Human Milk Banking Guidelines

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Justification: WHO and UNICEF state that the use of human milk from other sources should be the first alternative when it is not possible for the mother to breastfeed. Human milk banks should be made available in appropriate situations. The IYCF Chapter is actively concerned about the compelling use of formula feeds in the infants because of the non availability of human breast milk banks.

Process: A National Consultative Meet for framing guidelines was summoned by the IYCF Chapter and the Ministry of Health and Family Welfare, Government of India on 30th June, 2013, with representations from various stakeholders. The guidelines were drafted after an extensive literature review and discussions. Though these guidelines are based on the experiences and guidelines from other countries, changes have been made to suit the Indian setup, culture and needs, without compromising scientific evidence.

Objectives: To ensure quality of donated breast milk as a safe end product.

Recommendations: Human Milk Banking Association should be constituted, and human milk banks should be established across the country. National coordination mechanism should be developed with a secretariat and technical support to follow-up on action in States. Budgetary provisions should be made available for the activities.

Keywords: *Child survival, Human milk banking, Malnutrition,*

Breastfeeding is the best method of infant feeding because human milk continues to be the only milk which is tailor-made and uniquely suited to the human infant. All mothers should be encouraged to breast-feed their infants. When a mother, for some reason, is unable to feed her infant directly, her breastmilk should be expressed and fed to the infant. If mother's own milk is unavailable or insufficient, the next best option is to use pasteurized donor human milk (PDHM). India faces its own unique challenges, having the highest number of low birth weight babies, and significant mortality and morbidity in very low birth weight (VLBW) population. In our country, the burden of low birth weight babies in various hospitals is about 20% with significant mortality and morbidities [1,2]. Feeding these babies with breastmilk can significantly reduce the risk of infections. Hence the Government, health experts and the civil society must join hands to propagate the concept of human milk banking for the sake of thousands of low birth weight and preterm babies.

Though wet nursing had been in practice since mythological ages, modern human milk banking is in its infancy in India. Lack of awareness, leadership deficit, infrastructural and maintenance costs, and fewer neonatal setups are some reasons for the same. The first milk bank in Asia under the name of *Sneha*, founded by Dr. Armeda Fernandez, was started in Dharavi, Mumbai on November 27, 1989. Currently, the number of human milk banks (HMB) has grown to nearly 14 all over India but the growth of human milk banks has been very slow as compared to the growth of neonatal intensive care units. One of the major reasons for loss of interest in human milk banking was the promotion of formula milk by the industry. Keeping in mind the complications associated with formula feeding to the sick, tiny preterm neonates and mothers' inability to breastfeed in the initial period, there is a need to establish human milk banks in all level II and level III facilities. It was with this objective that a need to formulate guidelines for establishment and operation of human milk banks in our country was felt. These guidelines do not intend to present detailed scientific literature but are an attempt to back-up the establishment and operation of human milk banking with scientific methods.

LOCATION OF HUMAN MILK BANKS

Human milk banks are primarily focused to provide donor milk to high risk newborns admitted in the neonatal unit. Therefore, a location in close proximity or even inside the boundaries of neonatal unit is desirable. This also helps in administrative supervision by medical staff. Presence of human milk banks in the neonatal units is associated with elevated rates of exclusive breastfeeding rates in VLBW babies [3]. Postnatal wards or Well Baby clinics of large hospitals are most suited for

the purpose as donors are likely to be found in large numbers where medical and nursing staffs can encourage them to donate milk. Certain non-government organizations (NGOs) taking care of abandoned babies can also have a human milk bank in their facility.

THE RECIPIENTS

PDHM can be prescribed on priority for preterm babies and sick babies, babies of mothers with postpartum illnesses, and babies whose mothers have lactation failure, till their milk output improves.

Therapeutic benefits of breastmilk are noted in short gut syndrome, sepsis, and post-surgical gut healing in omphalocele, gastroschisis, bowel obstruction and intestinal fistulas. In extremely preterm infants given exclusive diets of preterm formula *versus* human milk, there was a significantly greater duration of parenteral nutrition and higher rate of surgical necrotizing enterocolitis (NEC) in infants receiving preterm formula [4]. It is possible to administer trophic feeds (gut priming by early enteral feeds) exclusively with human milk in VLBW infants with banked human milk [5].

If PDHM supplies are sufficient donor milk may be supplied for:

- Absent or insufficient lactation: Mothers with multiple births, who can not secrete adequate breastmilk for their neonates initially.
- For babies of non-lactating mothers, who adopt neonates and if induced lactation is not possible.
- Abandoned neonates and sick neonates.
- Temporary interruption of breastfeeding.
- Infant at health risk from breastmilk of the biological mother.
- Babies whose mother died in the immediate postpartum period.

INFRASTRUCTURE

There are no standard recommendations or specific guidelines mentioned regarding the space requirements for creation of human milk banks. The minimum requirement is a partitioned room of 250 square feets that can comfortably lodge at least the equipment required for milk banking, a work area for the technician as well as some storage space for records, administration and area for counselling donors etc.

Privacy is of paramount importance for area of breastmilk expression. Provision of music/television and a crèche helps in reducing stress of donors. Teaching videos of Kangaroo Mother Care (KMC), expression of breastmilk and advantages of breastmilk feeding can be shown under supervision of milk bank staff.

EQUIPMENTS

Pasteurizer/Shaker-water bath: It is essential to have a device to carry out heat treatment of donor milk at the recommended temperature of 62.5ºC for a period of 30 minutes (Pretoria Holder pasteurization method) prior to its use. A conventional pasteurizer is expensive and generally of dairy-industry size and is often not suitable for the quantity of milk to be pasteurized in a human milk bank. A well accepted alternative is the use of a shaker water bath with a micro-processor controlled temperature regulator, an electronic timer device and a shaker speed controller. The milk in the container is boiled through the steam and hot water in the water shaker bath. To avoid coagulation of the milk and to distribute heat evenly, the tray on which the milk containers are placed is shaken / wobbled. This shaker water bath should be double walled and made of steel. Its size varies according to the need of the milk bank, with the tray capacity varying from 9 to 24 containers of 200 to 400 mL capacity.

Use of other safer methods of pasteurization with better preservation of nutrients and other properties, like flash heat treatment, HTST (High Temperature Short Time; 72°C for 16 seconds) and ultra violet irradiation are still not being used in human milk banks routinely [6,7].

Deep freezer: A deep freezer to store the milk at -20^{0}C is essential in the milk bank. It is desirable to order a deep freezer with a digital display of the temperature inside it with an alarm setting. It is desirable to have two deep freezers for processed milk. First for storage of the milk till the post-pasteurization milk culture reports are available. This freezer should be locked at all times with access only to the technician, so that no milk is accidentally used till the culture reports are available. The second deep freezer is used for storage of the pasteurized milk once the culture reports are negative and the milk is considered safe for disbursement.

Refrigerators: These are required to store the milk till the whole day's collection is over and the milk is ready to be mixed and pooled for further processing. It is also required for thawing the milk before being dispatched. Preferably two different units should be used for these purposes. If not possible, then strictly earmarked areas should be kept in one unit for each purpose.

Hot air oven/Autoclave: A hot air oven / autoclave in the milk bank or centralized sterile service department is essential for sterilizing the containers used for collection

from donors, containers for pasteurization and the test tubes needed for sending milk culture samples to the microbiology laboratory.

Breastmilk pumps: For milk banking, hospital grade electric pumps are preferred as they result in better volumes of expressed milks and are relatively painless and comfortable to use. There is no major difference in the types of electrical breast pumps [8]. Manually operated breastmilk pumps designed to operate more physiologically by simulating the infant's compressive action on the areola during breastfeeding can be used with lower cost implications [9]. They can be reused with chemical disinfection/sterilization. Breast pumps can be a source of infection [10], and hence they should be cleaned properly [11]. Pump and its parts should be sterilized/disinfected as per manufacturer's instructions.

Containers: For collection and storing the milk, single use hard plastic containers of polycarbonates, pyrex or propylene are used across the world. However, in Indian experience, cylindrical, wide-mouthed stainless steel containers of about 200 ml capacity with tight fitting/ screwed caps are equally effective. They are easily available, and are durable, easy to clean and autoclave. There is no significant decrease in nutrient composition on storage; however, cellular components are reduced. Polythene milk bags are not suitable as they are fragile, associated with loss of lipids and vitamins and there is a risk of contamination, although some studies have challenged the loss of lipids [12].

Generator/Uninterrupted power supply: Every milk bank should have a dedicated centralized source of uninterrupted power supply backup to run the deep freezers and refrigerators in case of electricity failure.

Milk analyzer: It is desirable to have macronutrient analysis of breastmilk to estimate the calorie, protein and fat of a milk sample, using infra-red spectroscopy technology, in teaching hospitals as a step towards lacto-engineering.

ADMINISTRATIVE STAFF

Human milk banks should have a panel of consultants to guide overall development and functioning. It can include representatives from the areas of pediatrics/neonatology, lactation, microbiology, nutrition, public health and food technology. It should consist of a Director (for planning, implementing and evaluating the services), milk bank officer (usually a doctor, for day-to- day running of the bank and training), Lactation management nurses (for counselling mothers and assisting expression of breastmilk), milk bank technician (for pasteurization of breastmilk and microbiological surveillance), Milk bank attendant (for collecting, sterilization of the containers and maintaining hygiene), receptionist (for record keeping and public relations) and a microbiologist (for microbiology testing and infection control policies). General guidelines for staff are outlined in ***Box* I**.

Box I: GENERAL GUIDELINES FOR STAFF OF THE HUMAN MILK BANK

- Standard operating procedures (SOP) of the bank (which should be displayed at proper places) should be adhered to.
- Hygienic practices like proper hand wash, donning gowns, mask, gloves, trimming nails, 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.

DONOR POPULATION

The donor population is formed by healthy lactating mothers with healthy babies, who are voluntarily willing to give their extra breastmilk for other babies without compromising the nutritional needs of their own baby**.** The donors can include mothers attending well baby clinics, mothers whose babies are in neonatal intensive care units, those who have lost their babies but are willing to donate their milk, or lactating working staff in the hospital, and motivated mothers from the community. Donors are not paid for their donations.

Try to reach maximum donor population using variety of avenues. Spreading awareness about possibility of breastmilk donation in society by various means including mass communication can help in motivating donors. NGOs, social clubs and college students can play a good role in it. Criteria for breast milk donors [11] are outlined in **Box 2.**

COLLECTION OF BREASTMILK

After proper counselling, checking suitability for donation, getting written informed consent, history taking, physical examination and sampling for laboratory tests, the donor is sent to designated breastmilk collection area in the milk bank or in the milk collection center. Breastmilk is collected by trained staff with hygienic precautions, after method of breastmilk expression is chosen by the donor. Home collection of breastmilk is better avoided at present in our country due of the risk of contamination. Washing the breast with water before expression is as good as washing with

BOX 2: CRITERIA FOR BREASTMILK DONORS

Who can donate?

A lactating woman who:

- is in good health, good health-related behavior, and not regularly on medications or herbal supplements (with the exception of prenatal vitamins, human insulin, thyroid replacement hormones, nasal sprays, asthma inhalers, topical treatments, eye drops, progestin-only or low dose estrogen birth control products);
- is willing to undergo blood testing for screening of infections; and
- has enough milk after feeding her baby satisfactorily and baby is thriving nicely.

Who cannot donate?

A donor is disqualified who:

- uses illegal drugs, tobacco products or nicotine replacement therapy; or
- regularly takes more than two ounces of alcohol or its equivalent or three caffeinated drinks per day; or
- has a positive blood test result for HIV, HTLV, Hepatitis B or C or syphilis; or
- is herself or has a sexual partner suffering from HBV, HIV, HCV and venereal diseases OR either one has high risk behavior for contracting them in last 12 months; or
- has received organ or tissue transplant, any blood transfusion/blood product within the prior 12 months.
- is taking radioactive or other drugs or has chemical environmental exposure or over the counter prescriptions or mega doses of vitamins, which are known to be toxic to the neonate and excreted in breastmilk; or
- has mastitis or fungal infection of the nipple or areola, active herpes simplex or varicella zoster infections in the mammary or thoracic region.

disinfectant [14]. There is no rationale in discarding foremilk. Drip milk (the milk that drips from the non-feeding breast in some of lactating mothers) collected with the help of breastmilk shells has been found to be nutritionally inferior with lower fat content [15], and is not recommended for banking.

The breastmilk may be expressed manually (hand expression) or with breast pumps. Manual expression is a low cost and effective method of expression, and associated with less risk of contamination. Simultaneous breast expression in breastfeeding women is more efficacious than sequential breast expression [16]. Milk should be collected in properly labelled sterile container and transported to HMB under cold storage condition.

Processing

All batches of collected raw breastmilk should be refrigerated immediately till the serological report comes negative. Fresh raw milk should not be added to the frozen milk since this can result in defreezing with hydrolysis of triglycerides [17]. While mixing fresh raw breastmilk to frozen raw breastmilk previously collected from same donor, it should be chilled before adding to frozen milk [18]. For sick or preterm babies, it is advisable to use a new container for each pumping.

Before pasteurization, pooling and mixing may be carried out from multiple donors to ease the process of processing and storage. Pasteurization is carried out by Holder's method.

Microbiological screening of donor milk is done before (if there is no cost constraint), and as soon as possible after pasteurization. Pre-pasteurization microbiology can result in wastage of milk to the tune of about 30% in some cases [19]. Even after pasteurization, the endotoxins of organisms are still present in the milk in some cases but they have not been found to have any clinical effect on the baby. A bacterial count of 10^5 CFU/mL or more in raw breastmilk can be considered as an indicator of the poor quality of milk. Based on this and on the theoretical concern that heavily contaminated milk with specific bacteria (e.g. *S. aureus*, *E.coli*) may contain enterotoxins and thermostable enzymes even after pasteurization, expert panel selected 10^5 CFU/mL for total bacterial count, 10^4 CFU/mL for Enterobacteriaceae and *S. aureus* as threshold values, which are in consonance with milk banks operating in other parts of the world [13,20]. No growth is acceptable in post-pasteurization microbiology cultures. Whole batch of culture positive container of pasteurized milk should be discarded.

Storage

Pasteurized milk awaiting culture report should be kept in dedicated freezer/freezer area taking precaution not to disburse it till the culture is negative. Storage should be done 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. Culture negative processed milk should be kept at -20°C in tightly sealed container with clear mention of expiry date and other relevant data on the label. It can be preserved for 3 to 6 months. Random cultures of preserved milk before disbursal can aid quality assurance.

Disbursal

PDHM should be disbursed at physician's requisition from NICU physician after informed consent from the parents of the recepient. Preterm baby should preferably get PDHM from preterm donors. It should be done on

First-in-first-out basis from the storage. Transport of PDHM should be done under cold storage in the same pasteurized container till its use.

Frozen PDHM should be thawed by either defrosting the milk rapidly in a water bath at a temperature not exceeding 37^0C, or under running lukewarm water taking care that the cap of the container does not come in contact with the water as it is likely to get contaminated [21]. It should never be thawed in a microwave as this results in reduction in the IgA content of the milk and there is a risk of burns if the milk is used too soon [18]. Milk should not be refrozen after being thawed as this increases the hydrolysis of the triglycerides in the milk. While bringing to room temperature, it should be gently agitated to make a homogenous mixture before use and should be used preferably within 3 hours to prevent contamination.

Labeling and record keeping

HNB 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; from sterile container for collection of donation, pooling vessel and pasteurization container to storage containers. Labels should be water resistant and names and identifying details of donors, dates of pasteurization, batch numbers and expiry date should be clearly readable. Record keeping at all levels should be meticulous for Donor Record File containing consent form, donor's and her child's data, screening reports, pasteurization batch files, and for PDHM Disbursal Record File containing relevant data, including recipient consent form. Though rarely required, complications can be prevented with appropriate labeling and record keeping.

As incubation period for most infection varies from a few weeks to six months and appearance of symptoms is faster in infants and children, there seems to be no rationale for keeping records beyond five years, unless one is working in an area where milk kinship issue is of paramount importance.

Economic implications

Cost effectiveness of using banked human milk in neonatal intensive care units has been documented in Western countries, largely due to reduction in the rate of NEC [22]. In a country like ours, the cost of running a milk bank with potential cost-saving due to reduction in NEC, sepsis and duration of hospital stay have not been evaluated. Given the high incidence of sepsis and a large burden of premature births, this intervention may have the potential to result in substantial saving for the nation.

Conclusion

It is clear that artificial formula will never provide the broad range of benefits of human milk. Given the high rate of preterm births in the country and level of malnutrition that ensues in the postnatal growth in such babies after birth, there is an urgent need to establish milk banks across the country, especially in the large neonatal units of all hospitals. This document aims at providing expert opinion regarding the feasibility and operational guidelines for establishing milk banks in the country.

Note: This document is the abridged version of detailed guidelines. The detailed guidelines are available with IAP IYCF Chapter and can be obtained from the website *www.iycfchapteriap.org*

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