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Human Milk Bank



Policy Report
**HEALTH INSURANCE COVERAGE
FOR PASTEURIZED DONOR
HUMAN MILK**





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Human milk bank and pasteurized donor human milk

Breastmilk provides optimal nutrition for the development of infants and young children. The World Health Organization estimates that breastmilk could annually prevent over 800,000 child deaths in children under 5. However, many unfortunate infants, especially premature, low birth weight, or those with severe illnesses or malnutrition, do not have access to their biological mothers' milk. The use of informal donor human milk without pasteurization poses a potential risk of infections such as HIV, hepatitis B and C, syphilis, and several other diseases. The World Health Organization recommends donor human milk as the second choice after a mother's own milk for nourishing infants^{1,2}.

Human Milk Banks (HMB) are established in healthcare facilities that provide maternal and child health services. HMBs recruit donors from breastfeeding mothers, screen, collect, process donor human milk, manage and use pasteurized donor human milk (PDHM) to ensure that every child is fed with human milk, promote optimal health for infants and young

children. The human milk is donated on a voluntary, nonremunerated basis and should only be provided based on the clinical need of the recipient and under the guidance of healthcare professionals. Donor human milk is an alternative to infant formula for infants in need, not a substitute for the mother's own milk.

PDHM is human milk voluntarily donated by breastfeeding mothers who are healthy and have tested negative for HIV, Hepatitis B and C, syphilis, and have been heated to 62.5 degrees Celsius for 30 minutes and rapidly cooled to 4 degrees Celsius, then stored in a freezer at -20 degrees Celsius or lower. Screening donor human milk is testing pre- and post-pasteurization samples before being distributed to infants in use. This is the most common method used to pasteurize donor human milk in HMB worldwide, aiming to eliminate, reduce, or inactivate viral and bacterial agents, proven to be safe and effective, and preserving key components such as proteins, antibodies, and vitamins.

¹ *Maternal, newborn, child and adolescent health: guidelines on optimal feeding of low birth-weight infants in low- and middle-income countries.* Geneva: World Health Organization; 2011.

² *Standards for improving the quality of care for small and sick newborns in health facilities.* Geneva: World Health Organization; 2020.



Satellite human milk bank

Today, there are five HMBs in Viet Nam:

- Da Nang HMB at Da Nang Hospital for Women and Children in Da Nang (established in 2017)
- Tu Du Hospital HMB in Ho Chi Minh City (2019)
- Quang Ninh HMB at Quang Ninh Obstetrics and Paediatrics Hospital in Quang Ninh (2020)
- Viet Nam National Children's Hospital HMB in Ha Noi (2021) and Hung Vuong Hospital HMB in Ho Chi Minh City (2022)
- Two satellite HMBs at the Quang Nam Provincial General Hospital connected to the Da Nang HMB and at the Phuong Chau International Hospital in Can Tho City connected to Tu Du hospital HMB were both inaugurated in 2020.

In Viet Nam, there are approximately 1.4 million live births each year, including 41,000 preterm births and 54,000 low birth weight infants. It is estimated that around 35,000 preterm, low birth weight, or ill infants require about 100 liters in daily basis. At maximum capacity, the HMB network is able to pasteurize up to 102 liters of human milk per day meeting the nationwide demand through a cold chain transportation system.

After six years of operation

30,000

liters of milk
from **4,000** donating mothers.

Providing for over
55,000 newborns

On average,
each donor
contributes

25

liters of milk

The rate of
microbiologically
qualified milk is
continually improving.

74% → 95%
(2017) (2022)

No adverse incidents related to human milk usage have been recorded.

³ A satellite human milk bank has the same standard operating procedures as a human milk bank, except processing donor human milk.



Legal regulations for pasteurized donor human milk in Viet Nam

“ Article 43 in Law on Children regulating “The State prioritizes health and nutrition counseling, protection and care for children, especially children under 36 months old. The State shall adopt policies and measures to reduce the mortality rate among children, especially newborns”.



Circular No. 38/2016/TT-BYT

providing for measures for promoting breastfeeding at health facilities, including practice of “Ten steps to successful breastfeeding” and Baby-Friendly hospitals.

Decision 02/QĐ-TTg & 1294/QĐ-BYT

According to Decision 02/QĐ-TTg approving the “National nutrition strategy for the period 2021-2030 and vision towards 2045” and Decision 1294/QĐ-BYT dated May 19, 2022, which issued the “Action plan to implement the national nutrition strategy until 2025,” the Ministry of Health will develop health insurance policies covering PDHM for premature infants, low birth weight infants, and infants with medical conditions with no access to mother’s own milk, nutritional products for infants with metabolic disorders.

Decision 2394/QĐ-BYT

The Ministry of Health issued Decision 2394/QĐ-BYT on May 14, 2021, approving the document “The technical guideline for establishing and operating Human Milk Banks” regulating the conditions for establishing HMBs and satellite HMB, the priority for receiving PDHM, and the prescription by healthcare professionals. Currently, the pricing of PDHM products from healthcare facilities is approved by local People’s Councils, and there is no approved pricing by the Ministry of Health.



Recipients of pasteurized donor human milk

The prescription for PDHM starts after a medical examination and assessment of the infant's ability to tolerate milk through the digestive system. Early prescription is initiated when biological mother's milk is unavailable or insufficient and follows the instruction.

The priority for receiving PDHM is as follows:

1

Preterm infants at <37 weeks or low birth weight infants <2,500 grams

2

Infants diagnosed with ICD-10-coded diseases within the first 28 days of life, requiring care and treatment at healthcare facilities.

3

Infants of mothers with severe illnesses requiring intensive care, or death in postpartum, mothers taking proven breastmilk-affecting cancer medications, or mothers experiencing postnatal depression and being unable to express or breastfeed regularly.

4

Infants under six months old with special medical conditions: cancer, immunodeficiency, heart diseases, gastrointestinal diseases, etc which PDHM has been contributing to the treatment.

The use of PDHM is reassessed in every 24 hours. The required amount of PDHM for infants is determined based on gestational age, weight, medical conditions, and the number of days of use, follows the instruction.

Benefits of pasteurized donor human milk



Using PDHM is three times less likely to develop Necrotizing Enterocolitis (NEC) than using formula milk⁴.



PDHM reduces the risk of late-onset sepsis by 19% in the group of vulnerable, low-weight infants in the first 28 days of life compared to formula milk⁵.



PDHM helps reduce hospitalization days by 15 days and decreases the duration of total parenteral nutrition by up to 10 days compared to formula milk⁶.



Additionally, the rate of exclusive breastfeeding upon discharge increases by 10% in the neonatal intensive care unit (NICU) since the establishment of HMBs⁷.



Preterm infants fed with PDHM show better tolerance, less vomiting, fewer incidents of milk regurgitation and reduced diarrhea compared to formula-fed infants⁸.



Importantly, PDHM also helps reduce the incidence of bronchopulmonary dysplasia and severe intraventricular hemorrhage⁹.



With the existence of HMB, healthcare quality is enhanced, costs associated with medical care are reduced.

In Viet Nam, it is estimated that the health insurance fund will save 76 billion VND annually by reducing the treatment costs for diseases such as NEC, late-onset sepsis, bronchopulmonary dysplasia, and retinopathy of prematurity if all premature and low birth weight infants are provided with PDHM during hospitalization. Viet Nam's data also shows that since the introduction of HMB, mothers well recognize the importance of human milk, resulting in a significant increase in the rate of infants returning to exclusive breastfeeding. Therefore, when infants are fed with PDHM, it also has a community-wide impact, promoting breastfeeding in general, reducing neonatal mortality, contributing to a decreased risk of breast cancer for mothers, and increasing the IQ index for infants.



The indirect benefits of breastfeeding with human milk for the entire society amount to 48,000 billion VND (0.54% of GDP) per year.

⁴ de Halleux V, Pieltain C, Senterre T, Rigo J. Use of donor milk in the neonatal intensive care unit. *Semin Fetal Neonatal Med.* 2017 Feb;22(1):23-29. doi: 10.1016/j.siny.2016.08.003. Epub 2016 Sep 16. PMID: 27649995.

⁵ Quigley M, McGuire W. Formula versus donor breast milk for feeding preterm or low birth weight infants. *Cochrane Database Syst Rev.* 2014 Apr 22;(4):CD002971. doi: 10.1002/14651858.CD002971.pub3. Update in: *Cochrane Database Syst Rev.* 2018 Jun 20;6:CD002971. PMID: 24752468.

⁶ ESPGHAN Committee on Nutrition; Arslanoglu S, Corpeleijn W, Moro G, Braegger C, Campoy C, Colomb V, Decsi T, Domellöf M, Fewtrell M, Hojsak I, Mihatsch W, Mølgaard C, Shamir R, Turck D, van Goudoever J. Donor human milk for preterm infants: current evidence and research directions. *J Pediatr Gastroenterol Nutr.* 2013 Oct;57(4):535-42. doi: 10.1097/MPG.0b013e3182a3af0a. PMID: 24084373.

⁷ Kantorowska A, Wei JC, Cohen RS, Lawrence RA, Gould JB, Lee HC. Impact of Donor Milk Availability on Breast Milk Use and Necrotizing Enterocolitis Rates. *Pediatrics.* 2016 Mar;137(3):e20153123. doi: 10.1542/peds.2015-3123. Epub 2016 Feb 22. Erratum in: *Pediatrics.* 2016 Jun;137(6):null. PMID: 26908696; PMCID: PMC4771129.

⁸ Kreissl, A., et al., Starting enteral nutrition with preterm single donor milk instead of formula affects time to full enteral feeding in very low birthweight infants. *Acta Paediatrica, International Journal of Paediatrics,* 2017. 106(9): p. 1460-1467.

⁹ Carome, K., A. Rahman, and B. Parvez, Exclusive human milk diet reduces incidence of severe intraventricular hemorrhage in extremely low birth weight infants. *J Perinatol,* 2021. 41(3): p. 535-543.

¹⁰ https://www.aliveandthrive.org/sites/default/files/attachments/101490-000_CostofNotBreastfeeding_Viet_Nam_V3r6.pdf



Costs of pasteurized donor human milk



The price of PDHM per liter at healthcare facilities

1,400,000 VND
/1 liter



average, each premature, low-weight, or medically compromised infant uses

~ 0.63 liters of milk
/one treatment



a cost of approximately

for PDHM
~ 882,000 VND
/infant



The highest usage is 23,925 liters in the case of a COVID-19-positive mother with severe symptoms requiring treatment at a field hospital, for a premature infant born at 27 weeks weighing 1,100 grams.

The total cost
31,102,500 VND

covered voluntarily by the family aiming for the best possible outcome for the infant during the initial days of treatment in the neonatal intensive care unit.



The Health insurance fund covers the costs of PDHM for premature, low-weight, or medically compromised infants, it is estimated that the fund would need to allocate

~ 30.8 billion VND
equivalent to 0.46% of the
health insurance fund

Table 1. The estimation of the number of infants benefited and the costs of health insurance fund allocated for PDHM

Year	Coverage (%)	Number of beneficiaries	Payment (billion VND)	% Health insurance fund
2021	33.0	11,800	10.4	0.15
2022	39.0	13,700	12.1	0.18
2023	44.0	15,600	13.8	0.21
2024	49.0	17,400	15.3	0.23
2025	55.0	19,500	17.0	0.25
2026	62.0	21,800	19.2	0.29
2027	69.0	24,300	21.4	0.32
2028	76.0	26,800	23.6	0.35
2029	83.0	29,300	25.8	0.39
2030	100.0	35,000	30.8	0.46





International experiences

in the world

1909

The first HMB in the world was established in Austria

2023

over 700 HMBs in 60 countries



Brazil has the highest number, exceeding 200 HMBs

in the Southeast Asia region

1996

the first HMB was established in the Philippines

2019

the Southeast Asia HMB network was established

2021

the network approved the Minimum Standards for the Establishment and Operation of HMBs in the Southeast Asia region¹¹.

2023

41 HMBs (Myanmar 2, Philippines 26, Singapore 1, Thailand 1, Viet Nam 7)

2024

with new HMBs planned in Laos, Malaysia, and Indonesia

¹¹ <https://www.aliveandthrive.org/en/resources/minimum-standards-for-the-establishment-and-operation-of-human-milk-banks-in-southeast-asia>

Health insurance coverage for pasteurized donor human milk

The World Health Organization defines donated human milk as a health product originating from humans, like blood and blood products; corneas and musculoskeletal tissues; or other tissues such as hematopoietic cells or other cells; eggs and sperm used in supporting reproductive health treatment ¹².

Internationally, donated human milk is being defined and classified into the following categories:

Nutritional food

(Brazil, Denmark, Austria, Germany, Italy, the Netherlands, Ukraine)

Human tissue/medical products originating from humans

(France, Croatia, England, Scotland)

Medical nutritional food or food supplements

(Slovakia)

Regardless of the classification, most countries have incorporated donated human milk into their national policies and health insurance coverage, including France, Germany, Canada, England, Denmark, Sweden, Latvia, Norway, Slovakia, Scotland, Greece, Taiwan, Russia, Singapore, India, the Netherlands, Australia, Israel, Finland, Iran.

Among the five Southeast Asian countries with HMBs, three countries, namely Myanmar, Singapore, and Thailand, have included donated human milk in the insurance reimbursement list.

Decision No. 2394/QD-BYT dated May 14, 2021, learned from the good practices of European HMBs and built upon the classification of donated human milk as human tissue/medical products originating from humans.



¹² World Health Assembly, 70. Principles on the donation and management of blood, blood components and other medical products of human origin: report by the Secretariat. World Health Organization; 2017. <http://www.who.int/iris/handle/10665/274793>

Policy recommendations

Evidence from global literature and the results of six years of operation of the HMB network in Viet Nam consistently demonstrate the significant impact of PDHM on the treatment of preterm, low birth weight, and ill newborns. Annually, it saves up to 76.7 billion VND for the health insurance fund by reducing the costs of treating conditions such as NEC, providing parenteral nutrition for preterm, low birth weight, and ill newborns, reducing hospitalization time, and decreasing the use of antibiotics.

The World Health Organization defines donated human milk as a health product originating from humans, like blood and blood products. Currently, more than 25 countries have health insurance schemes covering PDHM. Among the five Southeast Asian countries with HMBs, three have incorporated donated human milk into the insurance reimbursement list: Myanmar, Singapore, and Thailand. However, the Philippines and Viet Nam are yet to specify this content.

The estimation indicates that approximately 35,000 infants may require about 100 liters of PDHM in daily bass. Today, Viet Nam has five HMBs and two satellite HMBs. The maximum capacity of the HMB network in Viet Nam is 102 liters per day, which is sufficient to meet the nationwide demand. If the health insurance fund covers the cost of PDHM

for preterm, low birth weight, and ill newborns, the annual expenditure would be approximately 30.8 billion VND, equivalent to 0.46% of the health insurance fund. Thus, the total cost from the health insurance fund (30.8 billion VND) is much lower than the potential treatment cost savings for the fund (76.7 billion VND). Health insurance coverage for PDHM will enable the HMB network to operate at maximum capacity. Consequently, all preterm and ill infants without mother's own milk will have access to PDHM, significantly reducing the infant mortality rate. In addition, there are indirect social benefits such as promoting breastfeeding, reducing the risk of diseases for mothers, increasing the IQ for infants, and providing future development opportunities, this represents a meaningful humanitarian investment for mothers, children, and the entire society.



¹³ World Health Assembly, 70. Principles on the donation and management of blood, blood components and other medical products of human origin: report by the Secretariat. World Health Organization; 2017. <http://www.who.int/iris/handle/10665/274793>



Implementing health insurance policies for PDHM is compatible with Article 43 of the Law on Children, Decision 02/QĐ-TTg, and Decision 1294/QĐ-BYT to accomplish the national nutrition strategy until 2025.

To implement this policy, it is crucial to promptly complete the legal framework as follows:

1

Develop a decision from the Ministry of Health guiding the use of PDHM for preterm, low birth weight, and ill infants at healthcare facilities, updating Decision 2582/QĐ-BYT from 2012 on guiding the care of preterm infants.

2

Develop a circular from the Ministry of Health specifying the maximum price and service fees for determining the standardized price per unit of qualified PDHM

3


Add PDHM to the list of health insurance benefits in the draft amendment to the health insurance law.



APPENDIX.

Table 1. Operation results of HMBs in Viet Nam

	Unit	Quang Ninh HMB	Da Nang HMB	Tu Du HMB	Quang Nam Satellite HMB	Can Tho Satellite HMB
Number of new human milk donors/month	BM	4	7	9	1	1
Amount of raw donor human milk transferred to HMB/day	Litre	4	5	12	0.5	0.5
Average amount of human milk donated by each donor	Litre	28	20	23	5	5
Number of PDHM users/month	Infant	513	141	600	4	3
Amount of PDHM used/day	Litre	3	4	11	0.5	0.5
Number of pasteurization batches	Batch	8	17	46	--	--
Amount of PDHM qualified/month	Litre	109	125	342	--	--
% of DHM discarded	%	10	10	8	--	--



Alive and Thrive (A&T) is an initiative to save lives, prevent illness, and ensure healthy growth and development. From 2009 to 2014, A&T demonstrated that rapid improvements in infant and young child feeding (IYCF) are possible in settings as diverse as Ethiopia, Bangladesh, and Viet Nam. In 2014, A&T began working in Burkina Faso, India, Nigeria, and throughout the Southeast Asia region, expanding its scope to include maternal and adolescent nutrition, and using agriculture and social protection programs as delivery mechanisms for maternal, infant, and young child nutrition (MIYCN). Currently, A&T is leveraging its robust network and knowledge base to strengthen systems and build capacity in these and other countries across Africa and Asia, and disseminate innovations, tools, and lessons worldwide. The A&T initiative, managed by FHI 360, is currently funded by the Bill & Melinda Gates Foundation, Government of Ireland, UNICEF, the World Bank, and other donors.

In East Asia Pacific (EAP), A&T provides strategic technical assistance to governments and a network of local partners with focus on eight countries (Cambodia, Indonesia, Laos, Myanmar, Papua New Guinea, the Philippines, Thailand, and Viet Nam) to facilitate policy and system reforms aimed at increasing investment and creating an enabling environment for MIYCN. With funding from the Government of Ireland, A&T is strengthening MIYCN service delivery with a focus on equity to reach the most vulnerable in Cambodia, Laos, and Viet Nam. With funding from the World Bank, A&T is utilizing global evidence to inform the Government of Papua New Guinea's social and behavior change strategy under a national multi-sectoral stunting reduction program. As an endorsed technical assistance provider to the Association of Southeast Asian Nations (ASEAN) Health Cluster, A&T supports the development of regional standards and collaborates with member states to improve the quality and coverage of MIYCN policies and programs throughout the region.

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