



Minimum Standards for the Establishment and Operation *of Human Milk Banks in Southeast Asia*

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Table of Contents

List of Abbreviations	6
Introduction	6
Definition of Terms	11
SECTION 1: Development of Minimum Standards for the Establishment and Operation of Human Milk Banks in Southeast Asia	12
Background	13
Human Milk Banks: Operational Principles	14
Prerequisites and Readiness for the Establishment of a Human Milk Bank	15
SECTION 2: Minimum Standards for the Establishment and Operation of Human Milk Banks in Southeast Asia	17
ORGANIZATION	18
Organizational structure and staffing	18
Staffing training	19
Facility	20
Location	20
Spatial Requirements	21
Facility maintenance and cleaning	21
Financing	21
Costs	22
Equipment	22
<i>Essential equipment</i>	<i>22</i>
<i>Milk expression</i>	<i>22</i>
<i>Milk storage equipment (containers)</i>	<i>23</i>
<i>Thermal storage equipment (refrigerators and freezers)</i>	<i>24</i>
<i>Pasteurizer</i>	<i>24</i>
<i>Hot air oven/autoclaves</i>	<i>25</i>
<i>Laminar air flow cabinet (Bio-safety cabinet).....</i>	<i>25</i>
<i>Utensils</i>	<i>25</i>
<i>Transportation equipment</i>	<i>25</i>
<i>Dishwasher (optional)</i>	<i>26</i>
<i>Human milk analyzer (optional)</i>	<i>26</i>

DONORS	27
Who are the donors?	27
Prioritization of donor recruitment	28
Promoting and sourcing human milk donation	28
Donor recruitment and selection	29
Donor screening	29
COVID-19 and donor selection	30
Donor physical examination	31
Donor screening—blood tests	31
Donor temporary disqualification	31
Donor exclusion	32
Donor approval	32
Donor education and support	32
Donor code of conduct	33
Donor deferral/duration of donating	33
Donor support after stopping donations	34
DONOR HUMAN MILK	34
DHM collection and storage in hospital	34
DHM collection and storage at the donor's home	35
Transportation of DHM within the hospital to the HMB	35
Transportation of DHM from donor's home to the HMB	36
Receiving DHM at the HMB	37
Hospital milk bank depot storage of raw DHM	37
Processing DHM	38
Thawing DHM	38
Pooling, mixing and pouring DHM	38
Testing DHM before pasteurization	39
Additional tests for DHM	40
Heat processing of DHM	40
Testing DHM after pasteurization	41
Post-pasteurization storage of DHM	41
Labelling of DHM (Table of required labelling)	41

Delivery of PDHM to receiving hospital/NNU	42
Tracking and tracing PDHM including recall	43
Documentation and record keeping in the HMB	44
Procedural and operational records	44
Record keeping by HMB	45
Record keeping by end user	45
Monitoring and Monitoring Team	45
Use of PDHM	46
Selection of recipients	46
Recipient prioritization	47
Recipient parent/guardian consent	48
Fortification of PDHM	48
Home use of PDHM	48
Disposal of PDHM	48
Disaster and emergency response	49
Appendix 1. Making space for human milk banks: Lessons learned from Viet Nam	50
Appendix 2. Lactation support for mothers	53
Appendix 3. Donor consent form template	54
Appendix 4. Additional recommendations for safe collection and processing of donor human milk during the COVID-19 pandemic	55
Appendix 5. Human Milk Banks in Southeast Asia: Minimum standards in monitoring and reporting	56

List of Abbreviations

A&T	Alive & Thrive	LBW	Low birthweight
BFHI	Baby Friendly Hospital Initiative	MOH	Ministry of Health
BMS	Breast milk substitute	MOHS	Ministry of Health and Sports
BPA	Bisphenol A	MOM	Mother's own milk
CFU	Colony forming unit	MMR	Mumps, measles, and rubella
COVID-19	Coronavirus disease 2019	MPHO	Medical product of human origin
DHM	Donor human milk	MRI	Magnetic resonance imaging
EMBA	European Milk Bank Association	MSDG	Minimum Standards Development Group
ELBW	Extremely low birthweight	NEC	Necrotizing enterocolitis
HACCP	Hazard Analysis and Critical Control Points	NHL	National Health Laboratory
HBV	Hepatitis B virus	NICU	Neonatal intensive care unit
HCV	Hepatitis C virus	NNU	Neonatal unit
HIV	Human immunodeficiency virus	PDHM	Pasteurized donor human milk
HMB	Human milk bank	PPE	Protective personal equipment
HMF	Human milk fortifier (also known as breast milk fortifier or BMF)	RDHM	Raw donor human milk
HMBANA	Human Milk Bank Association of North America	SCBU	Special care baby unit
HMBAP	Human Milk Bank Association of the Philippines	SOP	Standard operating procedures
ID	Identification	STD	Sexually transmitted disease
INGO	International non-governmental organization	TWG	Technical Working Group
KMC	Kangaroo mother care	UN	United Nations
		VLBW	Very low birthweight
		WHO	World Health Organization

Introduction

Human milk lies at the heart of the global standard for feeding newborn infants. The World Health Organization (WHO) recommends that

‘... infants should be exclusively breastfed for the first six months of life to achieve optimal growth, development and health’.¹

The WHO states:

... to meet their evolving nutritional requirements, infants should receive nutritionally adequate and safe complementary foods while breastfeeding continues for up to two years of age or beyond.²

...low birthweight infants, including those with very low birthweight, who cannot be fed mother’s own milk should be fed donor human milk. This recommendation is relevant for settings where safe and affordable milk-banking facilities are available or can be set up.³

In the context of the coronavirus disease 2019 (COVID-19) pandemic, WHO recommends:

... when severe illness in a mother prevents her from caring for her infant or prevents her from continuing direct breastfeeding, mothers should be encouraged and supported to express milk, and the breastmilk provided safely to the infant, while applying appropriate infection prevention and control measures. In the event that the mother is too unwell to breastfeed or express breastmilk, explore the viability of feeding with donor human milk.⁴

Human milk provides a complete source of nutrition for infants, including all of the essential macro and micronutrients, as well as bioactive components, for optimal growth and development. Breast milk substitutes (BMS) lack these human bioactive components because they are based on animal milks or plant-based liquids.⁵ Human milk optimally supports gut development and digestion and the establishment of a healthy gut microbiome and donor human milk (DHM) has been reported to favour an intestinal microbiome that is more similar to mother’s own milk (MOM) than BMS which in turn may benefit intestinal function and immune system.⁶

Human milk banks (HMBs) facilitate the safe sharing of breast milk donated by mothers with surplus milk. They were first established in the early twentieth century in Europe and North America, having evolved in centers that maintained directories of paid wet nurses who breastfed infants whose mothers were unable or chose not to nurse them. The formalized recruitment of milk donors spread throughout the globe during the twentieth century and, in response to growing knowledge of the science of breast milk and the importance of breastfeeding, there has been an increase in the number of milk banks since the start of this millennium. In 2020, over 750 HMBs operate in at least 65 countries.

¹ World Health Organization (WHO). *Global strategy for infant and young child feeding* (2003).

Available at <http://apps.who.int/iris/bitstream/handle/10665/42590/9241562218.pdf?sequence=1>. Accessed 8 August 2021.

² Ibid.

³ WHO. *Guidelines on optimal feeding of low birth-weight infants in low- and middle-income countries* (2011).

Available at https://www.who.int/maternal_child_adolescent/documents/9789241548366.pdf. Accessed 8 August 2021.

⁴ WHO. *COVID-19 Clinical management: living guidance* (25 January 2021).

Available at <https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-1>. Accessed 8 August 2021.

⁵ Almeida CC, Mendonça Pereira BF, Leandro KC, Costa MP, Spisso BF, Conte-Junior CA. *Bioactive Compounds in Infant Formula and Their Effects on Infant Nutrition and Health: A Systematic Literature Review*. *Int J Food Sci*. 2021;2021:8850080. Published 2021 May 14.

⁶ Parra-Llorca A, Gormaz M, Alcántara C, et al. *Preterm Gut Microbiome Depending on Feeding Type: Significance of Donor Human Milk*. *Front Microbiol*. 2018;9:1376. Published 2018 Jun 27.

- The first HMB in Southeast Asia was established at the **Central Women's Hospital in Yangon**, Myanmar in 1994. The second HMB in Myanmar opened in **Yankin Children's Hospital**, also in Yangon, in 2015. There are plans to open more in other states and regions in the country.
- In the Philippines, human milk banking was started at the Philippine Children's Medical Center in Quezon City in 1996. However, the first two milk banks with complete facilities were established in **Manila at Dr. Jose Fabella Memorial Hospital** and **the Philippine General Hospital** in 2008 and 2009, respectively. Currently, a total of 26 HMBs are operating in the country.
- The first milk bank in Viet Nam—located at **Da Nang Hospital for Women and Children**—was established in 2017, and has since become a model for milk banking throughout the country. A second milk bank was opened in 2019 at **Tu Du Hospital in Ho Chi Minh City**. In 2020, a third HMB was established at **Quang Ninh Obstetrics and Paediatrics Hospital** in Quang Ninh Province. Satellite HMBs are also operating, one at Phuong Chau International Hospital in Can Tho and another at Quang Nam Provincial General Hospital in Quang Nam Province.
- In Thailand, there are five HMBs operating. Three of these are in **Bangkok—located at Siriraj Hospital-Mahidol University, Ramathibodi Hospital-Mahidol University and at Queen Sirikit National Institute of Child Health**. The other two are located at **Prince of Songkla University at Songklanagarind Hospital in Songkhla and at Chiang Mai University/Maharaj Nakorn Chiangmai Hospital in Chiang Mai**. The opening of two more HMBs is currently being planned.
- An HMB is also operating at **the KK Women's and Children's Hospital in Singapore**. And the first milk banks in Indonesia and Malaysia are currently being established.

The mission of a HMB is to protect, promote, and support breastfeeding through the provision of safe and high-quality donor human milk (DHM) for those who need mother's milk but cannot receive it.

DHM is often reserved for preterm, low birthweight (LBW) and very sick infants as it has been shown to reduce morbidity and mortality through reductions in the incidence of necrotizing enterocolitis (which predominantly affects preterm and LBW infants), bronchopulmonary dysplasia (chronic lung disease of premature infants) and retinopathy of prematurity compared to infants fed with BMS.⁷ Very low birthweight (VLBW) infants may experience less feed intolerance and less delayed gastric emptying when fed DHM and while a review of randomized controlled trials has not confirmed this, the data from observational studies suggest a reduced length of hospital stay.⁸

HMBs provide a cost-effective and safe means of feeding infants who are without access to any or sufficient maternal milk or MOM and are able to fulfil the role of delivering optimal nutritional newborn care and exert a positive influence on the gut microbiome. They are mainly incorporated into local, regional or national healthcare systems and integrated into hospital facilities, including as part of a hub for breastfeeding support. In doing so they support WHO infant feeding recommendations. Furthermore, they should not be open to commercial interests or operate alongside conflicts of interest.

⁷ Villamor-Martínez E, Pierro M, Cavallaro G, Mosca F, Kramer BW, Villamor E. Donor Human Milk Protects against Bronchopulmonary Dysplasia: A Systematic Review and Meta-Analysis. *Nutrients*. 2018;10(2):238. Published 2018 Feb 20.

⁸ Yang, R., Chen, D., Deng, Q., Xu X. The effect of donor human milk on the length of hospital stay in very low birthweight infants: a systematic review and meta-analysis. *Int Breastfeed J* 15, 89 (2020). Published 2020 Oct 28.

Globally, the donors of human milk to HMBs may belong to one or more of several groups of breastfeeding mothers. These include those resident in hospital while caring for their infants in postnatal facilities, especially in kangaroo mother care (KMC) wards as well as those who are separated from their newborns while they receive neonatal care. Hospital staff members sometimes donate the milk they express while at work when there is a local HMB. Mothers at home with their infants are widely recruited as donors throughout the world and they usually express and store their milk at home prior to it being collected by the HMB. Some mothers voluntarily visit the HMB or an associated facility to donate milk. Finally, women may donate milk previously stored for their infants in hospital or at home. These include bereaved mothers.

Recipients of DHM are mainly preterm and LBW infants in hospitals, although all sick infants may be recipients, as well as infants whose mothers are temporarily unable to provide sufficient milk. Where supplies allow, infants at home may be fed DHM and it has also been provided to babies during emergencies in some locations. In Southeast Asia, this has been especially practiced in the Philippines where weather-related emergencies are not uncommon.

Human milk banking at its best is underpinned by an ethical code that ensures equity of access to DHM and to opportunities to donate human milk. It also steers and informs the duties of care owed to the donors who should never be coerced to give more milk than is optimal for their situation and no baby should be deprived of his/her own mother's milk as a result of milk banking activities. Payment for human milk can lead to exploitation of mothers and in some instances a greater likelihood of sub-standard or contaminated milk.

Despite regulations, there is a need for a heightened global understanding of the optimal ethical code for human milk banking operations and the use of DHM.⁹



⁹ Israel-Ballard K, Cohen J, Mansen K, et al. Call to action for equitable access to human milk for vulnerable infants. *Lancet Glob Health*. 2019;7(11):e1484-e1486.

Definition of Terms

Aseptic technique

A set of specific practices and procedures performed under carefully controlled conditions with a goal of minimizing contamination by pathogens.

Breast milk sharing

Breast milk of one mother shared to another mother's child without donor screening and milk processing at the human milk bank.

Cleaning

Process that physically removes contamination and many microorganisms using a detergent.

Decontamination

Any process that renders an item safe and fit for reuse.

Disinfection

A process that reduces the number of microorganisms to a level at which they are not harmful. Spores will not usually be destroyed.

Donor human milk

Donor human milk or DHM is human milk in excess of an infant's current and future needs that is donated by a mother to a human milk bank for use by a recipient infant that is not the mother's own. DHM is offered voluntarily and with no payment given to the donor mother. DHM is provided to the recipient infant based on clinical necessity. DHM is not an alternative to mother's own milk but is instead used as an alternative to formula and to serve as a bridge to ensure an exclusive human milk diet, as the mother is provided lactation support to build her milk supply for her own infant.

Donor human milk depot

Area fully equipped in line with human milk bank specifications, including with breast milk pumps, milk containers, refrigerator/freezer for exclusive expressed breast milk storage and freezer for screened, pasteurized donor human milk. All storage and milk handling processes comply with those of the human milk bank.

Donor human milk receiving room

Unit/departments in the hospital set aside for receiving raw donor human milk. All storage and milk handling processes comply with those of the human milk bank.

Donor human milk recipient

Infant or young child fed with pasteurized donor human milk from a human milk bank. This will usually take place under clinical supervision.

Exclusive breastfeeding

Infant receives only breast milk (including expressed breast milk from own mother or donor human milk from a milk bank) and nothing else, except for oral rehydration solution, medicines, vitamins and minerals if prescribed by a medical practitioner, i.e., no other fluids and no solid foods.

Fresh raw donor milk

Breast milk that has been freshly expressed and collected from a donor mother. For single donor collections, this should be stored immediately at $\leq -20^{\circ}\text{C}$ (20°C or colder) for no longer than three months prior to pasteurization. For human milk banks which pool 24 hour collections and pool from the same donor mother, this milk should be stored at $+2^{\circ}\text{C}$ to $+4^{\circ}\text{C}$ for a maximum of 24 hours after expression, pooled in liquid state, and stored at $\leq -20^{\circ}\text{C}$ (20°C or colder) for further processing/pasteurization.

Frozen raw donor milk

Unpasteurized breast milk frozen at $\leq -20^{\circ}\text{C}$ (20°C or colder), not exceeding three months from date of expression.

Hazard Analysis and Critical Control Points

The Hazard Analysis and Critical Control Points or HACCP process is widely accepted as the quality assurance and safety system best suited to human milk banking. It originates from and is widely used throughout the food industry.

Heat-processed/pasteurized milk

Heat-processed or pasteurized milk is fresh raw donor milk and/or frozen raw donor milk that has been heated according to set parameters.

Hub/satellite/storage unit

Milk storage facility for storing expressed breast milk and pasteurized donor human milk in line with human milk bank recommendations.

Human milk bank

A human milk bank or HMB is a service established to recruit and screen breast milk donors, collect donated milk, and then process, ensure microbiological safety, store, and distribute the milk to meet infants' specific needs for optimal health.

Human milk donor

A healthy lactating mother who volunteers to donate surplus breast milk for the benefit of other infants in need of human milk.

Human milk fortifier

Human milk fortifier or HMF is a dietary supplement added to breast milk to increase its energy, mineral, protein, or vitamin content. It is mainly used to enhance the nutritional status of premature babies and babies with very low birthweight or VLBW. HMF is cow's milk based although human milk based HMF is also available from commercial human milk companies.

Low Birthweight or LBW

Infant weighing less than 2500g at birth.

Milk kinship

Kinship based on the sharing of human milk which bars marriage between people of Islamic faith. Additional conditions on sharing (e.g., maximum number of occasions milk is shared) may also be in place—these should be defined at national level.

Minimum standards

Minimum standards are the core recommendations, protocols and activities or services that need to be provided in order to comply with nationally or internationally agreed guidelines or through the demonstration of their adherence, to pass a safety inspection.

Mother's own milk

Mother's own milk or MOM is breast milk expressed for consumption only by a mother's own baby.

Pasteurization

Pasteurization is a process in which foods are treated with mild heat to eliminate pathogens and extend shelf life. The current global standard for human milk is to a minimum of 62.5°C but no more than 63°C for 30 minutes (Holder pasteurization) followed by rapid cooling to minimize loss of the unique beneficial properties of the milk. Where fully automatic equipment is not used, heat processing should be immediately followed by rapid cooling as occurs with automatic pasteurizers.

Pathogen

A bacterium, virus, or other microorganism that can cause disease.

Pooled donor human milk/pooled pasteurized human milk

Human milk from more than one donor that has been pooled and pasteurized or from multiple donations of the same mother in the same pasteurization batch.

Preterm milk

Milk pumped within the first month postpartum by a mother who delivered before 37 weeks gestation.

Sanitize

Make sanitary by cleaning or sterilization.

Sterilization

A process that destroys microorganisms usually by bringing to a high temperature with steam, dry heat or boiling liquid.

Very Low Birthweight or VLBW

Infant weighing less than 1500g at birth.

SECTION 1

Development of Minimum Standards for the Establishment and Operation of Human Milk Banks in Southeast Asia

Background

The Minimum Standards for the Establishment and Operation of Human Milk Banks in Southeast Asia (henceforth referred to as the Standards) have been developed in collaboration with representatives of HMBs currently operating or being developed in the following countries in Southeast Asia: Indonesia, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Viet Nam. Of these, Indonesia and Malaysia are working towards the establishment of their first HMBs.

The Standards have been designed to provide core recommendations, protocols and activities that together comprise minimum acceptable requirements for the recruitment and screening of human milk donors and the donation, processing, storage, testing, labelling and distribution of DHM throughout Southeast Asia.

The aim of the Standards is to facilitate the further development of national, regional and local recommendations and guidelines as well as operating procedures for the safe and sustainable delivery of optimal quality DHM from HMBs to infants throughout the region. They will form the basis upon which HMBs in countries in Southeast Asia may be accredited and the basis on which related national legislations may be developed.

Where milk banks operate in the region, guidelines have been developed locally, and in some cases, nationally. The methodology for the development of the Standards was to collate and compare all of the recommendations from the partner groups together with published standards and guidelines from Europe and North America. Available guidelines from Myanmar¹⁰, Philippines¹¹ and Viet Nam¹² formed the core source material. Contextual issues such as the need for multiple languages, as well as cultural and religious implications of human milk banking were addressed and the clinical and ethical implications of the recommendations considered.

The Standards development was spearheaded by the Regional Human Milk Bank Network in Southeast Asia and benefited from the valuable inputs provided by the Network's core Technical Working Group (TWG) – Dr. Hikmah Kurniasari (Indonesia), Dr. San San Myint (Myanmar), Dr. Estrella Olonan-Jusi (Philippines), Dr. Sheila Ann D. Masangkay (Philippines), Dr. Chua Mei Chien (Singapore), Dr. Sopapan Ngercham (Thailand), Dr. Nguyen Thi Tu Anh (Viet Nam) and Dr. Nguyen Thi Thu Phuong (Viet Nam). Ms Gillian Weaver, international milk bank specialist and consultant, provided the overall guidance in the drafting and finalization of the Standards. Technical and experts' consultations were facilitated by the Human Milk Bank Association of the Philippines (HMBAP), with strategic technical and financial assistance from Alive & Thrive (A&T).

¹⁰ Ministry of Health and Sports, The Republic of the Union of Myanmar. *Guidelines for the Establishment and Operation of Human Milk Banks* (2019).

¹¹ Department of Health, Republic of the Philippines. *The Philippine Human Milk Banking-Manual of Operation* (2013). Available at <https://www.humanitarianresponse.info/en/operations/philippines/document/philippine-human-milk-banking-manual-operation-0>. Accessed 20 August 2021.

¹² Da Nang City People Committee – Department of Health. *Guidelines on Operating the Human Milk Bank at Da Nang Hospital for Women and Children* (2018).

Human Milk Banks: Operational Principles

The operational principles on which the Standards have been based include:

- Support for breastfeeding, together with its promotion and protection are at the foundation of all HMB operations.
- HMBs have an important role in lactation support which is best fulfilled when integrated into or working with lactation support services.
- A non-profit model is to be followed at all times although a processing fee may be collected to sustain operations.
- Minimum standards are to be followed by all HMBs.
- Training is available for all staff including updates and refresher courses.
- Additional safeguards may be introduced where this is financially and practically feasible to optimize safety and improve quality standards beyond the minimum acceptable.
- All milk donation is to be voluntary, without coercion or remuneration, and written donor consent should always be obtained.
- Only pasteurized donor human milk (PDHM) having microbial culture results that meet the requirements of this document can be used nutritionally. Pasteurization techniques currently considered safe and optimal are heat treatment at 62.5°C for 30 minutes (Holder pasteurization) followed by rapid cooling.
- Assure confidentiality and maintain privacy for both donor and DHM recipients with records managed by HMB staff.
- The use of PDHM is to be in accordance with clinical indications. In the event of surplus DHM or where it fails to meet the required criteria, it may be used, (with donor consent) for training purposes or for scientific research.
- To promote and ensure accountability, any adverse events related to HMB operations should be reported via the hospital's risk management system.
- Hazard Analysis and Critical Control Points (HACCP) principles are to be applied in the implementation of a quality control system that is followed by all staff and reviewed in accordance with the Standards. It will include donor recruitment and screening, collecting, storing, testing, processing and transporting milk, personnel, required documentation, premises and equipment (including maintenance), batch recall, external and internal auditing, non-conformance to processes, self-inspection, and continuous quality improvement.
- All staff are trained in HACCP so that each HMB can develop its own HACCP plan to identify the hazards and their critical control points, their monitoring and management.

Prerequisites and Readiness for the Establishment of a Human Milk Bank

The prerequisites for the establishment of an HMB are comprehensively addressed in the PATH Toolkit.¹³ They include:

1. Gather audit data to identify, explore and assess the need for DHM to augment maternal breast milk while also assessing room for improvements in the available support for optimal lactation and breastfeeding.
2. Identify the potential donor pool. Explore which group or groups of donors (in-patients, out patients, community based, etc.) will best provide safe and adequate supplies of donor milk.
3. Identify and collate existing policies, services and regulations that will impact on donor recruitment and all milk banking processes (including breastfeeding policies, infant and young child feeding policies, Baby Friendly Hospital Initiative (BFHI) accreditation).
4. Identify local leadership in all of the above.
5. Determine levels of acceptability of DHM among recipient populations and hospital staff.
6. Identify funding sources. Ensure that the hospital, groups of hospitals, regional health board, etc., are committed to provide the financial and human resources required to establish an HMB that will operate in accordance with these standards.
7. Assess likely costs, including:
 - i. Space, equipment, and materials (purchasing costs and costs for maintenance/service).
 - ii. Additional expenses for personnel/training.
 - iii. Cost for stationery/documentation.
 - iv. Cost for generator use in case of electricity failures.
 - v. Screening examinations of donors.
 - vi. Processing of donor milk.
 - vii. Microbiological testing of donor milk.
 - viii. Cost for development and distribution of health education materials
8. Conduct facility readiness assessment to identify suitable building/premises with adequate hygiene standards, space for all milk bank related activities including storage, access to utilities including assured power plus emergency back-up power, and safe water provision.
9. Confirm access to sufficient trained staff including clinical and operational management and cleaning/disinfection services.
10. Confirm availability of expert advisory team.

¹³ PATH. *Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs (2019)*. Available at <https://www.path.org/programs/maternal-newborn-child-health-and-nutrition/strengthening-human-milk-banking-re-source-toolkit/>. Accessed 11 August 2020.

11. Determine access to suitable laboratory services for screening of donors and microbiological testing of milk.
12. Explore access to supplies, suitable equipment and maintenance.
13. Explore the availability of transport links to recipient hospitals where relevant and the availability of transport to bring donated milk from donors' homes where applicable. Consider the associated distance and environmental conditions as these will impact on the safety and quality of the milk.
14. Explore the recognition and understanding of contextual issues that will impact on the establishment and operation of an HMB and the use of PDHM. These will include languages spoken and translations required, access to interpreters to facilitate taking and giving of informed consent.
15. Develop standardization of information and provision of answers to commonly asked questions to facilitate community understanding of HMBs and their role in support of breastfeeding.
16. Develop an understanding of how climate will impact on the work of HMBs—assess the adequacy of steps taken to mitigate extremes of weather.
17. Give due consideration to religious or cultural matters relevant to HMBs. Feeding an infant with breast milk from a different mother may have religious or cultural implications. Consult with religious leaders from within the region to be served, and respect all religious and cultural sensitivities on the use of PDHM. These may include additional recruitment and screening recommendations with regard to diet and alcohol use by the donor, and/or removal of anonymity and record keeping.
18. Explore the ethical considerations (for donors, recipients and their parents, staff) that should be considered when establishing HMBs. These include ensuring equity of access to PDHM (irrespective of ability to pay any costs) and to opportunities to donate.



SECTION 2

Minimum Standards for the Establishment and Operation of Human Milk Banks in Southeast Asia

This section reflects the consensus position of the Technical Working Group, composed of identified members of the Regional Human Milk Bank Network in Southeast Asia, which guided the development of these minimum standards.

Organization

Organizational structure and staffing

1. An HMB should have an Advisory Board and an Administrative Committee. These may comprise some or all of the same people.
2. The Advisory Board may operate at a central level as a wider resource for a number of HMBs. Its role is to provide general guidelines, oversee the implementation of procedures and protocols, act as a liaison with the medical community, and be available for consultation with milk bank personnel.
3. The Administrative Committee is chaired by the Medical Superintendent, and meets regularly to discuss strategies, problems, policies and practices. Its roles include planning, implementing and evaluating the services of HMBs. The committee members should include representation from senior medical (neonatal/paediatric/obstetric), nursing, infection control, technical and pathology staff, hospital quality management, milk bank staff in overall charge and also operational charge. A lactation specialist, parent representative, religious advisor and a milk bank secretary are desirable also.
4. Milk bank staffing comprises those who oversee and facilitate its day to day running.
5. All essential roles within the milk bank should be covered to ensure a safe, efficient and sustainable service, including duties of care to donors and recipients and their families. When manpower is at minimum, functions of available staff should be flexible.
6. Minimum essential roles in the milk bank include:
 - i. Clinical lead (HMB Director).
 - ii. Administrative and clerical including track and trace.
 - iii. Donor recruitment/specialist lactation support.
 - iv. Technical and/or biomedical.
 - v. Cleaner (outsourced).
 - vi. Microbiologist/pathologist (outsourced).
 - vii. Equipment technician/engineer (outsourced).

One person may coordinate and cover several roles, e.g., administration, donor recruitment/support. Where the HMB operations include feed preparation and dispensing, this role should be fulfilled by a professionally qualified staff member, e.g., registered nurse, dietitian.

Outsourced staff will usually be members of the local hospital staff if the HMB is located in a hospital setting.

7. An HMB should be assigned a supervisor with experience and competence in aseptic technique and all HMB operations.
8. The number of employees in an HMB will depend on the volume of work within each facility. A sufficient number of trained staff should be available to provide everyday cover for the HMB, allowing also for planned and unplanned leave, sickness and days off.

9. A staff code of conduct should be implemented and include:
- i. Standard operating procedures (SOP) of the HMB (which should be displayed and easily accessible to all staff) to be adhered to at all times.
 - ii. Staff to immediately report any illness they experience with symptoms of gastro-intestinal disturbance, pyrexia, respiratory infections, skin lesions and sores. Any requirements to comply with additional national health emergencies should be observed, e.g., isolation due to contact with confirmed cases of COVID-19.
 - iii. Local policies for managing illness to be adhered to.
 - iv. All staff should adhere to the requirements of the facility to maintain appropriate personal hygiene and dress code. Good hand hygiene should be maintained at all times.
 - v. Milk bank personnel should at all times wear personal protective equipment (PPE) when handling milk. This includes hair covering, clean gown, apron, mask and gloves. Gloves should be changed between handling raw and heat-treated milk. Shoes should be closed and non-slip. All protective clothing should be in compliance with the current hospital requirements.
 - vi. Any cuts or abrasions should be covered.
 - vii. Staff should not apply loose facial powders or chew any substance, e.g., betel nut.
 - viii. Eating, drinking (other than water) and smoking is prohibited in the HMB.
 - ix. Any additional safety measures introduced by law or by the facility in response to infections, e.g., COVID-19.

Staffing training

10. A written training policy should be developed and implemented.
11. All milk bank staff should receive ongoing training and continuous education that is relevant to their job.
12. HACCP training should be undertaken by all staff members (HACCP training materials are available as part of the PATH Toolkit¹⁴).
13. Training and performance records of milk bank staff should be recorded and their work audited periodically to ensure they:
- i. Are competent in performing their work.
 - ii. Understand the technical processes relevant to their work.
 - iii. Understand how the milk bank is organized and how its health and safety and quality systems work.
 - iv. Understand the regulatory, legal and ethical aspects of their work.

¹⁴ PATH. *Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs (2019)*. Available at <https://www.path.org/programs/maternal-newborn-child-health-and-nutrition/strengthening-human-milk-banking-re-source-toolkit/>. Accessed 11 August 2020.

14. New members of staff should have an induction period of sufficient duration and content to enable their competency in all aspects of their work. This should include:
- i. Lactation, breastfeeding and breastfeeding promotion including the benefits of breastfeeding and the importance of PDHM for preterm, underweight children or those suffering from diseases, mechanisms of milk production and methods of maintaining milk supply.
 - ii. Technical and equipment training.
 - iii. Ensuring the safety and quality of PDHM during its handling, pasteurization, storage and use
 - iv. Awareness of contextual, cultural and religious aspects of milk donation and the meaningfulness of human milk donation, and familiarization with local Fatwa, if applicable.
 - v. Donor recruitment and screening–selection process of human milk donors of HMB.
 - vi. Donor support including bereaved donors.
 - vii. Transporting milk.
 - viii. HACCP principles.
 - ix. Food hygiene—all staff preparing feeds should maintain food hygiene qualifications in line with local policy.
 - x. Ethics in relation to human milk banking.
 - xi. Staff hygiene.

Facility

Making Space for Human Milk Banks: Lessons Learned from Viet Nam is included as [Appendix 1](#).

15. All rooms/buildings included in the milk bank facility should meet local and national building regulations for both a health facility and a food processing unit.
16. The minimal requirement for a milk bank facility is to have areas for reception/milk collection, processing of milk, storage of milk and office/administrative space.
17. The processing room should comply with infection control recommendations for layout, facilities and materials used.
18. Access to both clean utility and dirty utility (sluice) facilities is required to facilitate infection control requirements with the arrangement of rooms providing one way direction of activities to facilitate good infection control.

Location

19. Clean, dry and well-ventilated area, that is separated from contamination and infection sources such as canteen, restrooms, infectious diseases departments.
20. Access to suitable toilet facilities that are clean and hygienic for the use of staff, donors and visitors.
21. Donors to have access to a designated space that is comfortable, clean and private and suitable for milk expression.

22. Where the milk bank serves a single hospital, the optimum location is usually a convenient space near the infant or essential newborn care unit. However, if the HMB is a resource for several hospitals, it may be less desirable or convenient to bring additional footfall, deliveries, etc., to this area.

Spatial Requirements

It is not essential for the required areas for HMB operations to be located in a single space. The optimal layout will be influenced by the operation being planned.

23. Sufficient space to ensure efficient and safe performance of all HMB operations. This should be informed by the intended scale of operations. The potential requirement for future expansion should be considered.
24. Hospitalized donors require access to a designated space that is comfortable, clean and private and that is suitable for milk expression. This may be located away from the HMB in a hospital setting e.g., close to the newborn care unit/neonatal unit/KMC ward.
25. Overall required space for equipment to facilitate mobility and cleaning (including around, behind and underneath).
26. A designated separate hand wash area should be available for use by milk bank staff upon entering clean areas and prior to milk handling.
27. Wash area for equipment.
28. The milk bank expressing area should have a separate hand washing facility for mothers.
29. A fully equipped office space is required for the maintenance and storage of records as well as all administrative activities.

Facility maintenance and cleaning

30. Expert infection control advice should be sought for the design or choice of doors, entrances, windows, ceilings, floor coverings and air conditioning system to minimize infection hazards and to ensure ease of effective cleaning.
31. Routine testing of water and of the emergency generator is required in line with hospital protocols.
32. Written guidelines, SOPs and cleaning schedules should be written for each unit, work area and equipment. These will cover cleaning, disinfection and maintenance.
33. All equipment and work surfaces should be thoroughly cleaned after use. Any spillages should be wiped up straight away with a clean disposable cloth or paper towel.
34. Food grade disinfectants should be used according to manufacturer's directions.

Financing

35. The financing of HMB operations should be free of conflicts of interest and the WHO International Code of Marketing of Breast Milk Substitutes and its subsequent resolutions should be adhered to.

Costs

36. Costs should be calculated as part of readiness exercises and advance planning to enable budgeting, financial projections and estimated savings. Economies of scale should be explored. It should be highlighted throughout that the costs of establishing, maintaining and operating HMBs are offset by the overall financial savings that result from increased rates of breastfeeding and subsequent reduced morbidities.

Equipment

The safe operation of HMBs is dependent upon the optimal use of equipment. A wide range of equipment is required to promote and maintain safety, ensure optimal thermal storage and treatments and facilitate track and trace operations. The purchase and use of locally sourced equipment with readily available access to in-house maintenance and repair services is an important consideration throughout.

37. Develop SOPs for the safe use and handling and scheduled monitoring and maintenance requirements of all HMB equipment. These should be readily available, routinely updated, signed off by the Administrative Committee and included in staff training.
38. Use, clean, calibrate (where relevant) and maintain all equipment in accordance with the manufacturer's recommendations.
39. Hospital engineers should be trained to maintain milk bank equipment where appropriate.
40. Update the records for all electrical equipment including purchase date, name of manufacturer and supplier, any unique identification (ID)/reference data, operational guides, electrical test data, maintenance record with name of personnel and any parts replacement.
41. Access to a computer, printer and label printer will facilitate tracking and traceability. However alternate means of maintaining records is also required in the event of computer breakdown.
42. A back-up generator is required with sufficient wattage to provide electricity to the freezers and refrigerators to prevent thermal instability in the event of loss of main generated electrical power.
43. All equipment and utensils used for milk expression and collection should be made of stainless steel or of bisphenol A (BPA)-free plastic that is easily cleaned and decontaminated, and will withstand temperatures of 120°C to prevent the formation of biofilms on surfaces.
44. Adequate cleaning and decontamination of the equipment used in feed preparation is mandatory to avoid *Cronobacter* spp biofilms contaminating subsequent feeds if not removed.

Essential equipment

Milk expression

45. Strict attention to hand hygiene is required for all methods of milk expression. Hand washing techniques should be taught to all donors and observed where possible.
46. Hand expression i.e., without the need for equipment other than a clean collection vessel, when well taught and effectively practised results in expressed milk that is low in contamination and has optimal nutritional content. All lactating women should be taught good hand expression techniques.
47. The use of breast milk pumps requires stringent attention to pump cleaning to prevent contamination of the milk.

48. Breast milk pumps should be disassembled and washed immediately after use in warm, soapy water, rinsed and disinfected between expressing following manufacturers' instructions.
49. Sharing breast milk pumps and breast pump parts can lead to cross infection and so shouldn't be recommended unless sterilized between mothers as per manufacturers' instructions.
50. Where available and affordable, for in-hospital use especially, hospital grade, multi-use closed system electric breast milk pumps are usually preferred as they have been shown to result in increased volumes of expressed milk as long as they are comfortable to use. Different size shields (funnel, flange) should be available to prevent nipple trauma which can occur when poorly fitting shields are used.
51. The surrounding areas and the casings of communally used electric breast milk pumps should be cleaned before and after use by the user or a member of staff to remove milk splashes and contamination from handling.
52. Check electric pumps daily for any visible signs of damage.
53. Ensure electric breast pumps are routinely checked and maintained by clinical engineering staff in accordance with manufacturers' instructions and local equipment protocols to ensure they are working safely and effectively and that milk has not been allowed to enter the pump's casing or its mechanism.
54. Users of electric breast milk pumps should be provided with a single user collection set and taught how to decontaminate and disinfect it after every use.
55. Manually operated breast milk pumps are available and cost less than electric pumps. They can be reused on a single user basis with disinfection or re-used by another user when sterilized between use.
56. Bicycle horn type breast milk 'pumps' with rubber bulbs should not be used by breast milk donors as these are a source of infection. Their intended function is to relieve breast distension. Discard any milk collected with this type of equipment.
57. Milk bank staff or ward staff should ensure that the numbers of breast milk pumps and clean accessories are sufficient for the numbers of donor mothers.

Milk storage equipment (containers)

58. Containers used for collecting and storing human milk should be of food grade, easily available, durable, easy to clean and preferably able to be autoclaved to reduce costs. There should also be no significant decrease in nutrient or bioactive components in the milk. Containers made from BPA-free hard plastics, food grade polyethylene and pyrex/glass are widely used globally. However, cylindrical, wide-mouthed stainless- steel containers with tight fitting/screwed caps are equally effective.
59. Containers for milk collection and storage should at all times be labelled correctly.
60. Leave sufficient space to allow for expansion on freezing. This will also allow for the containers to be submerged to above the contents line without water being able to enter via the caps/lids if the seal is not fully effective.
61. Check caps and lids for effectiveness. Containers require tight fitting/screwable lids to avoid ingress of contaminated water during pasteurization and handling and to avoid spillage.
62. Autoclaving plastic equipment can render it misshapen. Routinely inspect, discard where required and limit its frequency of use where necessary.



Thermal storage equipment (refrigerators and freezers)

63. Temperature monitors for measuring the internal temperatures of refrigerators and freezers require validating on a regular basis (at least every six months).
64. Use a system of external labels/colours for HMB freezers and refrigerators dedicated for raw DHM, PDHM awaiting microbiology results and microbiology-passed PDHM to help prevent milk errors.
65. To prevent the loss of stored DHM, agree on an emergency plan detailing interventions in the event of a mechanical or electrical failure. Identify suitable equipment that may be used in the event of an emergency.
66. Ensure freezer facilities do not become overcrowded and that frost and ice build-up is kept to a minimum and isn't allowed to accumulate around the containers of milk.
67. Defrost and clean freezers internally, at least every two months.
68. Clean fridges internally once a week or more frequently in the event of spillage.
69. Clean fridges and freezers externally daily, or more frequently as required.
70. Freezers for human milk storage require external temperature display and maintain a constant temperature of $\leq -20^{\circ}\text{C}$ (20°C or colder).
71. Equip refrigerators and freezers with temperature-sensitive alarms if not in-built.
72. Provide a minimum of two freezers to ensure separation of raw and pasteurized milk.
73. Use a quarantine system indicating the date and content to separate and identify raw milk, pasteurized milk without microbiological clearance, and pasteurized milk cleared for nutritional use without opening the freezers and refrigerators.
74. Commercial i.e., not domestic refrigerators are recommended for HMBs.
75. HMB refrigerators should maintain a maximum 4°C storage temperature, include in-built temperature monitoring and offer adequate air circulation.

Pasteurizer

Currently, the most widely applied method to ensure microbiological safety of DHM and preserve the bioactive components is Holder pasteurization. This process comprises rapidly heating the milk in containers placed in a water bath to 62.5°C, maintaining the milk at this temperature for 30 minutes, immediately followed by a reduction in temperature to 25°C within 10 minutes and further cooling to at least 10°C and to 4°C prior to freezing. The heat treatment can be achieved in a number of different ways including fully automated human milk pasteurizers that provide both heating and chilling in the same water bath, twin bath equipment where the milk containers are transferred from the heating bath to the chilling bath, shaking water baths that provide the heat treatment with the milk containers transferred to a separate chilling (iced) water bath, or blast chiller. Pasteurization equipment is available in different sizes accommodating runs from a maximum of one liter to a maximum of almost 20 liters. Alternative methods of heat treatment are also utilized in some milk banks (short time, high temperature, flash heating) and a number of alternative methods remain in the developmental phase.

Temperature of the milk containers during the pasteurization process are usually monitored through a thermometer or data logger connected to a probe in a water bottle placed in the middle of the pasteurizer. The pasteurization time begins when the probe temperature reaches the desired temperature of 62.5°C.

76. A certified pasteurizer, which produces heat treated milk meeting the internationally accepted parameters described above, with full data logging verification of 'milk' temperature throughout the pasteurization cycle, and rapid refrigerated cooling to 4°C is recommended.
77. Laboratory grade shaking water baths may also be used to pasteurize human milk if the temperature control is accurate and maintains the milk at the required temperatures. A means of safely and rapidly chilling the milk is also required.

Hot air oven/autoclaves

An electrical hot air oven/autoclave generates dry heat and may be used in the HMB for the purpose of sterilizing equipment such as milk containers and test sample containers.

78. All such equipment should meet the required temperature standards and be routinely checked and maintained in accordance with electrical hot air oven requirements.
79. The use of hot water sterilizers is not recommended due to the risk of contamination.

Laminar air flow cabinet (Bio-safety cabinet)

The use of a laminar flow or bio-safety cabinet will control the air quality within the immediate environment of the cabinet. Its use when pouring, testing or otherwise handling open containers of milk helps to prevent contamination of the milk with air-borne microorganisms. In the absence of such a cabinet, easily cleanable steel topped tables should be used for milk processing and for milk disbursing and consideration given to the environment that the milk will be exposed to.

80. The cabinet should be decontaminated in accordance with manufacturers' instructions prior to and immediately after each use.
81. The minimum technical requirement for the cabinet is manufactured in accordance with ISO 9001:2008.
82. The cabinet should be maintained in accordance with manufacturers' instructions (usually at least every six months) and the filters replaced as required.

83. An accredited vertical airflow system is preferable to horizontal flow.

Utensils

These include items such as measuring and mixing devices, scales, trays, spoons, sieves, bowls and jugs.

84. All utensils used for the pouring and mixing of human milk and for the preparation of feeds should be easily decontaminated and facilitate the use of aseptic techniques.

85. All items used by the HMB that come into contact with the milk should be sterilized between use.

86. Cup feeding is advised for term infants and tube feeding (gavage) or spoon feeding for preterm infants.

Transportation equipment

There will usually be a need to transport DHM to the HMB from where it has been expressed and/or stored. Even over short distances, the transportation equipment will be required to prevent the temperature of the milk rising leading to the proliferation of microorganisms. Test samples of milk will also require transporting to the microbiology laboratory.

87. Human milk should be transported to and from the HMB in a hard, insulated ice box with dry ice or frozen ice packs (not wet ice due to its contamination risk) and with the lid or cover securely in place.

88. Transport containers should be validated prior to use to ensure they are suitable for transporting human milk over the required distances in the local temperature conditions.

89. Transport containers should be easily cleaned, undamaged and able to maintain milk at +4°C or below if liquid and maintain it frozen where appropriate to allow safe transportation to and from the HMB.

90. The transport equipment should be cleaned and disinfected between every use, including the frozen ice packs.

91. The temperature of the transport equipment should be checked daily before use and routinely monitored. Replace ice packs with frozen ones as required.

Dishwasher (optional)

The use of a dishwasher does not replace the requirement for sterilization of equipment to avoid cross contamination.

92. If used, a dishwasher should reach a minimum temperature of 66°C and a minimum rinse temperature of 82°C.

Human milk analyzer (optional)

93. Mid infra-red human milk analyzers are designed to rapidly measure the macro-nutrients in human milk. They are costly, require careful calibration, may be easily damaged and analyses should only be made by staff who have been fully trained in their use and the interpretation of the results. The quality and value of DHM, as with all human milk does not solely lie in its nutritional content.

Donors

The work of HMBs is dependent upon the donor mothers who freely provide safe donations of expressed breast milk in sufficient overall volume to meet the needs of the recipients. DHM recipients are mainly premature, LBW or sick babies. The required volumes may be determined locally, regionally or nationally. Every HMB has an ongoing need for new donors to replace those who are no longer donating.

Who are the donors?

94. Human milk donors are healthy lactating mothers who volunteer to freely donate breast milk for the benefit of other infants in need of breast milk without compromising the nutritional needs of their own babies. It is usual for donors to belong to different categories of mothers including those in hospital with newborns, mothers of preterm, LBW or sick infants receiving hospital care, and mothers caring for their baby at home. Hospital staff who have returned to work but are breastfeeding their baby may donate some of the milk they express while at work.
95. Mothers in hospital should be optimally supported to establish their own lactation and breastfeed their infants. In the event of separation or a mother's infant being unable to fully breastfeed due to immaturity or illness, the mother should, without delay, be taught how to stimulate and maintain her lactation. This is so she can collect her colostrum and subsequently her breast milk for feeding to her baby, and if not required and with her informed consent, donate it to the HMB. Please see [Appendix 2. Lactation support for mothers.](#)
96. If it is not possible for an infant to breastfeed in hospital due to prematurity, infant or maternal ill health, the mother should be supported to express her breast milk.
97. Pump expression usually gives better results. However, hand expressing is a valuable skill and should be taught as soon as possible following delivery so that new mothers who are separated from their baby can start to collect their colostrum as soon as possible after the delivery.
98. Whatever volume of colostrum or milk is expressed it should be given straight to the mother's own baby unless contraindicated.
99. When breastfeeding is not possible, frequent expressing (8-12 times in 24 hours) including a night time expression is recommended as it will facilitate the initiation of lactation and help to maintain a good milk supply.
100. In the early days and weeks following an infant's birth, the mother may express more milk than her infant needs. She should be encouraged and supported to maintain her milk supply as it may be more difficult to increase lactation at a later stage.
101. Surplus expressed milk may be donated to the HMB if it cannot be stored for the mother's own baby, if the mother meets all the recruitment and screening criteria and if she provides written, informed consent to its donation to the HMB.
102. Mothers in hospital may express milk for their own baby and/or for donation to the HMB in a number of locations according to the local facilities and protocols. This includes hospital wards including KMC ward, the ward expressing room, the NICU expressing room, the lactation support/management center and the HMB expressing room.
103. In all locations, the facilities should be conducive to enabling hygienic milk collection with hand washing basins and 24-hour running water available.
104. They should offer calm and private facilities.

105. Teaching and supervision of expressing should be available and all staff involved should be in regular contact with milk bank staff to ensure that the milk collected for the HMB is transported there without delay.

Prioritization of donor recruitment

HMBs prioritize donor recruitment according to their circumstances. As most HMBs are located in or associated with hospitals, it is usual to concentrate on recruiting mothers who are in the hospital with their babies as follows:

106. Breastfeeding mothers who have premature newborns should be the first priority for promotion of DHM donation because their milk will most closely match the needs of the recipients. There are also time and labor savings in educating these mothers and in monitoring and collecting their DHM.
107. Recruit breastfeeding mothers whose babies are being cared for in KMC rooms in the hospital where the HMB or depots are located.
108. Encourage female staff who are breastfeeding and working for the hospital where the HMB or depots are located to express milk during working time and donate any surplus to HMB.
109. Breastfeeding mothers who have a child under 12 months old, especially those post discharge, who live in the same city where the HMB is located.

Promoting and sourcing human milk donation

Incorporate the concept of human milk donation wherever relevant. HMBs should:

110. Identify those who work with or come into contact with new mothers or mothers to be, for example in lactation and breastfeeding seminars, prenatal classes and prenuptial seminars.
111. Develop an active donor recruitment programme to provide a continuous stream of new donors to maintain an adequate milk supply. Recruitment can be increased if milk banks offer breastfeeding support and services to the donors.
112. Develop a communication strategy using mass media to facilitate the widespread dissemination of messages about milk donation. This, in turn, will promote breastfeeding. Examples of mass media are: newspapers, newsletters, magazines and journals, television and radio, social networking sites and other related media, public space advertisements (e.g., malls, bus stops, train stations).
113. Milk banks should coordinate with partner agencies e.g., government and private offices. Office administrators may be encouraged to establish breastfeeding and milk collection stations in their respective offices.
114. Reach out to different health centers and local community groups in the hospitals' catchment areas and encourage them to be involved in the education campaign on milk banking, recruitment of milk donors and the establishment of milk storage stations in the communities.
115. Approach residential communities and homeowner groups to help in the recruitment of milk donors.
116. Provide written information (in clear, non-technical language) posted at or left in: antenatal clinics, in- and out-patient departments, doctors' clinics, maternity wards in hospitals, birthing clinics, maternity and infant shops, breastfeeding shops.
117. Solicit direct referrals or recommendations from:

- i. Current and previous donors.
- ii. NICU staff.
- iii. Doctors in contact with postpartum mothers (family physicians, obstetricians and paediatricians).
- iv. Childbirth educators.
- v. Organizers and attendees of prenatal and postnatal classes.
- vi. Lactation support groups.
- vii. Women's groups and other non-governmental organizations working with mothers and children.

Donor recruitment and selection

Recruiting, selecting and screening human milk donors is a multi-step process to ensure a safe and voluntary source of DHM for the recipients. HMBs should be aware of the current health of prospective donors. This includes infection with communicable diseases and use of medications, drugs and other substances that may be present in the milk. These include nicotine and alcohol.

- 118. A discussion should take place with all prospective donors about any religious or contextual issues that may be relevant and they should be given the opportunity to ask any questions they may have.
- 119. All donors should undergo a rigorous screening process, including an interview to establish if they meet the requirements to become a donor.
- 120. Prospective human milk donors should undergo verbal and written screening involving answering a detailed health questionnaire.
- 121. Prior to initiating the recruitment process, each prospective donor should receive information about what the process involves, including what questions will be asked and that depending on her answer to any of these questions she may or may not be eligible to donate milk.
- 122. Each donor should provide her signed informed consent to donation. See [Appendix 3](#) for suggested template.
- 123. Prospective and current donors should never be coerced or encouraged to donate breast milk that their own baby/ies may need.
- 124. If a donor's milk can be stored for future use by her own infant this should be discussed with her.
- 125. If storage of surplus expressed milk is not possible check that the donor understands why this is the case.
- 126. Health professionals should ensure that ethical and safe practices are upheld when recommending or proceeding with donor recruitment.

Donor screening

- 127. Advise a prospective donor that she is not able to donate milk if she:
 - i. Currently smokes or uses nicotine replacement therapy (NRT).
 - ii. Is using, or has recently used, illicit drugs including (but not limited to) marijuana, methamphetamine, cocaine, heroin.
 - iii. Regularly drinks more than two ounces of hard liquor or its equivalents: 355ml or two cans of regular beer, 240ml of table wine in 24 hours.

- iv. Is using illicit drugs, alcohol or tobacco. She should be advised to stop exposure due to the risks of these to her infant and to herself.
- v. Has previously tested positive for human immunodeficiency virus (HIV) 1 or 2. However HIV positive mothers may opt to breastfeed their own infants after undergoing specialized counselling.
- vi. Belongs to any of the following high-risk groups for HIV/sexually transmitted diseases (STD):
 - Sexual partners of men known to be infected with HIV.
 - Drug users or sexual partners of drug users, who have injected themselves with drugs at any time.
 - Sexual partners of men who have had sexual intercourse with other men at any time.
 - Sexual partners of haemophiliacs known to be HIV-infected
 - Commercial sex workers (prostitutes).
 - Have received in the preceding six months blood donation or other blood products (except rhogam) while in a country where screening of blood donors is not routine.
- vii. Has been exposed to nuclear radiation (>1msv/yr).
- viii. Has received radiation treatment.
- ix. Has had any recent exposure to diagnostic, therapeutic or environmental radioactivity including radioactive iodine therapy. (In the event of radiation exposure mothers should seek specialist advice).
- x. Is in receipt of an organ or tissue transplant within the last 12 months (Antirejection medication that accompanies post organ or tissue transplant will also result in not being able to donate).
- xi. Has (or sexual partner has) had, within the previous 12 months, ears or other body parts pierced with instruments not intended for single use, permanent tattooing/make-up applied by needle.
- xii. Has (or has a sexual partner who has) had an accidental stick with a contaminated needle within the last 12 months.
- xiii. Is using mega-dose vitamin therapies.
- xiv. Follows a vegan diet without vitamin B12 supplementation (a vegan diet with B12 supplementation is acceptable).
- xv. Is taking medications known to be contraindicated for breastfeeding (e.g., antipsychotic medication). Refer to local or national pharmacologists/medications and breastfeeding experts if in doubt or to an international source of information.

COVID-19 and donor selection

The COVID-19 pandemic has introduced new challenges for milk banks including in the recruitment of milk donors. The high infectivity of the SARS CoV-2, coupled with the known airborne transmission and the many unknowns have resulted in the necessity for additional questions and precautions. See [Appendix 4](#) on the additional recommendations for safe collection and processing of donor human milk during the COVID-19 pandemic.

128. Ask prospective donors if they currently have, or have had, in the past seven days any of the following symptoms: dry, persistent cough; fever (>37°C); loss of sense of smell (anosmia) or taste. If yes, inform the prospective donor that she can qualify to donate only if she is symptom free for at least seven days.

129. Ask prospective donors if they have been a known contact for anyone who has tested positive for COVID-19 in the past 14 days. If yes, as long as they do not develop any symptoms, they should wait for 14 days since the contact before reapplying to the HMB.

Donor physical examination

130. If eligible, a general physical examination may be performed to rule out the presence of skin/breasts lesions and evidence of intravenous drug use or presence of tattoos. Additional health checks such as blood pressure, cardiac and lung function tests, and neurologic and psychiatric examinations may be included if deemed to be required.

Donor screening–blood tests

131. Donors are required to provide evidence via their medical notes of a negative antibody serology test result in the previous six months for Hepatitis B surface antigen, Hepatitis C, HIV and Syphilis (venereal disease research laboratory test (VDRL). Alternatively, donors should undertake a blood test for these that is arranged by the clinical lead for the HMB. Upon receipt of a written negative result for each test, the donor may be accepted if all other screening meets the requirements of these standards.

Donor temporary disqualification

132. Prospective or current milk donors with the following conditions are temporarily disqualified:
- i. *Varicella zoster* or *Herpes zoster* in the donor or family. A donor may be accepted again four weeks after infection starting from the time the lesions start to crust.
 - ii. Rubella in the donor or a family member. A donor may be accepted again four weeks after infection starting with the appearance of the rash.
 - iii. Recent immunization containing live rubella vaccine (e.g., mumps, measles, and rubella (MMR)). Four weeks after vaccination, a donor may be accepted again.
 - iv. During the 12-hour period following consumption of alcohol (hard liquor, beer, or wine).
 - v. Clinical mastitis and any active breast or nipple infections (monilial, fungal, eczema, *Herpes simplex* virus, shingles).
 - vi. Recent diagnostic radiation. (Usually acceptable to donate after three days).
 - vii. If a donor is known to be suffering from diarrhea she should temporarily stop donating her breast milk. However, she should continue to breastfeed her baby where relevant and following the essential hygiene standards, she should continue expressing for her baby.
 - viii. Short course medication use that does not comply with acceptable medications (each HMB should keep a list of acceptable medications that has been agreed nationally and updated annually).
 - ix. After any temporary disqualification, milk donation shall resume at the discretion of the medical director.

Donor exclusion

133. Prospective donors who do not meet the required criteria for acceptance as a milk donor should preferably be informed in person or by telephone or written letter. They should be offered the

opportunity to ask any questions they may have and be reassured that breastfeeding their own infant should continue.

134. Consider no longer accepting breast milk from donors who, despite support, consistently supply:
- i. Breast milk that does not meet the microbiological criteria.
 - ii. Small amounts of breast milk (the volume should be determined on an individual HMB basis in accordance with their requirements).

Donor approval

135. Confirm donor recruitment upon full approval following the screening via interview, questionnaire, physical examination and evidence of negative serology test results.
136. Inform donors in person where possible or by telephone or written confirmation that they have met all the requirements to be accepted as a human milk donor. Include any test results in a written letter.

Donor education and support

137. Education and training should be provided to all donors to lower levels of contamination in donor milk, avoid breast and nipple damage as a result of incorrect use of breast milk pumps, and to ensure only surplus milk is donated.
138. Donors require clear information that is appropriate for their circumstances.
139. Educational materials on milk donation and milk banking and breastfeeding support information should be available for mothers at the milk bank. Materials should be available in different languages where required.
140. In addition to donor education, offer practical, emotional and psychological support to donors as needed.
141. Donor education should include initial and ongoing training and include verbal and written guidance on best practice for:
- i. Preparation for milk collection—hair covering applied, hand washing/decontamination with soap and water or hospital detergent or with alcohol hand gel, breast washing with clean water or if required non-perfumed soap, wearing of surgical mask.
 - ii. Hygienic collection, storage (cooling, freezing, if appropriate), labelling and transport of milk including temperature and time requirements. The individual containers should be labelled with donor's name and ID, date of collection, term or preterm milk.
 - iii. Techniques for manual expression of milk.
 - iv. Correct use of a breast pump (as available) including its decontamination.
142. Advise donors that:
- i. Washing the breasts daily and wearing a clean bra daily (if worn) will help to minimize contamination of the milk.
 - ii. They will be provided with clean containers for their milk collection and that they should not use alternatives.
 - iii. Pump-expressed milk is acceptable if donors prefer this method.

- iv. Drip milk collected during or between feedings is usually nutritionally inferior to and more highly contaminated than expressed milk and should not be donated.
- v. They should not discard the first 10ml of expressed breast milk.
- vi. They should not touch the inside of the cap or the container.
- vii. They should fill each milk container 3/4 full (or leave one inch from the top of bottle) to allow room for milk expansion with freezing.
- viii. There are different options for storing expressed milk. Expressed milk should be frozen as soon as possible. Refrigerated milk samples may be collected over 24 hours and then frozen as one batch. Freshly expressed milk can be added to a bottle of already frozen milk, provided it is within a 24-hour collection and is less than or equal to the volume of milk already frozen in the container. The milk should be labelled with the date and time of the earliest expression.
- ix. Cleanliness of milk expression, storage and handling reduces the numbers and types of bacteria in expressed milk.
- x. If needed, donors can be supervised at home while collecting and storing donations to lessen discarded donations.
- xi. They should follow instructions for bringing home collected milk to the HMB for pasteurization.
- xii. They should check the temperature of their home freezer if applicable by ensuring any contents are frozen solid.
- xiii. They should maintain the cold chain using frozen gel/ice packs (not ice cubes) while transporting human milk to the HMB.
- xiv. Freshly expressed breast milk can safely be stored for up to 24 hours in a cooler with frozen gel packs.

Donor code of conduct

143. Donors are required to alert milk bank staff of:

- i. Any changes in their circumstances with regard to the donor screening questionnaire and infection risk.
- ii. Any illness (or in the case of COVID-19, any confirmed or suspected symptoms of infection in the family or other close contacts—high temperature, persistent cough, loss of sense of taste or smell).
- iii. Any loss of power affecting the home refrigerator or freezer.

Donor deferral/duration of donating

144. Take into account the size of the recipient population and the milk bank's stock levels when discussing how long a woman can donate milk.

Donor support after stopping donations

145. Explain to donors the reasons why they have been asked to stop donating. If appropriate, explain the reason why the milk bank has strict criteria (immunocompromised, preterm and sick infants) and that this should not stop her from breastfeeding her own baby.

Donor Human Milk

DHM collection and storage in hospital

Appropriately stored refrigerated expressed breast milk leads to minimal changes in immune components.

146. Monitor twice daily the temperatures of all refrigerators and freezers used for DHM storage (raw and heat treated) wherever they are located. Records should be maintained by the HMB.
147. Store raw milk in the refrigerator prior to pasteurization for a maximum of 24 hours.
148. The recommended temperature in refrigerators where DHM is stored is +2°C to +4°C (do not exceed 7°C).
149. After a maximum of 24 hours, transfer containers of raw liquid milk to the freezer.
150. Freezers used for storing human milk should maintain a temperature of $\leq -20^{\circ}\text{C}$ (20°C or colder).
151. Refrigerate raw milk immediately following expression. Chill the newly collected milk prior to adding to chilled milk. The information on the first container remains the same. Note on the label that an additional expression has been added.
152. All hospital breast milk refrigerators and freezers should be locked and in a locked room to prevent access by any unauthorized person.
153. Store breast milk for donation in lidded containers, separately from other milk feeds, in a dedicated refrigerator or freezer.
154. Visibly blood-stained milk, milk with unusual color and milk with unusual particles should be discarded at the staff's discretion and the donor contacted and recommended to be checked by a lactation specialist nurse, midwife or doctor.
155. Ensure all breast milk is labelled with the name or identity number of the donor, the date and time it was expressed and any medications taken within the previous 24 hours.
156. Use ALERT stickers in the event of two or more donors with the same name to immediately bring this to the attention of staff.
157. Arrange for breast milk donations to be transferred to the HMB refrigerator or freezer as soon as possible and within a maximum of 24 hours.
158. In the event of an audible refrigerator or freezer temperature alarm, or of daily temperature monitoring revealing suboptimal temperatures, inform HMB staff immediately and arrange for the DHM to be transferred to the HMB.

DHM collection and storage at the donor's home

159. Provide donors with milk containers and instructions for use in accordance with HMB recommendations, highlighting the need for good hygiene. The containers should be:
 - i. Collected by donors from the HMB or HMB depots or satellite unit.
 - ii. Delivered to the donors' homes (e.g., by couriers or HMB staff when donated milk is being collected).

- iii. Labelled prior to filling.
- 160. Require donors to check and ensure their refrigerator and/or freezer is clean and suitable for storing DHM.
- 161. Donors are required to check and record their refrigerator and/or freezer temperature. If there is no thermometer available, noting that the equipment is operating as usual is adequate. Alternatively, milk bank staff should check during a home visit.
- 162. Ask donors to place milk containers in the coldest part of the refrigerator, if used, and not to store them in the door. The coldest part of the refrigerator is at the bottom and at the back, however it may be subject to spillage from food on the shelves above.
- 163. Ask donors to protect or cover their expressed milk containers and to store them away from other food (e.g., with a clean plate or plastic box lid). Placing the containers in a clean polythene bag or plastic box will also help to prevent contamination by other food and by other users.
- 164. Milk bank staff should contact donors regularly to offer support, and to arrange for milk to be collected or delivered by the donor to the HMB or HMB depot or satellite unit.

Transportation of DHM within the hospital to the HMB

- 165. Follow all relevant local or national laws and guidelines introduced as a result of COVID-19 or other infectious diseases including social distancing.
- 166. Agree on timings for collection and delivery of DHM from departments/units.
- 167. All DHM to be delivered to HMB refrigerator/freezer as soon as possible but within a maximum of 24 hours from time of expressing.
- 168. Transport DHM within hard, insulated carrier (cool box) dedicated for transporting fresh or frozen raw human milk (see section on Equipment). Clearly label the carrier with details of the contents, the destination address, and that the contents should be transferred to a fridge/freezer immediately on arrival at the destination.
- 169. Transport donor milk in secure, tamper-evident containers and packaging where possible.
- 170. Protect containers of breast milk from contamination between different mothers' containers using a new/clean paper bag or plastic bag while being transported within the hospital e.g., from postnatal ward to HMB.
- 171. Use frozen gel type coolant blocks (not wet ice) for transporting breast milk during journeys longer than a few minutes.
- 172. Fill any empty spaces with crumpled paper or clean towels or extra coolant blocks if small volumes of milk are being transported.
- 173. Where possible use shaded corridors for transporting DHM to the HMB.
- 174. Monitor the temperature of the milk following transport.
- 175. On arrival at the HMB, the fresh, chilled or frozen milk should be checked and transferred immediately to the raw, untested milk section of the HMB refrigerators or freezers.
- 176. Decontaminate and disinfect transport boxes internally and externally between use.

Transportation of DHM from donor's home to the HMB

177. Follow COVID-19 rules as stated in Item 165.
178. If donor milk is transported to the milk bank by a contracted third party, ensure that a documented agreement is in place to maintain the conditions of the DHM needed.
179. Compliance with the agreement should be monitored
180. Milk collections should be made using either:
 - i. an identified collection vehicle in the community.
 - ii. the milk collection vehicle or hospital ambulance of the milk bank.
 - iii. private vehicle of milk bank staff.
181. Define critical conditions for transport, including temperature and time limit, to ensure that donor milk remains frozen during transport.
182. Ensure the temperature of the milk is maintained throughout the journey by avoiding placing the cool box next to the vehicle's heater or under strong day-time heat.
183. Fill any spaces in the cool bag/box with frozen coolant blocks/ice packs to help maintain the temperature of the chilled or frozen milk throughout transport.
184. In instances, where donors are requested or may wish to deliver their own milk to the milk bank, they should also follow the milk bank's requirements for transport.
185. All deliveries of DHM to the HMB should be met by staff member, and the milk transferred immediately to the raw, untested milk section of the HMB refrigerators or freezers.

Table 1. Storage of fresh raw and pasteurized donor human milk

Storage condition	Storage temperature	Storage limits		Notes
		Raw DHM	PDHM	
Room temperature	16°C- 30°C	as short as possible	3-4 hours	counted from the storage
Domestic refrigerator	8°C- 15°C	12 hours	12 hours	counted from the storage
Refrigerator at the HMB	≤ 4°C	24 hours	24 hours	counted from the storage
Freezer of the HMB	≤ -20°C	to the pasteurization: 3 months	to the usage: 6 months	counted from the expression
Freezer compartment of the domestic refrigerator	≤ -15°C	2 weeks	2 weeks	counted from the storage—milk is still in use

Receiving DHM at the HMB

186. When a mother's milk expression is completed it should be handed to the relevant staff member depending on the location e.g., NICU nurse, KMC unit nurse, HMB nurse.
187. Stringent measures need to be taken to prevent contamination and cross contamination.
188. Record time of pick-up, place of expression and time of arrival at the milk bank.
189. Check and record label details including donor ID, time and date of collection, milk volume, details of the state of the milk (i.e., liquid, frozen), and any unusual observations.
190. HMB staff should follow all recommendations for handling of the containers of milk.

Hospital milk bank depot storage of raw DHM

Milk bank depots and satellite units enable milk banks to extend the reach, scope and level of their activities.

191. The responsibility for the activities of milk bank depots and satellite units lies with the HMB, and the same guidelines and SOPs should be followed.
192. Do not store raw DHM and PDHM in the same freezer or refrigerator. Have a separate freezer or refrigerator for raw DHM, PDHM awaiting microbiology results and microbiology-passed PDHM.
193. Provide clean milk containers in accordance with HMB recommendations to the human milk depots for provision or delivery to donors.

Processing DHM

Processing DHM involves some or all of the following: thawing milk if frozen; labelling containers using adhesive labels or permanent marker pen; pooling milk (single donor or multiple donors); sampling DHM for microbiological testing prior to heat treatment; pouring milk into individual containers for pasteurization; pasteurizing the milk; testing a representative sample; and freezing the PDHM awaiting laboratory test results.

194. Process all donated milk under hygienic conditions.
195. Practice good hand hygiene at all times following the hospital hand washing protocols.
196. Wear sterile gloves when handling human milk, change them in between that of different donors and between handling raw and pasteurized DHM.

Thawing DHM

197. All DHM should be completely thawed before pasteurization to ensure uniform heat treatment.
198. Methods of thawing include:
 - i. Thaw milk overnight in a refrigerator and pasteurize within 24 hours of having thawed.
 - ii. Thaw at room temperature with careful monitoring and transfer to refrigerator while some ice crystals remain (to avoid milk becoming too warm).
 - iii. Rapid thawing while partially submerged in warm water (up to 37°C). Do not allow lid to be submerged or containers to tip over in the water.
199. Document time milk commenced thawing in the pasteurization records.
200. Do not refreeze thawed milk unless it has been pasteurized first.
201. Do not use a microwave to thaw milk as it can create uneven temperatures¹⁵ and encourage microbial growth. It also leads to destruction of valuable bioactive human milk components,^{16, 17}.
202. Once thawed, minimize handling time at room temperature. Avoid the milk temperature exceeding 7°C.

Pooling, mixing and pouring DHM

Globally there is no consensus on pooling milk. There are different options.

- Milk is not pooled. Instead, pasteurize DHM in the container in which it was collected. This requires milk to be in the same size and type of container and with similar volumes in each container (to avoid very small volumes receiving the same heat treatment as larger volumes).
- Create a single donor pool i.e., mix together a number of separate expressions or donations from a single mother.

¹⁵ U.S. Food and Drug Administration. *Once Baby Arrives from Food Safety for Moms to Be*. Available at <https://www.fda.gov/food/people-risk-foodborne-illness/once-baby-arrives-food-safety-moms-be>. Accessed 23 August 2021.

¹⁶ Quan R, Yang C, Rubinstein S, et al. Effects of microwave radiation on anti-infective factors in human milk. *Pediatrics*. 1992;89(4 Pt 1):667-669.

¹⁷ Sigman M, Burke KI, Swarner OW, Shavlik GW. Effects of microwaving human milk: changes in IgA content and bacterial count. *J Am Diet Assoc*. 1989;89(5):690-692.

- Pool milk from several donors, usually up to a maximum of six.
203. Document all pooling including the volumes and the names or ID numbers of all donors whose milk is included in each pool.
 204. Pool DHM in sterile containers (flasks or jugs), mix gently with a sterile stirrer.
 205. Where available, pool milk within a cabinet under a laminar flow hood. Alternatively use an easily cleanable stainless-steel surface away from air inlets or ventilation.
 206. After pooling, aliquot the milk into individual containers, mixing gently between each container poured.
 207. If taking a pre-pasteurization test sample, do so halfway through the pouring and mixing process.
 208. Do not overfill the containers.
 209. Pour the same volume per container to facilitate equal heat treatment for each one.
 210. To prevent ingress of water during the pasteurization process, all containers should be tightly closed with new or sterilized caps.

Testing DHM before pasteurization

Globally there is no consensus on the testing of DHM for its microbiological content. Recommendations vary between testing some or all samples of milk prior to pasteurization, and/or testing representative samples of milk from each pasteurized batch after some or every pasteurization run. There are cost as well as safety implications to these different testing regimes.

Raw milk, when hygienically collected by healthy women, contains several hundred different species of bacteria. These do not normally pose a risk to healthy infants and many are beneficial. Pathogens may also be introduced through maternal infections, inadequate storage and poor handling. Pasteurization kills or inactivates most microorganisms, however activity may remain in the event of high levels of contamination and the presence of organisms such as *Bacillus* species that release heat resistant spores during the process. Testing human milk for the presence of viable microorganisms before pasteurization provides detailed information about the microbiological quality of the raw milk, and therefore of its safety. Testing after pasteurization provides a more general assessment of the quality of the milk and the efficacy of the heat treatment. Testing milk imposes an economic burden on the milk bank and these standards aim to minimize costs without compromising safety. When milk does not meet the required criteria, it should be discarded. Hygienic collection of milk will lead to greater volumes of milk being available and reduce overall costs in providing sufficient milk to meet the need.

The consensus of the TWG was that performing routine pre-pasteurization tests on every sample of milk or every pool (where milk is pooled prior to aliquoting) is neither cost effective nor necessary. However, as pre-pasteurization tests provide an indication of adherence to milk collection, storage and handling techniques, it is recommended as a means of monitoring overall standards. Testing random samples of milk before pasteurization during the first six months of operation of an HMB will provide useful information on milk quality. Testing subsequent donations in the event of milk failing to meet the required criteria will indicate whether the standard improves after discussion with the donor.

211. There is no requirement to test all donated milk prior to pasteurization.
212. For HMBs that do not routinely perform pre-pasteurization tests, test raw DHM in the event of specific concerns about the microbiological quality of the milk.

213. Test a random sample of milk from every new donor during the first six months of operation of a newly established HMB.
214. In the event of milk failing to meet the required criteria, test subsequent samples from the same donor after additional donor training on the collection, storage and handling of milk.
215. Discard DHM that fails to meet the following criteria:
 - i. $\leq 10^5$ CFU/ml total viable count.
 - ii. $\leq 10^4$ CFU/ml *Staphylococcus aureus*.
 - iii. $\leq 10^4$ CFU/ml Enterobacteriaceae.
 - iv. $\leq 10^4$ CFU/ml organisms of fecal origin.
 - v. absence of *Pseudomonas aeruginosa* and other *Pseudomonas* species.

Additional tests for DHM

216. It is possible to test donated breast milk for contamination with bovine (cow's) milk. In the event of suspected adulteration, discard the milk. If testing is felt to be warranted, use a validated test. And if positive for bovine milk, discard all the donated milk from that donor and do not accept further donations unless she was not responsible for the error.

Heat processing of DHM

217. Pasteurize DHM as soon as practically possible after expression and within 24 hours if refrigerated and within three months if frozen.
218. Pasteurize donated milk at 62.5°C for 30 minutes (Holder pasteurization) followed by rapid cooling using appropriate equipment (see section on Equipment).
219. Operate all equipment in accordance with manufacturers' instructions.
220. Clearly display a copy of the SOP covering DHM pasteurization.
221. The pasteurization process should be carried out strictly in accordance with the manufacturers' instructions.
222. A data logger, attached to a temperature probe immersed in a container of water and placed within the DHM containers in the water bath, should be used to obtain a record of the milk temperature throughout every cycle.
223. Temperature records should be checked and recorded for conformity.
224. The record of the pasteurization should be signed, stored and maintained for a minimum of 10 years for every batch of milk/every pasteurization cycle.
225. In the event of nonconformity with the temperature and time parameters, the milk should not be passed for nutritional use unless in consultation with the HMB clinical lead.
226. Every container of milk should be labelled to enable identification and traceability.
227. Required details for tracking include the donation/expression date, donor ID number, quantity, date of pasteurization and expiry date. PDHM is expired if it that has been stored for three months or longer.

228. Acceptable methods of labelling include pre-printed heat and water-resistant labels and indelible permanent marker pen.
229. The labelling should be applied on the bottle and not solely on the cap to prevent errors when the milk is being decanted.
230. Alternative methods of processing DHM with better preservation of human milk properties may be used in the future if validated processes and cost-effective equipment become available.

Testing DHM after pasteurization

231. Perform a post-pasteurization test on a representative sample from every batch of PDHM.
232. Randomly select a container from the basket or apparatus holding all the containers in the pasteurizer. Transfer the remaining containers of PDHM to the freezer labelled 'PDHM awaiting clearance'.
233. Either send the whole container or a sample from its contents to the microbiology laboratory for testing.
234. Test samples should be transported immediately to the laboratory using cold chain transport or stored in the refrigerator and sent as soon as possible if awaiting additional samples.
235. Following culture results, only retain and use those batches of PDHM where the test sample was culture negative, i.e., demonstrated no growth after 24 hours.

Post-pasteurization storage of DHM

236. Transfer PDHM to the appropriate freezer to await test results.
237. Store in the same container that is used for pasteurization to prevent contamination.
238. Following test results, remove all failed milk from freezer and discard. If there is a plan to use failed milk for future research, keep in a separate freezer at $\leq -20^{\circ}\text{C}$ (20°C or colder).
239. Maintain culture negative milk at $\leq -20^{\circ}\text{C}$ (20°C or colder) freezer. Ensure containers are labelled with batch number, expiry date and the contents, i.e., PDHM. The pasteurization/freezing date may also be useful if not clear from the batch number.
240. If PDHM is to be provided to external facilities or to families in the community, label DHM with the name or logo of the HMB.
241. Organize freezer contents to ensure PDHM does not pass its expiry date. It is helpful to store it in date order to enable the oldest milk to be used first.

Labelling of DHM (Table of required labelling)

242. Ensure all human milk is appropriately labelled to enable the user to identify the donor (using unique ID that relates back to the donor), the date of expression or expiry, and the status of the milk (raw, pasteurized, tested, passed for nutritional use).

Table 2. Required information on label of donor human milk

Required information on label	
Label on raw milk bottles	<ul style="list-style-type: none"> • Unique identification information of the human milk donor • Expression date and/or due date of pasteurization • Milk status: raw, not in use
Label on pasteurized donor human milk bottles—final product of the HMB	<ul style="list-style-type: none"> • Unique identification information of the human milk donor or donors in the event of pooled DHM • Pasteurization run/batch number • Testing results: qualified • Milk status: pasteurized and ready-for-use • Expiration date
Label on each thawed PDHM bottle	<ul style="list-style-type: none"> • Unique identification information of the human milk donor or donors in the event of pooled DHM • Pasteurization run/batch number • Testing results: qualified • Milk status: pasteurized and ready-for-use • Expiration date • Start time of thawing
Label on donor milk cup/bottle after aliquotation	<ul style="list-style-type: none"> • Unique identification information of the human milk donor or donors in the event of pooled DHM • Pasteurization run/batch number • Testing results: qualified • Milk status: pasteurized and ready-for-use • Expiration date

Delivery of PDHM to receiving hospital/NNU

243. The HMB should devise a means of receiving confirmed orders based on clinically approved requests from units and where agreed, from external hospitals.
244. Requests for PDHM may be received via telephone, email or written request form with the frequency and timing of the orders agreed by the HMB.
245. Confirm that stores of pasteurized PDHM are available to meet the requested volumes and consider future stocks required and prioritization needs in the event of stocks being low.
246. HMB staff are responsible for ensuring that the correct volumes of PDHM are delivered in response to the orders received.

247. Provide PDHM with maximum frozen storage time possible before its expiry date.
248. If PDHM is thawed in the HMB, aliquoted and delivered for use by named infants, ensure accurate labelling including recipient name prior to the milk leaving the HMB.
249. When thawing PDHM either:
 - i. Thaw slowly at 4°C for up to 24 hours in the refrigerator of the HMB (use within 48 hours from start of thawing); or
 - ii. Thaw more rapidly by standing containers in previously boiled water cooled to ≤37°C until PDHM is completely thawed, ensuring the water does not reach the cap. Transfer to refrigerator prior to or immediately on completion of thawing (use within 24 hours of being thawed).
250. Store thawed PDHM in the refrigerator at a temperature of ≤4°C.
251. Discard thawed PDHM not used within the recommended time.
252. Transport all PDHM safely and appropriately to its destination in compliance with transport equipment using trained staff and maintaining the cold chain at all times. Document transport details to receiving units.
253. All PDHM should be accompanied by documentation that facilitates its correct delivery and provides the information needed by the end users to complete the records and ensures traceability of the milk.
254. The PDHM receiving units/wards are responsible for checking and confirming that the milk has been transported safely (temperature and time), has arrived in the required condition, is labelled correctly, is within the expiry date and/or time, is accompanied by the correct documentation, and is urgently transferred to the appropriate refrigerator or freezer as required.

Tracking and tracing PDHM including recall

255. It is the responsibility of the receiving neonatal unit or other recipient unit or ward to maintain and keep accurate records of the use of PDHM as follows:
 - i. Register of PDHM dispensed.
 - ii. Register of recipients of PDHM.
256. The register of PDHM dispensed should include:
 - i. Location.
 - ii. Date of administration.
 - iii. Recipient name, hospital number, date of birth.
 - iv. Clinical detail e.g., gestational age at birth.
257. The recipient's medical and nursing notes should include:
 - i. The prescription/medical request for PDHM.
 - ii. Name, location and contact details of ordering physician or hospital.
 - iii. Details of the PDHM fed—date, time, volume, identification details from the label on the container, any relevant post feed details re: tolerance, if noted.
 - iv. Name, date of birth of the child receiving the donor milk, date of transferral into department/unit.

Documentation and record keeping in the HMB

258. The following records should be archived in the HMB:

Table 3. Records of donor and PDHM information

Records	Information to be archived
Records of human milk donor	<ul style="list-style-type: none">• Personal information of the human milk donor• Signed consent form for voluntary milk donation• Questionnaire and screening results• Results of serological tests• Donation log
Records of pasteurization batch	<ul style="list-style-type: none">• Information of milk bottles to be pooled: ID code of the human milk donor• Pasteurization run/batch number• Document the results of all microbial tests before and/or after pasteurization• Information on pasteurization batch, including duration and temperature of pasteurization (whether automatically recorded by the pasteurizer or manually by the operative)• Human milk receiving units or milk disposed of due to disqualification

Procedural and operational records

259. The following records are required to ensure full traceability as well as adherence to the standards and operating procedures:

- i. Log of milk received at the milk bank with date and time.
- ii. State of milk on arrival (freshly expressed, frozen, thawed, appearance if unusual).
- iii. Identification of milk donor (donors if a multi-donor pool).
- iv. Batch information.
- v. Date and time pooled and aliquoted.
- vi. Containers per batch.
- vii. Microbiologic results pre-pasteurization (if ad hoc tests performed).
- viii. Amount of milk pasteurized, with dates and time.
- ix. Microbiologic results post-pasteurization.
- x. Freezer, refrigerator—daily temperature records.
- xi. Calibration records for all equipment.
- xii. Equipment maintenance checks.

260. Maintain updated copy of National Milk Bank Guidelines.
261. Maintain a detailed manual of SOPs that are periodically reviewed and updated in consultation with the Milk Bank Committee.
262. Maintain additional milk bank documents and files including:
 - i. Training and performance records of milk bank staff.
 - ii. Equipment and supplies manufacturers' instructional guides.
 - iii. Supplies inventory.
 - iv. Milk bank financial records.
 - v. Attendance and minutes of administrative meetings.

Record keeping by HMB

263. All records critical to the safety and quality of the PDHM should be kept for a minimum period of 10 years in the event of any future medico-legal issues.
264. Records related to the ID of the donors and recipients will require further storage in the event of any future potential milk kinship questions and so 30 years is recommended.
265. Confidentiality of all records related to donors and recipients is required.

Record keeping by end user

266. The end user hospital/clinic should maintain and keep the following records:
 - i. Child receiving PDHM.
 - ii. Indications for use.
 - iii. Any relevant clinical outcome details.
 - iv. Signed informed consent for receipt of PDHM by parent/guardian/caregiver.
 - v. ID number from all containers of PDHM received by each recipient.
 - vi. Conditions of PDHM on arrival from the HMB.
 - vii. Temperature conditions during storage of PDHM.
 - viii. Storage duration
 - ix. Thawing
 - x. Any milk aliquotation

Monitoring and Monitoring Team

Monitoring of all the processes and their documentation is required at every working step of the HMB. Monitoring includes mock batch recall, external and internal auditing.

267. Implement a quality control system that includes clearly described monitoring. The recommended quality control system for human milk banking is HACCP.

- 268. Identify the monitoring team and team leader with established accountability, authority and responsibility.
- 269. The monitoring team should demonstrate adherence to the national/regional guidelines and manage risks that can affect the safety and quality of the PDHM.
- 270. Monitor the tracking of donated milk from the donor through to the recipient to ensure it is complete and able to be performed for all donor milk being collected, processed and issued from the HMB.
- 271. Perform a mock batch recall within six months of establishing a HMB, and annually thereafter.

Use of PDHM

Every effort should be made, in accordance with WHO, BFHI and national recommendations, to optimally support every new mother to breastfeed her infant. When MOM is insufficient, PDHM is the recommended choice for feeding LBW and preterm infants as well as all hospitalized infants when sufficient safe supplies of PDHM are available. It is rare for mothers to be unable to provide any MOM, although in the event of maternal illness, preterm delivery and separation, it may take several days or longer for her to meet her infant's needs. Equally, it may happen that the mother is unable to maintain her lactation and her infant requires supplementation at a later stage, especially before the baby is able to directly breastfeed and stimulate and increase the mother's milk supply. There are also some circumstances in which a mother's milk may not be recommended for her infant (e.g., if undergoing chemotherapy).

- 272. Maternal colostrum should be the first feed and when babies are unable to feed directly at the breast, optimal help and support should be provided to the new mothers to express and collect their colostrum and feed it to their infant.
- 273. PDHM should only be used when there is no MOM or insufficient MOM.
- 274. The availability of PDHM should not allow it to be prioritized over the MOM as the latter is higher in nutritional value as well as in the non-nutritional bioactive components that provide immunological support for the infant.
- 275. Assist mother-baby dyads in establishing a breastfeeding relationship.
- 276. Full term healthy newborns should not be given PDHM as a prelacteal feed.
- 277. Prioritize the provision of PDHM to preterm infants that was provided by a donor with a preterm infant and that was expressed during the first 30 days post- delivery.
- 278. Prioritize sick and preterm infants to receive PDHM that has been stored in total for less than three months.
- 279. All facilities receiving PDHM should undertake training of staff to ensure receipt, handling, storage, thawing and use of PDHM is in compliance with national standards and HMB/hospital hygiene SOPs.

Selection of recipients

- 280. Provide recipients with PDHM from the same batch where possible to minimize exposure to different donors.
- 281. Match age of recipient with age of donor's infant where possible.
- 282. Only dispense PDHM from HMBs that adhere to these Standards.

283. Do not dispense raw DHM. In the event of specific clinical requests for frozen raw donor milk, i.e., non-heat processed milk, additional serology testing criteria for donors and additional testing of DHM would be necessary, in addition to alternative storage recommendations. These are not considered here.
284. Only dispense PDHM for clinical use by prescription or by hospital purchase order after assessing maternal milk supply and any medical contraindications to breastfeeding.
285. Indications for PDHM include:
- i. Prematurity.
 - ii. Malabsorption.
 - iii. Feeding intolerance.
 - iv. Immunologic deficiencies.
 - v. Congenital anomalies.
 - vi. Post-operative surgical conditions.
286. If supplies of PDHM are sufficient, milk may also be dispensed by prescription in the following situations:
- i. Lactation failure/insufficient.
 - ii. Adoption.
 - iii. Illness in the mother requiring temporary interruption of breastfeeding.
 - iv. Health risk to the infant from the milk of the biological mother.
 - v. Death of the mother.
 - vi. When supplementation is needed.

Recipient prioritization

Suggested order of priority for receiving PDHM:

- Premature at <32 weeks or <1,500 g birthweight.
- Infants with complex congenital heart diseases.
- Infants with severe diseases/after surgery, especially due to gastrointestinal conditions.
- Preterm or LBW infants without diseases.
- Full-term infants without diseases.
- Infants under six months of age who have special medical conditions (cancer, immunodeficiency, heart diseases, gastrointestinal conditions, and others).
- Healthy infants with mother making insufficient milk during the first days after delivery following medical indication. The use of PDHM is temporary when mothers, for special reasons, do not have enough milk for their baby.

Note: Additional causes of absence of MOM may be maternal ill health, contraindications e.g., radioactive treatment, death or abandonment of infant.

287. Criteria for stopping using PDHM are when there is sufficient MOM or when the clinical condition has improved and stocks of PDHM cannot sustain continued use.

Recipient parent/guardian consent

288. Provide parents of infants meeting the criteria for PDHM with information about the processes involved in making PDHM safe and available. Written information available in local languages facilitates the taking of informed consent.
289. Prior to the use of PDHM with any infant, obtain written consent from a parent or guardian in line with hospital protocols for the taking of consent.
290. Where PDHM is provided for feeding to a baby being cared for at home, the consent should include acknowledgement that the safe condition of the PDHM is only guaranteed up to the time it is collected and agreement to follow instructions on the handling and storage of the PDHM.
291. In case of refusal by the parents, and their informed decision is to use milk formula or raw breast milk from a different donor, a waiver should be signed by parent and physician absolving the hospital and clinicians of responsibility in the event of harm.

Fortification of PDHM

Human milk fortifiers (HMF) are available to purchase from commercial companies. They are generally made using cow's milk although human milk derived HMF is also available from commercial human milk companies.

292. When clinically indicated, and in line with unit protocols and clinical request, PDHM may be supplemented or fortified by the addition of macronutrients and/or micronutrients in liquid or powder form.
293. Use aseptic technique and follow the manufacturer's instructions including for its storage, when adding fortifier to PDHM.
294. PDHM may be fortified in the milk preparation area of the NNU or in the HMB (pasteurized milk handling area only).
295. Document the use of fortified PDHM in an infant's medical and feeding notes.

Home use of PDHM

296. Where supplies allow, the home use of PDHM may be supported in accordance with clinical decisions and any local requirements.

Disposal of PDHM

297. Ensure safe disposal of PDHM by HMB staff in accordance with local protocols for products of biological origin.

Disaster and emergency response

In disaster and emergency situations, mothers and infants may be separated and stressful situations may lead to a decrease or a temporary cessation of milk production. At such times, the use of BMS may introduce additional risks. If PDHM can be safely delivered and fed to infants in such scenarios, its use should be explored and supported. However, families should be counselled and informed that where breastfeeding can be continued, supplementary feeds should be avoided or minimized to enable the mother's milk supply to return to normal. Avoid the use of feeding methods that interfere with breastfeeding.

298. Where the use of PDHM in disaster and emergency situations is deemed safe and appropriate it should be supported by HMBs in the region.



Quang Ninh Human Milk Bank

Making space for human milk banks: Lessons learned from Viet Nam

Human milk bank (HMB) services are an essential component of a breastfeeding-friendly health system. HMB services give at-risk infants, such as those born pre-term or low birthweight, access to the multiple benefits of breastmilk when they need it the most. Alive & Thrive (A&T) and other partners have been supporting the Da Nang Department of Health and Tu Du Hospital to set up the first two HMBs in Viet Nam. The HMB at Da Nang Hospital for Women and Children (DNHWC) was established in 2016, while the HMB at Tu Du Hospital was established in 2019. A&T has developed this brief in order to share information, resources, and lessons learned from the experience of setting up the first HMBs in Viet Nam.

The set-up of an HMB depends on the local environment and needs of the community, underscoring the importance of conducting a facility readiness assessment before establishing a new HMB. The two HMBs in Viet Nam have two very different designs. While the HMB at DNHWC has most of the components in one location within the hospital, the HMB at Tu Du Hospital integrates various components and services within existing hospital services and structures, a decision that was based on a facility assessment conducted by A&T. For example, the donor recruitment unit at Tu Du is based at the main entrance of the hospital, the counselling and lactation room is closer to the human milk processing facility, and the processing facility is closer to donor human milk recipients (near the neonatal intensive care unit, NICU). Below are lessons that can be shared from the experience in Viet Nam:

The best location in a hospital for an HMB is near the NICU or in the department of pediatrics or neonatology

The space designated for the HMB must be clean and dry, far from infectious places such as kitchens, public toilets, and infectious disease departments. This increases security and prevents heat, flies, and contamination penetrating the milk bank area.

- It is beneficial to have designated areas for milk expression, where milk collection and donation take place.
- The arrangement of rooms, doors, and windows must ensure that raw milk, pasteurized donor human milk, clean equipment, milk disposal and dirty equipment are in one-way circulation to ensure infection control. This arrangement should be discussed and agreed with the infection control department.
- There should be areas for milk storage, milk pooling, and milk pasteurizing that meet local criteria for infection control.
- The design of the space should prioritize functionality and minimize the costs of necessary upgrades and repairs

What should a human milk bank look like?

To invest in an HMB, a hospital must explore how to best upgrade a space that can be made suitable for the freezer storage, sampling of donor human milk, and handling of raw breast milk, as well as for processing the milk using human milk pasteurization equipment. The space allocated must meet the national regulatory standards for a clean space for food handling, and for the provision of electricity and water supplies, in accordance with recommendations for clinical services (e.g., being linked to a back-up generator for the freezers and routine testing of water supplies to ensure an uncontaminated supply). The maintenance of records (computerized and paper) requires a fully equipped office space, as well as a means of storing records according to the guidelines. The pasteurization room must meet the standard of a sterile room and comply with the infection control department at the hospital.

Work surfaces should be stainless steel, and all joints sealed with materials that can be effectively cleaned and disinfected. The surfaces should comply with food hygiene regulations.

Splash-back areas should be made of stainless steel for any areas behind work surfaces where breast milk may be open to the atmosphere (i.e., when it is pooled, mixed, or aliquoted). The use of a laminar flow cabinet, which has glass or acrylic sides, is an exception. This facilitates effective decontamination and disinfection.

Clean-up area. This should be a designated area within the preparation and processing room. The processes of preparation and clean up must be separated. Small equipment can be sterilized in an autoclave (external to the milk bank) or a dishwasher. When a dishwasher with an 82°C final rinse cycle is used, a single sink for pre-rinsing is sufficient. If bottles are reused, a two- or three-compartment sink with a rinse nozzle is suggested, along with bottle-washing brushes. A two- or three-compartment sink will allow the washing and rinsing of equipment to be separated.

Flooring, walls, and ceilings should be made of a material that can be easily maintained and cleaned and are compliant with food hygiene regulations.

Storage area. All stored items (e.g. consumables, small pieces of equipment, etc.) should be stored separately from the milk preparation, testing, and processing room. This is to avoid a build up of dust and to prevent boxes, which may have been stored in warehouses, from being taken into the clean room. The storage area should be set up with easy-to-clean shelves that are accessible without requiring steps or ladders, where possible. If steps are needed, store infrequently used items on high shelves. All stored items should be placed in labeled areas on the shelves. There should be no storage of boxes or containers on the floor. Stock use-by dates should be checked regularly and rotated when storing to avoid the use of out-of-date products. The use-by dates of all products (e.g., sterile jugs) should be checked before use.

Milk preparation area. The area where containers of breast milk are placed on surfaces to sort and label, as well as any preparation areas, should contain a stainless-steel work surface, a hand washing sink, with hand-free taps, and antibacterial hand washing and drying facilities in accordance with food hygiene regulations.

Power and water supplies. There should be water provision for the pasteurizer to meet national and institutional standards. Adequate electrical outlets with appropriate power should be provided for the equipment within the room and be compliant with local and national standards. Electrical outlets for the refrigerators and freezers should be backed by an emergency generator in case of power failure. Lights within the unit should be enclosed and allow adequate illumination

Ventilation and room temperature. Clean air should be supplied through the ventilation system. The temperature of the milk bank rooms should be ambient, without large variations. Air conditioning will help to avoid breast milk becoming too warm during testing and prior to processing and will facilitate the efficient operation of the refrigerators and freezers, as well as provide a comfortable working area for milk bank staff. The use of electric fans- other than extractor fans – should be avoided in the processing room.

Clean-up area. This should be a designated area within the preparation and processing room. The processes of preparation and clean up must be separated. Small equipment can be sterilized in an autoclave (external to the milk bank) or a dishwasher. When a dishwasher with an 82°C final rinse cycle is used, a single sink for pre-rinsing is sufficient. If bottles are reused, a two- or three-compartment sink with a rinse nozzle is suggested, along with bottle-washing brushes. A two- or three-compartment sink will allow the washing and rinsing of equipment to be separated.

All equipment and utensils used within the processing room should be made of stainless steel or other nonabsorbent material. All equipment and utensils should be easy to clean and decontaminate and able to withstand temperatures of a commercial dishwasher. Strong and persistent biofilms can form on surfaces

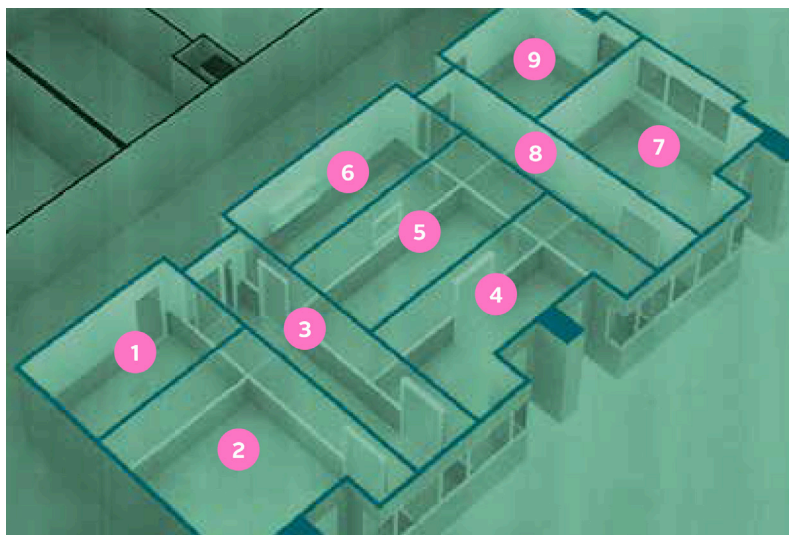
such as steel, plastic, silicone and latex. Proper cleaning and decontamination of feed equipment are essential to avoid *Enterobacter sakazakii* biofilms, which can contaminate subsequent feeds.

Cleaning. The unit must be cleaned daily and deep cleaned on a weekly basis. All waste bins must be covered, foot operated, and emptied daily.

Throughout the world, there are HMBs of many different sizes and shapes, depending on the local context and the HMB scale. For a busy urban hospital, Tu Du's design included 11 rooms.

1. Room for Human Milk Bank Office (12.5m²)
2. Room for clean-equipment/consumable storage (21.2m²)
3. Corridor 1 (for clean equipment and raw milk transportation) (15.8m²)
4. Room for raw milk storage (13.7m²)
5. Room for milk pooling and pasteurizing (19m²)
6. Room for milk splitting (13.5m²)
7. Room to process the dirty equipment (16.2m²)
8. Corridor 2 (for dirty equipment transportation) (12.5m²)
9. Room for HMB staff (11.4m²)
10. Room to provide counseling and receive milk from community (13m²)
11. Room for milk expression and provide counseling (29m²)

In Tu Du hospital, rooms 1-9 are in one block, as shown in the picture below, but the rooms 10 and 11 are in other blocks of the hospital, based on their situation.



References

1. Dr. Jayashree Mondkar, Dr. Ruchi Nanavati, Dr. Armida Fernandez. *Guidelines for Human Milk Banking, Second Edition*. Department of Neonatology, Sion, Mumbai. 2014.
2. Gillian Weaver and Kimberly Amundson. *Human Milk Bank Project Landscape in Da Nang, Viet Nam*. 2016.
3. Tu Du Hospital. *Human Milk Bank initiative*. 2018.

Lactation support for mothers

In the event of separation, or a mother's infant being unable to fully breastfeed due to immaturity or illness, the mother should without delay, be taught how to stimulate and maintain her lactation. The following can be done to initiate milk supply without infant suckling:

1. Begin milk expression after delivery, as soon as maternal condition permits. Hand expression i.e., without the need for equipment other than a clean collection vessel, when well taught and effectively practised results in expressed milk that is low in contamination and has optimal nutritional content. All lactating women should be taught good hand expression techniques.
2. If available, electric or manually operated breast milk pumps may also be used. Breast milk pumps should be washed immediately after use in warm, soapy water, rinsed and disinfected between expressions following manufacturers' instructions.
3. Warm compress on the breast, gentle stroking and light massage may help maximize breastmilk production.
4. Frequent expressing (8-12 times in 24 hours), including a night time expression, is recommended as it will facilitate the initiation of lactation and help to maintain a good milk supply.
5. Keep a record of the time as well as the volume of milk produced during each milk expression.
6. Express milk at baby's bedside when possible. Encourage skin-to-skin-contact (kangaroo mother care).
7. As soon as the infant is able to suckle, offer the breast. The infant may also be put on an empty breast during gavage feedings.
8. Give supportive care and encouragement.



Quang Ninh Human Milk Bank

Donor consent form template

DONOR CONSENT FORM ¹⁶			
<p><i>This form should serve as a template for creating a donor consent form for potential human milk donors. Modify this example form according to your country guidelines and context.</i></p>			
<p>Purpose:</p> <p>The informed consent form provides a record that ensures the donor understands her responsibility in maintaining the safety and quality of donor milk and consents to it.</p>			
<p>Include:</p> <ul style="list-style-type: none"> • Date, time, and signature of consent. • Translation of document into local language familiar to the mother. • Donor's consent for the HMB to access her ANC medical records and permission to release them to appropriate HMB staff and health department officials. • Donor's consent to process and provide her DHM to an infant other than her own child. • Section for HMB staff details, including date of informed consent, signature of staff, and name of staff. 			
<p>Additional elements to consider:</p> <ul style="list-style-type: none"> • Detailed summary of the donation process, including milk handling, collection, treatment, processing, storage, and distribution. • Donor's rights to limit or discontinue the use of their DHM. • Option of receiving acknowledgment of her gift of donating human milk. • Record of supplementary information on the donation process offered to the donor. 			
<p>Description of human milk donation (its benefits, risks, and alternatives)</p> <p><i>Include the constituents of human breast milk and what the donor milk will be used for.</i></p> <p>Human milk provides the best nutrition for infants and young children. It further promotes normal growth and development and helps to reduce the risk of illness.</p>			
<p>Consent to be a human milk donor</p> <p><i>Declaration statement of informed consent, date, donor details, and HMB staff details.</i></p> <ol style="list-style-type: none"> 1. I meet the legal age requirement (18 years or older) and I am fit to donate human breast milk. 2. I understand that my donated milk will be microbiologically tested and that my test results will be kept confidential. 3. I understand that the HMB will make decisions for discarding unsuitable milk. 4. I will inform staff when my health/lifestyle status changes (disease/medication) that would prohibit me from donating. <p>I confirm that I am unaware of any reason why my donated breast milk should not be safe to use for these babies.</p>			
Donor name:	Signature:	Date:	Unique identifier/ID:
Name of interviewer:	Designation:	Signature:	

¹⁶ This consent form template was sourced from the PATH publication entitled *Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs--A Guide for Track and Trace Documentation* (2019). Available at https://path.azureedge.net/media/documents/PATH_HMB_Toolkit_5_Track_and_Trace_Documentation.pdf. Accessed 12 August 2021.

Additional recommendations for safe collection and processing of donor human milk during the COVID-19 pandemic

Routine safety and quality assurance measures during donor screening and serologic tests, raw milk collection, pasteurization and microbiological testing should be strictly implemented to ensure donor milk is free of any contamination before it is dispensed to recipients.

With the current COVID-19 pandemic, consider the following additional measures to strengthen safety procedures in the handling and processing of donor human milk:

1. Donor screenings

- i. Should include information on travel to or residence in a country/area with reported local transmission of COVID-19, history of recent illness, including among family members and close contacts, with emphasis on the following signs and symptoms: fever (temperature of more than 38°C), cough, difficulty of breathing, sore throat, nasal congestion, loss of sense of smell (anosmia) or taste, diarrhea, cluster of influenza-like illness in the household, community of residence, or workplace in the past 14 days.
- ii. Other pertinent information required by national guidelines for COVID-19 case identification.

2. Breastmilk expression

Donor mothers who reside in areas where COVID-19 is spreading in the community must wear a face mask when expressing their milk. They should wash their hands thoroughly with soap and water before and after expressing. If expressing breastmilk using a pump, they should be advised to wash their hands before touching any pump components or containers. The recommended procedures for proper pump cleaning and disinfection should be followed (wash the pump and containers after every use with liquid soap, such as dishwashing liquid and warm water, then rinse with hot water for 10-15 seconds).¹⁷



¹⁷ World Health Organization (WHO). Frequently Asked Questions: Breastfeeding and COVID-19 for health care workers (dated 12 May 2020). Available at https://www.who.int/docs/default-source/maternal-health/faqs-breastfeeding-and-covid-19.pdf?sfvrsn=d839e6c0_1. Accessed 13 August 2021.

Human Milk Banks in Southeast Asia: Minimum standards in monitoring and reporting ¹⁸

1. Background

A human milk bank (HMB) is based on five pillars and four foundational activities. The pillars are: 1) safety; 2) quality; 3) networking and information sharing; 4) awareness, advocacy, promotion; and 5) sustainability. The foundational activities are: 1) quality assurance; 2) auditing and tracking; 3) breastfeeding promotion and support; and 4) guidance for clinical provision of donor milk. Monitoring and reporting are critical to the operation of an HMB (PATH 2019).¹⁹ In addition, networking and information sharing within a country and across countries in the region will facilitate collaboration amongst HMBs.

2. Purposes of HMB monitoring and reporting

- Provide timely routine monitoring data to optimize the functionality of the HMB
- Ensure all activities of the HMB meet standardized protocols including tracking and tracing of donor human milk
- Facilitate networking and information sharing within the health facility and among HMBs

3. Developing a regional minimum standard for HMB monitoring and reporting: rationale and way forward

There are a large number of HMBs in Asia, with an increasing number in Southeast Asia (Figure 1).²⁰ Based on a demand for knowledge sharing and mutual support, the Regional HMB Network of Southeast Asia was established in 2019. In 2020, the network began developing regional minimum standards using a consultative approach. Through discussions with HMB leaders it established a need for specific monitoring and reporting systems which could facilitate implementation, monitoring, and data sharing across HMBs in the region.

Specific objectives of the monitoring system minimum standards are to:

1. Provide guidance to individual HMBs or in-country HMB networks seeking to upgrade or streamline their existing monitoring systems in order to improve HMB services; and
2. Develop a digital system for reporting and presenting key aggregated data from the HMB to the national and regional level for advocacy and knowledge sharing.

¹⁸ As of August 2021

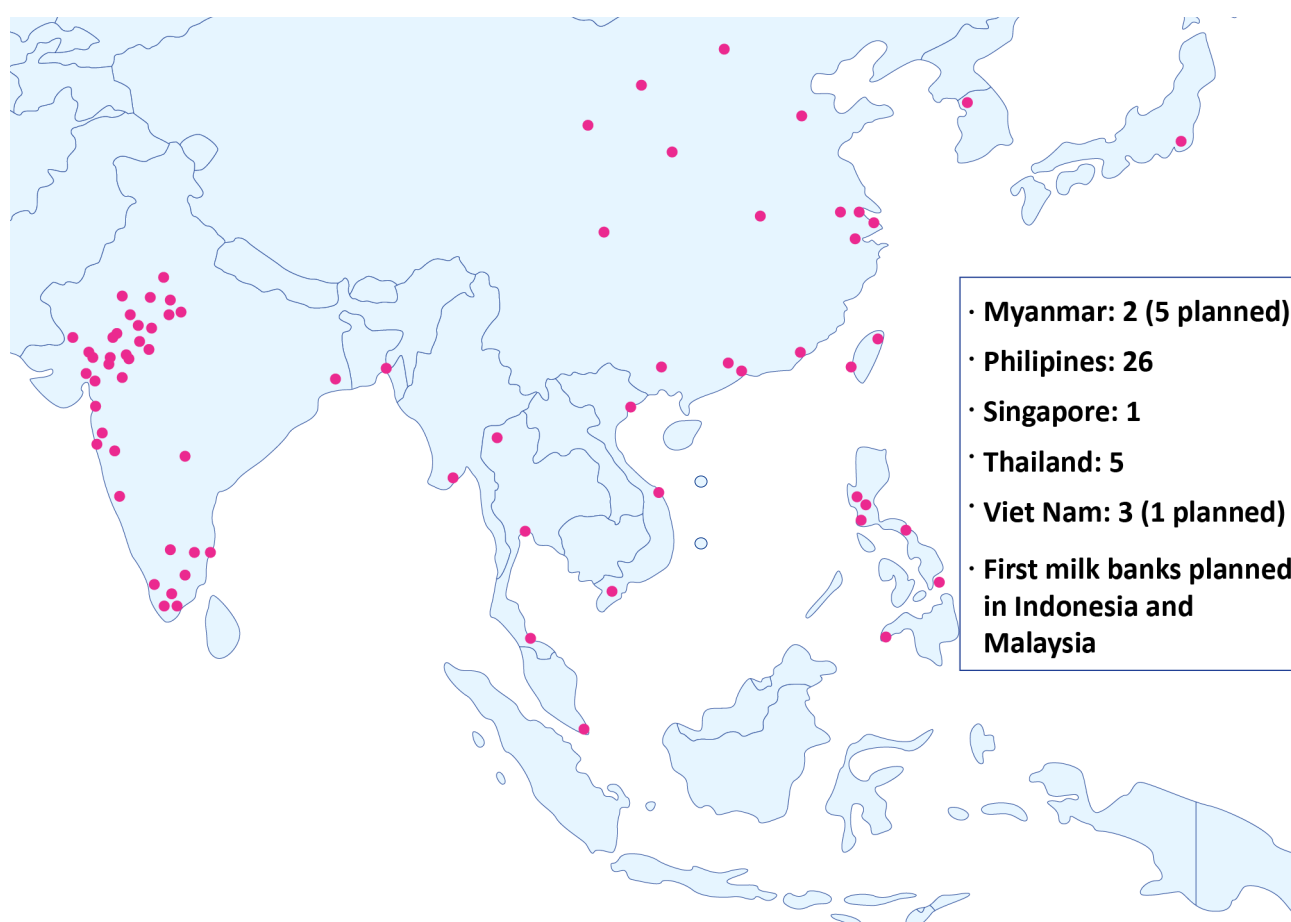
¹⁹ PATH. *Strengthening Human Milk Banking: A Resource Toolkit for Establishing and Integrating Human Milk Bank Programs--A Global Implementation Framework*. Seattle, Washington, USA: PATH; 2019

Tableau Public. *Human Milk Bank Global Map* Washington DC: Tableau Public; 2020 [<https://tabsoft.co/39Lc6c3>]

²⁰ Tableau Public. *Human Milk Bank Global Map* Washington DC: Tableau Public; 2020 [<https://tabsoft.co/39Lc6c3>]

There are large variations across HMBs and countries in terms of: 1) standard operating procedures and guidelines; 2) level of investment (resources, staff, time); 3) capacity of HMB and hospital staff; 4) IT capacity and infrastructure of the HMB; and 5) vision and interest of the managers and staff. Monitoring systems are therefore likely to vary significantly. However, most HMBs share common features in terms of the type of data they collect and the level at which they use and collect it. In general, data is collected and used at three main levels: at the HMB itself (facility), national, and regional.

Figure 1. Human milk bank network in Southeast Asia

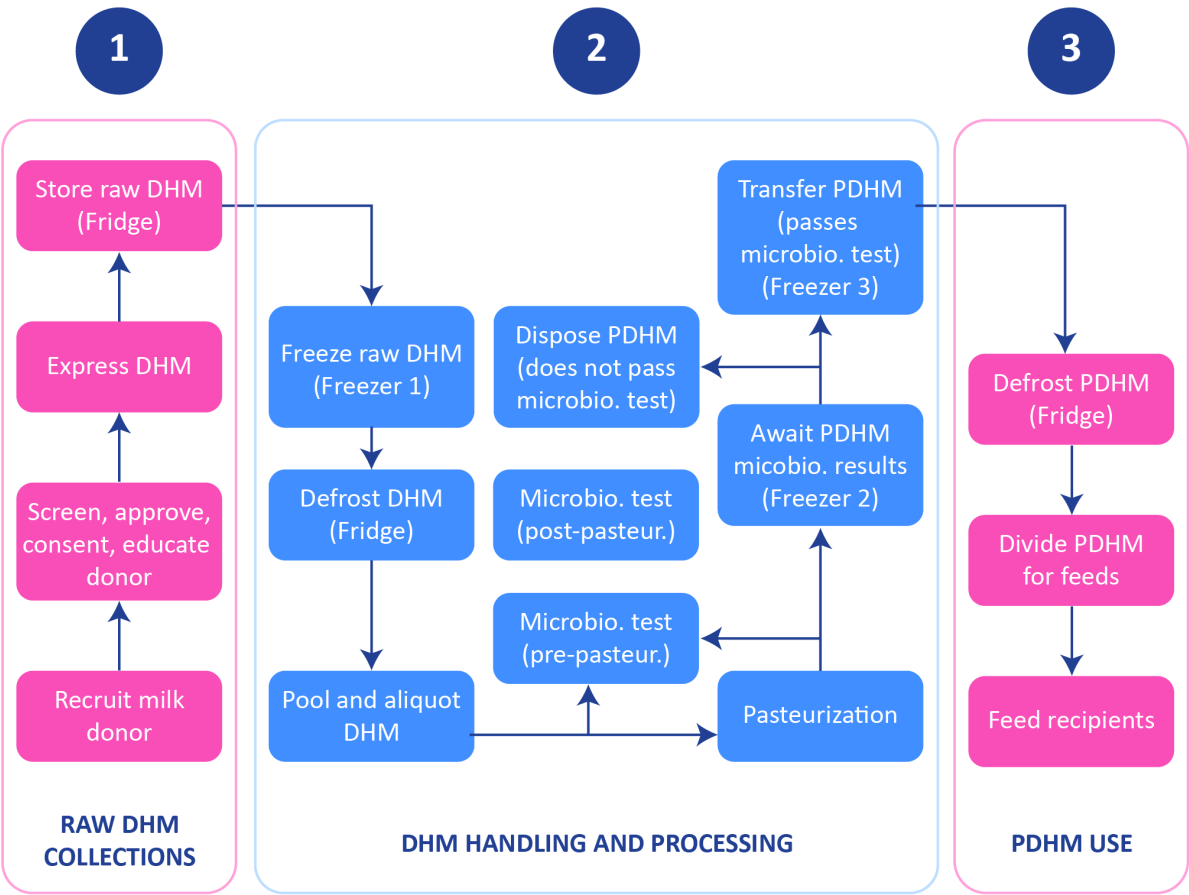


At the HMB facility level, although the system may differ by location, data is typically tracked using an agreed list of core indicators. This list includes operational and output indicators that assist HMB managers and staff during the operation of the HMB. A subset of indicators at the HMB facility level can then be tracked and provided to higher levels for use by hospital managers, Departments of Health, Ministry of Health, and the HMB association / network.

Despite the different standard operating procedures across HMBs and countries, there are typically three processes which are common to all (**Figure 2**), namely:

1. Raw donor human milk collection;
2. Donor human milk handling and processing; and
3. Use of pasteurized donor human milk use.

Figure 2. Operation Diagram of the Human Milk Bank at Danang Hospital for Women and Children.



Note. This diagram explains the process that donor human milk follows through the human milk bank pathway from donor to recipient to maintain safety and quality.
DHM = donor human milk; micbio. = microbiological; pasteur. = pasteurization; PDHM = pasteurized donor human milk.

4. Recommended indicators for human milk bank and its network

By adopting a minimum list of indicators across these three processes, selected data can be collected and compared across HMBs and within the national and regional network. **Table 4** includes a set of recommended indicators for all HMBs in the region, indicating the level at which data is collected and each indicator’s priority, for discussion and agreement among network members.

Table 4. Recommended Indicators

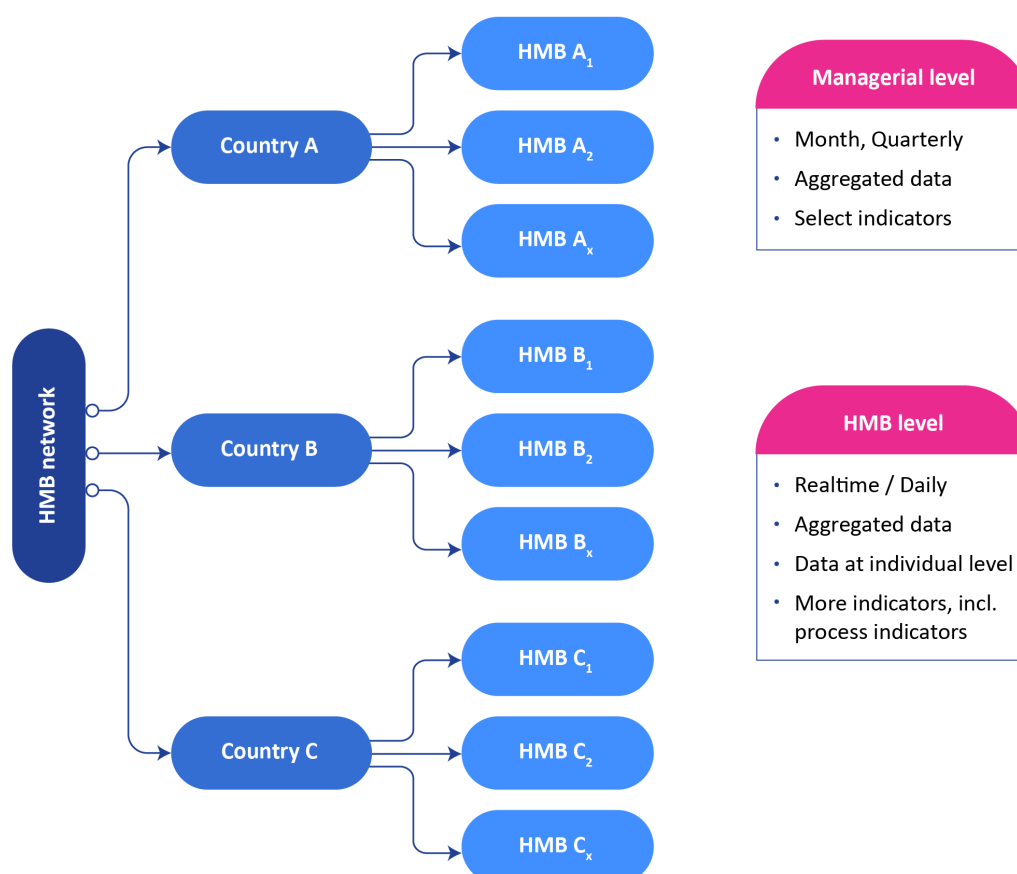
Indicators	Level ¹	Priority ²
1. Raw donor human milk collection		
1.1. Number of events that promote HMB (>10 mothers)	O	B
1.2. Number of group counseling sessions for donor recruitment (≤ 10 mothers)	O	B
1.3. Number of lactating mothers who attended counseling sessions for donor recruitment (total):		
1.3.1. One-on-one	O M	A
1.3.2. Group	O M	A
1.4. Number of mothers who maintained interest in donating after attending counseling sessions for donor recruitment	O	B- C
1.5. Number of mothers screened	O	B- C
1.6. Number of lactating mothers screened and who met all requirements to be donors	O	B- C
1.7. Number of eligible human milk donors taught proper hygiene and donation skills	O	B- C
1.8. Number of new donors	O M	A
2. Donor human milk handling and processing		
2.1. Volume of donor milk collected (L)	O M	A
2.2. Volume of donor milk used for pasteurization (L)	O	B
2.3. Volume of pasteurized donor milk (PDHM, L) for use (i.e., passed tests/ criteria)	O	A
2.4. Passed pre-pasteurization test (L)	O	C
2.5. Passed post-pasteurization test (L)	O	C
2.6. Volume of donor milk discarded (L)	O	B
2.7. Volume of PDHM at the HMB at the time of reporting (L)	O	B
2.8. Reasons for discarded donor milk (text)	O	B- C
2.9. Volume of donor milk transferred (e.g., to satellite HMB or other location)	O M	A
3. Pasteurized donor human milk use		
3.1. Volume of distributed PDHM (L)	O M	A
3.2. Number of newborns who used PDHM from HMB	O M	A
3.3. Volume of PDHM distributed to infants (L) (Can use 3.1 to proxy)	O	B- C
3.4. Average number of days using PDHM (days)	O	C

¹ Levels: O: Operation at HMB level; M: Managerial level² Priority: A: Strongly recommended; B: Recommended; C: Good to have

5. Recommended reporting structure of human milk bank and its network

Figure 3 presents a proposed flow of HMB data collection and reporting, from the individual HMB to the managerial level (which includes the hospital manager and in-country leaders from Departments of Health, Ministry of Health, etc.) and finally up to the regional level.

Figure 3. Proposed flow of HMB data collection and reporting



To meet the monitoring needs, there will be two main results.

1. The first is to support HMBs to maintain and/or upgrade their existing monitoring system at the facility level. Different HMBs, especially within a country, might decide to develop and use a similar platform to reduce the cost and increase compatibility and knowledge sharing. With the improved infrastructure and knowledge and skills relating to information and technologies, a full or partial electronic monitoring system is recommended.
2. The second result is to develop a digital system to facilitate reporting and present key aggregated data from the facility level up to higher levels. The system is planned to be piloted in Viet Nam and Myanmar, then expanded to other countries. Upon agreement on the system and indicator, the electronic monitoring and reporting system will be designed, and an online electronic system set-up and tested in selected countries. Following this, its use will be promoted to a larger network in Southeast Asia and beyond.



Human Milk Bank Network
Southeast Asia



Quang Ninh Human Milk Bank

