1.2. Number of events (more than 10 participants, including mass media, hospital, and community activities)	BM 1	Count column 9
1.3. Number of mothers approached by HMB staff, other health workers, or volunteers (in groups, individuals, events)	BM 1	Summary of column 7, 8, 9
1.4. Number of potential mothers	BM 1	Column 10

Indicators	Form	Calculation method
1.5. Number of mothers starting to donate milk in the month	BM 3	Count as screening form
1.6. Number of mothers ending donation (e.g., over-age children, sick, or ending donation)	BM 3 or BM 4	BM 2: End date, or BM 3: Self-calculate
2. Information regarding the milk receipt, handling, storage, and distribution at HMB. **3.** Milk volume calculated in milliliters (mL)		
2.1. Amount of collected raw DHM (mL)	NH 1.1	Column 2
2.2. Amount of raw DHM for pasteurization (mL)	NH 1.2	Column 2
2.3. Number of pasteurization batches	NH2	Count the number of pasteurized series records
2.4. Amount of PDHM with qualified microbial test (mL)	NH 1.4	Column 2
2.5. Amount of PDHM disqualified due to microbial test (mL)	NH 2	Column 3
- Amount of PDHM disqualified due to microbial test before pasteurization		
- Amount of PDHM disqualified due to microbial test after pasteurization		
- Amount of PDHM disqualified due to microbial test before and after pasteurization		
2.6. Amount of DHM discarded or lost due to various reasons (mL)	NH 1.1, 1.2, 1.3, 1.4.	Column 4; Self-calculate

Indicators	Form	Calculation method
2.6. Percentage of milk discarded (%)		Criteria 2.6, 2.2
2.7. Amount of available PDHM at the time of reporting (mL)	NH 1.1, 1.2, 1.3, 1.4.	Column 5; Self-calculate
3. Information related to the milk usage in the department		
3.1. Number of new infants receiving DHM from the HMB in the month	KH 4	Starting date
3.2. Average duration of PDHM use	KH 4	Starting date and end date, divided by no. of infants
3.3. Amount of used qualified PDHM (mL)	KH 3	Column 8
4. Supporting supervision		
Number of monitoring/support/assessments	Report	Calculate

BM 1. Donation mobilization logbook

Date (1)	Time (minute) (2)	Implementer (3)	Place						Potential (10)
			HMB (4)	Pediatrics/Neonatology (5)	Other (specify) (6)	Personal (7)	Group (8)	Event (9)	

For each audience and mobilization event, write the date, time, and implementer (columns 1-3); location (columns 4-6); and enter the number of attendants in the corresponding column according to the event: column 7 for an individual consultation, column 8 for group consultation, and column 9 for other events. Through the mother's advocacy and commitment, write the number of potential donors in column 10. At the same time, list in BM 2.

At the end of the month, write a summary for columns (4-10) and report the number to HMB staff if it is from other departments. HMB staff produces general data of columns (4-10) to put in the monthly report.

BM 2. Donor profile

SCREENING FORM (Circle the corresponding number to select or fill in the blank)

Date of interview: ……/……/ 20…..

Donor name:……..

Year of birth: ……..

Age:…….; under 18 years old, stop interviewing

Address: House number: …… street:……. , ward :……., District:……City:.....

Mobile phone: ……

Child's birth of date: ……/……/ 20…..

Place of birth: 1) Hospital ……...

2) Other ……..

Child's gestational age at birth: ……. week

Weight at birth: ……. Gram

Delivery method: *1. Vaginal birth 2. Cearean birth*

Who told you about human milk donation? (Multiple choices)

1. Medical staff at the HMB
2. Medical staff at Department of Obstetrics (during pregnancy check-up)
3. Medical staff in the Postpartum Department
4. Medical staff at the Department of Neonatology
5. Other mothers or people
6. Never heard of milk donation

How do you know about human milk donation? (Multiple choices)

1. Posters
2. Leaflets
3. Magazines, Newspaper
4. Events
5. Facebook (Fanpage)
6. Website / Internet
7. Short video
8. Other ……..
9. Not available

Here I would like to ask you for some more information. All information will be kept confidential and will only be used to select donors for milk donation. All information will directly affect the health of your infant and the milk recipient. There are 10 screening questions below:

	Question	**No**	**Yes**
1.	Have you received blood transfusions, blood products (eg: red blood cells, platelets, plasma, serum ...) or transplants of organs (e.g., liver, kidneys, skin, breasts ...) within the past six months?	0	1

2.	Have you had a history of treatment for hepatitis B, C, tuberculosis or cancer?	0	1
3.	Are you currently using any kind of medication, traditional medicine, addictive substances, chemicals, or been exposed to radiation? If yes, please list:	0	1
4.	Have you ever tested positive for any of the following: HIV, hepatitis B, hepatitis C, syphilis? (circle "yes" if positive for any of the diseases)?	0	1
5.	Have you been vaccinated for Rubella or MMR (mumps, measles, rubella) over the last four weeks?	0	1
6.	Currently do you smoke or use nicotine replacement therapy (gum, transdermal patch, nasal spray, inhaler, sublingual tablets/lozenges, electronic cigarettes…)?	0	1
7.	Do you drink more than two units of alcohol per week? An alcoholic unit is equivalent to 1/2 cup of liquors (25ml, 40%), or a small glass of wine (100ml, 12%), or a cup of beer (200ml, 5%).	0	1
8.	Have you used any drugs such as opium, marijuana, cocaine, heroin, marijuana, narcotics, ecstasy…?	0	1
9.	Over the last six months, have you had unsafe sex (without a condom) with anyone at risk of HIV, hepatitis B, hepatitis C or syphilis infection?	0	1
10.	Over the last six months, have you had a permanent tattoo?	0	1
Reviews/comments from screening staff (if any):			

Blood test results (within six months from the screening date):

[ ] Negative for HIV, HBV, HCV and syphilis [ ] Print test result

[ ] Eligible for consent; _____ (full name and signature of screening staff)

CONSENT FORM FOR VOLUNTARY HUMAN MILK DONATION

(Human milk donor reads and signs)

Human milk is the best nutritional source for infants and newborns. Human milk supports their physical and intellectual development and prevents diseases. Human milk is the only food source that contains all the nutrients, factors for growth, anti-inflammatory and immune components. **Mother's milk is the best choice for infants and newborns.**

However, when the mothers own breast milk is not available, donor milk from a Human Milk Bank is the first alternative. Pasteurized donor human milk is **safe** and **does not contain any preservatives**, but **retains almost intact** nutrients, factors for growth and immune components.

I confirm:

1. I am over 18 years old.
2. I will donate the excess milk when my infant has been appropriately fed. I will maintain a healthy lifestyle (e.g., do not use alcohol, tobacco, drugs) while breastfeeding and donating milk.
3. I know that my milk will be stored, handled, and tested to ensure its safety. Health staff will assign donor human milk to the recipients according to the regulations of the Human Milk Bank.
4. I do not expect to receive compensation for milk donation to the Human Milk Bank.
5. I have the right to stop donating milk at any time without affecting the health care for my child and myself.
6. I will talk to Human Milk Bank staff about any health problems while donating. Phone number of the Human Milk Bank is……
7. I understand all information about me, including my medical records and test results, will be kept confidential.

I give the Human Milk Bank permission to use the milk I donate to the newborns who are being cared for in the hospital and do not have mother's own milk.

CONSENSUS	…… / …… / 20……	
	Donor	Health staff
PARTICIPATE IN DONOR EDUCATION	…… / …… / 20……	
APPROVED	…… / …… / 20……	
DONOR CODE		

END OF DONATION …… / …… / 20…..

BM 3. Monitoring logbook of milk donation activities (when using the electronic form, do not use this form because it relates to BM 2 form, and enter the number of donations in electronic form)

ID	**Information about human milk donors**			**Date**			**Donations** (Record date of receipt in the upper line and number of mL below. Expression date is written on the container label)									
	First and last name	Date of birth	Phone number	Screened	Approved	Educated	1	2	3	4	5	6	7	8	9	...
(1)	(2)	(3)	(4)	(5)	(6)	(7)										

Column (1-7) summarized from the Donor Profile (BM 2). Mothers write three lines apart. Write information about the donations horizontally. If more than 30 times, write on the below line.

NH 1. Milk amount tracking sheet at pasteurization room (print in size A4)

- Stick the form on the refrigerator to monitor the milk amount at different stages in the HMB.
- At the end of the month, collate and fill in the monthly report.

Type of cabinet (tick the corresponding code):

NH 1.1. Freezer 1 (Raw milk)	HN 1.2. Refrigerator (Thaw)	HN 1.3. Freezer 2 (Waiting for test results)	HN 1.4. Freezer 3 (Ready to use)

Month …… / 20… ..

Date	**Amount in the cabinet** (mL)	**Used amount** (mL)	**Discarded, lost amount** (mL)	**Available amount in the cabinet** (mL)
(1)	(2)	(3)	(4)	(5)
0				
1				
...				
31				
Total:				

Line 0, column (5): Enter the amount of milk from the end of the previous month.

Columns 2-4, if there are ≥ 2 times of activities, write each time, separated by a plus sign (+): Example 100 + 200.

NH 2. Pasteurization batch record (this form is for legislation, not for tracking purposes)

A. THAWING	Hours, Date	Refrigerator temperature	Implementer
Begin:	…… hour …… minutes; …… / …… / 20…		
End:	…… hour …… minutes; …… / …… / 20…		

Information about thawed DHM:

Donor code	Donor name	Number of bottles	Total mL	Deadline for pasteurization
1.				
2.				
3.				
4.				
5.				

B. POOLING AND ALIQUOTING FOR PASTEURIZATION		
Begin	…… hour …… minutes; …… / …… / 20..	**Requirements:** [ ] The milk is thoroughly thawed [ ] Under laminar flow hood

C. TESTING	Number of samples	Sample code
Before pasteurization		[ ] print test results
After pasteurization		[ ] prints test results

D. PASTEURIZATION	Hour: start: _____ end: _____ [ ] print batch chart	
Batch number: ……..	Number of pools: …….	The total amount of milk: ……. jar; .... mL

Implementer: Signed _____ Full name _____

Date …… / …… / 20…

APPROVAL

Donor code	Bottle number	Total volume (mL)	Approver
Eligible for use:			…… / …… / 20… Signed _____ Full name _____ Comments (if any):
Discard:			

NH 3. Logbook for milk delivery from HMB (each month printed on an A3 paper; this form is for legislation. Can skip this form if file in the electronic form and connected with NH 1.4. and integrated signature)

Month …… / 20…

Date	Neonatology			Other departments		
	Bottle ID (ID_Bo)	No of ml	Sign	Bottle ID (ID_Bo)	No of ml	Sign
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1						
2						
...						
31						

KH 1. Consent form of Pasteurized donor human milk use

Unit: 1) Newborns ……; 2) Postpartum ……; 3) Other …….

Human milk is the best nutritional source for infants and newborns. Human milk supports their physical and mental development and prevents diseases. Human milk is the only food source that contains all the nutrients, factors for growth, anti-inflammatory and immune components. **Mother's own milk is the best choice for infants and newborns.**

However, when mother's own milk is not available, donor milk from a Human Milk Bank is the first alternative. Pasteurized donor human milk is **safe** and **does not contain any preservatives**, and **retains almost intact** nutrients, factors for growth and immune components.

My name is ……. I am the mother (primary caregiver) of ……. I understand that:

1. Donor human milk is **stored, tested, pasteurized, and used according to** the **regulations of Human Milk Bank**.
2. Donor human milk is **safe to use for newborn infants** including those born low-birthweight, preterm and sick. Milk is prescribed by the doctor according to the HMB regulations.
3. **All donors must meet the safety criteria.** They are **healthy, have a healthy lifestyle** (do not use alcohol, tobacco, drugs), have been tested and are negative for HIV, hepatitis B, hepatitis C, and syphilis. All information about the donor, including her health status and test results, will be kept confidential.
4. Donor milk from the Human Milk Bank is limited and may not be enough for all infants in need.
5. The hospital will collect a fee related to the use of donor human milk to pay part of the operation of the Human Milk Bank. This fee is approved by the provincial Department of Health.
6. As the infant's mother I will try to get milk for my infant by expressing 8-12 times in 24 hours.
7. I am over 18 years old. If under 18 years old, it is necessary to have someone older than 18 to sign on your behalf

As explained by the attending doctor, **I agree to use** and **pay fees** for **donor human milk** for my infant in accordance with the regulations of the hospital.

… / …… / 20…

Signature of child's mother or caregiver: Health staff

_____ _____

KH 2. Summary sheet of information related to the PDHM recipient

- When the infant starts receiving pasteurized donor human milk, complete questions 1-12, 13, 14 based on the medical record and retain with the medical record. Enter information via computer to have the children's database updated. (KH 3 and 4).
- Information is updated daily from KH 3 and KH 4 (page 2 of KH 2)
- Write the total amount of used milk from the KH 4 to the corresponding lines on the page (2) daily. The computer automatically fills in the sentences 16-18 when information is not updated from KH 3 and 4.

Unit 1) Neonatology: ……; 2) Postpartum: ……; 3) Others: …….

1. Medical record number: ……	2. Full name of the infant (uppercase): ……
3. Date of birth: …… / …… / 20…	4. Gender: *1. Male 2. Female*
5. Mother's full name: ……	6. Father's full name: …….
7. Address: House number ……, street: ……., ward: ……	
District ..... Province / City .... Mobile phone: ……	

8. Delivery method: *1. Vaginal birth 2. Caesarian sections*

	Date	Diagnosis/condition [1]
9. Hospitalization	…… / …… / 20 …	
10. Enter into the department	…… / …… / 20 …	
11. Transfer to different department	…… / …… / 20 …	
12. Discharge/ Hospital transfer	…… / …… / 20 …	

[1] Enter the information of transfer, discharge with the condition (recovery, serious illness, hospital transfer due to serious illness, etc.) in line the diagnosis of transferring hospitals.

Information related to the use of Human Milk

13. Indications to use pasteurized donor human milk. Multiple choice; collated from medical indications for use:

Infant	Mother
1. Sick and low-birthweight <1,500 kg. 2. Sick and preterm <32 weeks. 3. Severe neonatal disease. 4. Preterm or low birthweight. 5. Full-term newborn whose mother donated DHM 6. Full-term newborn without illness. 7. Infant <6 months with special diseases (cancer, immunodeficiency, heart disease, gastrointestinal disease).	1. The mother is too weak to express milk. 2. The mother is absent due to illness or death. 3. The mother is taking drugs contraindicated to breastfeeding (radioactive substances). 4. The mother does not have milk in the first few days after birth for any reason.

14. Starting date of use: …… / …… / 20 …; 15. End date: …… / …… / 20 …

Summary of usage (Synthesize from the following page for paper form to electronic form):

16. Days of use (count in column 2): …….. day

17. Total of used milk (sum column 3): …….. mL

18. Fee for PDHM (sum column 4): …….. dong

Proposed by	Checked by	Data entry by
Date …… / …… / 201…	Date …… / …… / 201…	Date …… / …… / 201…

Amount of used pasteurized donor human milk by recipient

(1 copy in the medical record and 1 copy at the hospital bed; summarize daily from the starting date of receiving PDHM)

1. Medical record number: …… 2. Full name of the child: …….

5. Mother's name: ..... 3. Date of birth: …/ … / 20… 4. Gender: *1. Male 2. Female*

No. (1)	**Date** (2)	**Total mL** (3)	**Fee** (4)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
…			

No.	**Date**	**Total mL**	**Fee**
26			
27			
28			
29			
30			
31			
32			
33			
34			
35			
…			

In column (2), fully write the first date, the following days can be abbreviated (for example, only insert date, month).

In column (5), record the summary statistics for each payment cycle, for example, for the first seven days, circle lines 1-7 and write the corresponding amount in the last line (line 7).

KH 3. Monitoring book for each PDHM bottle at the department

Using unit: 1) Neonatology …… .; 2) Postpartum: ……. : 3) Other …….

ID_Bo	**Receive**		**Thaw**		**Open**		Milk amount after thawed (mL)	Use: 1. End 0. No	Unused milk amount (mL)	**Name of child - mother** (the pair of child-mother is separated by semicolons)
	Date	Hour	Date	Hour	Date	Hour				
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)

For each bottle, write sufficient information for the column 1-8. Only write date and time once if bottles are received at the same time.
In column (9), enter 1 if fully used, and 0 if not fully used and record the amount of milk that has not been discarded in column (10). Type the name of the child-mother who received milk from the bottle.
At a fixed time of the day, write the date in the ID_Bo column and summary of milk after being thawed (column 8) and unused (column 10) and estimated milk consumption = column (8) - (10).

KH 4. Monitoring the use of pasteurized donor human milk in the department

Unit: 1) Neonatology: …… ; 2) Postpartum: …… ; 3) Others: ……

Starting date: …… / …… / 201…

Child's name (1)	**Mother's name (2)**	**Room Bed (3)**	**Indication**		**Note (6)**	**Feeding time**												**Total PDHM (8)**
			Times **(4)**	ml /time **(5)**		7-8	9-10	11-12	13-14	15-16	17-18	19-20	21-22	23-24	1-2	3-4	5-6	
					Enough BM													
					ml													
					Enough BM													
					ml													
					Enough BM													
					ml													

This sheet is used at the department to help the nurse to calculate the amount of PDHM needed. As an indication in the medical record, fill in columns (1-5 as directed) for each child.

At each feeding time, the nurse asks the mother about the amount of breast milk (whether through direct breastfeeding or expressing). If enough, enter 1, and leave the ml box blank. If not enough, write down the milk amount to be ordered from HMB. Summarize and write in column (8) at the beginning of the morning (before 7:00) and the corresponding in form KH4 for each infant.

Human Milk Bank

BỘ Y TẾ
MINISTRY OF HEALTH

Supported by

Irish Aid
Rialtas na hÉireann
Government of Ireland

alive&thrive
nourish. nurture. grow.