## **REVIEW ARTICLE**

# Establishment of the First Religiously-compliant Human Milk Bank in Bangladesh

Mohammod Mozibur Rahman<sup>1</sup>, Soofia Khatun<sup>2</sup>, Nazneen Kabir<sup>3</sup>, Wahida Khanam<sup>4</sup>, Akhil Maheshwari<sup>5</sup>, Mohammod Shahidullah<sup>6</sup>

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#### **A**BSTRACT

Human milk banks (HMBs) collect, screen, process, and dispense donated human milk (HM). There are more than 500 large HMBs in the world but only a few are functioning in Muslim countries, and that too on a limited scale. Human milk banks that are similar to those in the Western countries have been difficult to establish in Muslim countries as Islamic laws do not allow the consumption of unidentified donated milk from multiple donors. Human milk is known to be important for nutrition in premature and critically ill infants, and so there is a well-recognized need to develop religiously compliant and conditionally identified HMBs in Muslim countries. In these milk banks, every mother's milk is processed and stored separately, and the milk provided by one mother can be provided to an infant from a different family only after appropriately counseling both families about the Islamic laws of prohibition of future marriages between milk siblings. Documents related to these issues are provided to both families and data need to be maintained for future reference. In this article, we recount the educational, financial, and infrastructural challenges that we faced in establishing religiously-compliant HMB in Bangladesh. There is already a noticeable reduction in infant mortality in our region.

Keywords: Breastmilk, Human milk bank, Large for gestational age, Microbiological screening, Newborns, Premature, Triglycerides.

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#### Introduction

Human milk banks are an important asset in the care of premature and critically ill newborn infants who do not have access to their mother's own milk (MOM). 1-3 These services collect, screen, store, process, and dispense HM donated by nursing mothers, who may be biologically related or not, for feeding the recipient infants. 3,4 The World Health Organization (WHO) emphasizes that the best alternative when a biological mother is not able to breastfeed her infant(s) is to use HM from other sources. They have estimated that if every woman all over the world optimally breastfed her baby, the lives of 800,000 young children could be saved every. 5,6 Recently published research and systematic reviews support the conclusions that breastfeeding and HM are the reference normative standards for infant feeding and nutrition. Beneficial effects of donor milk remain significant and donor milk is still highly-preferable when MOM is not available.

Human milk is the best source of nutrition for all newborns, whether they are born at term or preterm; or are appropriate-, small-, or larger-for-gestational age.<sup>3,8</sup> It contains a variety of bioactive factors, which are known to promote the maturation of the infant's immune and digestive systems.<sup>6,9</sup> Human milk is known to protect against necrotizing enterocolitis (NEC) and neonatal sepsis.<sup>7</sup> The American Academy of Pediatrics has also recommended donor human milk (DHM), even if in part, due to a reduction in occurrence of NEC.<sup>4,10</sup> A systematic review and meta-analysis of data from clinical trials shows that DHM has a protective effect against NEC in preterm and low-birth weight when compared to formula.<sup>11</sup> Unfortunately, MOM is not available at all or in insufficient quantities in many infants for some social, biological (premature birth, maternal illness, or drug intake), or yet unclear reasons.<sup>12</sup>

If MOM is not available or sufficient for an infant, milk donated by other women or a wet nurse that is processed, verified for safety, and stored appropriately in a HMB may be of help.<sup>13</sup> In <sup>1</sup>Department of Neonatology, Institute of Child and Mother Health (ICMH), Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh; Special Care Newborn Unit and the Neonatal Intensive Care Unit, Institute of Child and Mother Health (ICMH), Bangabandhu Sheikh Mujib Medical University (BSSMU), Dhaka, Bangladesh; Human Milk Bank, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh

<sup>2,4</sup>Department of Paediatrics, Institute of Child and Mother Health (ICMH), Bangabandhu Sheikh Mujib Medical University (BSSMU), Dhaka, Bangladesh

<sup>3</sup>Department of Obstetrics and Gynaecology, Institute of Child and Mother Health (ICMH), Bangabandhu Sheikh Mujib Medical University (BSSMU), Dhaka, Bangladesh

<sup>5</sup>Global Newborn Society, Clarksville, Maryland, United States of America <sup>6</sup>Department of Neonatology, Bangladesh Institute of Child Health (BICH), Dhaka, Bangladesh

Corresponding Author: Mohammod Mozibur Rahman, Department of Neonatology, Institute of Child and Mother Health (ICMH), Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh; Special Care Newborn Unit and the Neonatal Intensive Care Unit, Institute of Child and Mother Health (ICMH), Bangabandhu Sheikh Mujib Medical University (BSSMU), Dhaka, Bangladesh; Human Milk Bank, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, Phone: +880 1713409258, e-mail: rmujib75@ amail.com

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North America, HMBs have provided milk from a single donor or by pooling the milk from up to 5 women before distribution.<sup>14</sup>

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The first HMB was established in 1909 in Vienna, Austria. Since then, many such facilities have been established and at least 500 large HMB organizations are currently active in 38 countries worldwide. Brazil has an extensive network of 217 HMBs, and is considered to have the most cost-efficient system of milk banking in the world. However, despite all progress, the HMB movement remains constrained in the Muslim world. We have been able to establish a sizeable HMB service in Dhaka, Bangladesh, despite some resistance during its inception. In this article, we recount the educational, financial, and infrastructural challenges that we faced in establishing this religiously compliant and conditionally identified HMB. These services have already begun to positively impact the infant mortality in our region.

# HUMAN MILK BANK MOVEMENT IN THE ISLAMIC WORLD

In Muslim countries, the development of HMB facilities has remained constrained in number and scale. <sup>14,16–20,24–36</sup> The Islamic tradition recognizes breast milk as the optimal source of nutrition for infants, but religious-ethical reservations have curtailed the enthusiasm to develop HMBs. <sup>37</sup> There are a few notable, pioneering HMBs in Turkey, Kuwait, Iraq, Iran, Pakistan, and Malaysia. <sup>24,25,33,35,38</sup> Kuwait, Iran, and Malaysia have a few more facilities in planning. <sup>25</sup> There is a need for religious education so that the involved parties truly understand the message from the leaders. <sup>17</sup> We also need to develop more religiously compliant, conditionally identified HMBs, which will be different from those in the West where milk from many mothers can be pooled and pasteurized. <sup>35</sup> There is a need to establish norms for developing HMBs in the Muslim world to protect the best interests of infants while respecting the tradition of milk kinship. <sup>38,39</sup>

One possible religiously compliant option for Islamic families is to promote HMBs is to offer milk from only one donor to a baby.<sup>20</sup> The identity (ID) of the donor and recipient needs to be carefully preserved, and the information should be shared with both families.<sup>17,40</sup> Juggling a baby and a full-time job is always a challenge for a mother anywhere in the world.<sup>41</sup> The problems have been particularly difficult in the promotion of HM feeding for us in Bangladesh, and so we wanted to share our experience as we are just beginning to develop the HMB movement. In Bangladesh, about 3.6 million women are employed in the garments industry, which is a particularly labor-intensive and time-consuming effort. 42 Many of these industrial facilities do not yet have dedicated space for nursing mothers to express milk in comfortable privacy.<sup>43</sup> To develop wholesome solutions, mothers need the means to transport/ship the expressed HM in a timely fashion, and possibly crèche facilities that would empower them to carry their growing infants to their places of work for periodic feeding. Workplaces should be in accordance with International Labor Organization Maternity Protection Convention 2000 (No. 183) Article 9:1.44 A woman should be provided with the right to one or more daily breaks or a daily reduction of hours of work to breastfeed her child. To achieve this goal, there is a need to develop HMBs; these are the best institutionalized and safely-established repositories of donated milk.45

Some of this information about how working women can best comply with the religious guidance can be accessed on the web at http://www.nicuicmh.org. We will also provide smartphone apps

about the HMB facilities to the donor and recipient families for their future reference. To assist them in complying with the Islamic laws, we also explain and provide the Surah An-Nisa, the Surah-4, verse-23 of Al-Quran, 46 with translations in Bangla and English to promote understanding. The following verse is particularly important: Forbidden to you (for marriage) are: your mothers, your daughters, your sisters, your father's sisters, your mother's sisters, your brother's daughters, your sister's daughters, your foster mother who gave you suck, your foster milk suckling sisters, your wives' mothers, your step daughters under your guardianship, born of your wives to whom you have gone in – but there is no sin on you if you have not gone in them (to marry their daughters), the wives of your sons who (spring) from your own loins, and two sisters in wedlock at the same time, except for what has already passed; verily, Allah is Oft-Forgiving, Most Merciful.

#### Religious and Moral Guidance

We sought guidance from renowned religious scholars and clerics in Bangladesh. In Islam, two infants who have been fed milk from one woman are perceived as "milk siblings". 36,47 It is both illegal and sinful for two milk siblings to marry each another. 20,36

We have established a process to obtain HM in a medically-appropriate/safe and religiously compliant way in our medical center. There is a sequence of sequential steps:

- We provide preliminary verbal guidance and written/printed information to both the donor and the recipient groups.
- · Both groups should express awareness of the following:
  - Various medical options that are available.
  - How the Islamic laws view the acceptance of donor milk and understanding of the religious concept of milk siblings.
  - Need to consent to prevent future marriages between milk siblings.
  - Need to prevent breastfeeding-related relationships as these are illegal according to Islamic laws.
- We provide a complete information pack containing a consent form, donor and recipient ID cards, donor and recipient voter ID cards, hospital discharge papers mentioning the names of baby's own biological mother and father, milk mother's name, photographs of the donor and the recipient.

#### NEED FOR HUMAN MILK BANK IN DHAKA

Our neonatal intensive care unit (NICU) at the Institute of Child and Mother Health, (ICMH), Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh is an established level III care center, where we have now treated several thousand critically ill patients every year for several decades. 48 We treat both inborn and outborn babies, and a large proportion of these infants can benefit from access to HM. However, as in every NICU, not every infant has access to MOM due to maternal illness, ongoing drug treatment, or even the death of their mothers during labor or due to concomitant illness(es) that might become more severe during pregnancy. 49,50 We also have a second set of families where the mother is able to produce more milk than her infant needs, and she has to discard her precious milk to find comfort from breast engorgement and/or mastitis.<sup>51</sup> Our team has long wondered about whether we could utilize this HM while remaining compliant and maintaining our reverence for the Islamic law.

# DEVELOPMENT OF A RELIGIOUSLY COMPLIANT HUMAN MILK BANK IN BANGLADESH

The idea of establishing an exceptional HMB in Bangladesh was conceived in January 2019 following visits to HMBs in Mumbai, India and in Valencia, Spain. <sup>52,53</sup> After reviewing the Islamic laws and scientific literature, we formally requested the Director General of Health Services (DGHS)<sup>54</sup> and the Ministry of Health and Family Welfare<sup>55</sup> for approval of an HMB. We also applied to the Islamic foundation<sup>56</sup> for religious clarification and to get a Halal certificate. <sup>17,20,57</sup> Several meetings were held with the administrators and the Islamic group. The facilities were equipped in the first week of November 2019 and the staff members were trained in the subsequent 3 weeks. The HMB was inaugurated in December 2019. <sup>58</sup>

#### Infrastructure

The HMB facility has well illuminated rooms with at least 500 square feet carpeted area, which are situated near or within the NICU or in the facility for kangaroo mothering care corner.<sup>48</sup> These areas are designed to provide optimal hygiene, comfort, and privacy. It has several compartments including the following:

- · A waiting area with reception and crèche.
- A counseling area.
- An area for donation/collection of HM that is designed to help maintain the privacy of the donor.
- · Working space for personnel and storage of equipment.
- · A toilet block within the facility.

### **Equipment**

The milk bank facility is equipped <sup>59,60</sup> with the following (Fig. 1):

- A pasteurizer with special shell to pasteurize small amount Individual mother's milk (Fig. 1A).
- A laminar airflow machine (Fig. 1B).
- A hot air oven (Fig. 1C).
- Steeliness steel containers labeled with heat- and water-resistant ID numbers (Fig. 1D).
- Deep freezers (Fig. 1E).
- High-quality breast pumps (Fig. 1F).
- A data-entry system and ID card printer.

We currently collect, process, and preserve  $50-250\,\text{mL}$  of HM daily, which can be served to  $50-100\,\text{newborns}$ .

### Compliance with the Islamic Laws

Our HMB is running according to the Islamic laws. <sup>19,20,36</sup> Critically ill newborns whose lives are not sustainable without breast milk are prioritized for service. Islamic literature is provided to both the donor and the recipient groups.

- Activities of this HMB have been supervised by the Ministry of Health and Welfare, DGHS and the Islamic Foundation.<sup>54–56</sup>
- If the infant's parents follow a different religion, their laws of that specific religion are followed.
- No financial exchanges are done between donor and recipient groups.
- Milk of one mother is given only to one infant. Donor and recipient receive ID cards with specific information, including



Figs 1A to F: Equipment used in our HMB. (A) Pasteurizer. We use small-volume shells to pasteurize aliquots of milk as small as 25 mL; (B) Laminar airflow to combat external contamination; (C) Hot-air oven to sterilize milk containers at 300°C; (D) Stainless steel container with a heat- and water-resistant ID sticker; (E) Deep freezer that can store milk at –26°C for up to 18 months; and (F) High-quality breast pump that can help express 250 mL or more milk within 15 minutes. The personnel staffing these areas include trained physicians, nurses, one computer operator and one counselor to run this bank properly.



the address of both groups, their telephone numbers, and email addresses. The milk bank is run under the supervision of a committee that includes a Mufti, a journalist, nutritionist, pathologist, public representative, and the leadership of the milk bank, Department of Pediatrics, and the ICMH.

- Milk is collected from mother after proper medical checkup, screening and consent. Individual mother's milk is collected, processed by pasteurization and preserved separately in separate food grade container after labeling with a sticker. Consent papers, which include photographs of the donor and recipient are given to both groups.
- Every year, an annual report is provided to the district marriage registration.
- All information is preserved online at the website www. nicuicmh.org and in the smartphone apps of the HMB for future reference.
- A compact disk with video recordings of the information is given to both groups.
- Milk mother's and father's name is mentioned in the hospital discharge papers along with own father's and mother's name.
- In near future, we plan to include the milk mother's and father's name in the national ID cards as needed.

#### **Collection of Human Milk**

After proper counseling, checking suitability for donation, getting written informed consent, obtaining detailed medical history, physical examination, and laboratory tests, the donor is sent to a designated HM collection area in the HMB. Milk is collected by trained staff with hygienic precautions by manual expression, which has the advantages of low cost, high efficacy, and low risk of contamination. Donors who want to donate regularly can also simultaneous bilateral breast expression by using good quality breast pumps. Milk is collected in properly labeled sterile container and transported to HMB under cold storage condition. All data of donor and recipient with contact number is to be maintained in soft- and hard-copy records.

### **Processing of HM**

All batches of collected raw breast milk is refrigerated immediately until the serological reports are available and reassuring. <sup>64</sup> Fresh raw milk is not added to the frozen milk since this can result in deep freezing with hydrolysis of triglycerides. <sup>65</sup> When fresh raw breast milk to frozen raw breast milk previously collected from same donor, it is chilled before adding to frozen milk. <sup>59</sup> For sick or preterm babies, it is advisable to use a new container for each pumping; we are constantly evaluating various approaches for optimal storage. <sup>66</sup>

Individual mother's milk is pasteurized in individual containers and no pooling and mixing is carried out from multiple donors. <sup>18,36</sup> Pasteurization is carried out by Holder method. <sup>67</sup> If the cost issues are manageable, microbiological screening of donor milk is done as soon as possible after pasteurization. <sup>68</sup> No bacterial growth is acceptable in post-pasteurization microbiology cultures. <sup>69</sup>

#### **Storage of Processed HM**

Prior to the availability of culture reports, pasteurized milk is kept in dedicated freezers and not disbursed. <sup>70</sup> It is stored in the same container that is used for pasteurization; it is advisable not to transfer processed milk in other containers as it has risk of contamination. <sup>71</sup> Culture negative processed milk should be kept at  $-26^{\circ}$ C in tightly-sealed containers that are labeled with clearly

mentioned expiry dates and other relevant data. It can be preserved for 3–18 months. <sup>72</sup> Random cultures of preserved milk before disbursal can aid quality assurance. <sup>73</sup>

#### Disbursal

Processed milk is disbursed at the requisition from the physician after informed consent from the parents of the recipient. Preterm babies are prioritized to milk from preterm donors on a first-infirst-out basis from the storage. Transport of milk should be done under cold storage in the same pasteurized container until it is used. Frozen milk is usually thawed by either defrosting the milk rapidly in a water bath at a temperature not exceeding 37°C, or under running lukewarm water. He ensure that the cap of the container does not come in contact with the water as it is likely to get contaminated.

Human milk should never be thawed in a microwave as this can reduce the immunoglobulin A (IgA) content.<sup>75</sup> Also, HM should not be refrozen after being thawed as this increases the hydrolysis of the triglycerides in the milk.<sup>65</sup> While bringing to room temperature, it should be gently agitated to make a homogenous mixture before use.<sup>76</sup>

### Labeling and Record-keeping

Human milk bank should have an operational objective of ensuring full traceability from individual donation to recipient, and maintaining a record of all storage and processing conditions. Written standard operating procedures should be followed. Confidentiality of records should be maintained by the milk bank. Proper labeling at all levels is mandatory. Labels should be water resistant and names and identifying details of donors, dates of pasteurization, batch numbers and expiry date should be clearly readable.

# General Guidelines for Staff of the Human Milk Bank

Standard operating procedures of the milk bank<sup>77</sup> should be displayed at proper places:

- Hygienic practices such as proper handwashing, donning gowns, mask, gloves, trimming nails, and locking long hairs should be maintained.
- Gloves should be worn and changed between handling raw and heat-treated milk;
- Staff should undergo regular health checks and be immunized against hepatitis B.
- There should be a program for ongoing training of the staff.

# Importance of Human Milk Bank in COVID-19 Pandemic

Standard recommendations during the COVID-19 epidemic suggest that who test positive mothers can feed their babies with infection control and prevention measure. If the mother-baby dyad test positive for COVID-19, breast feeding is not contraindicated. If both the mother and her newborn are hospitalized and separated from each other, expressed breast milk can be given. If there is an HMB, expressed HM can be stored and will be able to provide milk to her own baby.

#### **Economic Implications**

The cost-effectiveness of using banked HM in the NICUs is established in Western countries, largely because of lower rates of NEC. <sup>10,86–89</sup> The costs of running a HMB in Bangladesh have not



Figs 2A to C: Changing public perception of HMBs in Bangladesh. (A) A critically ill infant with multi-system organ failure; (B) With improving survival of critically ill infants such as in image in subpart (A), we are seeing increasing public interest in ways to salvage these infants. Human milk is finally getting its well-deserved recognition as a therapeutic measure. The panel shows a newspaper article and the photograph on the right is from our NICU that was published in social media; the images show changing public perception of HM as a treatment measure. With their financial constraints and low hopes of survival of the infants, many of these infants used to be abandoned by their families; (C) Progressive improvement in infant mortality rates have now encouraged parents to seek previously unrecognized therapeutic measures such as use of banked HM. All images reproduced after due parental consent.

been specifically evaluated yet. However, as prematurity and sepsis are two major causes of neonatal mortality in Bangladesh similar to other countries, 90 early initiation and ensuring exclusive HM feeding can reduce the burden of sepsis and reduction of neonatal mortality by nearly a fifth. 91 Human milk feedings can be a major cost savings for the nation. 92 (Figs 2A to C).

#### Conclusion

In the Western countries, establishing HMBs is a common initiative for the benefit of premature and critically ill newborn infants who are unable to receive their mothers' milk for various reasons. However, in Muslim countries, the development of such facilities remains constrained in capacity, location, and the number of potential beneficiaries. The Islamic tradition recognizes breast milk as the optimal source of nutrition for infants, but there are religious-ethical reservations in developing public facilities to share HM. We have successfully developed a religiously compliant and conditionally identified HMB in Bangladesh that strictly follows the guidelines of the Islamic laws. There is a need for

careful collection and preservation of the identifying information of our patients and their families to prevent any marriages between milk siblings. We have been able to convince our social, administrative and the learned religious leaders about the need and potential benefits of this service. This model system can be replicated in other Muslim nations as it has the potential to save the lives of critically ill infants.

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#### Other Co-authors with Major Contributions

Rubiya Parvin, Department of Neonatology, Institute of Child and Mother Health (ICMH), Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh; SM Zahid Arefin, Institute of Child and Mother Health (ICMH), Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh; Mohammad Abdul Mannan, Bidhan Chandra Poddar, and Nazmul Hossain, Department of Paediatrics, Institute of Child and Mother Health (ICMH), Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh; Sameena Chowdhury, Department of



Obstetrics and Gynaecology, Institute of Child and Mother Health (ICMH), Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh; The Obstetrical and Gynaecological Society, Dhaka, Bangladesh; MA Mannan, Department of Neonatology, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh; Saria Tasnim, Department of Obstetrics and Gynaecology, Institute of Child and Mother Health (ICMH), Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh; Tahmina Begum, Department of Paediatrics, Bangladesh Institute of Research and Rehabilitation in Diabetes, Endocrine and Metabolic Disorders, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh; Department of Neonatology, Bangladesh Neonatal Forum, Dhaka, Bangladesh; Mahbubul Haque, Department of Neonatology, Bangladesh Institute of Child Health. Anup Kumar Saha, Department of Laboratory Medicine, Institute of Child and Mother Health (ICMH), Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh; Arjun Chandra Dey, Department of Neonatology, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh.

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