RESEARCH PAPER

A Landscape Analysis of Human Milk Banks in India

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Received: October 26, 2018; Initial review: January 28, 2019; Accepted: June 20, 2019.

Objective: To evaluate the existing status of human milk banks in India with reference to infrastructure, human resources, funding mechanisms, operating procedures and quality assurance. **Methods:** A pretested questionnaire was administered to 16 out of 22 human milk banks across India, operational for more than one year prior to commencing the study. **Results:** 11 (69%) milk banks were in government or charitable hospitals; only 2 (12.5%) were established with government funding. 8 (50%) had a dedicated technician and only 1(6%) had more than five lactation counsellors. Milk was collected predominantly from mothers of sick babies and in postnatal care wards followed by pediatric outpatient departments, camps, satellite centers, and homes. 10 (63%) reported gaps between donor milk demand and supply. 12 (75%) used shaker water bath pasteurizer and cooled the milk manually without monitoring temperature, and 4 (25%) pooled milk under the laminar airflow. 10 (63%) tracked donor to recipient and almost all did not collect data on early initiation, exclusive breastfeeding or human milk feeding. **Conclusion:** Our study reports the gaps of milk banking practices in India, which need to be addressed for strengthening them. Gaps include suboptimal financial support from the government, shortage of key human resources, processes and data gaps, and demand supply gap of donor human milk.

Keywords: *Breastfeeding*, *Breast milk expression, Lactation, Storage, Prematurity*.

India has the highest number of preterm births in the world and breastfeeding rates are suboptimal [1,2]. Providing breastmilk to these babies, especially those with very low birth weight (VLBW), if they do not have access to their mother's own milk due to reasons such as mother's sickness, separation, or temporary lactation issues, is a challenge. This leaves them more vulnerable to infection and death [3-5]. When mother's milk is unavailable, pasteurized donor human milk is recommended as the next best infant feeding option for VLBW babies [6-8]. Human milk banks (HMBs) collect, pasteurize, test, and store safe donor milk from lactating mothers, and provide it to needy infants [9]. Though India's first HMB was established in 1989, HMBs in the country gathered momentum only in the last 3-4 years. [10]. Published data on status of these HMBs is not available. This study was conducted to evaluate the existing status of HMBs with reference to infrastructure, human resources (HR), funding mechanisms, operating procedures and quality assurance in order to identify gaps to be addressed to strengthen HMB systems.

Methods

This cross-sectional survey was conducted from August 2016 to February 2017, after obtaining permission of the Institutional Ethics Committee at Lokmanya Tilak Municipal Medical College and General Hospital, Mumbai. At the time of conducting the study, there were 30 HMBs in India. An online questionnaire was sent to 22 HMBs that had been operational for more than one year at the time of start of this study. The objective was shared telephonically with the HMB in-charge. The questionnaire captured information on location of HMB, availability of space, equipment and personnel, guidelines followed, operational procedures, including donor recruitment, screening, milk collection, processing, dispensing, utilization and infection control mechanisms, and quality assurance measures followed during various processes, including equipment maintenance, standard operating procedures and hygiene protocol.

Six HMBs from different geographical zones were visited for conducting onsite interviews of the HMB personnel to reaffirm the data. The study team obtained informed consent of the participants. No identifying information (names or addresses) of respondents and facilities were retained in the electronic version of the data records. Data were analyzed using MS Excel and

primarily included descriptive analysis, proportions and cross tabulations.

RESULTS

Of the 22 eligible HMBs, 16 participated in the study. Nine were run by government medical colleges, two by charitable hospitals, and five by private hospitals. HMBs in charitable and public hospitals were clubbed for analysis as their structure and functioning was similar. All HMBs were operated by the Neonatology units and were located near the neonatal intensive care units (NICU), except one. The size of the milk processing area ranged from 100 to 862 square feet and 200 to 300 square feet in public and private hospitals, respectively. The setup cost of a HMB varied from INR 10,00,000 to 75,00,000. The establishment of 14 HMBs was funded by external agencies (50% by the Rotary) and the remaining two by the government. The recurring expenditure for ten centers were borne by the hospitals, three were supported by the National Health Mission and two by private donors. Availability of equipment for milk collection, storage, pasteurization and equipment sterilization is shown in ***Table* I**. All HMBs reported the use of electric hospital-grade breast pumps for milk expression. In 10 HMBs, milk was stored and pasteurized in stainless steel containers, and the remaining used polypropylene containers. Indigenous shaker water bath was used for pasteurization in 13 HMBs, and five used automated imported pasteurizer of which; two had both.

The HR available for running the HMBs are shown in ***Table* I**. Doctors and nurses conducted counseling in three HMBs that did not have any dedicated lactation counselors. Only two (both private hospitals) provided breastfeeding counseling during antenatal care. Eight HMBs had a full-time technician to undertake pasteurization while in the rest, lactation counselors performed this task. Milk culture in public hospitals was conducted by the hospital laboratory services run by the Microbiology department and the private facilities outsourced the testing. Almost all HMBs reported that they did not collect data on early initiation, exclusive breastfeeding or human milk feeding. Fourteen HMBs adhered to a set of guidelines, two reported using the Human Milk Bank Association of North America (HMBANA) guidelines [11], and one used the Perron Rotary Express Milk guidelines (Australia) [12]. The remaining reported using their own standard operating procedures based on HMBANA [10] or the Indian Academy of Pediatrics guidelines [13].

Fifteen HMBs recruited donors whose babies were admitted to the NICU and postnatal care (PNC) wards. Eight HMBS also recruited donors from mothers visiting the well-baby clinics and the pediatrics out-patients department (OPD). Five HMBs additionally collected milk through community-based camps. Six HMBs also recruited home-based donors, including one that exclusively used a home-based model with the same mothers donating over a long period. Four HMBs had satellite collection centers. All HMBs screened donor mothers; criteria for acceptance included general clinical examination and negative blood tests for HIV, Hepatitis B, and VDRL in antenatal period in the past six months. Most HMBs pooled donor milk from multiple mothers. Two pooled at the site of collection and four under the laminar airflow. All used the Holder Pasteurization method. Four used fully automated pasteurizer and the rest used shaker water bath and cooled the milk manually without monitoring temperature. Three public HMBs conducted pre-pasteurization culture to screen the milk. All conducted post-pasteurization cultures and discarded milk with any positive microbiological test report. In

TABLE I AVAILABILITY OF HUMAN RESOURCES AND EQUIPMENT IN PUBLIC AND PRIVATE HUMAN MILK BANKS (*N*=16)

Variables	*Public sector (n=11)*	*Private sector (n=5)*
Human resource- Full-time staff		
Neonatologist/Pediatrician	11 (100)	5 (100)
Dedicated HMB manager	2 (18)	0 (0)
Dedicated technician	7 (63.6)	1 (20)
≥5 Lactation counselors	0	1 (20)
Data entry operator	2 (18)	0
Human resource- Part time staff		
Technician	0 (0)	1 (20)
Lactation counselors	0 (0)	1 (20)
Data entry operator	1 (9)	0 (0)
Equipment		
Pasteurizer (shaker water bath)	10 (91)	3 (60)
Pasteurizer (fully/semi-automatic)	3 (27.2)	2 (40)
Laminar air flow	2 (18)	2 (40)
≥2 Electric breast pumps	11 (100)	5 (100)
>1 Deep freezer* (-20°C ±2°C)	6 (54.5)	3 (60)
Separate deep freezers for raw and pasteurized milk	5 (45.4)	3(60)
One freezer[#]	4 (36.3)	3(60)
1 refrigerator	7 (63.6)	4 (80)
>1 refrigerator	3 (27.2)	1 (20)

All values in no.(%); [#]with separate shelves to store raw milk, pasteurized milk, milk whose culture report was awaited, and safe pasteurized milk.

most HMBs, microbiological culture was done from individual containers. Four HMBs pooled milk under the laminar flow, and conducted batch-wise microbiological tests. Only one discarded milk as per the Bio Medical Waste Management Guidelines of the hospital [14, and the rest discarded it in the sink.

Fourteen HMBs labeled the containers manually while two labeled digitally. The labels contained information on date of donation, batch number or container number, and date of pasteurization. Four also mentioned expiry dates on the label. Four public and two private HMBs stored preterm and term milk separately, and mentioned it on the label. One private HMB also mentioned the nutritional content of the milk. All bat one HMBs distributed pasteurized donor human milk on prescription. Two private HMBs charged a processing fee to the recipients. Frozen milk was transported in cold chain to the neonatology units after which it was refrigerated and then thawed using warm water baths before feeding. The duration between thawing and consumption was about 2 to 6 hours in most HMBs. Ten HMBs tracked donor to recipient by recording the donor milk batch and the container number (pool from multiple mothers) against the recipient's name. Only one tracked donor milk from single mother to baby. All followed the processes outlined in ***Fig.* 1**.

All HMBs followed infection control measures. These included donor mothers washing hands and cleaning their breasts with water before expression. The containers in which milk was collected were tightly secured to prevent any contamination during pasteurization. Staff of most HMBs used disposable caps, face masks and gloves while handling milk. The staff in all HMBs received orientation on hygiene protocol. One

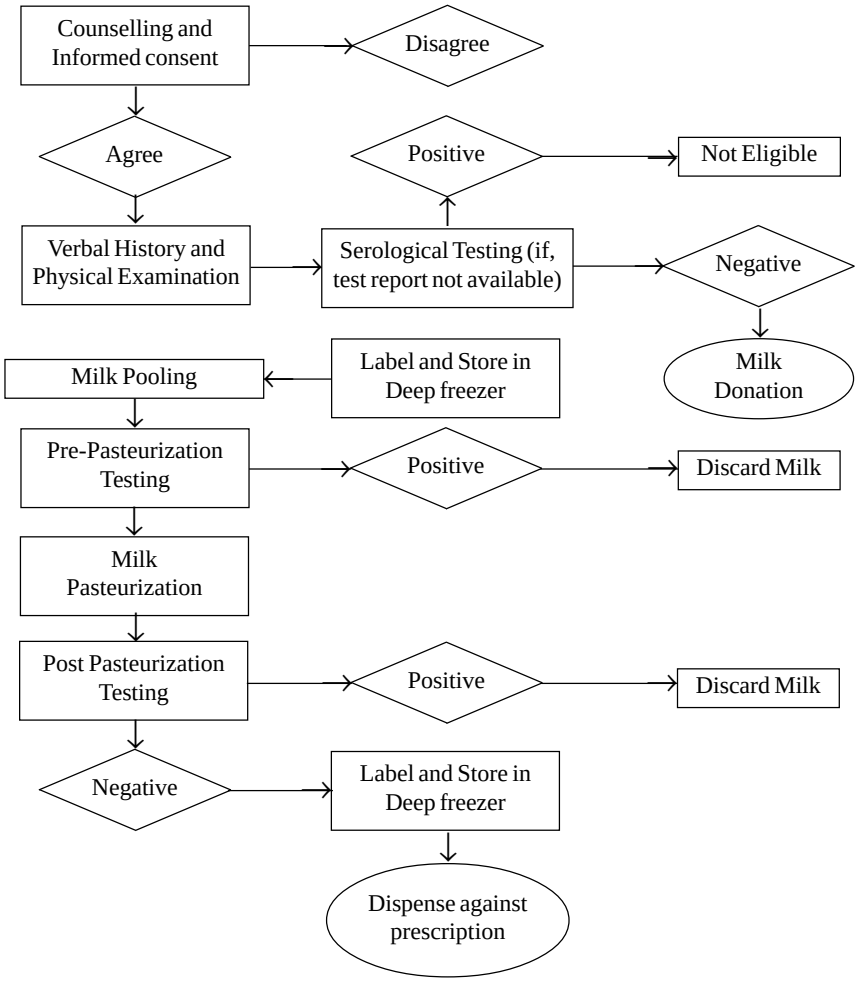

FIG. 1 *Human milk bank processes in the surveyed human milk banks.*

WHAT THIS STUDY ADDS?

- The survey identified few gaps in human milk banks in India that need to be addressed to strengthen these facilities for better neonatal outcomes.

HMB had a committee for infection control. The processing room of 15 HMBs had restricted entry. 12 HMBs had equipment under Annual Maintenance Contract (AMC); in the rest, only the pasteurizer was under AMC. Fifteen HMBs had uninterrupted power supply.

Nearly one-fourth (range: 5%-38%) of mothers who delivered in these hospitals donated milk. The annual number of donors, volume of milk collected and recipient babies is presented in ***Table* II**. Informed consent for donation was obtained in 13 facilities, and consent from recipient's parents/guardians was obtained in 14 facilities. Most provided donated milk to preterm babies, sick full-term neonates in NICU, orphans, or babies of mothers with poor lactation. Facilities reported 30% to 50% of the babies in NICU and 10% to 20% babies in PNC ward required DHM for a variable period after birth. Ten HMBs reported gaps between demand and availability of DHM. Processed donor milk was used within a week or fortnight because of high demand in most HMBs. DHM was fed to VLBW babies for 5-15 days on an average during hospital stay.

DISCUSSION

This study offers an insight into the state of HMBs in our country and serves as a baseline assessment of HMBs. A limitation of this study was that onsite visits to all HMBs were not carried out for confirmation of these findings. Moreover, about one-fourth of the eligible HMBs did not participate in the survey, and few questions were left unanswered by participating centers. Analysis was performed based on the information shared by the facilities, and is prove to 'reporting bias' .

We noted wide variations in the cost of establishing HMBs across facilities. Imported automated pasteurizer and hospital grade breast pumps accounted for the bulk of the capital costs. Innovations are needed for developing indigenous and cost effective models for these. equipments. Most HMBs were established with funding from external agencies suggesting the need for a greater government involvement for establishing and running HMBs, The Brazilian Network of human milk banking has successfully demonstrated the effectiveness of a government supported, nationalized, human milk banking as part of integrated breastfeeding program [9]. There is a need to have more lactation counselors and dedicated technicians in facilities to ensure availability of quality lactation support to mothers, feeding data, and safe DHM. Need for continuous support to mothers for breastfeeding has been reiterated globally which in turn motivates mothers to donate milk [15,16]. Our study analyzed that DHM can benefit five million babies annually in India. Donor milk was collected from multiple sites in the participating centers. However, community- and satellite centre-based collection need to be encouraged to close the demand-supply gap as many HMBs reported having short supply. Standardized guidelines on collection of milk through camp and home based donors are needed.

More than half of the HMBs used stainless steel containers for collection, which is unique to India. Steel has good conductivity which may help in faster heating and cooling cycles and should preserve milk nutrients better. However, such data comparing the effect of steel, glass and polypropylene containers on the composition of the stored milk are not available. The use of laminar airflow in more HMBs will ensure aseptic pooling of milk. Pre-pasteurization culture of milk, which is not being followed across all HMBs, should be implemented uniformly.

TABLE II ANNUAL STATISTICS OF DONORS AND RECIPIENTS IN PARTICIPATING HUMAN MILK BANKS (*N*=16), 2015-16

Variables	*Median (Range)*	*Public sector**	*Private sector**
Number of donors	600 (70-4000)	1938	316
Volume of milk collected (liters)	382 (30-1085)	498	230
Volume of banked milk utilized (liters)	293 (27-1047)	469	174
Number of recipients	500 (80-3993)	1480	261

**Average number at the participating centers.*

The National Guidelines on Lactation Management Centers in Public Health Facilities released by the Government of India in 2017 positions HMBs as comprehensive lactation management centers (CLMC) to universalize access to breast milk for babies. CLMCs support breastfeeding and milk expression for sick babies, encourage kangaroo mother care and provide pasteurized donor human milk to needy babies lacking access to mother's milk [17]. The gaps brought out by this study should be addressed during the scaling up of HMBs/ CLMCs as per the national guidelines. Next steps in scaling up involve ensuring sustainable funding and human resources, technology innovation, ensuring uniformity of quality assurance procedures and standards including operationalizing Hazard Analysis Critical Control Points systems, accreditation, robust data tracking system and recording feeding data for informed program decision making. Given the suboptimal status of newborn nutrition in India, strengthening HMBs will contribute to increasing access to lifesaving human milk for all babies, as part of newborn nutrition and care.

Acknowledgments: Dr S Sitaraman, SMS Medical College, Jaipur; Dr Poonam Singh, SMIMER, Surat; Dr Suchandra Mukherjee, Institute of Post-Graduate Medical Education and Research and Seth Sukhlal Karnani Memorial Hospital, Kolkata; Dr Kumutha, Government Hospital for women and children, Chennai; Dr Kamalrathnam, Institute of Child Health, Chennai; Dr. Sandhya S Khadse, BJ Government Medical college and Sassoon General Hospital, Pune; Dr Shailaja Mane, Dr DY Patil Medical College, Hospital and Research Centre, Pune; Dr Umesh Vaidya, Sahyadri Hospital, Pune; Dr Rajan Joshi, Deenanath Mangeshkar Hospital and Research Centre, Pune; Dr Vandana Kumavat, Rajiv Gandhi medical college, Chhatrapati Shivaji Maharaj Hospital, Thane; Dr Swati Manerkar, LTMMC and GH, Mumbai; Dr Ruchi Nanavati, KEM Hospital, Mumbai; Dr Sudha Rao, Wadia Hospital , Mumbai; Dr Rajesh Boob, Dr PDM Medical College, Amaravati; Dr Jaishree Kulkurni; Fernandez Hospital, Hyderabad; and Dr Raghuram Mallaiah; Fortis La Femme, New Delhi for their support in facilitating data collection. Our special gratitude and acknowledgment is extended to Kiersten Israel-Ballard Associate Director, Maternal, Newborn and Child Health and Nutrition Global Program, PATH and Sudip Mahapatra, Regional Monitoring and Evaluation Specialist, PATH, for reviewing the research design and report. We also extend our thanks to Paramita Kundu for her support in writing this manuscript and Manu Bhatia for providing editorial support.

Contributors: RCS: conceptualized the research design and protocol, provided inputs on the research tool, analysis and interpretation of the data, and contribute to manuscript writing and revised it; JM: administrative and technical guidance on the research, design of research, and provided critical inputs on writing of the manuscript; SS: contributed to research design, conceptualized the research tool, and inputs to manuscript writing; MMS and AK: data collection, analysis, manuscript writing; RD: analyzed the study results, supported interpretation and contributed to the manuscript writing and revision. All authors approved the final version of manuscript, and are willing to be accountable for all aspects of study.

Funding: This project was funded through a grant from the Margaret A. Cargill Philanthropies to PATH.

Competing Interests: None stated.

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