
GUIDELINES FOR THE ESTABLISHMENT & OPERATION OF HUMAN MILK BANKS



Compiled by

**Infant and Young Child Feeding Subspecialty Chapter of Indian
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PREFACE

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 cost, fewer NICU setups etc 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 number of human milk banks has grown to nearly 14 in all over India but the growth of human milk banks have been very slow as compared to the growth of new 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. India faces its own unique challenges, having the highest number of low birth weight babies and significant mortality and morbidities in VLBW population. 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. Hence there is a need to formulate guidelines for establishment and operation of human milk banks in our country.

Though these guidelines are based on the experience and guidelines from other countries, changes have been made to suit Indian culture and needs without compromising scientific evidences. It does not intend to present detailed scientific literature but is an attempt to backup the execution of establishment and operation of human milk banking with scientific methods.

This document aims at providing expert opinion in the country regarding the feasibility and operational guidelines for establishing the milk banks. The purpose of this document is to ensure quality of donated breastmilk as a safe end product. It addresses detailed technical aspects, safety concerns and legal aspects. It is expected that all Human Milk Banks operating in India use this Guideline to address issues arising out of its functioning and socio-political willingness and environment.

The Infant and Young Child Feeding Subspecialty Chapter of Indian Academy of Pediatrics is actively concerned about the quality assurance of growing human milk banking in the country and need to maintain uniformity so that best outcomes are possible. The National Consultative Meeting for forming this guideline was summoned by the Chapter at Gurgaon on 30th June 2013, with representation from various stakeholders like Pediatrics Academia and Practices, WHO, UNICEF, NIPPI, GOI, Human Milk Banks, Preventive and Social medicine, PFHI, PATH, FOGSI and other NGOs. After an extensive literature review and discussions sessions at the meeting these guideline has been drafted. The Chapter is open to critical suggestions for betterment of the guidelines and its updating.

IMPORTANT INFORMATION

While using this guideline it is advised that health care professionals take responsible decisions appropriate to the individual situations using their clinical and scientific judgment, in communication with donor and recipients' parents and guardians and be informed about the updated information in doing so.

It is advised to all the organizations using this guideline to make their own individualized written Standards of Operations and protocols.

Human Milk Banks should include activities which protect, promote and support breastfeeding. They should comply by the laws of the land including IMS Act.

ABBREVIATIONS

AAP: American Academy of Pediatrics

BMI: Body Mass Index

CFU: Colony Forming Units

CMV: Cytomegalo Virus

COO: Chief Operating Officer

CSSD: Central Sterile Services Department

ECFR: European Council For Fatwa And Research

ELBW: extremely low birth weight

FIFO: First In First Out

GI: Gastro Intestinal

GIT: Gastro Intestinal Tract

Hb: Hemoglobin

HIV: Human Immunodeficiency Virus

HMASA: Human Milk Banking Association of South Africa

HMBANA: Human Milk Banking Association of North America

HSV: Herpes Simplex Virus

HTLV: Human T lymphotropic Virus

IgA: Immunoglobulin A

ILO: International Labor Organization

IMS: Infant Milk Substitute Act

KMC: Kangaroo Mother Care

LBW: Low Birth Weight

LSCS: Lower Segment Cesarean Section

NEC: Necrotizing Enterocolitis

NGO: Non Profit Government Organization

NICE: National Institute for Health and Care Excellence

NICU: Neonatal Intensive Care Unit

NRHM: National Rural Health Mission

OPD: Out Patient Department

PDHM: Pasteurized Donor Human Milk

PNC Ward: Post Natal Care Ward

PPH: Post Partum Hemorrhage

RDA: Recommended Dietary Allowance

SOP: Standard Operating Protocol

UIPS: Uninterrupted Power Supply

UNICEF: United Nations International Children's Emergency Fund

VDRL: Veneral Disease Research Laboratory

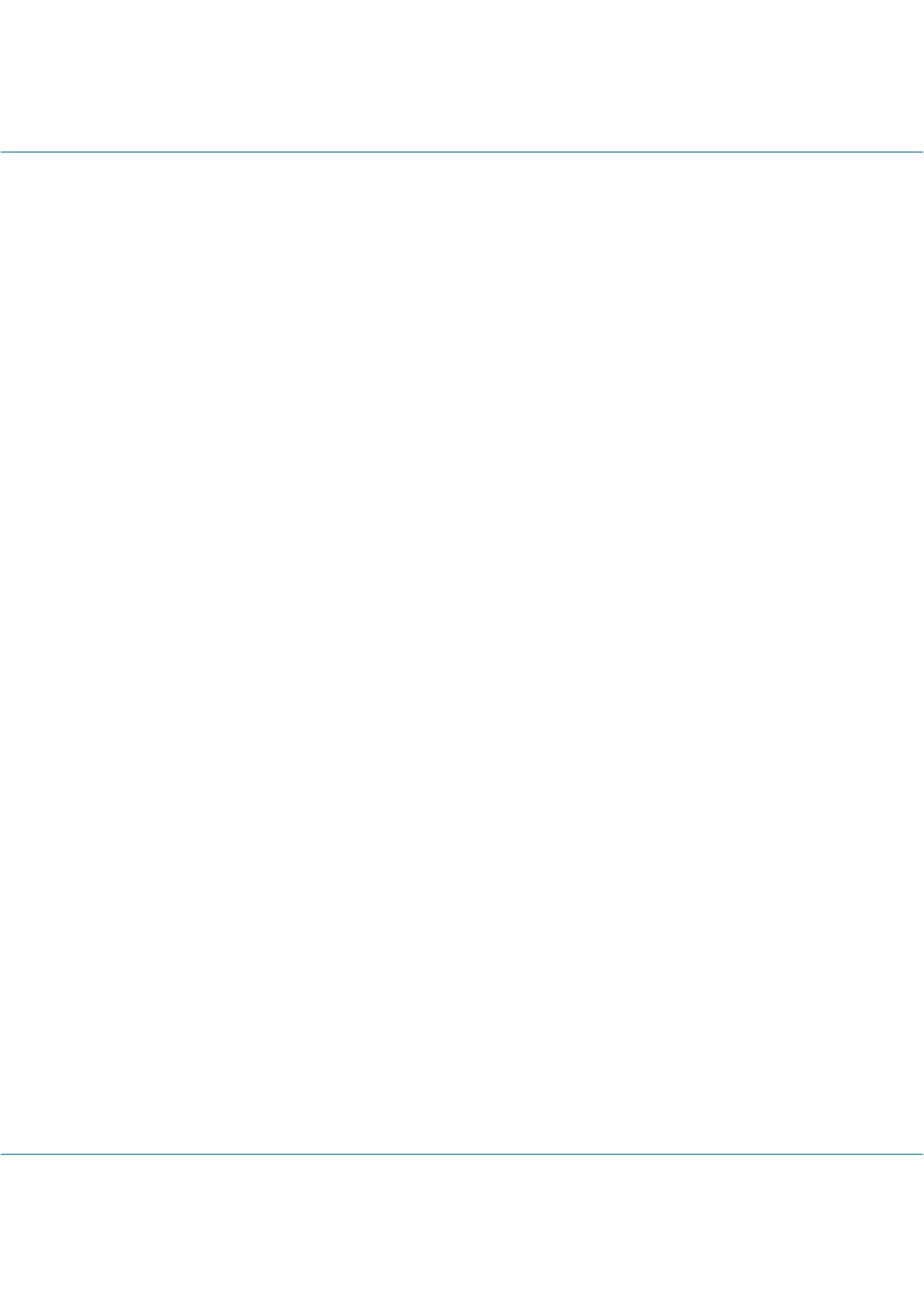
VLBW: very low birth weight

WHO: World Health Organization

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INTRODUCTION

Breastfeeding is best method of infant feeding, because human milk continues to be the only milk which is uniquely suited to the human infant. All mothers should be encouraged to breast feed their own infants. When a mother, for some reason, is unable to feed her infant, her breastmilk should be expressed and fed to her infant. If mother's own milk is unavailable or insufficient, the next option is to use PDHM. In our country the burden of low birth weight babies in various hospitals is about 30% to 40% with significant mortality and morbidities (1),(2),(3). Feeding these babies with breastmilk can significantly reduce the risk of infections.

There has been a definite cost effectiveness of using banked human milk in neonatal intensive care units observed in western countries largely by reduction in the rate of NEC (4). In a country like ours, the cost of running a milk bank with potential cost saving due to reduction in NEC, sepsis rate and duration of hospital stay have not been adequately 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.

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 for establishing milk banks across the country especially in the large NICUs of all hospitals.

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.

In 1980 the World Health Organization and UNICEF jointly declared: "Where it is not possible for the biological mother to breastfeed, the first alternative, if available, should be the use of human milk from other sources. Human milk banks should be made available in appropriate situations."(5) The American Academy of Pediatrics (6) has stated that human milk is superior for infant feeding and is the preferred feeding for all infants, including sick and premature newborns, with rare exceptions. When direct breastfeeding is not possible, expressed human milk should be provided. The United Kingdom Association for Human Milk Banking (www.ukam.org) (7) and the Human Milk Banking Association of North America (HMBANA) (www.HMBANA.com) have both published guidelines for the establishment and operation of Human Milk Banks. Much of the information contained in this document has been taken from these Guidelines with modifications to suit Indian culture and feasibility.

INFRASTRUCTURE FOR HUMAN MILK BANK

Location of human milk bank

Human milk banks are primarily focused to provide donor milk to high risk newborns admitted in neonatal unit. Breastmilk is of special importance for sick preterm and low birth weight infants who are admitted to N.I.C.U (8). The recently published N.R.H.M. guidelines also recommend this concept (9). Presence of human milk banks in the NICUs is associated with elevated rates of exclusive breast feeding rates in VLBW babies (10). 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. Donors will be available where large numbers of lactating mothers is present like postnatal wards of government hospitals and medical colleges where they can be encouraged to donate milk by medical and nursing staffs.

N.G.O's and Spiritual organizations with the help of medical professionals can encourage lactating mothers in the community to donate their milk to help the high risk neonates. Certain NGOs who take care of abandoned babies may have a human milk bank in their facility.

Space requirement for milk bank

There is no standard recommended size for a milk bank. The minimum requirement is a partitioned room of 250 square feet 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.

Space requirement for milk expression/collection

It is recommended to have an area earmarked for milk expression and collection where mothers can express milk comfortably. It can be either in the area adjacent to NICU or post natal wards or in the well baby care follow up OPD. Privacy is of paramount importance. Provision of music/television and a crèche helps in reducing stress of mothers. Teaching videos of KMC, expression of breastmilk and advantages of breastmilk feeding can be shown under supervision of milk bank staff.

This area also should serve the general purpose where the mothers have an opportunity to interact with the lactation support nurses or lactation counselors to seek help & support for their lactation problems, interact with other mothers, an area where mothers can express milk for their own babies as

well as the area where hospital based collections from donor mothers can be carried out.

Besides this it is also desirable to have an area within the NICU where mothers can comfortably express milk for their babies if they are on gavage/spoon/dropper feeds.

Equipments required in the milk bank

(See detailed specifications and using instructions in Annexure – III)

Pasteurizer/ Shaker-Water Bath

It is essential to have a device to carry out heat treatment of all available donor milk at the recommended temperature of 62.5°C for a period of 30 minutes (Holder pasteurization) prior to its use. This can be achieved using a conventional pasteurizer. However a conventional pasteurizer is extremely 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 for pasteurization of donor milk. The breastmilk in the container is heated through the steam and hot water in the water shaker bath. To avoid coagulation of the milk and to ensure even distribution of heat, the tray on which the breastmilk containers are placed is shaken/ wobbled.

This shaker water bath should be double walled. The inner chamber should be of stainless steel and the outer chamber can be of stainless steel or mild steel. The size of the shaker water bath varies according to the need of the milk bank, as per the number of containers that need to be pasteurized at one time, with the tray capacity varying from 9 to 24 flasks/stainless steel containers of 200 to 400 mL capacity.

Equipments for Flash Heat Treatment

Where pasteurizer is not available, an effective low cost alternative called flash heat treatment can be used for pasteurization. This has been shown to inactivate HIV (11) in donated breast milk samples and has been found to be nutritionally safe as well (12). This needs a simple heater or hotplate, a pan that is used to boil water, in which a glass jar containing the breastmilk can be placed. Water in the pan is heated till it is boiled. At this time milk reaches a temperature sufficient for effective pasteurization (13). The process can be monitored through a common android phone application along with a temperature sensor (14).

Deep Freezer

A deep freezer to store the milk at -20°C is essential in the milk bank. This may be a vertical model with refrigerator-like shelves. Such models are available in larger sizes of 285 to 300 liters. For smaller capacity deep freezers, the horizontal models with racks can also be used.

It is desirable to order a deep freezer with a digital display of the temperature inside the deep freezer with an alarm setting if the temperature rises above the set temperature.

A separate deep freezer for preprocessed milk is needed to keep the donated raw milk which awaits pasteurization.

It is desirable to have two deep freezers for processed milk:

1. First for storage awaiting culture: It is used 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.
2. The second deep freezer is used for storage of the pasteurized milk once the culture reports are available and are negative and the milk is considered safe for disbursement.

In case of space constraints, different shelves of the same deep freezer may be earmarked for storing milk with reports available and those awaited but must strictly be operated by the milk bank technician with no access to the end user unit staff.

Refrigerators

Separate refrigerators are required for:

1. To store the milk till whole day's collection is over and ready to be mixed for further processing. (In case where separate deep freezer is not available for this purpose)
2. Thawing the milk that is to be dispatched for use.

Hot Air Oven / Autoclave

A hot air oven / autoclave in the milk bank or centralized service is essential for sterilizing the containers used for collection from donors, containers for pasteurizing and storing the milk, and the test tubes needed for sending milk culture samples to the microbiology lab. CSSD facility of the hospital can be utilized for this purpose.

Generator / Uninterrupted Power Supply

Every milk bank should have a dedicated source of uninterrupted power supply in the form of a generator, UIPS or inverter to run the deep freezers & refrigerators in case of electricity failure.

Additional desirable equipments

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

Equipment required at site of milk expression & collection

Breastmilk pumps

Different types of milk pumps are available including manual, battery operated or electrical (for specifications see annexure III)

- For milk banking hospital grade electrical 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 (15). Electrical breast pumps are very effective for long term expression as they create a pumping rhythm similar to that of a sucking baby and may elicit the milk ejection and prolactin reflexes more efficiently. However the problem of these breast pumps is that they are costly and can cause damage to mother's nipple if suction pressure is too high.
- If there are cost constraints, 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 (16). As a piston type of milk pump costs around Rs. 2000/- per pump, it is cost effective to have several of these for breastmilk expression as they can be reused.
- Breast pumps can be a source of infection (17) and hence pump and its parts should be sterilized / disinfected properly as per manufacturer's instructions.
- The bicycle horn type of milk expression pumps should never be used as they are difficult to keep clean.

Containers for milk collection & storage

- All containers must be labeled properly.
- Containers should not be filled full as milk expands when frozen.
- Containers should have tight fitting/screwable lids to avoid spillage.

Different collection & storage containers that are used include:

- **Polythene milk storage bags** are fragile, easily punctured and it is difficult to pour milk from them. Also the risk of contamination is greater (18). Milk bags should not be used for milk storage. They are associated with loss of lipids and vitamins and there is a risk of contamination, although some studies have challenged the loss of lipids (19).
- **Hard plastic containers** of polycarbonates, pyrex or propylene are used in many milk banks abroad. They do not interact with nutrients and cellular components of milk. However lactoferrin, lysozyme & the titers of S-IgA and antibodies to *E.Coli* have been observed to be reduced significantly. However these containers need to be used carefully as they may crack easily. They have to be discarded after single use because with repeated use of polycarbonate plastic containers, there is a fear of increased migration of bisphenol-A into the milk, posing hazards to babies.
- **Stainless steel containers** of cylindrical shape and wide mouth with capacity of about 200 mL and tight fitting/screwed caps are used In developing countries, as they are easily available and are durable, easy to clean and autoclave. Experience at the Indian milk banks shows that stainless steel containers are most suitable containers in Indian circumstances. There is no significant decrease in nutrient composition on storage; however, cellular components are reduced.
- **Glass containers** can also be used but then be checked for chipping. They can be re-used but have to be well washed and sterilized or washed on high temperature cycle in a washer like dishwasher.

Administration and Staff of the milk bank

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. In cases of banks established by NGOs there can be a governing body headed by a Director.

1. The Director

Generally, the head of the neonatal services serves as the Milk Bank Director who is overall in-charge of milk bank and whose role is planning, developing, implementing and evaluating milk bank services. This is a part time position involving no extra cost.

2. Milk Bank Officer /Chief Operating Officer

Milk Bank Officer is usually a doctor preferably from public health and responsible for overall day to day functioning, administration, training, promotion and updating of the milk bank, taking consents from donor and

recipients and taking decisions on medical technical and nontechnical administrative aspects. S(he) has to report to the head of the unit.

3. Lactation Management Nurses

For milk banking to become established and effective, the lactation management nurses play a pivotal role. This is a full time job.

There should be at least one dedicated lactation nurse whose primary job is to help mothers with lactation problems, to motivate mothers to donate milk, to organize the milk collection, to dispatch the donated milk to the bank & to ensure cleaning, disinfection and sterilization of pumps and other equipments as required.

Depending on the work load of the bank and to ensure collection in different areas like the postnatal wards, well-baby clinic, additional dedicated lactation nurses may be required.

4. Milk Bank Technician

Milk Bank Technician looks after all the day to day activities in the milk bank, is responsible for pasteurization of milk, microbiological surveillance, collection of culture reports, maintenance of records and disbursement of milk.

5. Milk Bank Attendant

Milk Bank Attendant's job is to clean and sterilize the milk containers and breastmilk pumps, to transport the milk to the milk bank from the collection sites, to take samples for culture to the microbiology department and to collect the reports; to maintain hygiene levels in the office and other rooms.

6. Microbiologist

Microbiologist carries out the cultures and sends the reports to the milk bank. If there is an infection control committee in the hospital then infection control microbiologist may share this workload and be responsible for infection control practices including screening of donors.

7. Receptionist cum Record keeper

- Counsels women who come to milk bank and maintains Counseling Register containing data updated about women counseled, who agreed to donate, who will get back to the bank etc.,
- Does documentation filing and maintenance of the Donor Record Files and Recipient Record Files,
- Maintains inventory of stationery items used in the office,
- Maintains comfort and decorum of waiting area.

Minimum staff requirement:

- If it is not feasible to have all the above staffs, then basic minimum staffs required are Lactation Management Nurse and Milk Bank Technician. Sister-in-charge of NICU can co-ordinate the collection and transport of milk to the bank and regular hospital attendant can take up the job of cleaning. Technician can maintain the records of collection and disbursal. Unit head can be overall in charge for the functioning of the bank. Microbiology work can be shared with the regular hospital microbiology staff.

General guidelines for staff

- Gloves should be worn and changed between handling raw and heat-treated milk.
- Staff should adhere to the SOP of the milk bank which should be displayed at proper places as in case of a NABL accredited laboratory.
- Staff should follow hygienic practices like proper hand wash, donning gowns, mask, gloves, trimming nails, locking long hairs.
- Staff should undergo regular health checks and be immunized against Hepatitis-B.

Training of personnel working in milk banks

A formal training course for all technical staffs is required in lactation management, breastfeeding support and promotion, and communication skills. Receptionist and other staffs involved in non medical work should also undergo training in communication skills and breastfeeding support and promotion.

Visit to a well established functioning milk bank by the team of doctor, nurse and technician and microbiologist for 2 to 3 days observing and understanding all the steps of milk banking should be a part of training of staff of milk banks being newly established.

All milk bank staffs should be given ongoing training related to their job responsibilities and record of it should be maintained.

At the end staffs should

- fully understand the technical aspects of their jobs,
- fully understand how the milk bank, its health, safety and quality system works,
- fully understand the regulatory, legal and ethical aspects of their work,
- be competent in doing their jobs.

Cost approximation of setting up & running a milk bank

- Deep Freezer: Rs.40,000 to 1 lakh
- Pasteurizer: Rs. 40,000 to 1 lakh
- Refrigerator: Rs. 25,000
- Milk Pumps with adequate lacta sets: Rs. 60,000 to Rs. 1 lakh
- Hot air Oven: Rs. 50, 000
- UPS / generator: 1 to 2 lakh.
- Total: 3 to 6 lakhs.
- Recurring Cost: Staff salaries - 10 to 12 lakhs per year.
- No financial incentives to donors, no cost to recipients.

A majority of banks have voluntary donors. In North America, not for profit milk banks (HMBANA) are generally hospital based and sometimes community based, function independently, and are operated with hospital or grant funding. Each bank charges a processing fee for dispensed donor milk ranging from \$ 3 to \$5 per ounce (20). Most milk banks in India are not charging for the collection or dispensing of milk. The donation is voluntary and donors are not paid for it.

LEGAL & ETHICAL ISSUES IN HUMAN MILK BANKING

The human milk or breastmilk must be provided to those children who are compromised or in vulnerable state of health because of their nutrition and body needs. One of the major issues milk banking faces is the possibility of transmission of an infectious disease via the donated milk. Parents may fear accepting donated milk for this reason, while doctors may feel that the benefits of donated milk are outweighed by the possible legal implications (21). Getting the best possible start in the life is the birth right of each and every newborn baby. Similarly giving the best possible nourishment to its offspring is the right of each and every mother. These rights are protected not only under the Constitution of India in the Article 47, which states that it is the duty of the state to raise the level of nutrition and the standard of living and to improve public health but also under the Convention on the Rights of the Child 1989, the *Innocenti Declaration 1990*, the International Code 1981, the ILO convention 2000, the IMS Act 1993 as amended in 2003 and the various World Health Assembly resolutions declared from time to time.

WHO and UNICEF, made a joint statement in 1980: "Where it is not possible for the biological mother to breast feed, the first alternative, if available, should be the use of human milk from other sources. Human milk banks should be made available in appropriate situations." (5)

Legal and ethical issues related to human milk banking are:

1. **Establishment of human milk bank:** At present there are no laws governing human milk banks in India. France is the only country where human milk banks are governed along with blood banks. Therefore every neonatal unit can establish a human milk bank on its own after obtaining appropriate permission from their respective institutes/hospitals.
2. **Payments to the donor:** Whereas most milk banks run on free voluntary donations from mothers, some donors can be paid their cost of travel and screening charges. A milk bank cooperative in USA pays 1\$ /oz of milk supplied (22).
3. **Commercialization of human milk bank:** Efforts to setup a company that sells human milk bank have been made in past (23). The government must ensure that such activities are nipped in the bud.
4. **Claims on transmission of infection:**
 - a. Due to feeding of donated milk from milk bank in the event of an outbreak due to contamination of supplied milk: There is only a single report of outbreak due to contamination of pasteurizer so far in the literature (24).

- b. However, it is a potential problem and should be taken care of during the process of informed consent to the family of the recipient. Failure to do so and document it may lead to legal problems.
 - c. Due to feeding of donated milk from milk bank in the event of a baby contracting a hospital acquired infection while still in neonatal unit: This aspect must be taken care during information sharing and consent taken from recipient's parents.
 - d. Due to feeding from milk bank after discharge of a baby if a baby develops infections known to be transmitted through breastmilk. This aspect must be taken care during information sharing and consent taken from recipient's parents.
5. **Religious issues** like milk kinship among Muslims: This issue has been debated among Muslim scholars. There is no unanimity of opinion. However, European Council for Fatwa and Research (ECFR) in 2004 has accepted donation by Muslim mothers and acceptance of milk by Muslim baby as legal. Most countries in Arab world have not accepted this idea (25). At present there is no official position among Indian Muslim scholars on it.
6. **Duration of keeping records of the donors and recipients.** HMBANA recommends that records of donor and recipients be stored till the recipient is of 21 years age (26). Whereas NICE guidelines recommend that records be kept till the recipient is 30 years old (7). 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. In India the blood bank records are retained for a minimum period of five years (27).

Therefore, the donor mother as well as recipient mother should be counseled and informed written consent should be obtained for both donation of milk from donor and for feeding the donated milk from recipients' parents. There is need to provide quality assured safe human milk to the recipient.

There is need for the government and the policy makers to frame the guidelines, legislations and rules so as to protect the rights of the mother and child. There is every possibility that the breastmilk i.e. "Liquid Gold" can be sold in the commercial market once it is available in the milk banks. The government should ensure that there is no commercialization of human milk by various stake holders specially the multi-nationals.

The gender discrimination and exploitation of the mother and misuse of the human milk must be prevented at all cost.

DONOR MANAGEMENT

Donor Population

The mothers, who are lactating and willing to give extra breastmilk for other babies without compromising the nutritional needs of their own baby, form the donor population. They may be:

- Mothers who have babies admitted in the neonatal unit or wards,
- Mothers who come to attend outdoor department for well baby care, immunizations and other ailments,
- Lactating staffs working in the hospital,
- Mothers who have lost their babies or cannot give milk to their own babies due to some reason but are willing to donate their breastmilk voluntarily,
- Lactating mothers motivated by community and other awareness means.

Human Milk Banks should have policy of taking breastmilk donations on voluntary basis. Donors are not paid for their donation.

Counseling and Motivating

Maximum donor population should be reached using variety of avenues. Spreading awareness about possibility of breastmilk donation in society by various means of mass communication can help motivating donors.

Possible routes of recruiting donors can be:

- Those who have already donated and by their recommendation
- Staff of NICU/PNC ward/Pediatric clinics
- Pregnancy and child birth educators/counselors and their class attendees
- Breastfeeding support groups especially women's social clubs
- Mass Medias

Counseling and motivation sessions may be conducted by health care workers, lactation experts, trained nurses or social workers in groups or individually in post-natal wards, nurseries, outdoor departments, immunization clinics and social group's gatherings. Involvement of NGOs and formation of peer groups can also help a lot.

Counseling may be verbal or aided by pictures, posters, videos, role plays and utilization of various media.

The donor mothers should be counseled regarding:

- The need and efficacy of donated human milk and its benefits to the recipient baby without harming her own baby,

- Donor evaluation prerequisites: the process of screening, giving authentic medical records, serologic testing and her physical examination for medical conditions mentioned in donor selection criteria,
- Procedure of consent,
- Process of breastmilk collection, transport to the milk bank, processing, storage and disbursal of donated milk to the needy babies,
- Maintenance of lactation and tackling with problems related to it.

Potential donor can be counseled in person or telephonically. Generally a face to face communication along with video on the process of breastmilk collection is most effective method of counseling as it provides opportunity for answering the questions of donor mothers and alleviates anxiety.

Counseling and consent document should be preferably in local language easily understood by the one being counseled or addressed. It should be in clear and non-technical language.

Consent

After counseling and motivating donor mother's written informed consent should be obtained. Donor mothers should know about the process of milk donation, medical screening and serologic testing and have to understand that they have no claim over the donated milk once donated. Records need to be maintained for 5 years as recommended by blood banks⁵. (See consent forms – Annexure-II)

Screening

After counseling, motivation and consent, the donor mothers should be screened for suitability of donation by reviewing her health records and asking relevant questions regarding criteria mentioned in the section of donor selection below. The following should be enquired and documented before breastmilk collection in a donor screening Performa (see Annexure - I) (7):

1. Health of the donor mother's own baby.
2. Historical data of drug intake, smoking, exposure to chemicals, high risk behavior and other data mentioned in donor selection section. It can be done through a questionnaire given to mother and filled by her with help of trained person.
3. Examination of local breast lesions and disease states of mother to ensure eligibility as given below in section of donor selection.
4. Serological screening (see details below).

Donor Selection

Donor mothers must:

1. Be in good health and health related behaviors.
2. Not be regularly on most medications or herbal supplements (with the exception of postnatal vitamins, human insulin, thyroid replacement hormones, nasal sprays, asthma inhalers, topical treatments, eye drops, progestin-only or low dose estrogen birth control products).
3. Be willing to undergo blood testing for screening of infections. (usually it is at the milk bank's expense).
4. Have enough milk after feeding her baby satisfactorily and the baby is thriving nicely.

A woman would NOT be a suitable donor if she: (7),(28),(20),(29)

1. Uses illegal drugs.
2. Smokes or uses tobacco products or nicotine replacement therapy.
3. Regularly takes more than two ounces of alcohol or its equivalent per day or more than three caffeinated drinks (total of about 150 to 200 mL) daily.*
4. Has a positive blood test result for HIV, HTLV, Hepatitis B or C, or Syphilis.
5. Has high risk behavior for HIV transmission.
6. Had a sexual partner at risk for HIV, HTLV or Hepatitis and venereal diseases in the past 12 months:
 - a. Including anyone with hemophilia or anyone who has used a needle for injection of illegal or non-prescription drugs.
7. Has received organ or tissue transplant, any blood transfusion/blood product within the prior 12 months.
8. Is taking radioactive drugs.
9. Has chemical environmental exposure known to be toxic to the neonate and excreted in breastmilk.
10. Is taking category L3, L4 and L5 drugs e.g. amiodarone, antineoplastic drugs, diethylstilbestrol, disulfiram and tamoxifen. (further information may be availed from <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?Lact>) * (30)
11. Has viral exanthema at present. *
12. Has active lesions of herpes or chickenpox on the breast.*

13. Daily uses over-the-counter medications or systematic prescription not permitted for donor milk. For medication compatibility/safety with breastfeeding check out with standard literature. Medical advice should err on the side of caution.

* may be a temporary contraindication for donation.

** for Creutzfeldt-Jacob disease

Temporary disqualification

Active donors are temporarily disqualified from donating milk under the following conditions:

1. Any acute infection, including clinical mastitis and monilial/fungal infections of the nipple or breast.
2. During the 4 week period following a case of rubella or varicella in the household starting from when the lesions crust over.
3. During the one week period following a reactivation of latent infection with HSV or varicella zoster of the breast or thorax starting from when the lesions crust over.
4. During the 12 hour period following consumption of alcohol (hard liquor, beer or wine).
5. During the 8 days following donors' or its partner's receipt of a tattoo administered in a regulated site using sterile needles and single-use only dyes.
6. During 28 days following donors' receipt of live virus vaccine for measles, mumps and rubella.
7. During the 3 months following receipt of any live virus vaccine including chicken pox, rotavirus, polio and typhoid.

During continuing donation period donors are instructed to report an illness/high risk behavior amounting disqualification in them or in the household to the milk bank. The Milk Bank Officer may temporarily disqualify the donor for illness or medication issues. Redonation can be resumed later at the discretion of the Milk Bank Officer.

Serological Testing

All tests should be undertaken in a standard reliable laboratory and preferably in the same hospital where milk bank is established. Ensure that laboratories communicate the results of serological testing clearly and that they provide appropriate interpretative comments.

All reports must be attached with the consent form and checked at the time of collecting donation.

A donor having positive blood testing should be referred to a health care provider of her choice for follow-up, and a copy of the lab report sent to her and her health care provider. Any milk from this potential donor, which has been held at the milk bank should be disposed off safely.

Tests to be done

- Serological Screening for HIV-1, HIV-2, VDRL and Hepatitis B and C can be taken as mandatory (20). Each country can modify these prerequisite tests as per local epidemiologic data (31). Hepatitis B and C may be placed as optional in resource poor settings in accordance to south African guidelines (32).
- Screening CMV is not recommended for pasteurized milk and as HTLV is not reported in India, its testing is not required (33),(34). Blood banking guidelines also do not recommended routine screening of CMV and HTLV (35).

Perform all serological screening tests at the time of enrolling for donation after taking consent. If they have been done recently in last 3 months (as in the present pregnancy) there is no need to repeat the tests unless there is a history of any recent viral illness or high risk behavior. *If there is concern about the donor's HIV status, a repeat rapid HIV test should be done every three months* (32).

Retesting

The NICE guideline does not recommend repeat serological testing while the donor is donating milk, but current UKAMB guidance recommends that 'ideally' donors should be retested at 2-monthly intervals (36). Expert opinion indicates that milk banks in UK currently screen donors a maximum of 3 times a year, with some milk banks screening at the time of enrolment and not routinely repeating.

Repeating the test is not required when mother continues to donate, unless history is suggestive of contraindications/disqualification as listed in section of donor selection or in the event of high risk behavior in donor or her sexual partner. High risk behavior includes multiple sex partners, overt alcoholism. Persons likely to be at high risk include injection-drug users and their sex partners, persons who exchange sex for money or drugs, sex partners of HIV-infected persons, and MSM or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test (37).

BREASTMILK EXPRESSION

Breastmilk production

Milk is produced in the secretory alveoli of breast tissue. Each alveolus is surrounded by myoepithelial cells, which contract under the influence of oxytocin and ejects milk into lobules. The lobules drain into ductules which unite to form a larger lactiferous duct. They are easily compressible and dilate with expulsion of milk from the alveoli during milk ejection reflex.

Techniques of breastmilk expression

Breastmilk expression can be done either manually or by a breast pump.

Manual Breastmilk Expression

Manual expression is a low cost and effective means of expression and associated with the least risk of contamination. Manual expression is the most preferred technique of milk expression when a mother is expressing milk to feed her own baby. Earlier studies showed that the incidence of bacterial contamination was lesser with manual expression if the first 5-10 mL were discarded. However this has not been verified in subsequent studies (38),(18).

Drip milk i.e. the milk that drips from the non-feeding breast in 20% of lactating mothers, collected with the help of breastmilk shells has been found to be nutritionally inferior with lower fat content and is not recommended for banking (39),(40).

Technique of manual breastmilk expression

The most accepted technique of manual expression of breast milk is the Marmet Technique (after Chele Marmet) (41).

It is done in 3 steps (see Figure 1):

- *Position* the thumb and 2 fingers about 1” to 1½” behind the nipple on the outer edge of areola. Place the thumb pad above and the finger pads below in form of the letter C. The fingers are on the milk reservoirs which lie beneath them. Avoid cupping the breast.
- *Push* back the fingers towards the chest wall but avoid spreading the fingers apart. For large breasts, first lift the breast and then push towards the chest wall.
- *Roll* / compress thumb and fingers together towards each other at the same time. This empties milk from the ducts.

Repeat the same sequence rhythmically: position-push-roll-position-push-roll. This movement should be repeated at about one per second.

Next position the thumb and fingers sidewise and repeat the same sequence to empty all ducts.

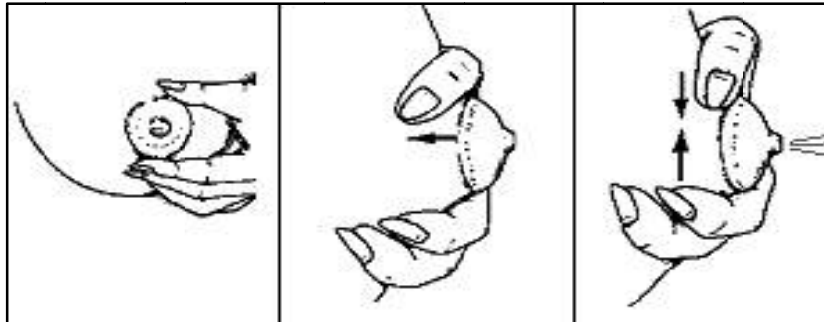
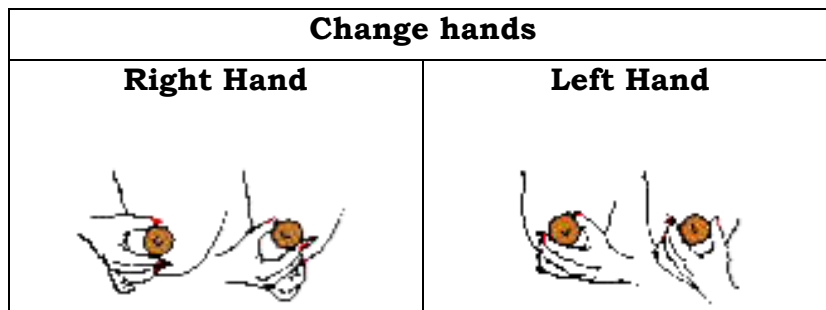


Figure 1: Technique of Manual Expression of Breastmilk: The Position, Push, Roll sequence

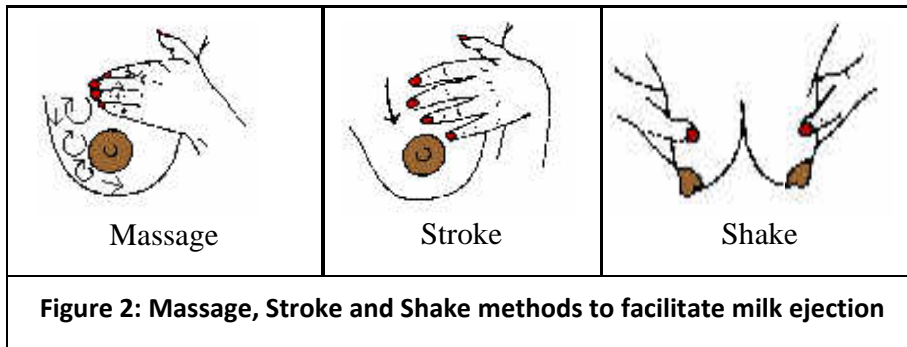


Advices to mother for manual expression

Mother must be explained about hygiene while expressing breastmilk. She has to thoroughly wash her hands with soap and running water and then dry them with a clean towel. She should also be taught about breast stimulation by stroking and massage to improve ejection.




Milk ejection can be improved by

- **Massaging** the milk producing cells and ducts:
 - Start at the top of the breast, press firmly into the chest, move fingers in a circular motion on one spot on the skin.
 - After a few seconds repeat the same in another area.
 - Spiral around the breast towards the areola using this massage.
- **Stroking** the breast area from the top of the breast to the nipple with light tickle like strokes. Do that around the whole breast. This helps in relaxation and stimulates more milk ejection.
- **Shaking** the breast while leaning forward so that gravity will help the milk ejection (see Figure 2)



- Expressing frequently and emptying the breasts completely stimulates more milk production.
- Baby’s suckling causes nipple stimulation and thereby stimulates more milk production. Hence even if the baby is preterm and on gavage feeds, non nutritive sucking will improve lactation.
- If expression is by a breast pump, then double (simultaneously from both breasts) pumping yields more milk (42) as prolactin levels are higher in such cases.
- If milk flow is not good then a warm flannel can be kept on the breast for few minutes.
- Having a photo of the baby or thinking about the baby stimulates milk flow.
- Mother can express milk soon after feeding her own baby or in between feeds. More emptying makes more milk.

Movements to be AVOIDED during manual breastmilk expression (see Figure 3):

Figure 3: MOVEMENTS TO AVOID WHILE MANUAL EXPRESSION OF BREASTMILK		
		
Squeezing	Pulling	Sliding
Avoid squeezing the breast. This can cause bruising	Avoid pulling out the nipple and breast. This can cause tissue damage	Avoid sliding on the breast. This can cause skin irritation, burns and bursting

Use of electrical breast pump

- Mother should be explained about how to use it.
- Breastmilk expression must be maintained at least 8 times/day till the baby is ready to put to the breast.
- Elicit the milk ejection reflex before applying the pump. Breasts can be gently massaged with the flat of the fingers.
- Breastmilk expression should begin immediately after stimulation.
- During breastmilk expression gently stroke or massage the breast.
- Ensure that the pump is attached properly.
- Use the lowest suction to maintain the flow.
- Cease expression when milk flow stops.
- Equipment needs to be washed thoroughly with detergent and stored dry in between two uses.
- Simultaneous breast expression in breastfeeding women is more efficacious than sequential breast expression (42).
- Double pumping can be encouraged if possible.

COLLECTION OF BREASTMILK

Ways of Collection

Designated milk collection areas

Donor mothers may be sent to designated milk collection rooms in the milk bank or in the milk collection centers/posts like outpatient department or indoor department of hospitals. Their milk is collected by trained staff from the milk bank department. This procedure is generally followed in milk banks in our country (28).

Home collection system

The mothers can also become donors from home. Milk bank or health care workers identify and get in communication with potential donors or these may be the same mothers who were donating milk while they were in hospital. Donor mothers can themselves contact the milk bank or health care workers.

Donors may themselves transport the milk to the milk banks or it can be collected by the centre. In resource limited setting home collection and donation from home is not advisable as it entails additional risk of infection. In India at present there is no home collection system. At most banks usually the donor population is cross-sectional i.e. donations are done till mother is in hospital or when she attends well baby clinic or at camps. With increasing longitudinal donor population (i.e. same donor donating for prolonged time like weeks or months continuously) a home collection system may need to be in place with proper precautions and specific counseling process.

Mass collection at camps

Another unique method for collection of large amount of milk quickly is to organize human milk donation camps like blood donation camps. Donations are taken under supervision and support of milk bank staffs. Donor mothers are invited and motivated by women's social groups, pediatricians, obstetricians and other volunteers. Originally conceptualized and successfully organized regularly at Surat by Surat Pediatric Association Charitable Trust, now it is practiced at other places like Udaipur also. Maintaining cleanliness during collection and transportation is of utmost importance.

The process of collection

- Donor should be given written and verbal guidelines on expression, handling and storage of breastmilk and also operation and maintenance of breast pumps if they opt for expression by breast pumps.
- Method of expression: She is explained about the procedure of manual expression versus breast pump expression. She is explained use and maintenance of breast pumps, and then she chooses the method of expression.
- The donor collection area should have comforting quiet environment and privacy. It should be away from area where contamination can occur like bathrooms or general visiting areas.
- After counseling, checking suitability for donation, getting a written informed consent, history taking, physical examination and blood sampling when required, the donor is sent to the designated collection area.
- She is made comfortable in the collection area. If needed she may breastfeed her own child and put her/him in the cradle. An attendant or relative or milk bank staff assists in doing so.
- Both the donor and lactation management nurse performs thorough and rigorous hand wash with soap and running water, and then dry them on hand drier or clean disposable towel. Hand washing is to be done even if expression is not manual.
- The lactation management nurse cleans the breast using clean lukewarm water. Washing the breast with simple water before expression is as good as washing with disinfectant (43). Donors should observe good hygiene and should have daily bath. Breasts should not be washed with bactericidal or routine soaps frequently.
- Donor is explained the procedure of breast massage which can stimulate breastmilk production and let down.
- The donor undergoes breast massage with help/supervision from nurse. Nurse monitors the comfort level of donor.
- Next the donor expresses breastmilk into sterile container for collection of fresh raw breastmilk donation. The container should have a label with donor ID number and date of expression.
- After completion of collection breasts are cleaned with tissue paper/sterile cloth.
- Donated breastmilk is sent for further processing.
- After each use the electric or manual pump is dismantled and sterilized for next use.

- The donor mother is given a DONOR CARD with her registration number on it for future donations. If the milk bank practices giving human milk to recipients outside their hospital she can also be given REPLACEMENT CARD
- While undergoing multiple donations over a long period donor mother is given ongoing support and advices on breastfeeding and its maintenance and troubleshooting related problems. She is advised to contact milk bank in case of any deviation in her and her sexual partner's health status and health behavior amounting to disqualification.

Transport of donated milk to the human milk bank

Freshly expressed breastmilk should be transported to the human milk bank at the earliest, preferably within two hours and should be stored in refrigerator or ice till it reaches the milk bank. The transport container used must be insulated, rigid; clean and disinfected. Coolant blocks should be used in it and the empty space in the container should be filled with bubble wrap.

If stored in the refrigerator, the containers should be placed in the coldest area, distant from the door and should be transported to the human milk bank at the earliest, not later than 24 hours.

Donor is explained this so that she understands it properly if milk is transported from outside.

DONOR MILK PROCESSING

The fresh raw breastmilk should be kept in pre-process milk freezer/refrigerator. Fresh raw milk should not be added to the frozen milk since this can result in defreezing with hydrolysis of triglycerides (44). While mixing fresh raw breastmilk to frozen raw breastmilk previously collected from same donor, it should be chilled before adding to frozen milk. For sick or preterm babies it is advisable to use a new container for each pumping. Whole day's collection should be processed by mid-day so that cultures can be sent in time to the laboratory.

Mixing & Pooling: Donated breastmilk from multiple donors is transferred from donations collected in small containers to larger glass flasks/pasteurizer containers. Each pool (which usually includes milk from 3 to 5 donors) should be thoroughly mixed to ensure an even distribution of milk components. Names & ID of donors in each pool should be recorded.

Microbiological Screening of Donated Milk

Microbiological screening of donated and pooled milk should be done as soon as possible after and/or before pasteurization according to the protocol of the bank. The contamination level should be maintained at zero level at all possible areas.

Pre-pasteurization culture

In developing countries it is not feasible because of cost constraints. Pre-pasteurization microbiology can result in wastage of milk to the tune of 30% in some cases (31). In western countries it is done wherever possible in order to know the extent of contamination and the efficacy of pasteurization process. Before treatment, there are no set levels for colony count levels, but a rough guide is as follows:

- $<10^3$ CFU/mL: milk is used
- $>10^5$ CFU/mL: milk is not used
- 10^3 to 10^5 CFU/mL: milk is only used if organisms are skin commensals.

Heavily contaminated milk is discarded because pasteurization process is not effective on heavily contaminated sample.

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 (45).

Post-pasteurization culture

- Each container of pasteurized breastmilk is subjected to microbiological culture test. It is done in every human milk bank before the milk is dispensed.
- No amount of growth is acceptable in processed pasteurized milk. Entire batch tray is discarded if it doesn't meet acceptable bacteriological standards.
- During storage after first mandatory microbiological testing, at regular intervals of a fortnight or on monthly basis a unit of PDHM is randomly chosen from each batch tray and sent for bacteriological test. This helps in quality control checking.

Method of culture

- Milk sample is incubated in the culture media for 48 hours at 35°C.
- McConkey agar media is widely used for the purpose.
- Hence a certified microbiology laboratory and lab technicians are must in the institution where milk bank is established.

Pasteurization of Donated Breastmilk

Pasteurization of human milk is necessitated by the fact that majority of milk samples grow one or more bacteria before milk pasteurization. 62% of the pooled samples grew one lactose-fermenting gram negative rod and 19% grew another bacterium. 4% samples were contaminated with *Staphylococcus aureus* and 8% with alpha streptococci. After pasteurization 93% samples did not grow bacteria reflecting efficacy of holder pasteurization (46).

The fresh raw donated milk should be immediately pasteurized after collection. Pending that it should be kept in refrigerator specially designated for such milk. That refrigerator should not be used for storing post pasteurized milk.

Method of Pasteurization

Holder method of pasteurization using 62.5°C for 30 minutes is widely used. Properties are better preserved at this temperature without compromising bacteriological safety.

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) (47) and ultra violet irradiation are still not being used in human milk banks routinely.

Recently a low cost but effective flash heat method has been developed in Africa & is recommended to be used where there is no access to pasteurization facility and this method has shown to effectively inactivate HIV (11).

Operation of pasteurizer

- The stainless steel containers for the pasteurizer/shaker-water bath should be cleaned & sterilized.
- The fresh raw individual donated breastmilk collected in small sterilized containers is poured in the larger sterilized stainless steel containers suitable to size of the pasteurizer. Collection from multiple donors can be pooled. Containers should not be filled more than four-fifths full in the container to allow for expansion of milk when heated.
- The containers are then placed in their specific slots inside the machine tray and clamped to avoid spillage. The bath canner is filled with water enough to submerge $\frac{1}{4}$ to $\frac{1}{2}$ portions of the steel containers.
- The temperature is set at 62.5°C; time is set to 30 minutes and shaking speed control to Level 1.
- After 30 minutes, containers are taken out, sealed tight and allowed to cool rapidly in slurry of ice, sample for post pasteurization culture is drawn and containers are kept in the deep freezer at -20°C. Post pasteurization no tampering should be done likelihood of contamination like aliquoting or transferring to other containers.
- Each containers of same batch of pasteurization are placed in one labeled Batch Tray. Then it is stored in the freezer designated for post-pasteurization milk awaiting cultures report. That should not be disbursed till culture reports come negative.
- After each batch of pasteurization the containers are sent for autoclaving after cleaning.

Post pasteurization culture

- It is done in every set-up before the milk is dispensed.
- No amount of growth is acceptable.
- 1 to 2 mL from each batch should be sent to microbiology lab for culture from each container. If the test report is positive then the entire pasteurized batch/container's pool is discarded depending on culture reports of other containers of the same batch of pasteurization

The containers with negative culture reports are transferred to deep freezer designated for culture negative pasteurized milk ready for disbursement.

LABELING, PRESERVATION AND DISBURSAL

Labeling

- Labeling material should be water resistant to avoid spoiling while handling and information clearly readable.
- Label of the sterile containers for fresh raw milk donation collection should have identifying details of donor like ID number and date of expressing.
- When there is pooling, record should be maintained on how many donor's milk is mixed and pooled in each pool with their ID numbers. The record keeping should have pool number with IDs of the pooled donations.
- The label code on pasteurized container should have: container serial number; batch number ID; pool number; date of pasteurization; date of freezing and expiry date.
- Batch wise information of which donor's milk is there in each batch tray should also be maintained.

Preservation and Storage

- Fresh raw breastmilk is safe for four to six hours at room temperature i.e. 15°C to 25°C. It can be stored in the freezer compartment of the refrigerator for five to seven days and in the deep freezer at minus 20°C for six months.
- Storage should be done in the same container which is used for pasteurization. It is advisable not to transfer processed milk in other containers as it has risk of contamination.
- The pasteurized containers with negative culture reports are tightly sealed and then placed into a labeled Batch Tray. According to its date of collection the Batch Trays are placed in the post process deep freezer at minus 20°C. The milk can be stored for 3 to 6 months without any bacterial growth.
- Practice FIFO method i.e., old milk should be first used up.

Distribution/Requisition Process

- Donor milk should be dispensed by prescription from the recipient's physician after informed consent from recipient's parents.
- The health care provider has to fill in the PDHM requisition form. The form data should be kept in records.
- The PDHM should be taken out of processed deep freeze on FIFO basis i.e., oldest milk being used first. It is then allowed to come to room temperature. As per the requisition, the exact quantity in mL, with the name & registration number of the baby, should be transported in ice cold packs, preferably in vaccine carriers.
- It should be transported to the recipient hospital under cold storage at earliest. Usually it is in the same premises hence the time taken is very less.

- Maintain record of disbursed PDHM with details of recipient and details of disbursed milk.

Recipients

Donor Human Milk can be prescribed for treatment of medical conditions like:

- **Prematurity:** The potent benefits of human milk are such that all preterm infants should receive human milk (20). If mother's own milk is unavailable despite significant lactation support donor breastmilk should be used. The premature infant will have a better start in life (48). 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 NEC in infants receiving preterm formula (49).
- **Necrotizing Enterocolitis:** Donor breastmilk is associated with a lower risk of NEC and the presence of active enzymes in the breastmilk enhances the maturation of the underdeveloped gut (48),(50). Babies with necrotizing enterocolitis benefit from PDHM the most.
- **GIT Conditions:** Therapeutic benefits are noted in short gut syndrome, sepsis, and post surgical gut healing in omphalocele, gastroschisis, bowel obstruction and intestinal fistulas, etc. (20). In infants having mal-absorption, feeding intolerance, immunodeficiency & chronic or persistent diarrhea, who are bottle fed or receiving top feeding, it has been well documented that once given donor human milk their condition resolves (51). It is possible to administer trophic feeds / gut priming exclusively with human milk (52).

If supplies of banked milk are sufficient:

Other than above mentioned indications PDHM may be dispensed by prescription for a large variety of situations, including but not limited to:

- **Absent or insufficient lactation:** Mothers who deliver twins, triplets or quadruplets, who can't, secrete sufficiently to breastfeed their neonates can opt for this best option.
- **Adoption or surrogacy:** For babies of non-lactating mother who adopted a neonate if induced lactation is not possible, donor milk is the next best option.
- **Abandoned neonates and sick neonates from orphanage** admitted to NICU or Pediatric ward, will be benefited from donor human milk (53).
- **Temporary interruption of breastfeeding:** Babies separated from their mothers due to maternal illness, postpartum problems and emergencies like post-partum hemorrhage, eclampsia and other serious medical illnesses;

neonates of mothers with acute or chronic illnesses who are unable to breast feed their baby can be provided with this option.

- Infant at health risk from breastmilk of the biological mother.
- **Babies of mother who dies** in the perinatal period.

Recipient priority in case of short supply:

- Preterm babies especially in the first few days, till their mothers are able to secrete adequate milk.
- Sick preterm infants, with illnesses like necrotizing enterocolitis, GI surgeries.
- Babies of mothers with postpartum illnesses.
- Babies whose mothers have lactation failure till their milk output improves.
- Babies delivered by cesarean section when mother's own milk not available.

Guidelines for Use of Donor milk in the Hospital Setting

- The amount which will be required for 24 hours can be taken out from deep freeze of milk bank and stored in regular refrigerator for 24 hours.
- As time permits, thaw frozen breast milk by transferring it to the refrigerator for thawing or by swirling it in a bowl of warm water bath at a temperature not exceeding 37°C, or under running lukewarm water taking care that the cap does not come in contact with the water as it is likely to get contaminated (24),(54),(55). Frozen PDHM should be completely thawed, brought to room temperature and gently agitated to make a homogenous mixture before use and be used preferably within 3 hours to prevent contamination.
- Microwave heating is not recommended because microwave action can continue after removal from oven, there is a risk of burns if the milk is used too soon. Hot spots may occur and overheating can damage protein and vitamins. this results in reduction in the IgA content of the milk (56).
- Thawed pasteurized milk should not be refrozen; it increases hydrolysis of lipids and increases risk of contamination.
- Preterm baby should preferably get PDHM from preterm donors.
- A copy of the recipient consent form must accompany first orders. A copy should also accompany the recipient's medical records.

Complications from administration of donated milk

Complications from administration of PDHM from human milk banks are rare. They could arise if safety standards are not maintained and could be from:

From donor

- If donor has not been screened appropriately.
- If donor conceals facts about medications, drug abuse, high risk behavior, etc.
- History of recent infection.

From processing of milk

- Contamination of donated milk while handling.
- Loss of immune modulatory proteins, immune active cytokines, antioxidants and growth factors due to heat treatment (57).

AAP recommends use of pasteurized human milk when mother's own milk is not available with strict quality control and with adequate monitoring in spite of the above risks (6).

RECORD KEEPING & TRACKING

Human Milk Banks should have an operational objective of ensuring full traceability from individual donation to recipient and maintaining a record of all storage and processing conditions. There should be standard operating procedures written and followed. Confidentiality should be preserved by the milk bank about its records and data. Though rarely required, complications can be prevented with appropriate labeling and meticulous 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. In India the blood bank records are kept for a minimum period of five years (27).

For every donor a Donor Record File should be maintained with the Donor Consent Form; Donor Registration details; Donor Screening Performa; & Serological Reports; Date of birth and gestational age of infant and its health condition and record of each donation made by the donor.

Similarly Recipient's Record File with name of responsible person giving requisition, details of recipient, Recipient Consent Form, PDHM batch tray & container details, indication of use and feedback if any should be maintained.

The following records should be maintained:

By the collection staff

- Name, donor ID and indoor number (for donors from hospital) of donor.
- Record of donor's blood testing reports of HIV, VDRL and any other tests done such as Hepatitis B etc.
- Date of breastmilk collection.
- Place of collection like PNC wards, NICU, Preterm care unit, OPD follow up cases, Camp, Designated collection center/post, etc.
- Volume of breastmilk collected.
- Whether pooled or not.

By milk bank technician

- Date of collection.
- Received container from which area.
- Volume of breastmilk in container.
- Date of pasteurization and sending sample for culture.
- Culture report.
- Suitability of PDHM for use based on culture report.
- Date of issue (on FIFO basis)
- Place of issue.
- Number of babies receiving banked milk.

By recipients feeding staff

- A copy of the recipient consent form must accompany first orders.
- A copy should also accompany the recipient's medical records.

FLOW OF EVENTS IN HUMAN MILK BANK

Donor management

- Identification & motivation of donor
- Counseling of donor
- Selection of eligible donor
- Donor registration with all necessary details
- Written informed consent of donor
- Screening of donor with history, physical examination and serological testing

Collection

- Taking donor to designated milk expression area
- Education and training in expression of breastmilk
- Selection of method of expression
- Hand washing by donor and nursing assistant
- Expression of breastmilk in sterilized labeled container
- Dismantling and sterilization of pumps if used for collection
- Preparation and giving a Donor Card for donor

Processing

- Refrigeration of individual donated container till serology reports arrive
- Discarding donations from serology positive donor. Informing positive report to donor and advising necessary follow up with physician

- Thawing of donated milk once donor's serology comes negative
- Pooling of donated breastmilk in pasteurizer's containers
- Pasteurization of donated milk
- Post pasteurization microbiology testing of all batches

Storage

- Tight sealing of PDHM
- Labeling of milk batch with expiry date
- Preparing batch tray of pasteurized containers
- Keeping PDHM in separate locked freeze till microbiology report arrives
- Discarding microbiologically positive PDHM
- Transfer of microbiologically negative PDHM in post process deep freeze
- Testing of random milk sample for bacteriology before disbursal

Disbursal

- Receiving request for PDHM supply
- Written consent from parent(s) of the recipient baby
- FIFO system to take out frozen PDHM
- Dispatch of PDHM under proper storage conditions.
- Thawing of milk and storing in NICU freeze till used

ANNEXURE-I: DONOR SCREENING PERFORMA

(This information will be treated as confidential)

ID number:		Date:	
Demographic data:			
Name:			
Address:		Phone no.:	
		Age of donor: _____ years	
		Birth date/age of child:	
Collection Center ID:		Referring doctor:	
History:			
Tobacco consumption:	Y / N	Alcohol use:	Y / N
Medicines/herbs/addictive drugs/others:	Y / N	Details:	
Present illness:			
Past illnesses/chronic disorders:	Y / N	HIV:	Y / N
Detail:		Jaundice:	Y / N
High risk behavior:	Y / N	Tattoo in last 3 mo.:	Y / N
Blood product/transplant in last 1 yr:	Y / N	Silicone implant:	Y / N
Live vaccine to donor in last 3 mo.:	Y / N	TB	Y / N
High risk behavior in partner/donor	Y / N	Child thriving well:	Y / N
Laboratory reports:			
HIV 1&2:	HBsAg:		VDRL:
Others:			
Details:			
Examination:			
Breasts: Mastitis / local skin lesions / other General & Systemic examination:			
Name of Counselor:			Sign

ANNEXURE-II: CONSENT FORMS

- These forms should be printed & filled in local/vernacular language.
- They should be in triplicates so that a copy is placed in milk bank, with recipient's hospital records and with donor/recipient.

Donor's Consent Form

I/We have been informed about the human milk banking, wet nursing etc. We have also been explained about advantages and disadvantages of mother's milk as far as the nutrition, growth & development of the baby is concerned. We have also been informed that if I donate my milk as per the guidelines my baby will still get adequate milk as far as its needs are concerned.

I/We have been informed about the processing of donated breastmilk and its intended uses. I/We have been informed that once donated the milk will not be returned back to me/us. I/We have also been informed that the milk shall be used for the needy babies irrespective of religious, commercial and any other nonmedical considerations.

I also declare that I am not suffering from any illness/disorder or having behavior which can be risky through my breastmilk to the recipient baby.

I agree to undergo necessary clinical examinations and laboratory blood reports and share the findings of past and present reports with the human milk bank.

I/We have been explained all these in the language known to me/us and I/we are signing this form without any pressure/coercion and after satisfying my/our queries/doubts.

Donor ID number: Name of the Donor: Age: Address:		Signatures
Name of the relatives	Relationship with donor	
Witnesses		
1)		
2)		
Place:		Date & time:

Recipient's Consent Form

I/We have been informed about the human milk banking, wet nursing etc. We have also been explained about advantages and disadvantages of mother's milk as far as the nutrition, growth & development of the baby is concerned as compared to other milks.

I/We have been informed about the processing of donated breastmilk and its intended uses.

I/ We have been informed that all the precautions have been taken to make the donated breastmilk disease free, safe and quality assured. But, still some diseases may be transmitted to the recipient. After knowing various details and after satisfying my doubts /queries, I/we are willing to use this pasteurized donated milk for my/our baby.

I/We know that donor milk stocks are finite and it may not always be possible to meet every order.

I/We have been explained all these in the language known to me/us and I/we are signing this form without any pressure/coercion.

Requisition ID number Name of the recipient: Age: Address: Name of father: Name of mother:		Signatures
Name of the relatives	Relationship with recipient	
Witnesses		
1)		
2)		
Place:		Date & time:

ANNEXURE- III: Equipment Specifications & use

All equipments should be used, maintained and calibrated/validated according manufacturer's instructions and a record maintained of it.

Deep Freezer

- Storage capacity 200 liters
- Provides temperature of -20°C to -25°C
- Good quality micro temperature controller system with LED display of the temperature inside the cabinet with PT 100 sensor probe and audio visual alarm system to make user aware, if the temperature below or above set temperature due to mechanical or electrical error/fault
- Racks for storage of containers
- The door and walls be insulated with sufficient thickness high quality CFC free PUF insulation
- The door provided with good quality magnetic type gasket on inner side, so as to have the door sealed perfectly when locked
- Suitable for operation on 220 to 240 volt, single phase, 50 Hz, A.C. power supply
- Refrigerant used be non toxic, non hazardous, CFC/HCFC free

Pasteurizer/Shaker Water Bath

- Water bath shall be made up of double walled inner and outer chamber of stainless steel.
- Micro-processor controlled temperature regulation should provide temperature of 62.5°C and temperature constancy $\pm 0.5^\circ\text{C}$.
- Optimum temperature distribution should be throughout bath interior. Temperature display and setting digitally via LED display, in 0.1°C increments.
- Exact reproducibility of the preset temperature should be possible.
- Over-temperature cut out electronically, 5°C above set temperature, and electromechanical > 99°C.
- Instrument should have electronic timer with display and buzzer to provide set temperature for a fixed period time from 10 minutes to 2 hours.
- Constant shaking frequency, independent of load, should be possible.
- Maintenance free and durable shaking device electronically controlled and continuously set tables shaking motion with gentle start-up.
- Bath interior and shaking rack made up of stainless steel.
- Drain cock to empty the bath.
- Tray capacity of 16-20 flasks/stainless steel containers of 200 to 400 mL each

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- Shaking device by AC/DC geared motor 10-150 rpm & speed control by electronic speed regulator
 - Shaking tray made of stainless steel 304 quality with clamps for flasks
 - Facility for securing each container on the tray during pasteurization to prevent spillage
 - The clamps for the flask made of stainless steel 304 quality, to screw onto shaking tray, supplied complete with fixing material
 - Cleaning Process
 - The machine is cleaned once in every 3days or depending upon the scaling.
 - The entire water is drained out from the Drainage Point.
 - The machine is dry cleaned using a soft cotton cloth.

Hot Air Oven/ Autoclave Sterilizer

- The oven uses dry heat to sterilize articles at 100°C for 30 minutes.
- The machine is digitally controlled to maintain the temperature with a thermostat.
- Indicators and controls for temperature and holding time.
- The double walled insulation with air filled space keeps the heat in and conserves energy, the inner layer being a poor conductor and outer layer being metallic.
- Fan at the top helps in uniform distribution of the heat.
- The machine is fitted with the adjustable wire mesh plated trays
- The Glass containers are laid down on the racks whereas the other equipments are placed in the sterilization drum.
- A complete cycle involves heating the oven to the temperature of 100°C, maintaining that temperature for 30 minutes, turning the machine off and cooling the articles in the closed oven till they reach room temperature.

Breast Pumps



All breast pumps consist of a few basic parts: (58)

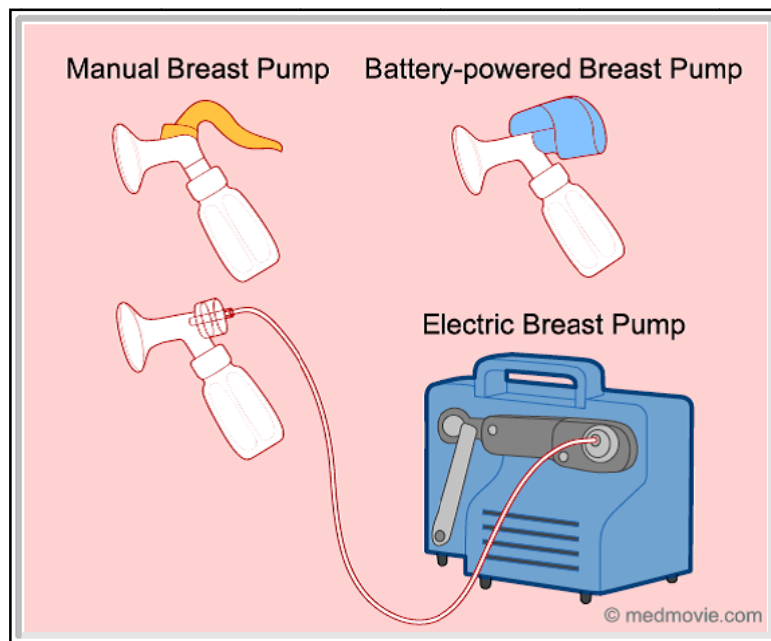
a. Breast Shield: a cone-shaped cup that fits over the nipple and the circular area surrounding the nipple (the areola).

b. Pump: creates the gentle vacuum that expresses milk. The pump may be attached to the breast-shield or have plastic tubing to connect the pump to the breast-shield.

c. Milk Container: a detachable container that fits below the breast-shield and collects milk as it is pumped. The container is typically a reusable one or disposable bag that can be used

to store the milk.

Types of Breast Pumps



There are three basic types of breast pumps:

- Manual pumps
- Battery-powered pumps
- Electric pumps

A breast pump is typically held in place by hand or by a nursing bra, a breast pumping bra or a band.

Breast pumps extract milk from the breasts by creating a seal around the nipple and applying and releasing suction to the nipple, which expresses milk from the breast. Each suction and release combination is called a cycle.

Manual Pumps

Once the breast-shield is placed over the nipple and areola, a handle or lever is squeezed to create suction and express milk from the breast. The breast milk is then collected in an attached container.

Some manual pumps have a small tube which is pumped in and out of a larger tube to create a vacuum that expresses milk and collects it in an attached container.

Another type of manual pump, called a bicycle horn pump, consists of a hollow rubber ball attached to a breast-shield. Some experts discourage the use of bicycle horn pumps because they may be difficult to clean and dry.

Battery-Powered and Electric Pumps

A powered breast pump uses batteries or a cord plugged into an electrical outlet to power a small motorized pump that creates suction to extract milk from the

breasts. It may have one or more long tubes connecting the breast-shield to the electric pump. The pump has a control panel with a dial or switch to control the degree of suction.

Some powered breast pumps can be adjusted to create different patterns of suction. Some manufacturers claim the adjustable suction allows the user to find a setting that closely mimics her nursing baby, including features with phases such as let-down. Let-down is the natural reflex which starts the release of milk when the nipple area is stimulated, such as by breastfeeding or breast pumping.

Because these breast pumps rely on a power source, women who use powered breast pumps should be prepared for emergency situations when electricity or extra batteries may not be available. If breastfeeding is not an option, having extra supplies for pumping and a back-up method, such as a manual breast pump, may help a woman maintain her breast pumping schedule during an emergency.

Pumping Types

There are two different pumping types: single and double.

Pumping Type	How it Works	Types of Breast Pumps
Single	Extracts milk from one breast at a time.	Most manual breast pumps are single pumps. Most battery-powered pumps are single pumps.
Double	Can be used to extract milk from both breasts at the same time. A separate breast-shield can be attached to each breast to stimulate both nipples at the same time.	Some electric pumps are double pumps.

Using a Breast Pump

Before using your breast pump for the first time it is a good idea to read through the entire instruction manual. The instruction manual can help you learn the correct way to assemble and use your pump. It should also include the manufacturer's contact information. If the instruction manual is missing from the box, check the outside of the box for a customer service line you can call to request a copy.

General Tips for Using a Breast Pump

Wash and Dry Your Hands

Before using your pump, wash your hands with soap, scrubbing for 10-15 seconds, then rinse with plenty of warm water. After washing, dry your hands thoroughly with a clean paper towel.

You do not need to wash your breasts before you pump unless you have been using a cream, ointment, or other product on your breasts that must be removed first. Check the labels on products you have been using and ask your doctor for advice.

Assemble Your Pump

Consult your pump's instruction manual for the proper way to assemble your pump.

Get Comfortable

Find a clean and comfortable place where you can relax and not be disturbed while pumping. If you have an electric pump, find an area near an outlet so you can plug the pump in. Some mothers find it helpful to hold their baby, or to have a picture of their baby in front of them while they pump.

Position the Breast-Shield(s)

Consult your instruction manual for tips on positioning your nipple in the breast-shield(s). Your nipple should fit comfortably in the center of the opening in the breast-shield(s). Gently adjust the breast-shield(s) until it feels comfortable without pinching, pulling or otherwise irritating your nipple or breast tissue.

Begin Pumping

If your pump is electric or battery-powered, turn the switch to the on position and the lowest suction and/or speed (cycle) setting. If you are using a manual pump, begin pumping. Consult your instruction manual for suggestions on an appropriate pumping speed. Adjust the speed until you find one that is comfortable for you.

What to Expect While Pumping

A qualified health professional, such as a certified lactation consultant, can help determine the best pumping method for you. Keep in mind that the amount of milk produced is different for everyone. A typical pumping session lasts about 10-15 minutes per breast, but you should only pump as long as it is comfortable and productive for you.

Your breast milk may not flow immediately after you start pumping, so try to be patient. When it does flow, your milk should be collected in the container attached to your pump. If milk is leaking out of your pump, stop pumping and

make sure you have assembled the pump correctly before trying again. If your pump continues to leak, call the manufacturer's customer service line for help.

When you have finished pumping, gently insert a finger between your breast and the breast-shield to break the vacuum seal. Remove the container or bag of collected milk from the rest of the pump, and label it with the date and time of pumping before storing it in the refrigerator or freezer.

Cleaning Breast Pump Parts

- All breast pump parts that come in contact with breast milk, such as containers, valves and breast shields, should be cleaned after each use. It is not possible to completely sterilize breast pump parts at home, even if you boil them. However, sterilization is not necessary to keep these parts safe and sanitary. You can do that by thoroughly washing away germs and bacteria with liquid dishwashing soap and warm water.
- Some breast pumps parts can be put in the top rack of a dishwasher. Consult your instruction manual to make sure pieces are dishwasher safe before you put them in the dishwasher.
- It is not necessary to clean breast pump tubing unless it comes in contact with breast milk. If you wash your tubing, make sure you hang it to air dry before attaching it to your breast pump. If small water drops (condensation) appear in the tubing after you have pumped, turn the pump on for a few minutes until the tubing is dry.
- Microwave sterilizers are available for breast pump parts, but these sterilizers do not meet the US FDA definition of sterilization. However, they will sanitize the parts, which is sufficient for processing between uses for a single user.

Cleaning the Electrical Unit for a Powered Breast Pump

- Electrical units, which hold the motor and batteries, should be wiped down with a clean paper towel or soft cloth after each use.
- The electrical unit should never be put into water or other liquids for cleaning. It should also never be cleaned using a microwave sterilizer.
- Some breast pump manufacturers make wipes just for cleaning breast pumps, which can make cleaning more convenient when you are away from home. Even if these wipes are used, breast pump parts that come into contact with breast milk should still be cleaned using liquid dishwashing soap and warm water before pumping.

Basic Cleaning Method

- Consult the instruction manual to determine which parts should be washed and the best method for removing parts that must be cleaned.
- Rinse each piece that comes into contact with breast milk in cool water as soon as possible after pumping.

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- Wash each piece separately using liquid dishwashing soap and plenty of warm water.
 - Rinse each piece thoroughly with hot water for 10-15 seconds.
 - Place the pieces neatly on a clean paper towel or in a clean drying rack and allow them to air dry.
 - Avoid using cloth towels to dry your pump parts because they can carry germs and bacteria that are harmful to your breast milk and your baby.
 - Once the pump parts are dry, assemble the pump before you store it or use it.
 - Try not to touch the inside of any parts that will come in contact with your breast milk.

Hospital Grade Milk Pump

- The Funnel area has soft round edges of Advanced Sealing Air Cushion which provides an airtight seal over the entire areola. This structure allows steady expression of milk with only a light suckling sensation.
- Only electric breast pumps with an isolated motor, which does not connect with the tubing, are suitable for multiple uses. Here each mother should have her own set of tubing.
- A suction strength dial of five pressure level settings and a suction cycle controller for regulating the speed of suction and adjustable vacuum facility
- Has a container stand which can be used as Funnel cover. This supports pump when left standing and hygienically protects the pump.
- The entire machine parts can be dismantled which makes sterilization easy and handy.
- Fully automatic operation with physiologically natural suction rhythm
- Silent vibration-free electric motor
- Single and double pumping should be possible
- Runs on electricity
- Overflow protection. No overflow into the pump possible.
- Can be used along with reusable kits or ready to use kit
- Working on 2-Phase Expression Technology preferable
- Operation
- The breast area of the donor mother is cleaned using clean cloth and lukewarm water.
- The funnel is placed on the mother's breast to cover the entire areola.
- The machine is switched on and the suction strength & cycle speed are set as per the comfort level of the mother.
- Milk expression begins and the milk is collected in the container attached to the machine.
- Once the milk is expressed, the machine is switched off. The Fresh Raw Milk in the containers is placed in the pre-process Freezer at (-5)°C.
- Mother's breast is cleaned with a damp cloth.

Cleaning

- After each use the machine is dismantled, rinsed with clean water to remove milk then washed with soapy water. All the parts are sterilized in the Pump Sterilization Machine.
- The container is sterilized by placing it in its unit and other parts like funnel, pipe, etc are placed in the accessories tray.
- Sterilization is done at 100°C for 9 minutes. No chemicals are used for sterilization of these parts.

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RECOMMENDED READING

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