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Review Article

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Strengthening of Human Milk Banking across South Asian Countries: A Next Step Forward

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ABSTRACT

Mother's milk is widely recognized as an exclusive source of nutrients, particularly for premature infants. However, there are situations when mother's own milk is inaccessible to newborns, in such cases, expressed milk from donor mothers is essential to cover the gaps. Human Milk Banks (HMBs) have been developed in several regions of the world to address such difficulties. Despite the fact that there are multiple active HMBs across the globe, there is a lack of comprehensive data on the relevance and operation of human milk banks across South Asian Countries (SACs) where the burden of infant death due to prematurity remains disproportionately high. Challenges like lack of technological facilities, funding channels and universal guidelines impede its full potential. Additional challenges include cultural beliefs, taboos, lack of awareness and knowledge also exacerbate such conditions. Therefore, there is an urgent need to comprehend the formation of universal guidelines and the recruitment of technical leaders for optimizing and promoting HMBs for fulfilling the needs of newborns. This review article addresses these issues in depth and discusses potential solutions to overcome such gaps.

Key Words: Human Milk Banking, New-born, Premature infants, Donor Human Milk, Lactational Management Unit, South Asian Countries

INTRODUCTION

Importance of Human milk and its banking

Breast feeding is a unique practice and mother's milk is an utmost necessity to infants for enjoying its absolute benefits.[1,2] Mother's milk is often considered as a "nectar of life"[3] because it is tailor made uniquely suited for human infants.[4] It provides complete nutritive and biological benefits to the neonates for their ideal health, growth and immunologic development.[5,6] The World Health Organization (WHO), the United Nations International Children's Emergency Fund (UNICEF) and The American Academy of Paediatrics (AAP) has recommended exclusive breast feeding (EBF) practices among the new-born, particularly preterm neonates for the first six months of their lives[7,8] to acclaim its potential benefits rather than using infant formula feeding.[9] However, there are a few circumstances in which infants do not have direct access to their mother's own milk (MOM) for their survival. The potential causes may be related either to or both the mother and the child. Varied causes for such inaccessibility may be due to illness, separation for certain reasons like abandonment, undergoing treatment of any kind, death of the new-born or the mother, delayed milk production etc.[1,2] In such scenario, donor human milk (DHM) (i.e., donated by other lactating women) is recommended to fill the gap.[2] Therefore, the process of collecting, screening, pasteurizing, storing and distributing the DHM basically on non-profit basis for neonatal feeding in the hospitals or for mothers who cannot afford to breastfeed their child directly is termed as "Human milk banking" [10] (Figure 1).

History of Human Milk Banking

The concept of donating human milk is not a new phenomenon and it dates back to history much older to the establishment of blood banks.[11] The first donor human milk bank (DHMB) was established in Vienna, Austria in 1909. However, in the recent years human milk banking has taken its strides all over the world and Brazil being the leading country with 212 milk banks with 113 milk collecting centres respectively.[11,12] The impression of "Human Milk Banking" came into limelight as a result of some popular media attention that highlighted "Breast milk as a gift of life" (Angel, The USA today, 2021).[13] Despite such attentions, the topic on "Human milk banking" still remains overlooked till date.[13]Although, there are more than 700 functioning HMBs globally, majority exists in Europe, South, North and central America and some

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countries in Asia. However, countries belonging to Low and middle income countries (LMICs) where infant and neonatal mortality and morbidity is high still lacks in availability of a single HMB or any guidelines related to its establishment and functioning.[1,14] Moreover, the global importance of Human milk banking was realized much recently during and after emergence of covid- 19 pandemic[15] when suspected or confirmed covid 19 mothers were isolated from their newborn that demanded concerns over mother's milk feeding. In such scenario, opinion from expert institutions demanded establishment and functioning of Human milk banking.[16]

Human milk Banking in South Asian Regions

Reduction in neonatal mortality through improved maternal and neonatal care has been the one of the biggest global health challenges especially across South Asian Countries (SACs).[1,10] The leading cause of deaths among the new-born is primarily associated with the complications related to prematurity.[1] Each year about 15 million infants are born prematurely resulting in 1 million deaths due to complications associated with prematurity which serves as the leading cause of neonatal mortality worldwide.[1] Research studies suggests the burden of premature births is significantly higher in LMICs like the Asian and Saharan regions.[17] According to new-born strategy report produced by UNICEF, 2016 stated most new-born deaths in SACs occurred due to prematurity and its associated complications.[14,18] It further states 60% of new-born are not breastfed within an hour of birth highlighting the need of strengthening the new-born care services like establishment of HMBs is of utmost importance in such regions.[18] However, in particular, there are relatively sparse information available on Human milk banking and its implications among many SACs. Currently a total of HMBs operating under SACs i.e., Afghanistan, Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka have been collated and presented in (Table 1).

Protective benefits to the infants and mothers

Breastfeeding has multiple benefits for both the child and the mother. Evidence synthesized from high income countries (HICs) suggests that use of DHM in infant feeding practices acts as "lifesaving drug"[23] as it reduces the risk of developing fatal conditions like neonatal sepsis, necrotizing enterocolitis and other complications for example retinopathy, diabetes, childhood obesity, neurodevelopmental impairment etc.[23,24] (Table 2) Such issues can be addressed through development of HMBs that help in promoting breast feeding in emergency situation especially when a new-born is admitted in the Neonatal intensive care unit (NICU).[25] However, DHM from an only source does not provide optimal nutrition to the beneficiaries.[26] Hence, a composite pooling of expressed human milk (HM) from diverse sources needs to be prepared for equal distribution of nutrients before pasteurization to constitute ideal for infant feeding.[27] Besides benefits to the newborns, there are many benefits for the mothers who practice breastfeeding directly or indirectly through expressed mother's milk like immediate benefits: post-partum weight loss, lactational amenorrhea, better bonding between mother and the child and long-term benefits: prevention from metabolic and cardiovascular issues, prevention from ovarian and breast cancer.[28,29]

Asia specific studies on Human milk banking

Although, there are varied research undertaken on several aspects specified to "Human Milk Banking," the countries across South Asia share their own unique challenges. The search strategy implemented to gather research findings related to Human milk banking yielded information primarily from HICs. While, there were relatively few information garnered from LMICs in particular, SACs. Therefore, based on our objective for strengthening Human milk banking, we explored the recent reports on South Asia's infant mortality rates (Table 3) which suggested an unconvincing fact that demands on increasing accessibility of neonates to HMB. Yet, a very few efforts have been implemented for scaling up such initiatives until today.

Studies on attitude and practice related to Human Milk Banking

The most recent findings from a cross sectional study based on knowledge and attitude among possible donor mothers about HMBs in one rural region of Bangladesh suggested 98.3% had no idea about the concept of Human milk banking. When enquired about the acceptance to DHM, 72% suggested their willingness to accept while, 28% suggested their unacceptability preferably due to religious concerns. While, about 99.2% did not know about the importance of Human milk banking practice in their country.[44] Similar perspectives had been reported in a study with similar objective conducted among Indian parous women. However, none of the respondents had any idea of Human milk banking. On the other hand, attitude on establishment of HMBs was much accepted among urban than in rural residents.[45]

Studies related to factors influencing establishment of Human Milk Banks

The major cause for disruption of establishment of HMBs in Muslim countries like Afghanistan, Pakistan and Bangladesh are primarily because of religious causes. Study suggests majority of HMBs are set up outside Muslim countries.[46] On extensive search it was concluded that countries which followed strict Islamic laws showed reluctancy in donating or accepting HM from HMBs.[11] Therefore, no studies could be sourced from any Muslim countries of South Asia. However, findings from a recent study conducted in a SAC i.e., India, collectively stated challenges for establishment of HMB in

broad terms i.e., Lack of system and community support that has been explained further.[47]

A. System related challenges includes:

i. Lack of facility wise lactational management centres (LMCs) as per structural matrix, i.e., Comprehensive Lactation Management Centre (CLMC) established in large scale district hospital or medical hospital where NICU is available, Lactation Management Unit (LMU) in Sub-district hospital and Lactational Support Unit (LSU) at delivery points and remote setting.

ii. Lack of adequate knowledge and human resources like lactational counsellors, technical staffs and health care providers to motivate mothers for participating in milk donation and to manage donated milk. Studies have found most of the mothers adapted the concept of Human milk banking from health care providers and accepted to donate and receive HM but expressed lack of proper knowledge on such area.

iii. Lack of financial mechanism at national levels for supporting HMBs. No specific funds are directed for their smooth functioning thus, they are allied into district funds. Therefore, streamlining of financial systems need to be strengthened.

iv. Lack of operational process like bathing facility for mothers before milk donation to ease contamination of milk, tracking facilities of the aliquot to help pooling of term and preterm milk separately, maintenance of electronic and manual records about donor information.

v. Lack of technical procedure like breast pumps, refrigerator, deep freezer, shaker water bath, autoclave sterilizer and poor-quality control measures like poor pests control, unavailability of laboratory reagents for lab cultures to identify potential contaminants needs to be curbed so as to ensure quality donor milk for the neonates admitted in the NICU.

B. Community related challenges includes:

i. Cultural barriers like traditional myths and taboos: religious barriers and development of "milk kinship" which means formation of bond between the neonate who had consumed milk from the donor mother that prohibits marriage between the milk brother and the sister in the future of the Muslim community hindered the mothers to become a recipient or a donor of HM.[46]

ii. Lack of awareness about Human milk banking and motivation among mothers about feeding choices highly influences their acceptability towards HMBs. Therefore, health care providers, community leaders like Accredited social health activists (ASHAs), Anganwadi workers plays a pivotal role in upskilling mothers related to Human milk banking.

Establishment of Human milk banks: An Integrated approach

Although, SACs have made considerable difference since past few decades, the sustainable development goals (SDG) target to reduce new-born mortality is still offtrack.[18] The UNICEF had made serious efforts to bring down new-born mortality from 32 per 1000 live births in the year 2013 to 28 per 1000 live births in the year 2017. However, according to a recent report released by World Health bank in 2020 stated the rate has further declined to 24 per 1000 live births[48] which is still far off from reaching SDG target 3.2 to reduce new-born mortality to less than 12 per 1000 live births. Yet, there is significant effort required to reduce premature mortality that needs to be implemented especially among high burden countries like Afghanistan, Pakistan and India (Table 2). Owing to the fact, establishment of HMBs on such regions has the potential to save endless lives through equitable access to HM. This could be achieved when HMBs will be implemented as a component within a comprehensive and integrated health system which will also serve on broader areas like nutrition and new-born care for protecting, promoting and supporting breastfeeding. However, a critical gap on lack of global consensus in informing the safety, quality and ethical issues pertaining to operationalization of HMBs and guidance on appropriate use of DHM persists till today.[18]

Evidence suggests that majority of existing HMBs is not being regulated at a national level let alone on global context. As a start, the current and future HMBs needs to develop minimum standards through consultation and collaboration with the pre-existing Human milk banking expert committee from regional and country level for establishment and operation of HMBs in regions of South Asia. The recommendations, protocols and guidelines must be combined to constitute minimum acceptable requirements for the recruitment of human milk donors as well as for the entire process of Human Milk Banking.[6,49]

Furthermore, these standards are intended to allow the ongoing development of national, regional, and local recommendations and guidelines as well as operating procedures for the safe and sustainable distribution of optimal quality DHM from HMBs to newborns throughout the area. These will not only serve as the foundation for the accreditation of HMBs across SACs but also for the development of corresponding national laws pertaining to examining and administration of Safety and Quality standards.[49,50]

As known earlier, SACs is one of the major contributors of neonatal prematurity that has been a leading cause of neonatal deaths worldwide. This is unacceptable considering that 75% of infant fatalities could be avoided through realistic, integrated and cost-effective treatments like necessary care during prenatal and the postnatal period, prenatal steroid injections, kangaroo mother care (KMC) and medicines to

combat new-born infections.[51] This could only be achieved when Human milk banking is integrated with breast feeding promotional programs. It is recommended that DHM should solely be used in situations where they could replace formula feeding rather than mother's own milk (MOM) which is superior in all aspects. System should be designed in a manner that could focus on both the mother and the neonate ensuring that if a mother has the potential to produce milk, the milk reaches the new-born even if the mother is separated for recovery and the infant is in a separate specialist ward.[49]

Initiatives to scale up HMB in South Asia

Many lacunae have been identified that hinders the scaling up of HMBs across regions of SACs majorly due to the absence of global guidelines. Following recommendation has been gathered and discussed that provides an apparatus for initiation of HMBs in LMICs regions.

A. Strengthening of Health system through integration of HMBs into new-born care:

Experts recommends the best place for establishment of HMBs is adjacent to NICU. Hence, a baseline assessment of the facility, cost and other feeding practices must be implemented to generate standard operating procedures (SOPs) prior to initiation of HMBs. Other implementation must include partnership of multiple stakeholders of ministry of health (MOH) who are intended to implement HMBs into new-born care and nutrition programs following a systematic triangulated approach i.e., Promotion of breastfeeding practices, Kangaroo mother care (KMC) and Pasteurized donor human milk (PDHM) following Mother Baby Friendly Initiative Plus model (MBFI+) formulated by PATH, an non-governmental organization (NGO) which works closely with the three tired health systems that aims to provide stabilization services along with secondary level of care to vulnerable and sick newborns. Approaches of MBFI+ has been accepted at a global context including countries such as South Africa and India. Recently, Vietnam, a country in Southeast Asia followed PATH's component for its comprehensive implementation of HMBs that has been discussed as follows.[1]

i. **Orientation and awareness of stakeholder's** involved in HMBs to various implementation process such as project initiation and funding process, Involvement of local leaders for the formation of Advisory board committee and Human milk banking multidisciplinary team such as such as paediatrician, gynaecologist, nurses, policy makers and key technical staffs to implement formative and facility based assessment to understand key barriers and facilitators.
ii. **Formulation of HMBs and capacity building** through upgradation of Human milk banking facilities with highly technical staffs and equipment's through the guidance of international milk banking experts. Time to time hazard analysis following standardized operating procedures to inform gaps and achieve optimal quality and safety in HMBs. Digitalization of information to ensure data accuracy and reduce paper based formats. Capacity building of all the technical staffs through implementation of training programmes on Human milk banking and its related topics.
iii. **Operation and stabilization** of HMBs through cost effective approaches, supportive supervision, mentorship for improvement of activities, periodic assessment and evaluation of equipment's, cost, staffing for maintaining quality and standard functioning of HMBs.
iv. **Augmentation through knowledge exchange** through establishment of resource toolkit for sharing information and global guidance. Supportive services through technical assistance for establishment of newer HMBs in regional hospitals. Initiation of planning for establishment of HMBs in newer hospitals across all global nations.

B. Expanding awareness through communications and advocacy at a global context through collaborative efforts.

Spreading awareness for motivation and counselling to the lactating mothers related to human milk donation and its importance to the recipient baby without affecting the needs of the donor's own baby through campaigns via effective communication techniques aided by pamphlets, posters, pictures, videos, role plays etc. These sessions could be delivered in the post-natal ward, immunization clinics, nurseries, peer gatherings through health care workers such as trained doctors and nurses, lactational workers, social workers, religious leaders etc.[52]

C. Improvement in Quality system through implementation of innovative technologies.

Improvement of quality through introduction of newer technologies that can be utilized to bring all HMBs together through a common global networking system. Implementation of cost-effective technologies such as use of health management information system (HMIS) for easier tracking and data retrieval, innovative techniques for screening, processing and storing that inactivates pathogenic microorganisms without interfering with the nutritive value of DHM etc [53] Although the practice of HMB is an age-old practice yet fewer research has been conducted so far.[54]

Ethical and legal issues pertaining to Human Milk Banking

a. **Formulation and operation of HMB**: Despite the growing importance of human milk banking, the majority of human milk banks still lacks its regulation at the national as well as in global capacity.[51] France being the exception where HMBs are regulated along with blood banks. Therefore, there is a need

for all the neonatal units to formulate HMBs on their own following appropriate guidelines from pre-existing HMBs and after acquiring necessary authorizations from their respective institution/organization.[55]

b. Transmission of infection and other contaminants: Plausible causes like transmission of bacterial and viral infection i.e., HIV, Hepatitis B, HTLV – 1 etc and contaminants for example marijuana, tobacco, and other illegal drugs among receiver infants through informal sharing of donor human milk.[55,56] It is therefore necessary to identify risk behaviours and screen for eligible donors who are free from any bacterial and viral infection and do not engage themselves in illegal drugs, alcohol or tobacco. Pasteurization of the pooled milk before its utility must be ensured to minimize potential fatalities.

c. Commercial exploitation: Issues like exploitation of vulnerable women for milk donation at stake of their own children's nutrition demands and health by few private companies to earn profit margins has been reported recently. Increasing demands for mother's milk especially among high income countries leads to exploitation of lactating women from LMICs.[57] Inappropriate marketing of mother's milk products through powdered forms, commercialization of adulterated mother's milk with other animal milk, supplementary resources mislead mothers to buy more from markets rather feeding their own milk. Moreover, commercialization of HM may disrupt government initiatives to formulate DHM. Therefore, stringent laws and regulations must be enacted by the government to stop such actions being marketed.[58]

d. Cultural Taboos: For instance, milk kinship has been debated since a long time especially among Muslim scholars who have strictly unaccepted the fact of establishment of HMBs in a Muslim world where unanimity does not stand as an option. While, in 2004, The European council for Fatwa and Research (ECFR) has made it legal for Muslim women and babies for milk donation and acceptance. It still remains unaccepted among most Arab countries in the world.[59]

e. Honorarium to mothers for HM donation: In the current scenario, HMBs usually runs under non-profit basis by some NGOs, and few supported by the Government. Milk is donated voluntarily by the mothers; thus, no compensation is usually paid. However, in the Western European regions, few NGOs pay mothers a minimal honorarium of 3 dollars for 1 Ounce of milk donated to the HMB including shipping charges. Few countries also provide a compensation for travel which encourages mothers for milk donation to HMBs.[55,13]

f. Recording and reporting of donor-receiver's information: Proper recording and reporting of donor's and receiver's information should meticulously be conducted for traceability in case of legal emergencies in case of milk kinship, fatalities after consuming DHM etc.[4] However, the incubation period of most of the infections varies from six weeks to six months therefore few research suggests retaining of records for a minimum of six months while some argue on retention till five years. On the contrary, *Human Milk Banking Association of North America* (HMBANA) has recommended a retention period till the recipient turns 21 years old while, National Institute for Health and Clinical Excellence (NICE) guidelines have a recommended period till 30 years.[55]

A next step forward

Considering the undeniable advantages of mother's milk, particularly for preterm infants, attempts to make easier availability and accessibility of mother's milk to all the infants are a moral obligation. Milk banking therefore plays a significant role in reaching this goal.[59] Very recently, functioning of such HMBs have provided a paramount benefit amidst the ongoing pandemic.[16] However, majority of HMBs reported a remarkable demand supply gap.[14] Therefore, the core reason for establishment of HMBs is to promote and strengthen breastfeeding practices at a global level especially among LMICs.

Meanwhile, it is also essential to identify potential issues that hinders for its progress. There have been many identified factors affecting to its full functioning for instance limited donors, risk behaviours among donors, cultural and religious barriers, chronic conditions, financial constraints etc. that needs be critically addressed.[12,60] Establishment of global and regional specific milk banking networks, formulation of policies and programmes to discourse those differences could acclaim major benefits.[61] Activities including awareness campaigns by the health care workers, community leaders play a significant role, decommercialization of DHM, establishment of religious compliant milk banks in Islamic countries adds to its overall development. However, there is a very scarce information available on these areas. Despite limitation, this study attempts to offer key insights which could serve as the baseline for the need of constituting Human milk banking networks, formulation of common guidelines and SOPs that will be helpful among policy makers, programmers, healthcare providers for improving service delivery especially for the new-born. In addition, this study could be the basis for further research on Human milk banking with context to all developing nations.

CONCLUSION

Human Milk Banking is an age-old practice that provides optimum benefits to the new-born especially to the premature infants. However, the South Asian Nations still needs advancement in terms of operationalization of HMB's at

Country, Region and Global level. This could be enacted only by developing regulatory bodies and operational policies to safeguard ethical use of DHM at all levels. Moreover, Breastfeeding promotional activities and collaborative efforts of all the Health and welfare departments could achieve to bring success in acceleration of HMB practices across South Asia.

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The author has no conflict of interest to declare.

AUTHORS' CONTRIBUTION

All authors contributed equally towards the data collection, data analysis & compilations

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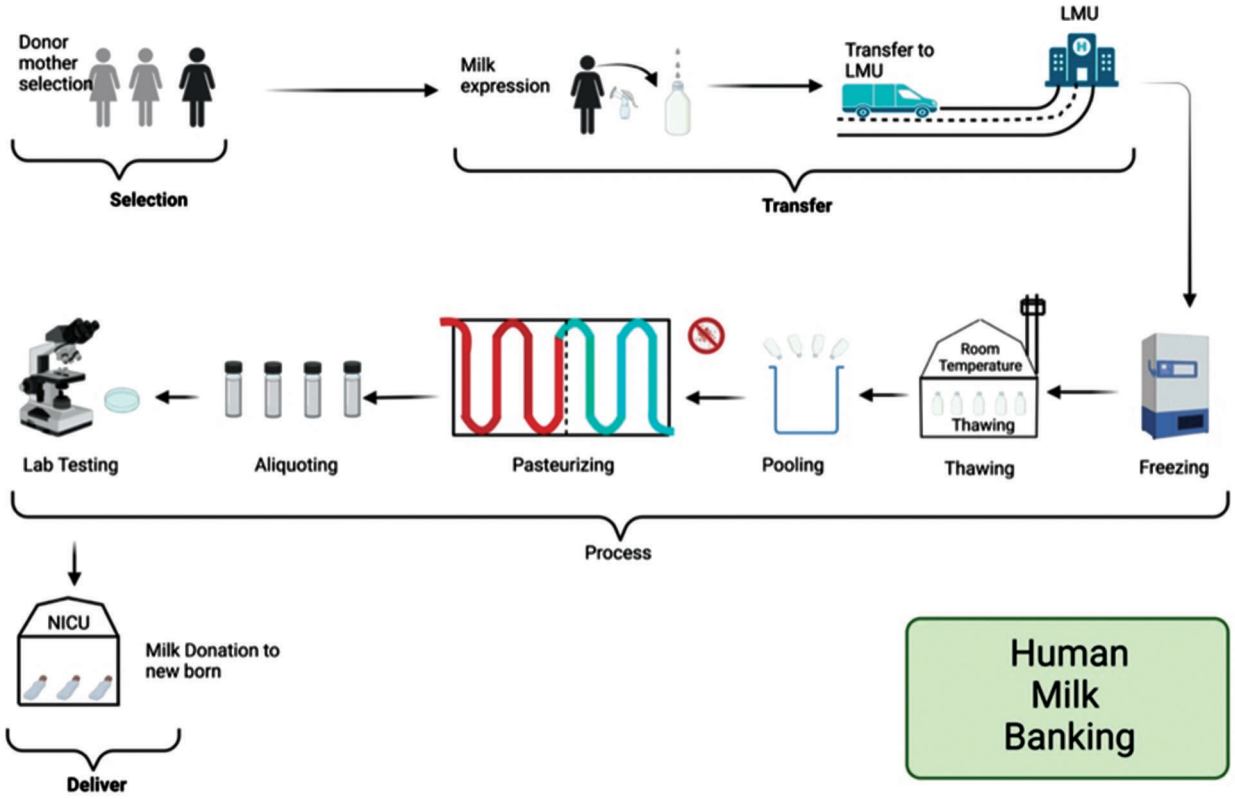

Figure 1: Process of Human milk banking.

Table 1: No of functional human milk banks across South Asian Countries.

Sl No.	South Asian Countries	Number of functional milk banks	Year of inception of first HMB	Additional information	References
1	00	Afghanistan	NA	NA	NA
2	00	Bhutan	NA	NA	NA
3	00	Bangladesh	2019, Dhaka (HMB currently closed)	Proposed for establishment of 04 HMBs by an NGO under "Strengthening multisectoral nutrition project"	(19)
4	90	India	1989, Mumbai	Proposed for expanding HMBs in many medical facilities across country following the National Guidelines on Lactational Management Centres in Public Health Facilities.	(20)
5	00	Maldives	NA	NA	NA
6	00	Nepal	NA	Proposed by government for the establishment of HMB in 2021	(21)
7	00	Pakistan	NA	NA	NA
8	01	Sri Lanka	NA	NA	(22)

Table 2: The burden of neonatal and infant mortality among South Asian countries. (Source: World bank data, 2020)

Mortality Indicators	World	SACs	Afghanistan	Bangladesh	Bhutan	India	Maldives	Nepal	Pakistan	Sri Lanka
Neonatal Mortality Rate (NMR)	17	24	35	18	15	20	4	17	40	4
Infant Mortality Rate (IMR)	27	32	45	24	23	27	6	24	54	6
Under 5 Mortality Rate (U5MR)	37	39	58	29	28	33	7	28	65	7

Table 3: Implication of Mother's own milk (MOM) on vulnerable infants.

Sl No.	Common infantile issues	Implication of mother's milk	Reference
	Infant mortality	Prevent newborns by reducing 12% of total mortality risks.	(29)
	Neonatal necrotising enterocolitis (NEC)	Feeding on MOM or DHM reduces risk of NEC by 6 to 10 folds among very low birth weight infant.	(30)
	Sepsis	Studies have found a dose-response association of increased HM feeding with decreased risk of sepsis and related NICU expenses. Sepsis risk is said to be reduced by 19% for every 10 ml kg/day increase in HM dosage.	(31)
	Retinopathy of prematurity (ROP)	Feeding human milk in extremely low birth weight babies has 75% less risk of ROP	(32)
	Sudden infant death syndrome (SIDS)	A minimum of at least two months of breast milk feeding is necessary to cut down the risk of SIDS to half.	(33)
	Broncho Pulmonary Dysplasia (BPD)	A daily dose of ≥50 ml/ (kg · day) HM in the first 4 weeks of birth significantly reduces the incidence of BPD among preterm infants.	(34,35)
	Diarrhoea	Complementary feeding induced diarrhoea is reduced among infants who are breastfed because the HM has the ability to hydrolyse the complementary foods. Thus, preventing diarrhoea.	(36)
	Leukemia	Breast feeding practice for at least 7 – 9 month duration reduces the risk of leukemia among new-born.	(37)
	Gastro intestinal infection	Breast milk reduces unspecified gastrointestinal infection by 64%.	(38)
	Metabolic diseases such as obesity, hypertension diabetes	Protects against development of metabolic disorders later in life.	(39)
	Poor growth	The growth velocity among breastfed infants is higher in the first few months with prolonged protection from obesity compared to formula feeding.	(40)
	Cognitive development	Choline, an essential micronutrient that is found in HM helps in increasing cognitive and memory function.	(41)
	Longer length of hospital stay	Infants who breastfed have a shorter length of hospital stay because of immunologic protection of HM from infections and late exposure to environmental pollutants.	(42)
	Increased cost and diminished Quality of life	If 100% premature infants are fed with breastmilk, it has a potential to save £46.7 million as a result of improved health outcome with a total gain in lifetime QALY of 10,594.	(43)