Sri Lakshmi Narayana Institute of Medical Sciences

Date 05/10/2019

From
Dr.V. Sivaprakasam
Professor and Head,
Department of Paediatrics,
Sri Lakshmi narayana institute of medical sciences,
Bharath Institute of Higher Education and Research,
Chennai.

To
The Dean,
Sri Lakshmi narayana institute of medical sciences,
Bharath Institute of Higher Education and Research,
Chennai.

Sub: Permission to conduct value-added course: Human Milk Banking Course

Dear Sir,

With reference to the subject mentioned above, the department proposes to conduct a value-added course titled: **Human Milk Banking Course** from December 2019. We solicit your kind permission for the same.

Kind Regards

Dr. V. Sivaprakasam

PAEDIATRICS HEAD
DEPT. OF PAEDIATRICS
SRI LAKSHMI NARAYANA INSTITUTE OF
MEDICAL SCIENCES
OSUDU, PUDUCHERRY

FOR THE USE OF DEANS OFFICE

Names of Committee members for evaluating the course:

The Dean: Dr Jayalakshmi

The HOD: Dr V. Sivaprakasam

The Expert: Dr Kaurppaiah Pandi

The committee has discussed about the course and is approved.

Dean	Subject Expert	HOD
Dr. G. JAYALAKSHMI, BSC., MBBS., DTCD., M.D., DEAN Sri Lakshmi Narayana Institute of Medical Sciences Osudu, Agaram, Kudapakkam Post, Villianur Commune, Puducherry - 605502.	ASSISTANT PROFESSOR DEPARTMENT OF PAEDIATRICS SRI LAKSHMI NARAYANA INSTITUTE OF MEDICAL SCIENCES	PAEDIATRICS HEAD DEPT. OF PAEDIATRICS SRI LAKSHMI NARAYANA INSTITUTE OF MEDICAL SCIENCES OSUDU, PUDUCHERRY

OFFICE OF THE DEAN

Sri Lakshmi Narayana Institute of Medical Sciences

OSUDU, AGARAM VILLAGE, VILLIANUR COMMUNE, KUDAPAKKAM POST,
PUDUCHERRY - 605 502.
[Recognised by Medical Council of India, Ministry of Health letter No. U/12012/249/2005-ME (P -II) dt. 11/07/2011]
[Affliated to Bharath University, Chennai - TN]

Circular

10.11.2019

Sub: Organising Value-added Course: Human Milk Banking Course., reg

With reference to the above mentioned subject, it is to bring to your notice that Sri Lakshmi narayana institute of medical sciences, **Bharath Institute of Higher Education and Research**, is organising **"Human Milk Banking Course "**. The course content and registration form is enclosed below."

The application must reach the institution along with all the necessary documents as mentioned. The hard copy of the application should be sent to the institution by registered/ speed post only so as to reach on or before 20 November 2019. Applications received after the mentioned date shall not be entertained under any circumstances.

Dean

Dr. G. JAYALAKSHMI, BSC., MBBS., DTCD., M.D.,
DEAN
Sri Lakshmi Narayana Institute of Medical Sciences
Osudu, Agaram, Kudapakkam Post,
Villianur Commune, Puducherry - 605502.

Encl: Copy of Course content

Course Proposal

Course Title: Human Milk Banking Course

Course Objective: To understand the need, functioning and management of Human Milk Banks in a tertiary care hospital.

Course Outcome: On successful completion of the course the students will have in depth knowledge on Human milk banking and its functioning

Course Audience: Final year MBBS Students

Course Coordinator: Dr. V. Sivaprakasam

Course Faculties with Qualification and Designation:

1. **Dr. V. Sivaprakasam – MD Paediatrics – Head of Department**
2. **Dr. Karuppaiah Pandi - MD Paediatrics – Assistant professor**

Course Curriculum/Topics with schedule (Min of 30 hours)

SlNo	Date	Topic	Time	Hours	Resource person
1.	1.12.2019	Introduction to human milk banking	2-4 pm	2	Dr. V. Sivaprakasam
2.	2.12.2019	Equipments and infrastructure needed for a human milk bank	2-4 pm	2	Dr. Karuppaiah Pandi
3.	4.12.2019	Screening for Donors	2-4 pm	2	Dr. V. Sivaprakasam
4.	5.12.2019	Collection and Storage of milk	2-4 pm	2	Dr. Karuppaiah Pandi
5.	6.12.2019	Disbursal of milk	2-4 pm	2	Dr. V. Sivaprakasam
6.	7.12.2019	CLMCs and LMUs	2-4 pm	2	Dr. Karuppaiah Pandi
7.	8.12.2019	Human resource for milk banks	2-4 pm	2	Dr. V. Sivaprakasam
8.	9.12.2019	Record keeping for LMCs	2-4 pm	2	Dr. Karuppaiah Pandi
9.	11.12.2019	Monitoring and Quality Assurance	2-4 pm	2	Dr. V. Sivaprakasam

10.	12.12.2019	Technical guidelines	2-4 pm	2	Dr. Karuppaiah Pandi
11.	13.12.2019	Pasteurisation of donor human milk	2-4 pm	2	Dr. V. Sivaprakasam
12.	14.12.2019	Scope of milk banks in future	2-4 pm	2	Dr. V. Sivaprakasam
13.	15.12.2019	Virtual tour of Human milk bank at BJMC	2-4 pm	2	Dr. Karuppaiah Pandi
14.	16.12.2019	Summary and discussion	2-4 pm	2	Dr. V. Sivaprakasam
15.	18.12.2019	Assessment	2-4 pm	2	Dr. V. Sivaprakasam
			Total Hours	30	

REFERENCES:

1. **Child Y. Infant and Young Child Feeding Human Milk Banking Guidelines 2015. 2015**
2. **Guidelines on lactation management centres- NRHM**

VALUE ADDED COURSE ON HUMAN MILK BANKING

1. Name of the programme & Code

Human Milk Banking Course and PECO 12

2. Duration & Period

30 hrs (December 2019- January 2020)

3. Information Brochure and Course Content of Value Added Courses

Enclosed as Annexure- I

4. List of students enrolled

Enclosed as Annexure- II

5. Assessment procedures:

One word question/answer - *Enclosed as Annexure- III*

6. Certificate model

Enclosed as Annexure- IV

7. No. of times offered during the same year:

Once (Decemberr 2019- January 2020)

8. Year of discontinuation: 2020

9. Summary report of each program year-wise

Value Added Course					
Sl. No	**Course Code**	**Course Name**	**Resource Persons**	**Target Students**	**Strength & Year**
1	PECO 12	Human Milk Banking Course	Dr. Karuppiah Pandi	Final year MBBS	20 (December2 019- January 2020)

10. Course Feed Back

Enclosed as Annexure- V

Dr. Karuppiah Pandi

RESOURCE PERSON

ASSISTANT PROFESSOR
DEPARTMENT OF PAEDIATRICS
SRI LAKSHMI NARAYANA INSTITUTE OF
MEDICAL SCIENCES

Dr.V. Sivaprakasam

COORDINATOR

PAEDIATRICS HEAD
DEPT. OF PAEDIATRICS
SRI LAKSHMI NARAYANA INSTITUTE OF
MEDICAL SCIENCES
OSUDU, PUDUCHERRY

Annexure- I

HUMAN MILK BANKING COURSE

PARTICIPANT HAND BOOK

COURSE DETAILS

Particulars	Description
Course Title	Human Milk Banking Course
Course Code	PECO 12
Objective	To understand the need, functioning and management of Human Milk Banks in a tertiary care hospital.
Further learning opportunities	Clinical benefits of Donor Human Milk in NICU
Key Competencies	On successful completion of the course the students will have in depth knowledge on Human milk banking and its functioning
Target Student	Final MBBS Students
Duration	30hrs November 2019- December 2019
Theory Session	10hrs
Practical Session	20hrs
Assessment Procedure	One word questions

B.2.1 Definition

Lactation Management Unit would be established in District Hospital/Sub district Hospital with functional SNCU with at least 12 beds where sick newborns are admitted for medical management. This unit should be established in vicinity of SNCU. The LMU would be set up with collection and storage facility of mother's own milk to fulfill the feeding requirement of their admitted sick babies.

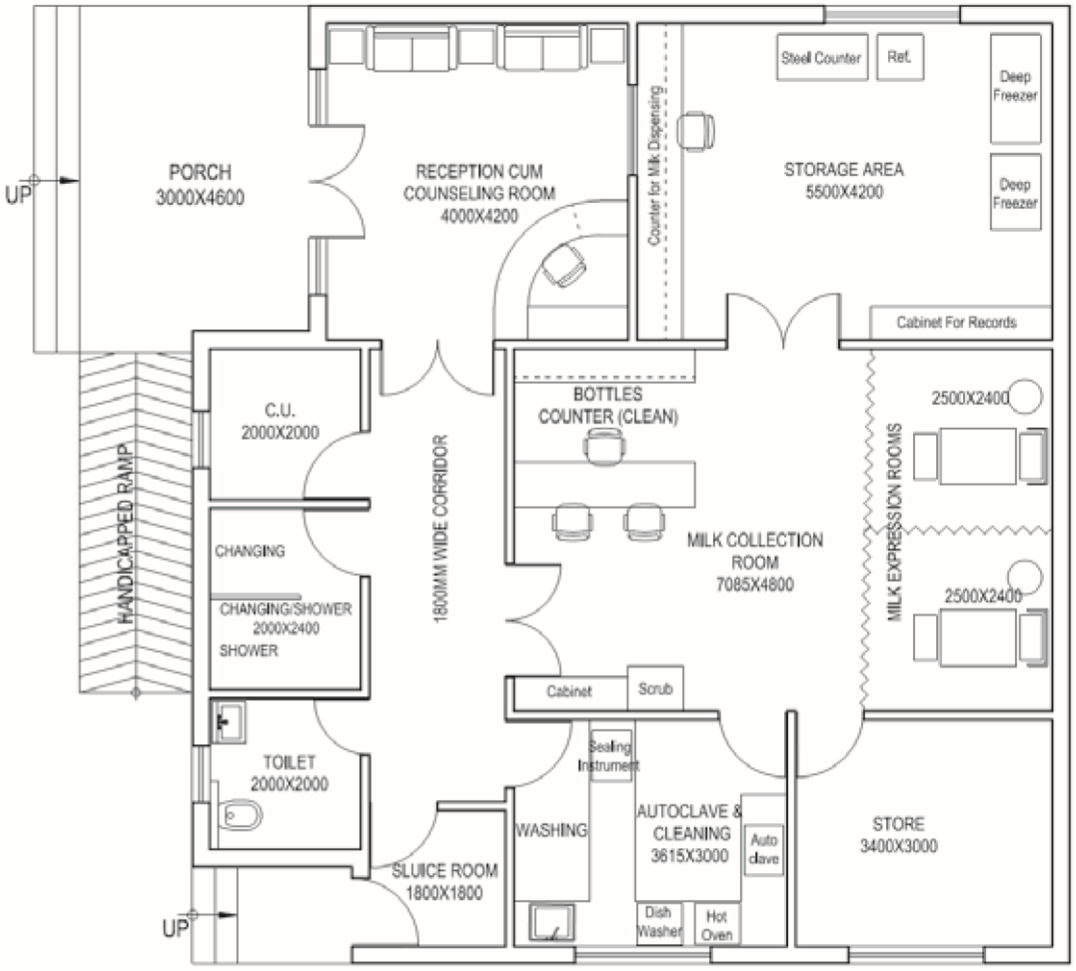
The salient features of Lactation Management Unit

- ⊙ No screening of mother is required as babies are fed by milk expressed by their own mothers.
- ⊙ Emphasis on milk expression, counseling and support for better let down along with use of electric and manual pumps.
- ⊙ Careful labeling of expressed milk and supervised dispensing.
- ⊙ Pasteurization and testing of milk is not required.

State and UTs need to prioritize establishing LMU in the district hospital where SNCU with high bed strength (20-30 beds) is operational. If the SNCU already has necessary facilities for milk expression, storage (refrigerator and deep freezer), cleaning of milk expression and feeding equipment along with hand washing area for mothers, establishment of LMU is not recommended.

B.2.2 Infrastructure Requirements

Optimum space requirement **for a LMU is approx. 160 Sq. Mts.** However, if the health facility with SNCU does not meet this minimum space requirement, facilities for milk expression, storage (refrigerator and deep freezer), cleaning of milk expression and feeding equipment along with hand washing for **figure 6:** Layout Design for LMU



AREA:-

BUILDING AREA = 139.0 SQ.MT.
PORCH AREA = 14.0 SQ.MT.
TOTAL AREA = 153.0 SQ.MT.

PROJECT:-	DRAWING TITLE:-	SR.ARCHITECT RAJEEV KANAUJIA	SCALE: NTS	DATE : 29/05/2017	NORTH	
CONCEPTUAL PROTOTYPE LAYOUT PLAN FOR PROPOSED LACTATION MANAGEMENT UNIT UNDER NHM	GROUND FLOOR PLAN	ARCHITECT SACHIN MAHINDRU	JOB NO.	DRG. NO. 01		
		CAD OPERATOR HARENDRA KUMAR	CENTRAL DESIGN BUREAU FOR MEDICAL & HEALTH BUILDINGS, MOHFW, NEW DELHI.			

mothers should be provided in SNCU/KMC area. Therefore, before establishing LMU, the district programme management unit must carry out an appropriate need assessment.

Following facilities should be available in the LMU:

- Machine pumping
- Milk Storage
- Thawing
- Washing facility
- Dispensing of milk
- Record keeping
- **Essential areas:**

The design of the LMU would be a simpler and smaller version of CLMC with following essential areas:

1. **Reception cum administrative area:** This would be a smaller room/space than that of CLMC.
2. **Counselling area:** Mothers of the new-borns admitted in SNCUs may be counselled in the postnatal ward. However, mothers of out born babies would require counselling for which a small counselling room would be dedicated.
3. **Milk expression area:** This area is similar to that of CLMC; however, would provide milk expression facility for fewer mothers (2-3).
4. **Cleaning area:** This area is similar to that of CLMC.
5. **Milk storage area:** This area would be equipped with horizontal deep freezer and a refrigerator with storage arrangement for collected Mother's Own Milk.
6. Shower and changing room for mothers and Sluice room A suggested layout for LMU is at Figure 6.

- No separate milk processing area and laboratory is required for the LMU
- For proper functioning of LMU one refrigerator exclusively for keeping human milk should be kept in theSNCU/KMC room as per existing GoI guidelines*.

B.2.3 Human Resource for LMU

The pediatrician in-charge of the SNCU/or any other full time available pediatrician in the health facility will be in-charge of the LMU. Staff in position in KMC and SNCU units as per respective GoI guidelines are to be deputed for operationalization of the LMUs after the prescribed orientation and skill training. However, in case of shortage of staff, the following staff are to be recruited for the LMU.

* Refer "Facility based Newborn Care Operational Guidelines, 2011" and "Kangaroo Mother Care and Optimal Feeding of Low Birth Weight Infants; Operational Guidelines" of MoHFW

Table B.3: Human Resource for LMU

Designation	Number of staff	Qualification	Responsibilities**
full-Time Post			
Lactation Support Staff (only female staff)	Two	ANM Essential Pre-requisite of selection: Candidates who have completed three months of hands- on training in Lactation Management in an established CLMC and at end of training cleared an skilled based examination conducted at the designated training centres.	Overall supervision of functioning of LMU. Routine rounds in SNCU including KMC ward for providing lactation support to mothers, motivating them to express milk and counselling. Facilitating and helping mothers in milk expression and providing sterile gowns, sterile bottles, and tubing for breast pump. Would carry out cleaning and autoclaving of the equipment and ensure proper storage and dispensing of milk. Bottle Labelling and record keeping.
Part Time Post			
Hygiene Helper (2 hrs for each shift: Morning and evening shift) Should utilize the existing staff working in the SNCU	Two	As per State norm	Over all cleaning of LMU as per standard hygiene protocol
Existing staff in the health facility to be utilised for LMU			
Neonatologist/ Paediatrician trained for SNCU/NICU	Two (One designated as main and another designated for additional charge)	MBBS, MD (Paediatrics/ Neonatology)	Overall supervision, ensure smooth functioning of LMU and ensuring in house expression and storage of human milk. Provide regular teaching to all staffs regarding lavational support and activities of LMU.

B.2.4. Cost of setting up for Lactation Management Unit (LMU)

Tables B.4 outlines the budget estimate for establishing a model LMU at a health facility. The indicative cost given below includes cost of LMU equipment, communication equipment including Computer, other electronic machines, furniture, recurring operational expenses per annum and HR salary for full time staff.

Table B.4: Budget Estimate to establish a LMU

Heads	one time cost	Recurrent cost (annual)
Human Resources		
Lactation support staff (2) @ 15,000/- P.M. each	15,000	3,60,000

Equipment		
LMU equipment (including cleaning and sterilization equipment)	7,10,000	
Heads	**one time cost**	**Recurrent cost (annual)**
Communication equipment (including computer)	30,000	
Other electronic machines	1,39,000	
furniture		
Furniture and miscellaneous items (including office utility items)	81,000	
Supplies, Cleaning materials, Consumables & Stationary		
LMU Supplies		25,000
Cleaning supplies and consumables		28,000
Office stationary and staff item (including miscellaneous items and registers)		16,000
Maintenance of equipment		36,000
Total	**9,75,000**	**4,65,000**
Grand Total		**14,40,000**

NoTE:

- All electronic and valuable equipment are to be maintained under Annual Maintenance contract and the contract to be managed by the health facility where LMU is located.
- Salary structure provided here is indicative and will vary as per State norm. In case part time HR is being provided, the cost for their salary is to be included in the total budget.
- As indicated under CLMC head, the budget of LMU also needs to be reflected in district/state plan.

Refer **Appendix 5** for detail equipment specifications.

C

Record Keeping for Lactation Management Centres (CLMC and LMU)

C.1 Donor Records

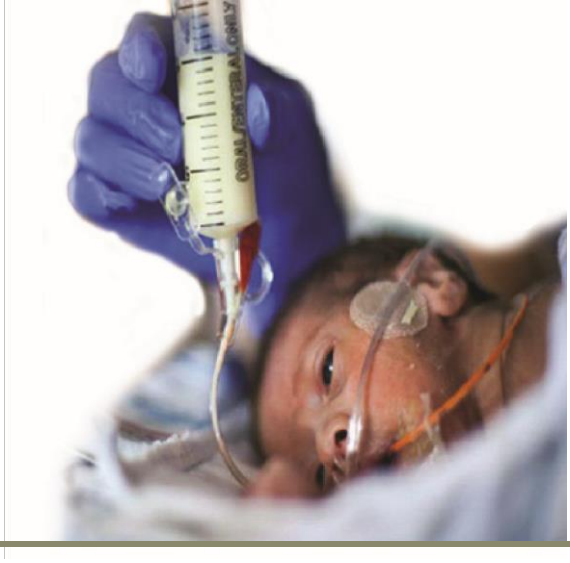
- Donor database which includes contact details and address for donor tracking.
- Initial donor screening form which includes:
  - Medical history
  - Birth history of infant (date, gestational age)
  - History of acute and chronic illnesses
  - Lifestyle choices (smoking, alcohol, drugs)
  - Physical examination
  - Antenatal records
  - Assessment of new-born health
  - HIV, Hepatitis, and VDRL screening results
  - Signed consent form agreeing to serological blood test, if needed
  - Signed consent form for the use of the DHM
- Donation log which includes:
  - Time and date
  - Volume of donation per donor
  - Receiving staff

C.2 Procedural Records

- Identification of milk donors comprising each pooled batch.
- Batch information should include:
  - Date and time of pooling and aliquoting
  - Containers per batch
  - Amount of milk pasteurised
  - Date and time of pasteurization
  - Heat treatment times and temperatures
  - Microbiological results post-pasteurization

D

Monitoring & Quality Assurance



- Date and time when DHM was moved to freezer for storage

- Freezer, refrigerator, incubator (in microbiology laboratory) and sterilization temperature records.
- Calibration records for all equipment

C.3 Administrative Records

- Financial Records
- Supplies inventory
- File folder for Annual Maintenance Contract (AMC) of equipment
- Attendance and minutes of administrative meetings
- Training and performance records of staff positioned in lactation management centre
- Register for audit/monitoring visit records/feedback records

C.4 Resource and reference documents

- National Guidelines on Comprehensive Lactation Centre Management
- Manual of Operations
- Preventive maintenance check book for equipment
- User manuals and manufacturers' instructional guides

Refer to **Appendix 6** for record keeping formats and auditing format.

D.1 Monitoring and Quality Assurance Mechanism

- Regular reporting for key indicators and supportive supervision visits are to be carried out for monitoring of CLMC and LMU functionality and outputs.

Key Indicators for National Reporting	Periodicity of Reporting		
	Monthly	Quarterly	Annually
Number of operational CLMCs in the State			√
Number of operational LMUs in the State			√
HR in position in CLMC/LMU		√	
Trained HR in position in CLMC/LMU		√	
Number of admitted sick babies who fed with donor human milk in health facility with CLMC	√		
Proportion of admitted sick babies who fed with donor human milk in health facility with CLMC	√		
Number of admitted sick babies who fed with expressed mother's own milk in health facility with CLMC	√		
Proportion of admitted sick babies who fed with expressed mother's own milk in health facility with CLMC	√		
Number of admitted sick babies who fed with expressed mother's own milk in health facility with LMU	√		
Proportion of admitted sick babies who fed with expressed mother's own milk health facility with LMU	√		
Number of supportive supervision visits made to CLMC			√
Number of supportive supervision visits made to LMU			√

D.1.1 Quality assurance

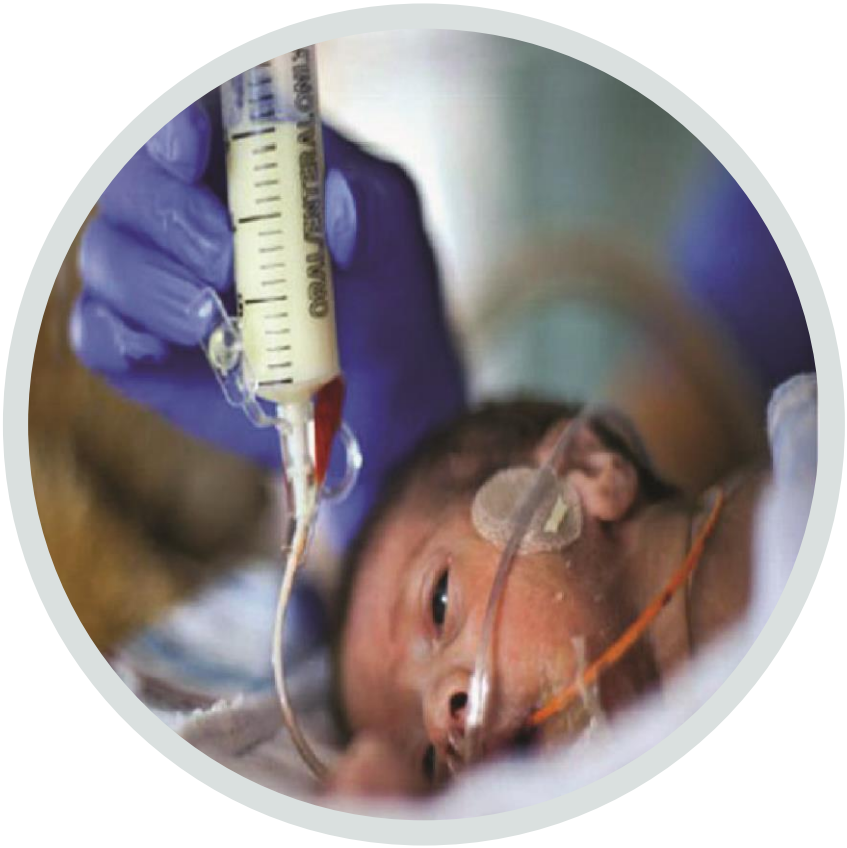
- For Quality Assurance (QA) and safety of DHM for consumption by babies, a robust quality assurance mechanism including Hazard Analysis and Critical Control Point (HACCP) system needs to be developed.
- Functional CLMCs and LMUs must be certified by quality assurance committees already established at State (SQAC), district (DQAC) levels and will be regularly audited to monitor the adherence and commitment to the national guidelines. A system for monitoring the quality of operations at CLMCs and LMUs would be operationalized by the SQAC and DQACs.
- The HACCP plan should be regularly audited and evaluated (annually) by a multi-disciplinary team consisting of facility based lactation management expert, quality assurance expert, neonatologist, microbiologist, etc.

Refer to **Appendix 4** for details on quality assurance mechanisms.

Things to Remember

1. The building should provide sufficient space for placement of equipment and storage of materials to permit sanitary operations for milk processing purposes.
2. Provision of proper precautions to reduce the potential for contamination of donated/collected milk, milk-contact surfaces and milk packaging materials.

3. Floors, walls and ceiling are constructed in a manner to permit adequate cleaning and maintained with good repair.
4. Droplets or condensate from fixtures, ducts and pipes does not contaminate milk, milk-contact surfaces or milk packaging materials.
5. Aisles or working spaces of adequate width are provided between equipment and walls to permit employees to perform duties unobstructed and to protect against milk, or milk- contact surfaces with clothing or personal contact.
6. Allow no pests in the area of milk processing. Effective measures are taken to exclude pests from the processing area and to protect against contamination of milk on the premises by the pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of milk, milk-contact surfaces and milk packaging materials.
7. Persons unnecessary to milk processing area are not allowed in the milk handling area while open containers of milk are being processed.
8. Cleaners and sanitizers are properly identified, stored in dedicated containers and kept away from milk processing area.
9. Adequate hand washing facilities are provided including a sink/scrub with hot and cold running water, soap or detergent and individual sanitary towels.
10. Pasteurizing, pouring, cooling and labeling of milk to be carried out in one room with a separate door which is closed whenever milk containers are open.
11. Designated areas or rooms for the cleaning of equipment and containers are provided.
12. There are separate deep freezers to store raw, frozen donor milk and pasteurized milk.
13. Freezer temperature logs are maintained for all freezers.
14. Toilet facilities should not open directly into any room in which milk or milk products are processed. Toilets, changing and shower rooms must have tight fitting, self-closing doors. Mother's Hand washing areas must have signage.



Section 2

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Step 3. Processing of Donor Human Milk 38

Step 4. Post Pasteurization Testing of DHM 44

Step 5. Post Pasteurization Storage of DHM 47

Step 6. Dispensing of Processed Milk 48

TECHNICAL GUIDELINES

Functions of Comprehensive Lactation Management Centre (CLMC)

Comprehensive Lactation Management centre will undertake a range of facility based activities to promote and support breastfeeding for all newborns including preterm, low birth weight and sick newborns through support of breastfeeding by skilled counseling, lactation management through human milk donation and Kangaroo Mother Care.

The processes in CLMC have six basic steps:

1. Screening of donor mothers
2. Milk expression and Collection
3. Processing of DHM
4. Testing of DHM
5. Storage of Pasteurized DHM
6. Dispensing of Processed Milk

figure 7: Algorithm for CLMC Processes: Six Basic Steps

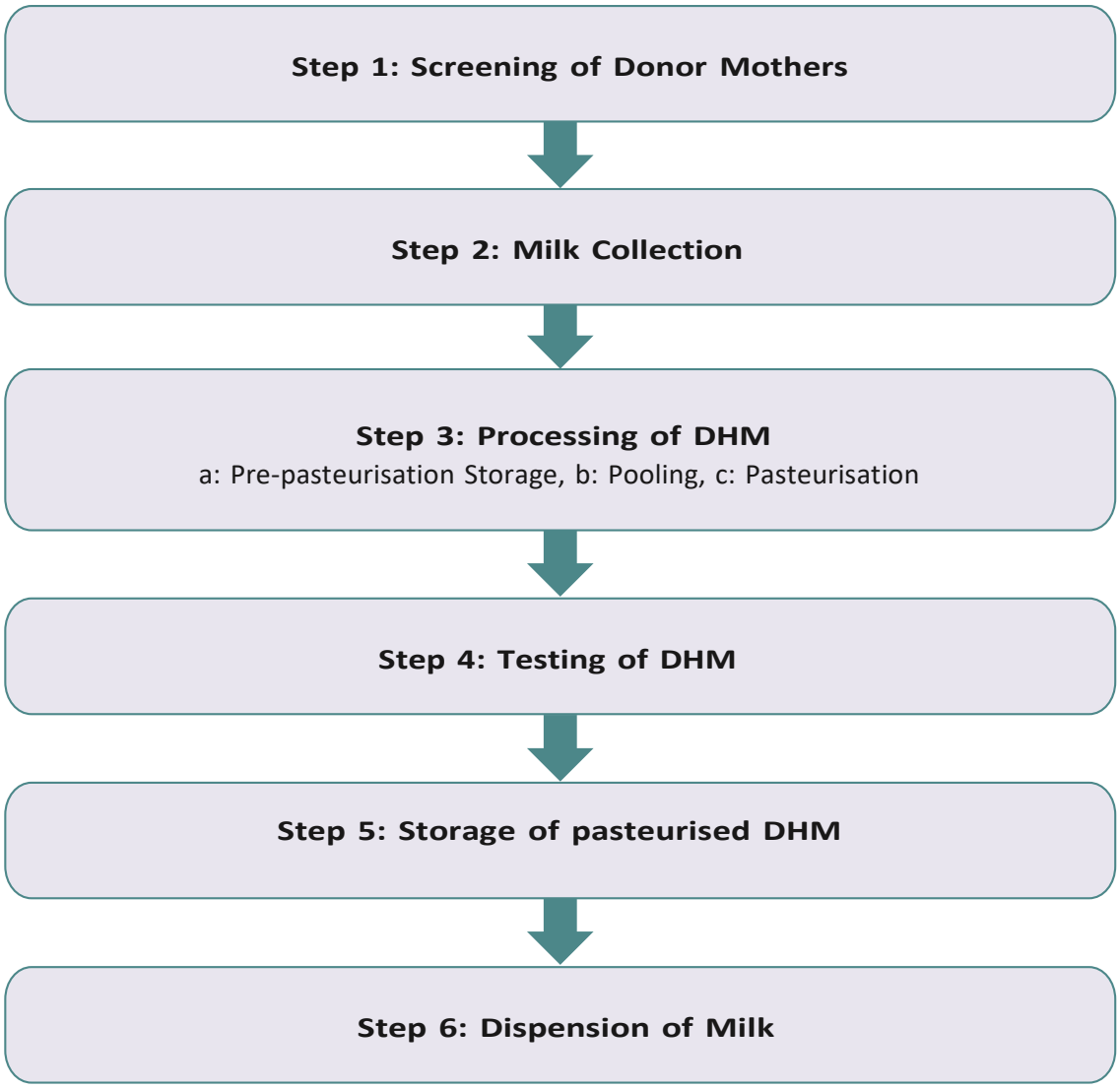
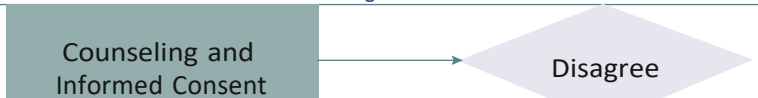


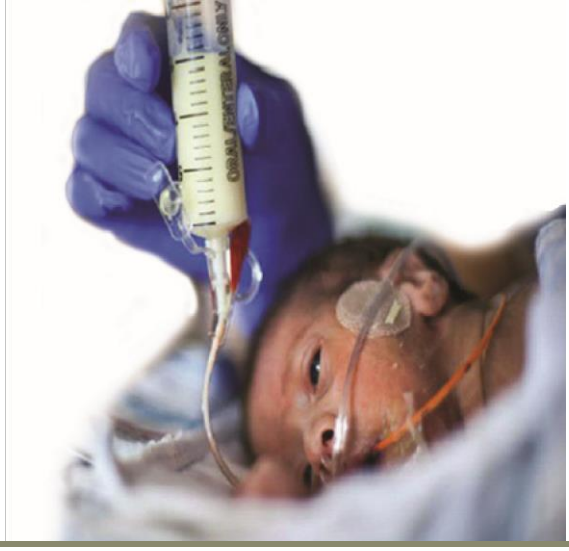
figure 8: Process Flow Chart for CLMC for donor milk utilization (Heterologous)


Counseling and Informed Consent
Disagree

STEP 1

1

Screening of Donor Mothers



1.1 Donor selection

A lactating woman who is willing to donate her surplus Expressed Breast Milk (EBM) should be considered as potential donor. Potential donors are screened verbally and in writing. The donors must be in good health as ascertained by history and physical examination.

For recruiting donors, following points must be adhered to:

- There should not be compromise on satiety for her own baby.
- Breast milk donation should be **voluntary and no incentive** should to be provided to the mothers.
- Mother should fulfil all donor eligibility criteria, as stated in the guidelines.
- The donation is to be **done only at health facility** and ***not*** promoted in community settings.

The potential donors could be:

- Mothers whose babies are in the NICU: Donors can be mothers whose babies are admitted in NICU and are not in a position to be fed or are on minimal enteral feeds. These mothers are encouraged to express milk frequently through the day to maintain their milk output and to donate excess of milk to the CLMC.
- Mothers in the postnatal wards and KMC wards: Within 48–72 hours after delivering, the milk production increases and mothers with a good milk output may be willing to donate their milk. Some mothers develop breast congestion and may need to express milk for relief. This expressed milk may then be utilized in CLMC.
- Mothers of babies visiting well-baby follow-up clinics/immunization sessions can be motivated to donate milk after ensuring they are in good health and complying with milk donation criteria.
- Lactating women among the staff of the hospital – Female staff of the health facility could be made aware about milk donation and encouraged to utilize the Lactation Management Centres (CLMC) as a location for pumping and expressing milk, thereby fostering a breastfeeding-friendly environment in the hospital.

1.2 Steps of screening at registration desk, before milk donation

- Mothers who volunteer to donate milk should be interviewed by the designated staff of CLMC using standard registration form which inclusion and exclusion criteria. The donor registration form needs to be in local language.
- Physical examination of the breast to check the presence of skin or breast lesions to be carried out.
- Informed written consent is to be obtained from the donor.

Refer to **Annexure 3** for format of Donor Registration cum Consent form.

1.3 Exclusion Criteria:

Potential donors are excluded based on following clinical issues unique to human milk and infants, including:

- Receipt of a blood transfusion/blood product within past 12 months.
- Receipt of an organ or tissue transplant, within past 12 months.
- Permanent *tattoo*/ears or other body piercing with other than single-use instruments within the last 12 months.
- Daily use of alcohol
- Donors must not be users of tobacco or nicotine products including gum or e-cigarettes. These include casual and occasional smokers.
- Chronic Infection (HIV, active TB etc.) relevant to breastfeeding, a history of hepatitis B, hepatitis C (optional), or a history of leukemia or lymphoma or treatment of any other cancer within the last 3 years.
- A sexual partner in the past 12 months who is suffering from/at risk for HBV, HCV (optional), HIV and venereal diseases or one who has high risk behavior for contracting them
- Use of medications: certain medications are permitted during milk donation and others are a cause for temporary referral and unacceptable donors.

  Prospective donors taking the following medications are allowed to donate milk:

  - Prenatal vitamins.
  - Hormonal replacement drugs that are normally found in breast milk; Human insulin, Thyroid replacement hormones, Hydrocortisone.
  - Nasal sprays
  - Asthma inhalers
  - Topical medications applied to the skin away from breast; topical medications applied to breast must be washed off thoroughly before expressing milk.
  - Eye drops
  - Progestin-only or low-dose oestrogen birth control products.
  - Inactivated vaccines, toxoids and allergy shots.
  - Selected human immune globulin products: Tetanus, Rabies etc.
  - Drugs given orally to mothers that are not absorbed (e.g. Aluminium, Calcium, Magnesium Antacids, Stool softeners, fibres, cymethicon).
  - Non-sedating anti-histamines.

Permissible medications are reviewed at least annually based on the latest available evidence and as per decision of the National Technical Resource group of GoI.

All other medications are contraindicated for human milk donation at CLMC (details in **Annexure 7**), though most will not be contraindicated when a mother is feeding her own baby.

1.4 Serological tests

Following screening blood tests are mandatory, if antenatal serological reports for them with in past 6 months are not available:

a. HIV 1 or 2

b. Hepatitis B

c. Syphilis/VDRL

d. Hepatitis C (optional)*

Antenatal serological tests conducted by a certified laboratory within the 6 months prior to donating milk will be considered and negative test results do not require confirmatory testing.

If lifestyle or medical issues suggest an increased risk of donation, deferral or retesting is at the discretion of the pediatrician/neonatologist in-charge of the CLMC.

There is no requirement of repeating these tests if the mother shows negative reports during her antenatal period done within 6 months from enrollment. However, the reports need to be seen and verified and in no case accepted on verbal basis.

1.5 Temporary Disqualification

Donors are instructed to report all illness in the household for evaluation of communicability and contamination of milk. Illnesses and exposures not related to milk safety do not require deferral periods such as common cold, conjunctivitis, and seasonal flu as long as medications are not needed. Potential donors with the following conditions should be temporary disqualified:

- If suffering from any acute infection or re-activation of a chronic illness (such as auto-immune disorder) that requires medication.
- Has cough for more than 2 weeks at the time of enrolment for donation.
- Has mastitis or fungal infection of the nipple or areola, herpes zoster of the breast and thorax.
- If suffering from active herpes simplex or has chicken pox infections.
- If received vaccinations for rubella, measles, mumps within past one month and Varicella vaccination within last three months.
- For one month following rubella or chicken pox infection in the household.

After a temporary disqualification, milk donation can resume at the discretion of qualified CLMC personnel.

If, the mother is not eligible, then she should be counselled about the importance of continued breastfeeding for her own baby or continuing to feed the baby with Expressed Breast Milk (EBM). These mothers should be provided with appropriate referral services for further diagnosis and management.

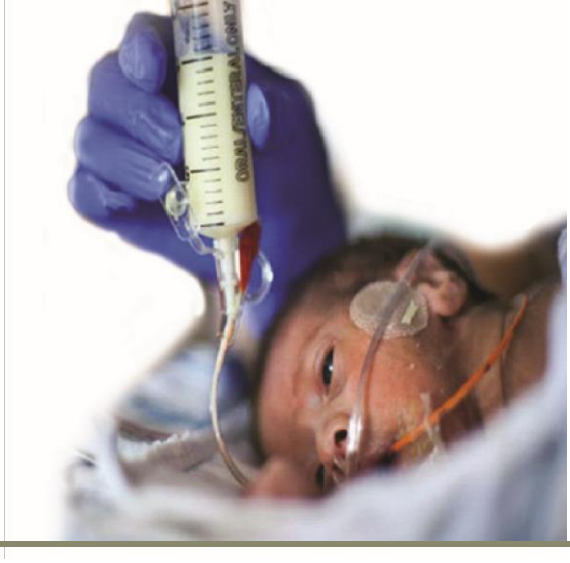
[*CDC Reference: Recommendations for prevention and Control of Hep C virus, MMWR, Oct 16, 1998, 47 (RR-19): 1-39]

Milk donation should be carried out for mothers who have completed donor screening. Sufficient care should be undertaken to properly label each bottle of donated human milk.

STEP

2

Milk Expression and Collection



2.1 Donor Counseling

Educating and sensitizing mothers as donors is most crucial aspect of milk donation and it is recommended as per the needs of the donor. They are given educational material informing them of characteristics of the high risk group or activities that might put them at risk for transmitting blood borne diseases. Making donors aware about proper methods and hygiene protocols to be followed during milk expression, collection, handling and storage is essential for safety and quality of DHM. The donor mother will be given specific verbal and written instructions in local language by the lactation counselor on the following:

- Hand washing and personal hygiene.
- Information on milk expression options, suitability of each method and collection techniques.
- Cleaning of breast pumps (detachable portions) and tubing.

Donor mother will also be encouraged to seek advice and support for lactation related problems

2.2 Preparatory activities

- **Shower:** The mother registered for donation should be greeted well, provided with autoclaved gown and asked to take a warm shower before entering milk collection room. For this purpose, dedicated shower rooms will be available. As the mother usually travel long distances and may be sweaty, it is preferable to take shower with plain liquid soap (and not antibacterial soap). For breast washing, no soap is prescribed other than daily shower as it may lead to cracked nipples. Showering serves two purposes- firstly to control milk contamination and secondly to have sufficient relaxation of the mother.
- Subsequently, the mother is then taken to milk collection room. Here the mother may consume food, if she is carrying it or else should be given hot drinks (milk based beverages) from the pantry.
- Ambience of milk collection room including privacy is an important factor influencing lactation process as Oxytocin modulated let-down effect plays a crucial role in the quantity of milk production.
- Donor Human Milk and Mother's Own Milk will be collected at CLMCs established at health facilities.
- At LMU only Mother's Own Milk will be collected and stored.
- Home collection of milk is not permissible.
- Lactation counselor would be actively involved during milk expression and collection, especially if the mother is donating milk for first time. The milk may be collected ideally by trained staff or the donor herself with assistance of a trained staff.

- If feasible, simultaneous expression from both breasts should be practiced as it is more efficient than sequential expression.
- Foremilk may not be discarded. However, drip milk i.e. milk passively collected from one breast while the baby feeds at the other, has been found to be nutritionally inferior and is thus not recommended for donation.
- Milk should be expressed by hand or using electric breast pumps which result in better volumes of expressed milk and are painless and comfortable to use when used appropriately.
- Mother should be provided with pre-labeled, sterile containers. The label should be waterproof and be able to withstand high and low temperatures.

2.3 Expression of Breast milk

There are two ways of expressing breast milk:

I. Manual Expression II. Expression using Breast Pumps

I. Manual Expression

Hand expression is usually gentler than a breast pump. Hand expression appears to produce a better Oxytocin response and milk ejection reflex. In a hospital setting, lactation counsellors/nurses should teach the mothers the art of hand expression of milk. Educate the mother to:

- Hold, handle, or cuddle the baby to stimulate the let-down reflex. Alternatively, take a few cleansing breaths and relax for at least five minutes.
- Sit comfortably and hold a clean container near the breast.
- Place the thumb and index figure on the breast around the areola, opposite each other.
- Support the breast with other three fingers.
- Press thumb and the index finger slightly inwards towards the chest wall.
- Press the breast between the fore-finger and thumb. Press and release. This should not hurt.
- Press areola in the same way from the sides, this ensures that milk is expressed from all segments of the breast.
- Avoid rubbing or sliding fingers along the skin.
- Express one breast for at least 3 to 5 minutes until the flow slows then express milk from the other side and repeat the process. To express breast milk adequately, it may take 20–30 minutes.

Before Manual Expression the Donor must

- Wash hands with soap and water
- Lather hand with soap and water for 15 seconds, paying particular attention to the area around and under fingernails.
- Dry hands with disposable paper towel or sterile single-use towel.

figure 9: Technique of manual expression of breast milk

II. Expression Using Electric Breast Pumps

- Hospital-grade electric breast pumps are recommended for use in Lactation Management Centres (CLMCs and LMUs).
- There are a number of designs, all of which have a funnel attachment which fits over the nipple and areola and work on a simple vacuum principle. Electric breast pumps are efficient and can be

adapted to allow single or double pumping. However, Bulb type pumps are strongly discouraged as they carry a high risk of contamination.

The technical specifications of electric breast pumps are at **Appendix 5.**

The user's guide book should be referred for instructions for using an electric pump.

- It is recommended that the baby should be kept close to the mother as this would help in let down reflex.
- Maintenance and cleaning of electric pumps and all of the accompanying accessories is critical to prevent contamination and potentially serious illness as a result.
- It is also important that mother is shown how to position and use the breast pump to avoid damaging her nipples or areola.
- Each mother should be provided sterilized tubing, funnel and milk container. This principle is to be strictly ensured. **There should be no sharing of breast pump tubing, funnel and milk containers among the donor mothers.**

Important instructions on use of Electric Breast Pumps

- Always remember to switch the pump off before removing the funnel from the breast.
- Double pumping reduces time of expression by 10-15 minutes and also allows for higher prolactin reflex which results in higher amount in less time. Pause for 30-60 seconds when the milk slows down.
- Stop pumping after 20-40 minutes or when the milk stops flowing.
- Milk donation should never be painful. Damaging of breast tissue should in no case be allowed by incorrect use of breast pump.
- If the mother has delivered the baby recently, and is secreting colostrum, it is advisable to express by manual expression only.
- Only electric breast pumps with an isolated motor, which does not connect with the tubing, are suitable for multiple use. Here each mother should have her own set of tubing.
- Express minimum 8 times/day or 100 minutes per 24 hours till baby starts to breastfeed.
- Mothers should be encouraged to express milk from both the breasts completely each time to maintain the milk output.
- In all cases the milk should be donated in the specified room in lactation management centres (CLMCs and LMUs).

2.4 Labeling of bottles at time of collection – Using Donor Human Milk at CLMC

All the expressed milk either using electric breast pumps or by manual expression to be used for should be clearly labeled with following information:

a. Name of the CLMC
b. Unique ID for the mother
c. Date of donation

d. Age of child- to know whether pre term/term milk
e. Date of collection
f. Site of collection

figure 10: Labeled milk bottles

g. Container number
h. Date of freezing
i. Date of pasteurization
j. Date of testing
k. Date of expiry

2.5 Labeling of bottles with mother's own milk at CLMC

All the expressed milk either using electric breast pumps or by manual expression,to be used only for her own baby and should be clearly labeled with following information:

a. Name of the CLMC
b. Unique ID for the mother
c. Date of donation
d. Age of child- to know whether pre term/term milk
e. Date of collection
f. Site of collection
g. Container number
h. Date of freezing
i. Date of expiry

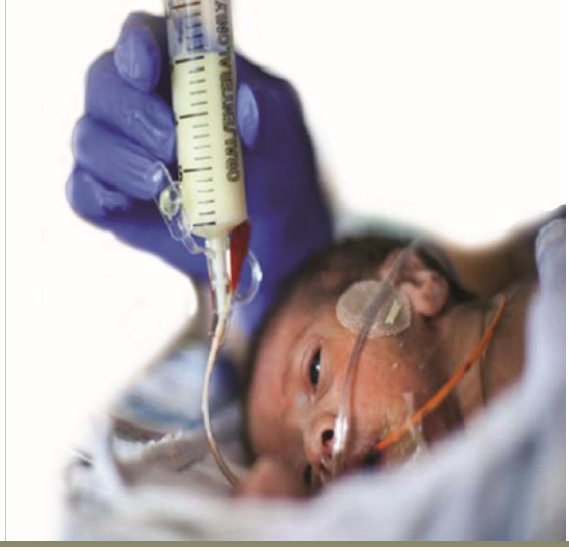
2.6 Logging of DHM

All donated milk is identified as relating to a specific approved milk donor. Logging of incoming milk includes estimating the volume of milk as well as observing for foreign matter or others sources of contamination such as broken storage containers.

STEP

3

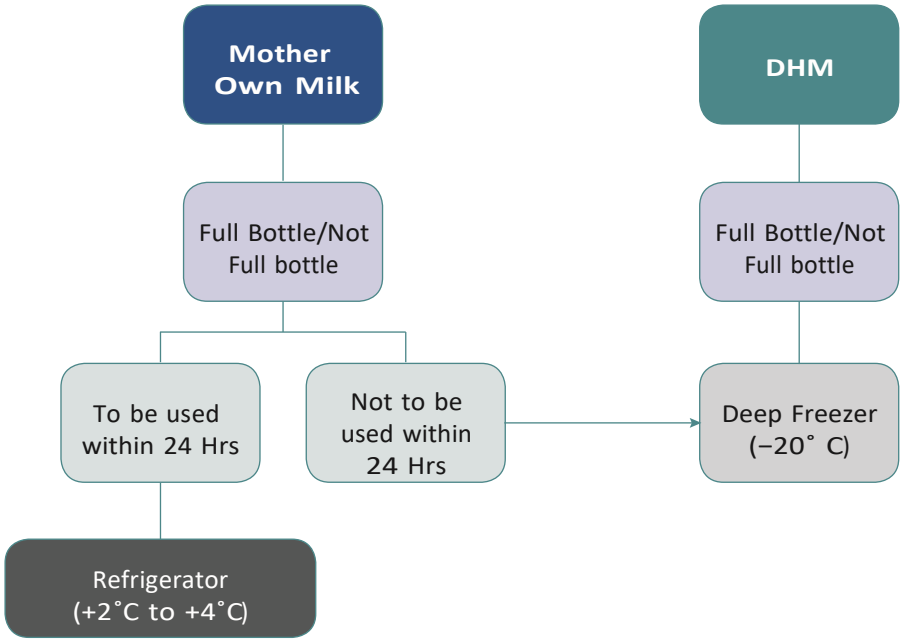
Processing of Donor Human Milk



3.1 Pre-Pasteurization-Storage of expressed breast milk

- Raw DHM awaiting pasteurization should be immediately transferred to a deep freezer at the temperature of (-) 20˚C for storage. Raw mother's own milk which will be utilized for feeding within 24 hrs. should be kept in refrigerator (+2˚C to +4˚C) and mother's own milk which is not expected to be fed within 24 hours should be immediately transferred to a separate deep freezer (–) 20˚C/in the deep freezer for DHM in separate racks labeled for MOM. This is to prevent bacteria multiplication and lipolysis. Raw DHM can be stored in a freezer (–20˚C) for a maximum of 3 months before it is pasteurized. It should not be stored for longer than this.

figure 11: Process Flow Chart for pre-pasteurization storage



No Shifting of container

The expressed milk should be stored in the specified container of donation and there should be no pouring of milk between containers as it leads to increased risk of contamination and loss of nutrients due to sticking to surface. The container should not be filled to brim, as milk expands while freezing.

Make of Container/Milk Bottle

- **BPA free hard plastic containers made from poly-propylene are to be used.**
- Ploy-carbonate containers are not recommended due to presence of BPA.

- Stainless steel containers are not recommended due to loss of cell counts during storage because of oligo dynamic effect of nickel.
- Soft polyethylene bags are not to be used.
- All containers should have tight fitting lids with capacity of **30ml and 100-110 ml.**

- The temperature of the freezer should be rigorously controlled i.e. in freezer equipped with recording thermometer and temperature sensitive audible and visual alarm. The recording of temperature of freezer and refrigerator should be done meticulously, twice a day. In case electricity fluctuations are reported, DHM should be discarded (if temperature cannot be maintained for 24 hrs.). Dedicated power backup must be ensured to maintain optimum temperatures.
- At the lactation management centres, freshly expressed MOTHER'S OWN MILK must be stored in a separate refrigerator or freezer as necessary.
- Also, frozen raw DHM should be kept separately from pasteurized DHM. The separation of frozen raw DHM from pasteurized DHM would be ensured by having deep freezers installed separately in processing room and storage room respectively.
- The DHM stored in refrigerator should be directly sent for pooling (after Donor clearance); however, the DHM which is frozen in the deep freezer has to be thawed.

There should be a separate compartment in the freezer and refrigerator for storage of per-term and term milk.

Don't

- Mixing of raw milk to frozen milk of the same mother is not allowed due to hydrolysis of lipids because of sudden decrease in temperature of frozen milk.
- Mixing of milk donated by same mother at different times should not be done. It should be collected in different containers, labeled with same container ID with different time and date.

3.2. Thawing of frozen raw DHM

- Shift the frozen DHM to a refrigerator overnight (not more than 24 hours) to allow milk to thaw slowly to 4°C.
- In case of an emergency, thawing can be done in a wide container of warm water (not to exceed 37°C) ensuring that water does not touch the lids of the containers and it does not fall over.
- Thawing should never be done in a microwave oven, as microwaving may destroy Immunoglobulin A and other antibacterial properties more than any other form of thawing.
- The outside of the container of DHM after thawing should be dried with clean paper towel. The content is gently agitated in order to uniformly distribute the constituents as protein, water and fat of expressed milk freezes and thaws at different rate.
- The time and date of the thawing should be documented accurately.
- Thawed milk should never be refrozen.
- Thawing should never be done in microwave oven, as microwaving may create 'hot spots' causing burn injury to the baby and it destroys IgA and other antibacterial properties more than any other form of thawing.

3.3 Pooling and Aliquoting of Milk

All persons working in direct contact with milk, milk contact surfaces and milk packaging materials conform to hygienic practices while on duty to the extent necessary to protect against contamination of milk.

Pooling

- The raw DHM bottles are taken from refrigerator for pooling and further pasteurization which should be done in the processing room.
- It is preferable to pool milk on steel slab in a laminar air flow system. However, a clean, hygienic working environment is also acceptable for pooling of raw DHM.
- A one liter sterilized conical flask made of borosilicate glass is to be used for pooling of DHM from preferably 3 mothers. The flask should be stirred with a sterile stirrer and swirled for homogeneity. This pooled raw DHM constitutes a batch (milk from 3 mothers). Each pooled batch should be provided a unique batch number (an alphanumeric code containing 8 letters) linked with registration number of all donors in that pool.

Aliquoting

- The pooled milk is then aliquoted into clean containers in a predetermined amount as per bottle size under all aseptic precautions, under laminar air flow.
- The containers shall be filled leaving adequate air space in the container to allow for expansion during freezing.
- All containers are filled to the same approx. level.
- The containers should be tightly sealed with sterilized caps to prevent contamination. Electronic sealing will be used. Sealing of DHM bottles is essential to control bacteriological contamination. Serial number should be allocated to each bottle after sealing the bottle.
- One sample of 10 ml of milk meant for pre-pasteurization microbiological culture will be collected in any sterile container/test tube.
- It is preferable to pool and label donor milk separately as colostrum, preterm, and mature milk. This will facilitate distribution of selected milk to different types of recipients based on their needs.
- During pooling, visual screening for hair/skin cells on the surface of each container may be undertaken. Use of fine sieve for segregating physical contaminants to be undertaken.

Pre-pasteurization Testing of Pooled DHM

- DHM is tested for microbial contamination to decide whether it is fit for consumption. Tests should

Do's

- Each pasteurization team member should thoroughly scrub her/his hands with liquid soap before wearing gloves.
- Gloves are always used when handling milk and changed between procedures and especially between handling raw and pasteurized DHM.
- All 'milk spills' should be immediately cleaned with soap and water.

Don'ts

- Pooling should not be undertaken for separate batches (each batch contains milk pooled by mixing DHM collected from 3 mothers not more then 5).

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be carried out twice, before and after pasteurization.

- Before pasteurization, sample from each batch of pooled raw donor milk is to be tested for Staphylococcus aureus colony count. Milk would be discarded if colony count is more than 10^4 CFU. Other microbes are accepted irrespective of colony count.
- Pre-pasteurization testing should be carried out after pooling of raw DHM. For this purpose, a sample of 10 ml of pooled raw DHM will be collected using sterile technique, in a sterile bottle used for pasteurization. This bottle will be marked **"P"** with its serial number.

3.4 Pasteurization of DHM

- Pasteurization eliminates bacteria while retaining the majority of the milk's beneficial components. This preserves Vitamin C content, prevents lipid peroxidation and inactivates CMV, HIV, and kills most pathogenic bacteria found in breast-milk.
- Pasteurization should ideally be undertaken each day. However, the frequency of pasteurization will depend on the quantity of milk collected.
- There are a number of methods of pasteurization/heat-treating of human milk. These fall broadly into two categories:
  - Low temperature, long time (LTLT)
  - High temperature, short time (HTST)
- For CLMC it is recommended to use a form of LTLT heat treatment also known as Holder Pasteurisation method. This method involves heating DHM to 62.5°C (+/–0.5°C) and holding at this temperature for 30 minutes. Following this, the temperature of the milk is then rapidly reduced to minimize heat damage to nutrients and provide a thermal shock to the organisms enhancing their destruction and preventing growth of spores. It is recommended that milk temperature of 25°C to be attained within 10 minutes of the completion of holding period of 30 minutes and that a final temperature of 4°C be attained prior to transferring the pasteurised milk to a freezer. The rate of cooling and the temperature of the milk at the end of the process affect the quality of the final product.

Choice of Pasteurizer

1. Fully-automated pasteurizer

- In this pasteurizer, the heating and cooling cycles are performed in same water bath. The heating cycle starts immediately after putting on the equipment and the milk is kept in the water bath once the temperature is achieved to 62.5°C. The timer starts counting for 30 min cycle once the temperature of 62.5°C is achieved in the sample container. It has a built-in cooling system that rapidly cools the milk after completion of 30 minutes holding at 62.5°C. It has temperature indication system to provide visual output of the temperature and data logger to record the temperature and time parameters throughout the process.
- The automated pasteurizer provides an integral system solution with less scope of human errors, an inbuilt standard cooling system, and a comprehensive solution for different types of bottles, sealing, level of submerging, automated time for heating and cooling etc.
- The automated pasteurizer has a comprehensive approach. This is advantageous in hot Indian climate, and in the context of variable competency of health staff in the country. However, it

involves much higher cost, large usage of RO water and non-availability of indigenous manufacturers for servicing facility.

Refer **Appendix 5** for specifications of pasteurizer.

2. Semi-automated

- This equipment has both heating and cooling inbuilt in the equipment with two separate baths for these operations. After completion of 30-minute heating cycle of pasteurisation, an alarm beeps and technician needs to manually lift and shift the milk tray in the cooling water bath compartment. It will also possess data display as well as recording facility to maintain all the records of process.

Indigenous make pasteurizers are available in India.

- A shaker water bath can also carry out holder pasteurization.
- While using a shaker water bath, it is recommended to run one test sample along with a batch of milk in a container containing the same volume of milk/water with a data logger (for recording temperature) immersed 2/3rd to the bottom of the container to ensure that the temperature of 62.5°C is achieved.

a) Heat Processing

- Aliquots of milk are processed by submerging the containers in the well-agitated or shaking water bath preheated to a minimum of 62.5°C.
- A control bottle containing the same amount of milk or water is also included for processing of every batch.
- It should have temperature probe (data logger) in the control container to document the process of pasteurization throughout the process. It is positioned such that approximately 25% of the milk volume is below the measuring point of the thermometer/probe, or according to manufacturers' instructions. Probe should not be touching the bottle in any way.
- The monitored aliquot is placed into the water bath with all other aliquots and is either positioned at the coldest area of the water bath, as identified during calibration checks, or positioned according to manufacturers' instructions.
- After the temperature of the monitored control bottle has reached 62.5°C the heat treatment continues for 30 minutes, maintaining the temperature and then ends immediately. Fluctuation during the heating process may be seen for short periods of adjustment where heat may briefly fluctuate between 62.5°C and 64.5°C.
- Milk temperature and bath temperature are monitored and recorded.
- Air bubbles released from milk containers indicate insecure caps/improper sealing – such bottles are discarded.

b) Repid Cooling

- In this process cooling needs to be done immediately. Following heat processing, the milk is rapidly cooled to 4°C using either the processing equipment manufactured to cool milk or ice baths within 10 minute.
- If ice baths for cooling are used, water source must be of adequate sanitary quality and equipment creating ice must be maintained as per manufacturers' instructions.

NoTE:

- Unless caps and equipment designed for submersion, caps need to remain above water level to prevent possible combination from water seepage.
- As processes are manual with this system, and might result in human error, **robust training** of the staff is essential.

3.5 Post Pasteurization Processing

- Randomly chosen aliquot of processed milk from each batch is labeled **"S"** and is sent immediately for culture to test bacteria count.
- Rest of the batch should be promptly stored in deep freezer (at –20°C). DHM awaiting culture report should be stored taking precaution that it is not dispensed until the culture reports are satisfactory.
- Cooled, heat processed milk can be stored sealed for up to 72 hours at 4°C for dispensing without freezing once bacteriological culture procedures and standards are met. Milk can then be frozen for later use if not needed immediately.

Labeling of milk

The containers are labeled for expiry date which should not be more than 6 month from date of expression of milk.

Caps of the milk containers need to remain above water level to prevent water seepage and bacterial contamination.

Do's

- Each pasteurization team member thoroughly scrubs her/his hands with antimicrobial soap before putting on gloves; gloves are always used when handling milk as part of the pasteurization process.
- The procedure to use the pasteurization machine should be followed as recommended by the manufacturer and hence should be well outlined in the SOP of lactation management centre.
- Irrespective of the type of pasteurizer being used, the data logger should be used that provides an electronic record of the heat treatment.

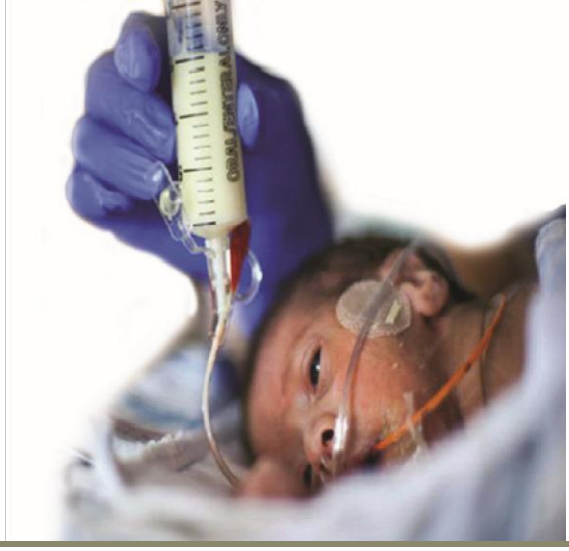
Don'ts

- There should be no exchange of milk between the bottles after pasteurization to reduce chances of contamination.
- Flash heating is not recommended.

STEP

4

Post Pasteurization Testing of DHM



- Microbiological testing of pasteurized DHM should be done after each cycle of pasteurization. There should be no growth on the plates of pasteurized DHM.
- Frequency of post pasteurization microbiological testing should be either at least once a month or every 10 cycles of pasteurization, depending on the date which comes first.
- Test should also be conducted on an ad-hoc basis if any new processes, equipment or staff are introduced, or if there are concerns about any part of the process.
- Any growth is not acceptable. In case of any growth reported, the entire should be discarded or used for research purposes.
- DHM should be discarded in the same way as any other clinical waste. Hence, local waste disposal policies should be followed.
- Tests for microbial contamination should also be investigated under instances of significant or unusual contamination.

Basic requirements of Testing DHM

I) Work area

A level II bio-safety cabinet or a level table with a Bunsen burner with ample surface area in a clean, well-lightedand ventilated room reasonably free of dust and draft.

(The microbial density of air in working area, measured in fallout pour plates taken during plating, should not exceed 15 colonies/plate during 15 min exposure.)

II) Rrequirements

Consumables	Instruments
Culture Media: CLED (cysteine lactose electrolyte deficient) or Columbia agar media	1. Incubator, 37°C 2. Refrigerator, to cool and maintain samples at 5°C. 3. Autoclave for sterilisation. 4. Water bath suitable for keeping melted agar media molten for use (at 50°C). 5. Petri dishes (glass or plastic). 6. Pipets with pipet aids (no mouth pipetting), glass spreading rods. 7. Dilution blanks, cotton etc.

If 1:10000 dilution contain “n” number of colonies, then CFUs in 1ml of the original sample (CFU/ml) should be = n x 10^4 (CFU/ml)

Interpretation of tests

I) For Raw donor milk before pasteurization

The milk is discarded if samples exceed a count of 10^4 CFU/ml for *Staphylococcus aureus*

II) For Pasteurized milk

Pasteurized milk that has a total viable microbial count of 10 CFU/ml or more should be discarded.

Process of Testing of DHM

General considerations

*All general safety measures of a microbiological laboratory should be followed

*Nutritional assessment of the DHM is not recommended.

- Pasteurised milk that has a total viable microbial count of 10 CFU/ml or more should be discarded. One ml of the pasteurized milk can be directly plated to count colonies (if, any) without dilution. Milk with more number of colonies will be automatically discarded.
- Plates and tubes should be appropriately labelled before starting the tests.

Serial dilution of milk

1. Sterile blanks are prepared containing 9 ml of sterile water or saline or PBS.
2. One ml of milk is transferred to the first sterile blank (this tube is labeled as 1:10).
3. The tube contents are mixed using the vortex mixer or by shaking properly.
4. Using another transfer pipette, one ml of the content of 1:10 tube is transferred to the next sterile blank tube (this tube is labeled as 1:100).
5. Content transfers are continued until 1:1000, 1:10000 dilutions (dilutions up to 10^{-4} are adequate).

After the dilutions are made the milk can be plated either by “spread plate” method or by “pour plate” method. Spread plate method is recommended because “pour plate” method may require expertise as the media can be poured only when appropriately cool.

Counting colonies

Colony forming units (CFU) in the sample should be determined by counting the colonies. Then a calculation of the viable cells in the original sample can be performed. Any plate containing less than 300 colonies but more than 30 colonies should be counted. This allows to estimate the number of cells or colony forming units (CFUs) in the original sample by counting the number of colonies and multiplying by the dilution factor of the plate.

Spread plate method

1. After all dilutions are completed; one ml of dilution is spread across the surface of the plate with a clean spreading rod.

2. The plates are placed inverted in a rack to be incubated.
3. The plates are examined after 24 hours for growth if any and identification (if necessary) is done by conventional methods.

Pour plate method

1. After all dilutions are completed; one ml of each dilution is added to a number of sterile petridishes and gently mixed with 15-18 ml of the appropriate molten, cool Columbia agar medium to ensure an even distribution of samples.
2. The medium is allowed to set on a cool horizontal surface.
3. The plates are placed inverted in a rack to be incubated.
4. The plates are examined after 24 hours for growth if any and identification (if necessary) is done by conventional methods.

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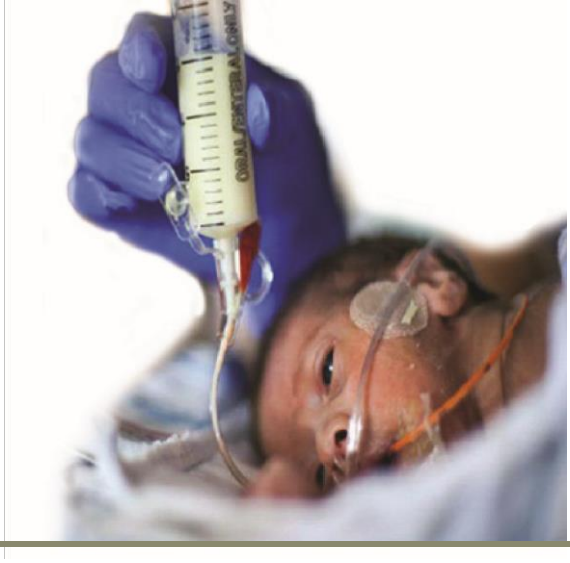
STEP

5

Post Pasteurization Storage of DHM



- Post pasteurized milk should be stored in deep freezer at -20°C. It is desirable to have deep freezers with a digital display of the temperature inside it with an alarm setting. Two deep freezers are required to store 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 use d for storage of the pasteurized milk once the culture reports are negative and the milk is considered safe for disbursement.
- Culture-negative pasteurized DHM kept at deep freezer –20°C can be preserved for 6 months. However, the milk may get rancid after 3 months due to lipolysis, but is still fit for consumption, though it would have altered taste.
- Cooled or thawed pasteurized milk can be stored in the refrigerator at + 4°C, and should be used within 24 hours.
- Lid of any pasteurized DHM bottle should not be opened until the milk is dispensed for use.
- It is advisable not to transfer pasteurized milk in other containers as it has risk of contamination.

Table B1: Critical Temperature and Time duration for storage of fresh raw milk, unpasteurized milk and Pasteurized milk.

LoCATIoN	TEMPERATURE	DURATIoN	REMARKS
fresh raw milk	Room temperature (≤ 25˚C)	Up to 6 hours	Containers should be covered and kept as cool as possible
Refrigerator (Unpasteurized milk)	4˚C (+2 to + 4˚C)	24 hours	Raw milk should be stored in the back of the main body of the refrigerator
freezers			DHM should be stored towards the back
Unpasteurized Milk		3 months	of the freezer, where temperature mostly remains constant
Pasteurized Milk	–20˚C	6 months	
PASTEURIzER (HoLDER PASTEURIzATIoN)			
a) Heat Processing	62.5°C	30 minutes	The temperature should be monitored continuously for any deviations from the norm
b) Rapid cooling built in cooling system	Final temperature of 4°C	To be attained within 10 minutes at the end of the holding temperature	Caps of the DHM containers need to remain above water level to prevent water seepage and bacterial contamination

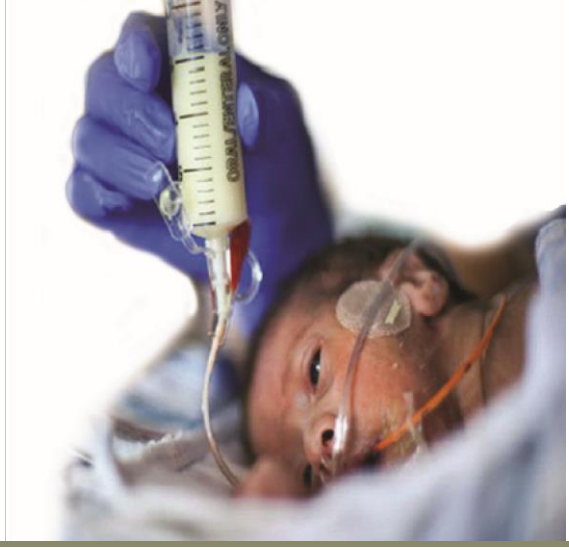
Source :

1. Donor milk banks: the operation of donor milk bank services, Issued : February 2010, NICE Clinical guideline 93, guidance.nice.org.uk/cg93

STEP

6

Dispensing of Processed Milk



2. H uman Milk Banking Association of South Africa, Best practice for the collection, storage and handling of human milk, Compiled 2008 and Updated 2011

- Milk from the CLMC should be dispensed on first-in, first-out basis such that the oldest milk is used first.
- The recipient should be given milk from the same pooled batch as much as possible.
- Processed donor milk should be disbursed only by physician prescription (requisition form NICU/ SNCU) after informed consent from recipient's parents.
- Mother's own milk to be used on the same day of expression, milk stored in refrigerator (up to 24 hours) will be dispensed and for use in subsequent days, the frozen mother's own milk stored in deep freeze will be dispensed.

Refer to **Annexure 4** for format for recipient consent form

6.1 Recipients of Donor Human Milk

Newborns who represent one or more of the following indications will be selected as recipients:

1. Premature and low birth weight babies: The largest group of recipients of donor human milk is preterm babies especially in the first few days, till their mothers are able to secrete adequate milk.
2. Sick preterm newborns recovering from illnesses like necrotizing enterocolitis and GI surgeries
3. Severe IUGR.
4. Newborns not having access to their own mother's milk or when the mother has a contraindication to breastfeeding/expressing milk.
5. Babies of mothers with problems like eclampsia, PPH, febrile illnesses.
6. Babies admitted to the unit whose mothers are not available (due to physical absence or death).
7. Babies whose mothers have lactation failure.
8. Exceptional cases, with medical justification.
9. Multiple birth (if needed).

Preterm baby should receive processed donor milk of pre term donor.

6.2 Thawing before use of DHM

- Prior to use, the DHM should be thawed preferably by transferring initially to refrigerator (at +4˚C). It can be refrigerated for a maximum period of 24 hours. Before dispensing of DHM for use in the wards it should be brought to room temperature.

- Pasteurised frozen milk after bringing to room temperature should be used for feeding as soon as possible. DHM has to be consumed within two hrs preferably and latest by 4 hrs. of storing at room temperature. The excess thawed DHM left after feeding the babies should be discarded immediately.

Rapid Thawing

In paucity of time frozen DHM may be thawed quickly in a container of warm water not exceeding +37˚C and ensuring water does not touch the lid. Once the DHM comes to chilled liquid form, DHM bottle should be dried and refrigerated (at +40˚C) until used.

- DHM container should be gently shaken before use to distribute the heat more evenly and uniform distribution of fat and micronutrients.
- Thawed milk should never be refrigerated or frozen again as repeated freezing-thawing cycle increases risk of bacterial contamination as well as increases hydrolysis of triglycerides.

Thawed milk should never be kept under the radiant warmer.

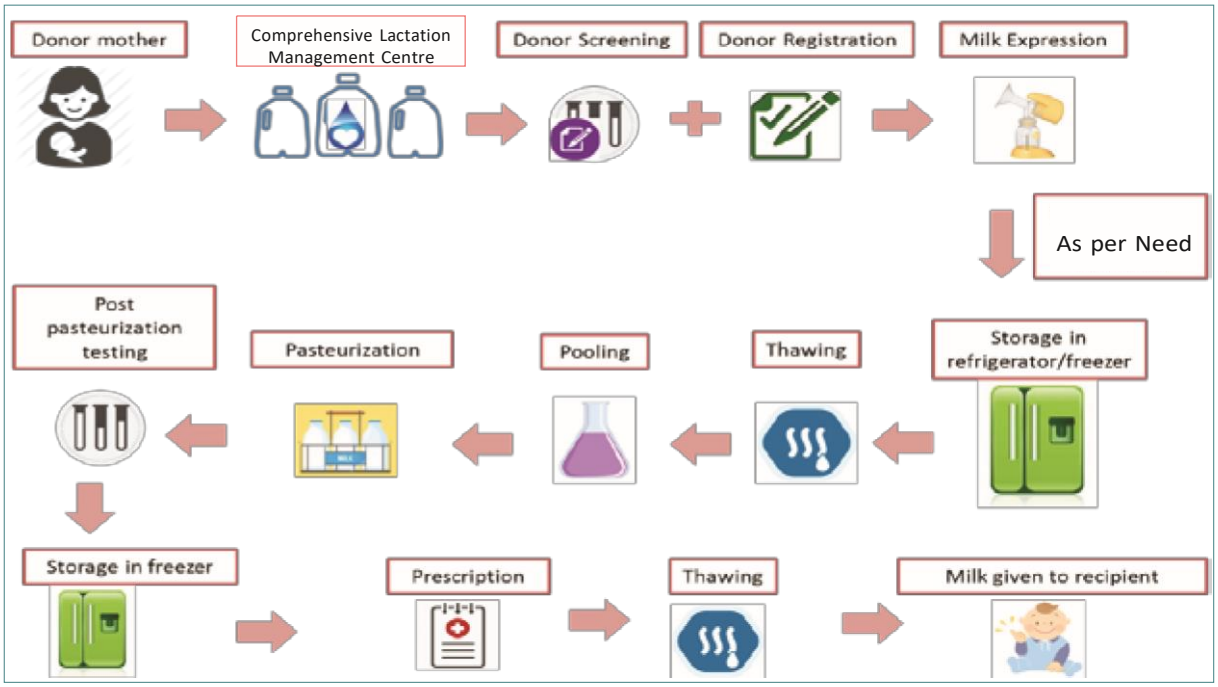
6.3 Estimation of DHM for dispensing from CLMC

- Amount of each feed volume of a newborn is calculated on the basis of her/his daily fluid requirement (for details please see FBNC guidelines of MoHFW).
- The NICU/SNCU nursing staff who is responsible for preparing feeding plans for the admitted babies will estimate the requirement of DHM in the NICU/SNCU on daily basis.
- Lactation support staff should coordinate with the NICU/SNCU nursing staff on daily basis to ensure that CLMC dispensing counter in-charge is in receipt of the estimated daily requirement of DHM one day prior to dispensing.
- Log needs to be maintained about the details of DHM disbursed and return of empty of bottles.

Feeding in NICU/SNCU: Points to remember

- Wash surface/counter top with antiseptic cleaner
- Wash hands
- Check labels of DHM container for appropriate and safe consumption (Term/Preterm, date of expiry, date of pasteurization, and time of dispensing etc).
- Appropriate labeling of syringes according to the newborns to be fed
- Tubing and syringes used for feeding should be changed every 4 hours
- Feeding tube should be labeled to ensure that feeding is not connected to IV port or vice versa

figure 12: Suggested Summary of Process for a CLMC



Hazard Analysis and Critical Control Point (HACCP) Practices in Lactation Management Centres

The day to day functioning of the lactation management centre is based on the principles of Hazard Analysis and Critical Control Point (HACCP) of the food safety industry, to ensure quality assurance at all steps followed in Lactation Management Centres. Quality assurance steps identified for the processes of Lactation Management Centre and SOPs are laid down to prevent the hazards to the maximum extent possible.

Table B.2: Possible Hazards and Critical Control Points

Sr. No.	Process	Hazard	CCP/GMP	Quality Assurance
1.	Donor Selection	Transmission of infections, especially viral infections like HIV, CMV, Hepatitis B, C, and other infections like syphilis. Other Infections like TB, acute febrile illnesses	Selection of donors based on history, examination and blood tests for HIV, Hepatitis B, VDRL within 6 months before milk donation Based on maternal history and examination	Levels of Assurance: ⊙ Donor selection criteria based on negative tests ⊙ Holder Pasteurization which destroys CMV, HIV. Prevention of other infections like TB, bacteremia in acute infections
2.	Donor Consent	Medico legal		Written donor consent

3.	Milk Expression and Collection	Potential for contamination especially bacterial contamination	GMP: training donors for safe expression of milk CCP: Milk Pump and container sterilization	⊙ Lactation counselors to train mothers in hand washing, clean expression and handling of expressed milk. ⊙ Training of lactation management centre personnel regarding cleaning and sterilization of containers and disinfection of milk pumps. ⊙ Ensuring sterilization temperature for equipment as per manufacturer guidelines

national Guidelines on **Lactation Management Centres** in Public health Facilities

Sr. No.	Process	Hazard	CCP/GMP	Quality Assurance
				⊙ Pasteurization of all milk containers before use. ⊙ Utilization of DHM only if post pasteurization culture is negative.
4.	Temperature maintenance in CLMC and during transport to the ward	Potential for contamination especially bacterial	CCP: Temperature maintenance at 4°C in fridge at CLMC Storage in icebox with cold gel packs up to 2 hours	⊙ Ensure refrigerator temperature is appropriate with thermometer/external digital read out of temperature. ⊙ Automatic switch to Generator/UPS/ invertors facility in case of power failure.
5.	Temperature Maintenance in Lactation Management Centres	Potential for contamination especially bacterial contamination	CCP Pre pasteurization temperature maintenance at 4°C if stored in refrigerator. Store for maximum 24 hours. Store in deep freezer at –20°C if pasteurization is planned after 24 hours	Ensure refrigerator and freezer temperature is appropriate with thermometer/external digital read out of temperature. Automatic switching on of Generator/ UPS/invertors facility in case of power failure.
6.	Pasteurization and Post Pasteurization Culture	Post pasteurization culture may remain positive if pasteurization is not carried out appropriately Potential for contamination with water during pasteurization procedure	GMP Holder pasteurization at 62.5°C for 30 minutes after temperature in test container reaches 62.5°C followed by rapid cooling to 4°C	Check temperature with thermometer dipped to 2/3 rd level in test container to ensure 62.5°C and 4°C post cooling. Sealing of containers or ensuring air tight lids for all containers. Post pasteurization culture sterile.

7.	Storage of raw, post pasteurization quarantine milk and post pasteurization culture negative safe milk	Potential for mixing of safe milk containers with raw or quarantine milk containers.	GMP Separate freezers/ shelves in freezers.	Use separate freezers for 3 groups of containers or different pre –defined shelves of same freezer. Restrict access to freezers to designated personnel only.
8.	Storage temperature Post Pasteurization	Potential for contamination and spoilage of milk	CCP Temperature of freezer –20°C Not above –18°C	Ensure freezer temperature is appropriate with thermometer/external digital read out of temperature. Automatic switching on of Generator/ UPS/invertors facility in case of power failure. Use separate freezers/shelves for quarantine milk and culture report negative milk. Label with expiry date if utilization of DHM is planned beyond 3 months from date of collection.
Sr. No.	**Process**	**Hazard**	**CCP/GMP**	**Quality Assurance**
9.	Storage of Disbursed Milk on Site	Potential for contamination and spoilage of milk.	Store in refrigerator if utilization is planned within 24 hours or in deep freezer if utilization planned > 24 hours	
10.	Thawing and Utilization of Milk	Potential for contamination and spoilage of milk	GMP Thaw by keeping in fridge over-night Stand in container containing warm water before utilization	DHM containers are not to be put in microwave. Utilization of DHM within 4 hours when thawed to room temperature.
11.	Consent for use for recipients	Medico legal		Written consent documented on patient's indoor paper or Lactation Management Centre form.
12.	Labeling and Record keeping	Medico legal		Appropriate labeling of every DHM container. Record keeping of donor data, culture records etc.

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3 APPENDICES

APPENDIX 11

Description of Individual Rooms in a CLMC

Reception Area	
Area and built of room	⊙ This would be the first room at the entrance with a suggested area of approx. 6.9m X 4.2m. ⊙ This area should be nearer to lift if situated in upper floors and should have a porch if located in ground floor.
Designated activities	⊙ All administrative formalities such as registering, screening and enrolment of the donor mother and tracking the process. ⊙ Record keeping including logistics data. ⊙ Dispensing of pasteurized DHM. For dispensing, a separate counter or window would be provided. This would limit unnecessary entry and crowd into the lactation management centre. ⊙ Provide waiting space for mothers. All mothers would be suggested to remove their shoes and should be provided with hospital slippers at the reception area.

Equipment/logistics	⊙ Reception counter ⊙ Intercom ⊙ Cupboard for records ⊙ Seating and waiting area for mothers with chairs/sofa ⊙ Computer and printer ⊙ Separate shoe racks for keeping shoes for mothers and hospital slippers for changing.
In-charge	⊙ CLMC Manager
Group Counselling Room	
Area and built of room	⊙ Suggested area: 4.8m X 5.5m
Designated activities	⊙ Group counselling session which should be open to mothers who have come for milk donation or are seeking treatment for any breast conditions hampering breastfeeding. The purpose of counselling is to promote breastfeeding and encourage milk donation for the CLMC as a parallel effort. The mothers with babies in NICU/ SNCU should be encouraged to join group counselling sessions. However, Lactation Support Staff should check that their need for being with their babies for feeding/expression of milk is fulfilled first.

Group Counselling Room	
	⊙ Thematic areas to be discussed are: • Initial breast feeding, exclusive breast feeding, procedures to be followed for milk donation (including Dos and Don'ts) along with display of videos of IEC materials on IYCF, hand washing and process of milk expression and cleaning of tubing.
Equipment/Logistics	⊙ Chairs to accommodate 8-10 mothers or more. This will depend on the size of the counselling room. ⊙ IEC material for display ⊙ Video display requirements (Television, video tapes etc.) ⊙ Breast models (mannequins)
In-charge	⊙ Lactation Support Staff
Shower and Changing Room	
Area and built of room	⊙ The suggested area: 2.4m X 2.0m
Designated activity	⊙ It is important for mothers to be clean and relaxed before donating milk. Showering serves two purposes - to control milk contamination and to relax the mother which may lead to better volume of donated milk. ⊙ In case mother has already taken a shower or hesitant to take one, she may directly be given a gown to change. However, the mother should be made to/ shown how to wipe the nipples using wet cotton swabs. Cleaning nipples with alcohol swab or soap is not required. The gowns should be autoclaved and kept in a dry place. ⊙ A dedicated shower room has been designed in layout plan. The cleanliness of the room should be maintained and it should not have an attached toilet. As the mothers usually travel long distances and are sweaty in humid conditions of the country, it is preferable to shower with a plain liquid soap (not anti-bacterial soap). For breast washing, no soap is prescribed other than daily shower as it may lead to cracked nipples.

Equipment/logistics	⊙ Shower with availability of hot and cold water ⊙ Exhaust Fan ⊙ Clean towels and gowns ⊙ Liquid body soap dispenser
Milk Expression and Collection Room	
Area and built of room	⊙ Suggested area approx. 68.5 sq. m. ⊙ This room should comprise of 5-6 well-defined milk expression areas separated by partitions/curtains where mothers can express milk in privacy. ⊙ The use of glass door and windows is not recommended in this room. ⊙ Entry of male members in this room should not be allowed to ensure privacy. If there is urgent need for such entry, all mothers engaged in milk expression should be alerted of this before-hand. ⊙ The room should be a quiet place with a comforting ambience, clean environment. Arrangement for pleasant soothing music may be made to help mother relax. ⊙ Infection control measures should be observed with highest standards. ⊙ Rigorous hand washing with soap and water and drying with clean or disposable towel should be stringently followed before entering the room. ⊙ Sterilized tubing, bottle and breast shield set should be packed and provided to each mother when entering the milk expression chambers. ⊙ This can serve as a place for informal conversation between the donors. ⊙ Mothers should not have access to any room beyond milk expression room such as cleaning/processing and dispensing rooms.

Milk Expression and Collection Room	
Designated activity	⊙ Expression of milk
In-charge	⊙ Lactation Support Staff

Equipment in Milk Expression room

1. **Hand scrub** just outside this area made of steel: foot operated.
2. **Scrub station:** 90-96 cm height with water taps. Both hot water and cold water, soap liquid and scrubber.

1

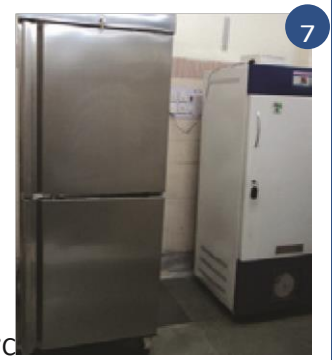
2

3. **Sterile bottles** with caps and facility for labelling.
4. **Steel table**
5. **wall mounted cupboard** for storing a) sterile bottles for collection; b) sterile tunings of breast pump which come in contact with milk; c) provision for hand written labels for identification .

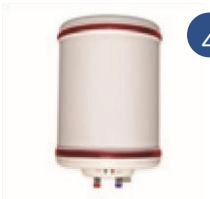
3

4

5

6. **one refrigerator (190l) with compressor** for mothers to keep their milk in the refrigerator under the supervision of nursing staff or by nursing staff herself. 7. **one vertical freezer** -20°C with compressor for keeping raw milk where the container is full and is not likely to be used within next 24 hours to be used by nursing staff only.	Storage of raw milk at 2° to 4°C 6 	Storage of milk at – 7  20°C
8. **Breast pumps** both mechanical as well as electrical hospital grade with tubing and each individual electric points usually the number is minimum 6.	8  	
9. **Music system** 10. **Sofa** for relaxation for mothers	9 	10 
11. 2.5 ton **Split AC** for 104.50 sq. Meter i.e. Milk expression room essentially and 24,000 British thermal unit per hour (BTU per hour) along with cleaning room.	11 	

Autoclaving/Cleaning Room	
Area & built of room	Suggested area 3.6 m x 3 m
Designated activity	To be used for cleaning, autoclaving and sealing of used bottles, tubing and washable part of breast pumps
In-charge	Lactation Support Staff
Equipment in the Autoclaving/Cleaning Room	
1. **Scrub station:** 2 bay scrub station and shall have sloping basin to eliminate back splash along with Soap bottle shelf. 90-96 cm height with water taps for hot water and cold water, soap liquid and scrubber for washing and rinsing the used reusable bottles along with tubing's of the breast pump. 2. **Steel table with sink** to keep the bottles and tubing's after rinsing with soap water.	1 
	2 

3. **Kitchen basket of steel or plastic** to drain out the water. 4. **Geyser:** 3 Lts. Electric Water Heater, Rust proof thermoplastic Body with Triple Safety System and Neon Indicators attached to the scrub station any one tap.	  
5. Washer and Thermal Disinfect or. 6. Hot air circulating oven.	 
7. Table top autoclave machine	 
8. **Steel table** for packing and wall mounted cupboard for storing. 9. **Heat sealer machine with cutter (200mm/400mm):** A machine used to seal products such as cleaned tubing's for breast milk pump, packing sterile bottle containers using thermoplastic materials like plastic bags, cellophane using heat. Sealing length 300mm appx. And sealing width 8-10mm	   
10. **Exhaust fan:** Must include a high quality mechanical back draft shutter that prevents outside air entering room when fan is switched off.	 

Milk Processing Room	
Area and built of room	⊙ The suggested area is 5.0m x 6.0m with glass doors to reduce risk of infection.
Designated activities	From milk expression and collection room DHM goes to this room for pooling and pasteurization. The activities carried out in this room are as follows: ⊙ Thawing before pooling ⊙ Pooling and making batch of pooled DHM ⊙ Aliquoting in pasteurising containers. ⊙ Pasteurization ⊙ Sealing of post pasteurised bottles ⊙ Labelling and documentation of Pasteurization
In-charge	CLMC Technician

Equipment in Milk processing room	
1. **Scrub station**	
2. **Refrigerator**	
3. **Horizontal Deep freezer**	
4. **Stainless steel table:** 4 feet length an	l two feet wide as working table
5. **Conical flask** at least one - liter capacity: 1000 ml Conical Flask Glass with Heavy Duty Rim, Borosilicate Glass with Approx Neck O.D. 56 mm. This can be autoclaved.	
6. **Stainless steel strainer**	
7. **Stainless Steel wire mesh basket**	
8. **Laminar flow cabinet**	

Milk Processing Room	
9. **A stainless steel table** (4 feet length and two feet wide) used for transferring into small bottles for pasteurization. While alliquoting milk, one should take aspetic precautions like use of cap, mask, sterile gloves, sterile sheet, sterile flask and sterile bottle.	  

10. **Cabinet for storing bottles**

11. **Milk bottles:** Reusable Milk Storage B ottles : Polypropylene. 100% free of Bisphenol – A Sterile reusable polypropylene bottles packed in sterile plastic bags.

12. **Bottle sealer with foil**

13. **Printer and water proof label**

- ⊙ Should produce high resolution Labels.
- ⊙ Should print more than 60 Labels per minute.
- ⊙ Resolution of 300x600 dpi.
- ⊙ Should be supplied with 100 compatible labels with the following specifications:
- Labels should be water proof.
- Can be peeled off easily.
- Size around 100 mm x 25 mm
- Can also be written with hand written labels with permanent markers.

Pasteurization prerequisite

14. **Hot water Geyser** : 10 liters

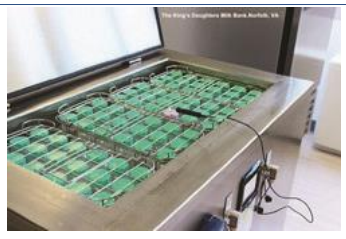
15. **Ro water system**

16. **Pipes** for outlet as per requirement of achine

17. **Air Exhaust fan:** should be on the ba ck side of pasteurizer : 18 cm from the floor.

18. **Split AC :** 1 ton

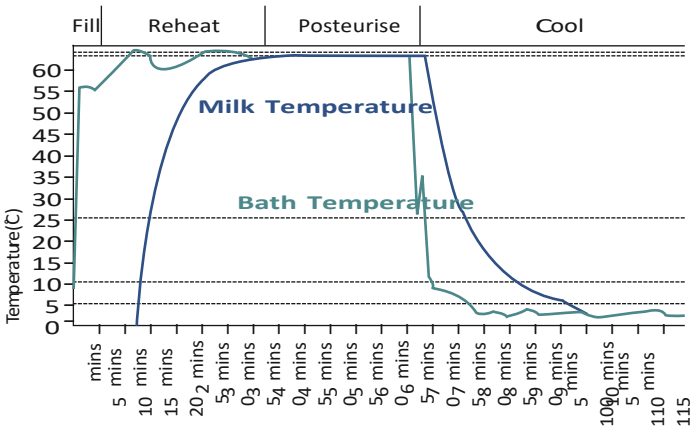
19. **Pasteurizer**



Milk Processing Room

20. **Data logger:** Holding for 30 minutes at 62.5°C and rapid cooling to 4°C within 20 minutes.

The data logger takes a reading of the milk temperature for every minute the milk is in the pasteurizer. The data logger also records the time and the date of the cycle. Once the pasteurization cycle is complete the information can be downloaded via the USB to the PC. This gives a permanent record of the satisfactory treatment of every batch.



Time and temperature graph at 62.5°C (144.5°F) for 30 minutes

Temperature Graph

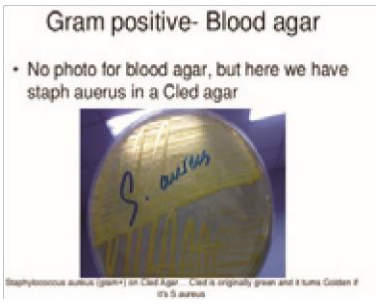
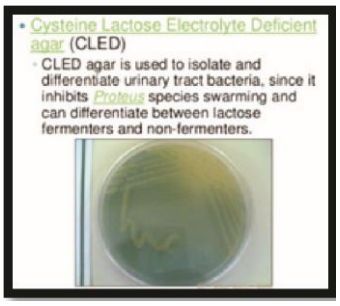
Storing of post pasteurized bottles

Microbiology Laboratory	
Area and built of room	⊙ The suggested area is 5.1m x 4.0m with glass doors. ⊙ The room should have a level II bio-safety cabinet and a level table with a Bunsen burner. ⊙ It should have adequate surface in room that is clean, well-lit, well-ventilated, and reasonably free of dust and drafts. ⊙ The microbial density of air in working area, measured in fallout pour plates taken during plating, should not exceed 15 colonies/plate during 15 min exposure.
Designated activity	⊙ Pre and Post-pasteurization milk testing is carried out here. ⊙ Post-pasteurisation milk sample is taken from test bottle identified per batch. Colony count is performed. ⊙ In case the milk sample tests positive as per norms, the batch of bottles from which this sample is collected should be discarded and proper documentation should be maintained along with back tracking of mothers. ⊙ All general safety measures of a microbiological laboratory should be followed.
In-charge	Microbiologist
Equipment in Microbiological Laboratory	

1. **Laminar flow cabinet** (Bio- safety cabinet) It is used in microbial inoculation and isolation studies as well as sterile storage of materials.	

Microbiology Laboratory	
2. **Refrigerator: 190 liters** This refrigerator is used for the storage of the stock solutions, chemicals, kits and nutrient media that should be maintained at certain temperatures.	
3. **Microscope with oil immersion lens**	
4. **Hot air oven** with temperature and time regulation.	
5. **Bunsen burner with Gas**	
6. **PH meter**	
7. **Lab Incubator**	
8. **Table top autoclave**	

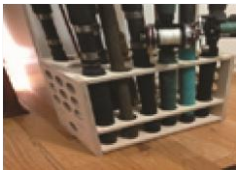
9. **water bath**	
10. **Shaker Incubator**	

Microbiology Laboratory	
11. **Media:** Agar, CLED agar media and MacConkey media CLED (cysteine-, lactose-, and electrolytedeficient) agar is a differential culture medium for use in isolating and enumerating bacteria. This is a valuable non-inhibitory growth medium used in the isolation and differentiation of urinary organisms and also of milk.	 
12. **Analytical balance**	
13. **Exhaust fan**	
14. **window 1 ton AC**	

Storage Area	
Area and built of room	⊙ The suggested area for this room is 4.4m x 6.0m.
Designated activities	⊙ Storage of post pasteurized and tested milk with separate space to store pre term and term milk ⊙ Regular temperature recording as per requirement ⊙ Dispensation of DHM by a counter/window
Equipment/Logistics	⊙ Refrigerator ⊙ Deep freezer with 24x7 power back up
In-charge	⊙ CLMC Technician/Lactation Support Staff
Equipment in Storage area	

1. **Vertical single door and Double door deep freezer** Milk storage room must have electrical point for running Two vertical –20°C freeze with voltage stabilizer and back up electrical supply. (Preferably double door) and One Vertical refrigerator for +2 to +4°C with voltage stabilizer Milk is stored in **deep freezer** at minus 20 degree. ⊙ First batch going inside the deep freezer should be the first batch coming out. ⊙ Milk kept in sealed bottles for dispensing: Dispense in a way that the earliest fortnight collected milk is dispensed first.	
2. A small 2 feet by 2 feet **steel table**	
3. A wall mounted **cupboard** for storing records along the entire wall	
4. Scrub station	
5. Air-condition Spit AC : 2 ton	
Sluice Room	
Area and built of room	⊙ The designated area should be 2.0m x 2.1m.
Designated activity	⊙ This room should contain a water reservoir with both inlet and outlet. ⊙ The water reservoir should be used to clean dirty mops, towel and other laundry before they're put in the washing machine.

Sluice Room	
	⊙ The ventilation system in the soiled utility/holding room should be engineered to have negative air pressure with air 100% exhausted to the outside. ⊙ Activities to be carried out in this room are: • Cleaning and washing. • Storing cleaning equipment and mobilizing to respective room.
Sluice room or Janitor room details with suggested equipment	
SLUICE RooM: 2 rooms or two parts of one big room	
1. **washing part:** This part of room will contain a water reservoir with both inlet and Outlet. Minimum dimension will be 4ft.wide x 3ft.front to back x 2ft. deep.	

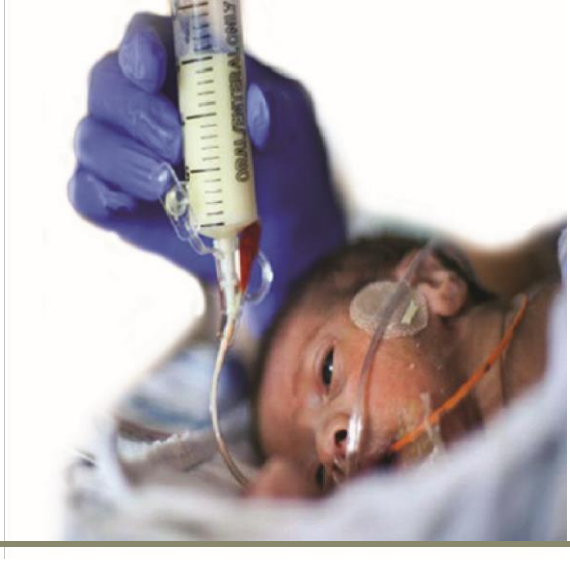
2. **Storage part:** It is the part of room for storage of clean mops, materials for cleaning, gloves and boots which are worn during cleaning. Other Housekeeping objects such as three bucket trolley should also be kept here.	
Details of cleaning equipment	
1. 2 bucket trolley with Mop Wringer with liquid detergent , soap and phenyl	
2. Broom and stick with bucket and dust pan	
3. Dust mop	
4. Magic mop set with 360° Rotating Pole & Steel Bucket preferably	
5. Janitor trolley with multiple function or **Multifunction Janitor** Cart :1) Bag Holder,2) Large Shelves, 3) Double Mop Bucket and Wringer.	
Sluice Room	
6. SS Room Dust Bins - 3L, made of stainless steel, covered, foot operated. At least 8 number and must be distributed in various places	
7. Water mop attached to a steel rod with mop replacement Effective and scientific way is to keep the mop in the reverse way along with handle Large Mop Upside Down Isolated on White	  

8. Window wiper	
9. **Microfiber cloth** for cleaning the floor (to be used with the mop handle) **Microfiber cloth** for *cleaning and mopping.* Microfibers are usually 0.9 or less deniers in diameter. For comparison a human hair is about 20 deniers, silk is about 4 deniers. Most microfiber cleaning cloths are made from split microfibers, which have even smaller strands; so small that they develop an atomic charge which attracts dirt and oils. This also means that their is more surface area in microfiber products which contributes to theirevaporative efficiency, i.e. they dry faster than any other fabric.	  
10. One Exhaust fan	
11. One ceiling fan within the sluice room.	
12. Folding laundry trolley for used linen and gown.	 
13. Proper dress with Rubber gloves and gum boots.	
14.Toilet cleaning would require separate rubber gloves and shoes along with toilet brushes and liquid cleaners as per hospital policy.	
15. Misc. Like squeeze, sponge, sponge mop, Bucket, scrub, Brush, garbage can color coded.	

APPENDIX

2

Scope of Work of CLMC & LMU Staff



FULL TIME POSITIONS

1. CLMC Manager: 1 Post

Job Description

- Promote, protect, and support breastfeeding.
- Support and promote the Comprehensive Lactation Management.
- In-charge of all staff of CLMC.
- Undertake rigorous supervision of all processes of CLMC and ensure quality assurance protocols are followed for safety of DHM.
- Microbiological surveillance.
- Supervise maintenance of all records (records for donors and recipients including consent forms, serological and microbiological test reports, milk dispensing and storage records).
- Provide inputs and decisions around dispensing of milk according to the protocols.
- Ensure the staff working in the CLMC are suitably trained and competent.
- Ensure there is adequate staff availability for the CLMC operations so that services are not compromised.
- Ensure communication with the team members on any contaminated milk/deviations.
- Aassessment of results, consult Paediatrician/Neonatologist in – charge of CLMC for taking decision on what to be done in case of any deviation from the protocols in any of the procedures.
- To maintain contact with the designated resource centre and key persons in the field for updating on safety measures and capacity building.
- *Qualification:* Graduate in Hospital Management.
- *Salary:* As per State norm
- (Indicative Salary: INR 30,000 per Month).

2. Lactation Support Staff (only female staff): 5 Posts

Job Description

- Promote, protect, and support breastfeeding.
- Support and Promote the Comprehensive Lactation Management.

- Routine rounds in postnatal ward, paediatric ward, SNCU including KMC ward for providing lactation support to mothers.
- Making mother aware regarding the CLMC facilities and motivating them to donate milk.
- Assist in recruiting and screening potential donors.
- Counselling mothers regarding breastfeeding and educating donors on milk expression techniques.
- Providing sterile gowns, sterile bottles, and tubing for breast pump to donors, facilitating and helping donors in milk expression.
- Would carry out cleaning and autoclaving of the equipment and ensure proper storage of milk collected at collection room and dispensing of milk.
- Bottle labelling and record keeping.
- In SNCU/KMC supervise nursing staff for thawing of milk, ensuring no refrigeration after thawing, following milk collection and dispensing safety protocols, maintaining cold chain.
- Documentation and record keeping.
- *Qualification:* Staff Nurse/Auxiliary Nurse Midwife.
- (Essential Pre-requisite of selection: Candidates who have completed three months of hands - on training in Lactation Management in an established CLMC and at end of training cleared a skilled based examination conducted at the designated training centres. This three months training is to be organized by State/District programme management unit).
- *Salary:* As per State norm. (Indicative Salary: INR 15,000 per Month).

3. CLMC Technician: One Post

Job Description

- Pooling of DHM
- Pasteurisation
- Storage of DHM
- Cleaning and maintaining all equipment that are used in the pasteurization process of milk and microbiological lab.
- Preparing and making labels and maintain records of pasteurization.
- *Qualification:* LT Diploma (DMLT) preferably with experience in microbiology.
- *Salary:* As per State norm (Indicative Salary: 18,000).

PART TIME POSITIONS

1. Microbiologist: 1 Post (Part Time)

Job Description

- Testing of pre/post-pasteurized milk samples and ensuring serology and record keeping of laboratory data.
- Periodic collection of water, air and surface swabs for bacterial culture.
- Relevant record keeping for the laboratory.
- *Qualification:* Masters in Microbiology (Pre-requisites: 10 days Training in Milk Cultures from designated training centre This 10 days training is to be organized by State/District programme management unit).
- *Salary:* As per State norm.

2. Hygiene Helper: 3 Post (Part Time)

Job Description

- Overall cleaning of the CLMC according to the protocols.
- Transporting DHM from well-baby clinic (if any) to CLMC premises.
- Transportation of dispensed DHM to NICU/SNCU/KMC.
- *Salary:* As per State norm.

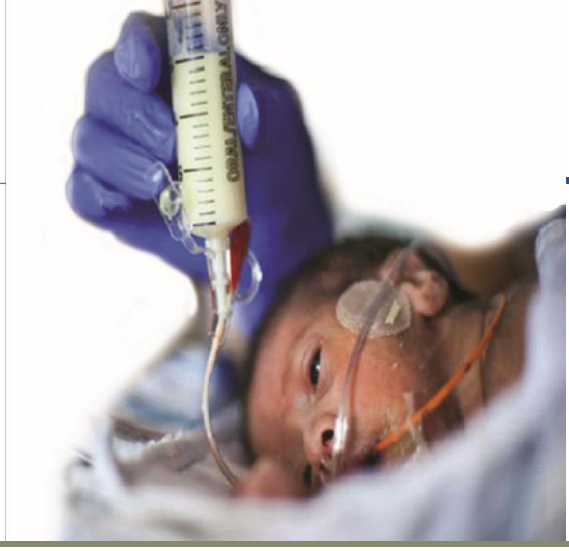
LMU

- **Name of The post:** Lactation Support Staff (Only female staff).
- **Number of Staff:** Two
- **Job Description:** Overall supervision of functioning of LMU. Routine rounds in SNCU including KMC ward for providing lactation support to mothers, motivating them to express milk and counselling. Facilitating and helping mothers in milk expression and providing sterile gowns, sterile bottles, and tubing for breast pump. Would carry out cleaning and autoclaving of the equipment and ensure proper storage and dispensing of milk, Bottle Labelling and record keeping.
- *Qualification:* ANM (Essential Pre-requisite of selection: Candidates who have completed three months of hands- on training in Lactation Management in an established CLMC and at end of training cleared a skilled based examination conducted at the designated training centres) *Salary:* As per state norm (indicative salary:15,000).

APPENDIX

3

Training Requirement



Facility based Lactation Management Training for CLMC Manager and Lactation Support Staff

Place of Training

CLMC, associated with a Special Newborn Care Unit and a Kangaroo Mother Care Unit located within a mother and child care hospital.

Trainees

CLMC Manager and Enthusiastic female nursing staff posted in SNCU or maternity wards associated with a Mother and child care hospital.

Trainers

Pediatricians having experience in lactation counseling and Facility based Lactation Management, Lactation counselors with previous experience.

Duration of training

5 days (40 hours) of structured and hands-on training session.

Batch size

6 - 12 participants in each batch

Overview of training structure

A separate guideline for conducting training for various categories of the staff needs to be prepared. A tentative schedule of minimum five days training needs to be chalked out. The knowledge and skills on areas like Anatomy and Physiology of breasts, importance of exclusive and supplementary breastfeeding, proficiency in understanding all the processes indicated in the guideline i.e. counselling, collection, storage, pasteurization, thawing, testing, dispensation and record keeping etc.

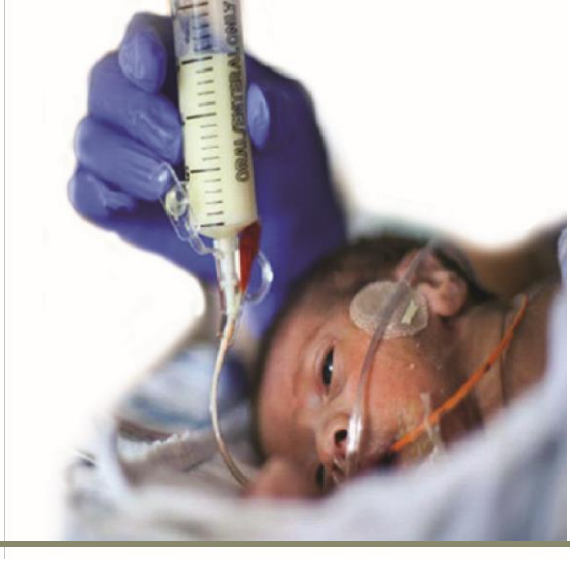
Other categories of the staff will also need to be oriented and trained in overall working of CLMC and also specific work assigned to them.

Training site should be one of the existing CLMC adhering and practicing the norms indicated in the guideline.

APPENDIX

4

Ensuring Quality in Lactation Management Centre Operations



I. National Quality Assurance Standards for Comprehensive Lactation Management Centre and Lactation Management Unit

A. Service Provision		CLMC	LMU
Standard A1	Services for promotion and adherence to early and exclusive breastfeeding are provided as per prevalent guidelines.	√	√
Standards A2	Services for collection, processing, storage and dispensing of Donor Human Milk are available.	√	
Standard A3	Services for expression, collection, storage and dispensing of mother's own milk are available.		√
B. Patient Rights			
Standard B1	There are no Physical , Informational or Financial barriers in availing the services.	√	√
Standard B2	Services are provided in dignified manner ensuring privacy & confidentiality as well as respecting societal and cultural preferences.	√	√
C. Inputs			
Standard C1	Lactation Management centre has adequate infrastructure and optimal layout for providing the mandated services.	√	√
Standard C2	Physical and fire safety measures have been implemented.	√	√
Standard C3	Adequate qualified and trained staff for rendering the mandated services are available.	√	√
Standard C4	Equipment and consumables for collection, processing and storage of Human milk are available as per defined norm and case load.	√	√
D. Support Services			
Standard D1	Maintenance and Upkeep processes are effectively implemented.	√	√
Standard D2	Procedures established for estimating the demand of donor human milk and maintaining the buffer stock to avoid stock out.	√	
Standard D3	Safe and comfortable environment is provided to donors and well as staff of lactation management centre.	√	√

Standard D4	Compliance to applicable statutory and legal requirements are ensured.	√	√

E. Clinical Services			
Standard E1	Procedures established as per guidelines for recruitment of Donors.	√ √	
Standard E2	Procedures established as per guidelines for screening of Donors.		
Standard E3	Implementation of optimal and scientific milk collection processes are ensured as per guidelines.	√	√
Standard E4	Labeling and pre-pasteurization storage of collected milk is done as per established protocols.	√	
Standard E5	Pooling and Aliquoting of milk is done as per established protocols.	√	
Standard E6	Pasteurization of Donor Human Milk is done as per protocol.	√ √	
Standard E7	Post Pasteurization testing of milk is done as per established protocol.		
Standard E8	Storage of pasteurized donor human milk is done as per established protocols.	√	
Standard E9	Established procedures for Intramural issue of Donor Human Milk.	√	
Standard E10	Optimal feeding practices are ensured in attached NICU/SNCU.	√	√
f. Infection Control			
Standard f1	Hand Hygiene and personal protection ensured during handling of Human Milk.	√	√
Standard f2	Sterility of processing and storage equipment are ensured.	√	√
Standard f3	Microbiological testing data are analyzed for improving the infection control practices.	√	
G. Quality Management			
Standard G1	Quality Policy and objectives have been defined and communicated to staff and users.	√	√
Standard G2	Hazard Analysis and Critical Control Point (HACCP) practices have been implemented as per guidelines.	√	√
Standard G3	Lactation management centre has documented and implemented Standard Operating Procedures.	√	√
Standard G4	Periodic review and Quality Improvement Processes are implemented.	√	√
H. outcome			
Standard H1	Key performance indicators (KPI) are measured.	√	√
Standard H2	Lactation management Centre strive to improve KPI and meet established benchmarks.	√	√

II. To ensure quality assurance at all steps, the day to day functioning of the CLMC and LMU should be based on HACCP principles. To develop an effective HACCP plan, the key CLMC staff including neonatologists, nurses, CLMC manager/technician, microbiologist, etc., should undergo mandatory training on HACCP. Consequently, SOPs should be laid down to prevent identified hazards from happening. These SOPs should clearly demonstrate identification of hazards, monitoring, trend analysis and establishment of corrective actions. In addition, the lactation management centres should continuously try to improve the

sanitary conditions of the premises and maintain proper hygiene.

Lactation Management Centre at health facilities should comply with the following:

Premises - maintenance and cleaning	⊙ The Lactation Management Centre should be located in a hygienic place and overall cleanliness should be maintained. All new units should be set-up away from environmentally polluted areas. ⊙ The interior area of the centre should have adequate space for all activities such as milk expressing, processing, storing etc. ⊙ The premise should be adequately lit, appropriately ventilated to maintain air quality so as to avoid aerial contamination of milk. ⊙ Floors, ceilings and walls should be smooth and easy to clean with no flaking paint or plaster. Floors should be cleaned with diluted phenyl/soap and water once every day and otherwise when required. Walls should be cleaned with standard disinfectant at least once a week. Dry mopping should not be permitted. ⊙ The floor and skirted walls should be washed as per requirement with an effective disinfectant to keep the premise free from insects. No spraying should be done during milk processing. It is preferable to use fly swats/flaps to kill flies. Windows and other openings should be fitted with net or screen to keep the premise insect free. ⊙ All equipment should be placed well away from walls to allow proper cleaning and inspection of the area. ⊙ The area should be free from any other equipment or item that is not part of the operation such as office files, stationary, old equipment etc. ⊙ All surfaces of pooling and pasteurising area should be cleaned with surface disinfectant before and after every use. ⊙ Door handles, switches etc. should be cleaned once a day with surface disinfectant. Lockers and drawers should be cleaned twice a week. ⊙ Dustbins should be washed daily with soap and water; polythene should be changed daily or if full earlier. ⊙ Hospital guidelines on biomedical waste management should be followed.
Water testing, supply and drainage	⊙ Water used in the operation should be potable and continuous supply should be ensured. In case of intermittent water supply, adequate water storage arrangement should be made. Chemical and bacteriological examination of the water should be done at regular intervals as recognized by the laboratories. ⊙ There should be an efficient drainage system and adequate provision for disposal of refuse. Drainage opening should be water-trap type so that no insects, flies or foul odour can enter the clean area from the drain.

Equipment maintenance and cleaning	⊙ Equipment and machinery should be of such design which permits easy cleaning. ⊙ The Lactation Management Centre should have adequate arrangement for cleaning of containers, tables, working parts of equipment etc. No vessel, container or equipment, the use of which is likely to cause metallic contamination injurious to health, should be employed to handle, pack or store human milk. ⊙ All equipment should be kept clean, washed, dried and stacked at the close of day to avoid growth of bacteria, mould, fungi or infestation. ⊙ The Lactation Management Centre should maintain a detailed manual of procedures. The procedure should be periodically reviewed and updated. All equipment manuals and user instructions of supplies should be available to the staff working in the centre, at all times. ⊙ Sterilization of all equipment and milk containers should be done according to manufacturer guidelines. ⊙ It is recommended that breast pumps parts should be sterilized by boiling. Breast pump used should be disassembled and washed thoroughly including small parts with detergent, rinsed well with warm water and then sterilized. ⊙ Autoclaves or hot air ovens, if used, should be monitored with physical and chemical indicators daily and with preferable biological indicators weekly. ⊙ Freezer temperatures should be recorded daily by a recording thermometer. The freezers should be equipped with temperature-sensitive alarms. ⊙ Storage and processing equipment should have scheduled maintenance checks and calibration as recommended by individual manufacturers. ⊙ Bio-safety cabinets or laminar air flow, if used, should undergo regular maintenance as per manufacturer's instructions for air flow, pressure gradient and HEPA filter efficiency.

Human resource	⊙ Eating, chewing, smoking, spitting and nose blowing should be prohibited within the premises. ⊙ All people working in operation should avoid wearing loose jewellery, glass items, false nails and other items that may fall into the milk. ⊙ Proper steps for hand hygiene should be practiced. Facility for hand wash with liquid soap and water should be available. Posters with pictures showing steps to hand washing should be displayed near all hand-washing areas for ready reference. Washing hands must not be done in sinks used for milk preparation or washing equipment. Hand-washing facilities should be kept in clean condition and good repair. ⊙ Staff in operational area should keep their finger nails trimmed, clean and wash their hands with soap and water and disinfect before commencing work. Scratching and touching of body parts, hair should be avoided during the operation. ⊙ Personal protective equipment including gloves, gown, cap and mask should be worn by the staff when handling milk, especially open containers, to prevent contamination of milk and milk contact surfaces such that: ⊙ Hair and beard is covered. ⊙ Sterile gloves are worn and changed between handling raw and pasteurised milk. ⊙ Clean cover gown, apron worn over clothing ⊙ Face mask is worn during milk handling. ⊙ Regular orientation on staff hygiene and equipment use should be provided for new staff or to entire staff when new equipment or supplies are purchased.

The list of accreditation bodies given by quality council of India for accredited quality certification is available here: http://www.qcin.org/nabcb/accreditation/reg_bod_qms.php.

APPENDIX

5

Equipment Specifications

Essential Equipments

1. Breast Pumps

MEDICAL DEVICE SPECIfICATIoN (Including information on the following where relevant/appropriate, but not limited to)		
Breast Pump		
Version no. :		1
Date:		Sept 2014.
Done by : (name/institution)		HCT/NHSRC
Name and Coding		
GMDN name		NA
GMDN code(s)		NA
General		
1. USE		
1.1	Clinical purpose	A breast pump is a device that extracts milk from the breasts of a lactating individual. Breast pump is an electrical devices powered by electricity or batteries.
1.2	Used by clinical department/ ward	NICU and PICU
Technical specifications for Hospital Grade Electric Breast Milk Pumps		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Pumping frequency 30 to 80 CPM and user adjustable. 2. Cushion inserted inside the breast cup so that it does not hurt the mother. 3. Suction Pressure 100 to 250 mm hg; user adjustable. 4. Able to express milk from both breasts simultaneously. 5. Collection bottles can be used for storage of milk. 6. Double alternating pumps/double cycling pumps. 7. Should be motorized breast pump units. 8. Should be hospital grade.
2.2	User's interface	Manual

MEDICAL DEVICE SPECIfICATIoN (Including information on the following where relevant/appropriate, but not limited to)		
2.3	Software and/or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	Portable
3.2	Weight (lbs, kg)	Compact unit (weight less than 4 kg)
3.3	Configuration	LCD/LED display suction timing
3.4	Noise (in dB)	<60db
3.5	Heat dissipation	NA
3.6	Mobility, portability	Yes
4 ENERGY SoURCE (electricity, UPS, solar, gas, water, Co_2 ....)		
4.1	Power Requirements	220-240 V AC + 10%, 50-60Hz power supply; 5A plug; TYPE D
4.2	Battery operated	NA YES (OPTIONAL).
4.3	Tolerance (to variations, shutdowns)	± 10% of input AC.
4.4	Protection	Electrical protection by reset table over current breakers or replaceable fuses.
5. ACCESSoRIES, SPARE PARTS, CoNSUMABLES		
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Reusable collection bottles along-with breast cups - 10 sets. 2. All kinds of tubes - 12 sets (if applicable). 3. Breast pump Valve and Membrane (Pack of 4 Valves and 2 membranes) 25 No. 4. Other accessories required for optimum functioning of the equipment.
Bidding/Procurement Terms/Donation Requirements		
6. ENVIRoNMENTAL AND DEPARTMENTAL CoNSIDERATIoNS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust ...)	1. Operating condition: Capable of operating continuously in ambient temperature of 10 to 40°C and relative humidity of 15 to 90% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50°C and relative humidity of 15 to 90%.
6.2	User's care, Cleaning, Disinfection and Sterility issues	1. Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAfETY		
7.1	Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CE (EU)/FDA (US) approved product. 2. Manufacturer/supplier should have ISO 13485 certificate for quality standard. 3. Electrical safety conforms to standards for electrical safety IEC-60601-1; IEC 60601-1-11; IEC 60601-3-2; IEC 60601-3-3; IEC 60601-4-2; IEC 60601-4-4; IEC 60601-4-5; IEC 60601-4-8; IEC 60601-4-11.

8 TRAINING AND INSTALLATIoN		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Supplier to perform installation, safety and operation checks before handover.
8.2	Requirements for sign-off	Certificate of calibration and inspection from the factory.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.

MEDICAL DEVICE SPECIfICATIoN (Including information on the following where relevant/appropriate, but not limited to)		
9. wARRANTY AND MAINTENANCE		
9.1	Warranty	3 years
9.2	Maintenance tasks	Maintenance manual detailing complete maintaining schedule.
9.3	Service contract clauses, including prices	1. Warranty of three years with free servicing (min. 3) during warranty. 2. AMC rates should not be greater than 3% of original cost.
10. DoCUMENTATIoN		
10.1	Operating manuals, service manuals, other manuals	1. User and maintenance manuals to be supplied in English. 2. Certificate of calibration and inspection to be provided. 3. List to be provided of equipment and procedures required for local calibration and routine maintenance. 4. List to be provided of important spares and accessories, with their part numbers and cost. 5. Contact details of manufacturer, supplier and local service agent to be provided.
10.2	Recommendations for maintenance	User/Technical/Maintenance manuals to be supplied in English.
11. NoTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning signs would be adequately displayed.

2. MILK CONTAINERS

MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)	
Milk Container	
Version no. :	1
Date:	JULY 2016.
Done by : (name/institution)	HCT/NHSRC
Name and Coding	
GMDN name	NA
GMDN code(s)	NA
GENERAL	
1. USE	
1.1 Clinical purpose	Milk container is required for collection and storing the milk.
1.2 Used by clinical department/ ward	NICU and PICU

Technical		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Milk containers of 3 sizes—50 ml, 100 ml, 200 ml; 50 of each size. 2. Milk containers are of two types: a. Polypropylene BPA free b. Glass Containers

MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)		
2.2	User's interface	Manual
2.3	Software and/or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	Portable
3.2	Weight (lbs, kg)	Compact unit
3.3	Configuration	NA
3.4	Noise (in dB)	NA
3.5	Heat dissipation	NA
3.6	Mobility, portability	Yes
4. ENERGY SoURCE (electricity, UPS, solar, gas, water, Co_2 ....)		
4.1	Power Requirements	NA
4.2	Battery operated	NA
4.3	Tolerance (to variations, shutdowns)	NA
4.4	Protection	
4.5	Power consumption	
5. ACCESSoRIES, SPARE PARTS, CoNSUMABLES		
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
Bidding/Procurement Terms/Donation Requirements		
6. ENVIRoNMENTAL AND DEPARTMENTAL CoNSIDERATIoNS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust ...)	NA

6.2	User's care, Cleaning, Disinfection and Sterility issues	Disinfection: MILK CONTAINER should be easy to clean and autoclave.
7. STANDARDS AND SAfETY		
7.1	Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/ or international	1. The material of construction should be of food grade.
8. TRAINING AND INSTALLATIoN		
8.1	Pre-installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)		
9. wARRANTY AND MAINTENANCE		
9.1	Warranty	1 year
9.2	Maintenance tasks	NA
9.3	Service contract clauses, including prices	NA
10. DoCUMENTATIoN		
10.1	Operating manuals, service manuals, other manuals	1. User manuals to be supplied in English/Hindi. 2. Certificate of calibration and inspection to be provided.
10.2	Recommendations for maintenance	1. All the rigid containers may be re-used but have to be washed preferably in a bottle washer or and sterilized appropriately. 2. Glass containers should be checked for chipping after every cleaning cycle.
11. NoTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	NA
11.2	Recommendations or warnings	NA

3. PASTEURIZER

MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)		
Version no.:		1.0
Date:		6/4/2016

Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Milk Pasteuriser
GMDN code(s)		NA
General		
1. USE		
1.1	Purpose	The purpose of the pasteuriser is to destroy pathogenic bacteria from milk and makes it safe for storage and consumption.
1.2	Used by	The machine is to be used in human milk banks.
Technical		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Inner and outer jacket made of stainless steel 304 grade 2. Easy to operate & handle. 3. Standard motor and gear box. 4. Outlet valve S.S.304 with TC clamp. 5. High speed stirrer for mixing. 6. Capacity for heating a minimum of 16 samples of milk with each sample jar not less than 330 cc volume. 7. Tank insulated glass wood. 8. Temperature gauge for showing temperature.

MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)		
		9. Rotation Controller regulator having varying speed from 10 to 100 rotations per minute. 10. Having jack-up facility for emptying and discharge without lifting the unit.
2.2	User's interface	Semi-automatic

2.3	Product Safety Features	1. Pasteurizer should be equipped with system that can heat the milk up to 63°C with sensitivity of ± 0.5°C with minimum fluctuation of temperature. 2. Equipment should have a holding arrangement for containers of milk immersed in water till the maximum level of milk in heating and/or cooling medium sufficient to give uniform heating and/or cooling to the milk. In no case, the bottles or containers to completely get immersed in water. The holder should have shaking arrangement sufficient to maintain the uniform temperature of milk and not to splash the milk inside the container. 3. The heating cycle should be designed in such a way that the milk receives desired temperature of 62.5°C and held for 30 minutes. 4. After completion of heating and holding, the temperature of milk is uniformly brought down to 25°C within 10minutes and further reduced to 4°C. 5. The heating medium should not have temp higher than 64°C ± 1 in order to avoid over heating of milk and minimize nutrient loss. 6. The pasteurizer should be equipped with data logging and storage, data analysis and generation of final report in various formats for effective analysis and corrective actions. 7. The water holding tank of pasteurizer should be self-drain type. 8. In case of fully automatic machine, there should be an audible alarm after completion of heating cycle and different alarm at end of cooling cycle. Later alarm should continue frequently till it is attended by an operator. 9. In case of semi-automatic equipment, it should have the following alarm systems: a After achieving set temperature. b Three minutes before completion of holding time for warning. c At the completion of holding time. d Achieving cooling set temperature (4°C) from 62.5°C in maximum 30 minutes. e Data logging system to record and retrieve all the data for analysis, evaluation and corrective action in appropriate formats to detect deviation. f Automatic water level maintenance in heating and cooling shaker bath. 10. In case of power failure a battery backup may be provided for continuous digital display of temperature of the pasteurizer.
2.4	Software and/or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	
3.2	Weight (lbs, kg)	
3.3	Configuration	

MEDICAL DEVICE SPECIfICATIoN
(Including Information on the following where relevant/appropriate, but not limited to)

3.4	Noise (in dB)	Audible beeper of minimum 65 dB
3.5	Heat dissipation	Inbuilt temperature control module
3.6	Mobility, portability	
4. ENERGY SoURCE (electricity, UPS, solar, gas, water, Co_2 ....)		
4.1	Power Requirements	Power Supply: 220 Volts
4.2	Battery operated	No
4.3	Tolerance (to variations, shutdowns)	Tolerance for 10% voltage fluctuations
4.4	Protection	Earthing for installation site, fuse for the machine
4.5	Power consumption	A maximum of 2.5 KW/Hr
5. ACCESSoRIES, SPARE PARTS, CoNSUMABLES		
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	List of all accessories, spare parts and consumables with rates and commitment of availability till the end life of the machine to be shared by the supplier.
Bidding/Procurement Terms/Donation Requirements		
6. ENVIRoNMENTAL AND DEPARTMENTAL CoNSIDERATIoNS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust ...)	1. Operating condition: Capable of operating continuously in ambient temperature of 10 to 50°C and relative humidity of 15 to 90% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50°C and relative humidity of 15 to 90%.
6.2	User's care, Cleaning, Disinfection and Sterility issues	To be detailed by the manufacturer.
7. STANDARDS AND SAfETY		
7.1	Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/ or international	1. Should be FDA/CE/BIS approved product. 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements.
8. TRAINING AND INSTALLATIoN		
8.1	Pre-installation requirements: nature, values, quality, tolerance	1. Availability of 15-amp socket. 2. Safety and operation check before handover.
8.2	Requirements for sign-off	Certificate of calibration and inspection from the manufacturer.
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance at least for two weeks. 2. Advanced maintenance tasks required shall be documented.
9. wARRANTY AND MAINTENANCE		

9.1	Warranty	3 years
9.2	Maintenance tasks	To be included in State Equipment Maintenance Program.
9.3	Service contract clauses, including prices	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached.
MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)		
10. DoCUMENTATIoN		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals to be supplied in English/ Hindi language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals (original and copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection. 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Recommendations for maintenance	List of important spares and accessories, with their part numbers and cost.
11. NoTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	1. Contact details of manufacturer, supplier and local service agent to be provided. 2. Any Contract (AMC/CMC/ad-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning signs would be adequately displayed.

4. LAMINAR AIR FLOW

MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)		
Version no.:		1.0
Date:		JULY 2016
Done by : (name/institution)		HCT/NHSRC
Name and Coding		
GMDN name		Laminar Air Flow
GMDN code(s)		NA
General		
1. USE		

1.1	Purpose	Laminar air flows are used to maintain a working area devoid of contaminants. Laminar Flow Cabinets create particle-free working environment by projecting air through a filtration system and exhausting it across a work surface in a laminar or uni-directional air stream. They provide an excellent clean air environment for a number of laboratory requirements.
1.2	Used by	Microbiology Technician
Technical		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	⊙ Working area: 4 x 2 x 2 feet. ⊙ Hepa Filter efficiency 99.99% for .3u particle or better. ⊙ Cleanliness: Class 100 ⊙ Particle retention: 0.3 micron. ⊙ Illumination > 700 LUX. ⊙ Noise level < 66 dB

MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)		
		⊙ Power supply: 220/240 V Single phase, 50 Hz AC. ⊙ Vertical Airflow. ⊙ Stainless Steel (Type 304) Construction. ⊙ Two glass outlet in working Area; one on each side wall. Pre mounted UV Lamp (30w) with separate switch.
2.2	User's interface	Semi-automatic
2.3	Product Safety Features	NA
2.4	Software and/or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Configuration	NA
3.4	Noise (in dB)	NA
3.5	Heat dissipation	NA
3.6	Mobility, portability	FIXED
4. ENERGY SoURCE (electricity, UPS, solar, gas, water, Co_2 ....)		
4.1	Power Requirements	Power Supply: 220/240 V Single Phase,50-60Hz AC.
4.2	Battery operated	No
4.3	Tolerance (to variations, shutdowns)	Tolerance for 10% voltage fluctuations.
4.4	Protection	Earthing for installation site, fuse for the machine.
4.5	Power consumption	NA

5. ACCESSoRIES, SPARE PARTS, CoNSUMABLES		
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. A spare UV Lamp (30w) - 2 Nos. 2. Hepa Filter for Chamber- 1 nos. 3. Gas Burner (Bunsen burner) - 2 nos.
Bidding/Procurement Terms/Donation Requirements		
6. ENVIRoNMENTAL AND DEPARTMENTAL CoNSIDERATIoNS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust ...)	Operating condition: Capable of operating continuously in ambient temperature of 10 to 50°C and relative humidity of 15 to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection and Sterility issues	To be detailed by the manufacturer.
7. STANDARDS AND SAfETY		
7.1	Certificates (pre-market, sanitary, ...); Performance and safety standards (specific to the device type); Local and/or international.	1. Should be FDA/CE/BIS approved product. 2. Manufacturer and supplier should have ISO 13485 certification for quality standards. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements.
8. TRAINING AND INSTALLATIoN		
8.1	Pre-installation requirements: nature, values, quality, tolerance	1. Availability of 15-amp socket; (TYPE D). Safety and operation check before handover.
MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)		
8.2	Requirements for sign-off	Certificate of calibration and inspection from the manufacturer.
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance at least for two weeks. Advanced maintenance tasks required shall be documented.
9. wARRANTY AND MAINTENANCE		
9.1	Warranty	3 years
9.2	Maintenance tasks	To be included in State Equipment Maintenance Program.
9.3	Service contract clauses, including prices	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached.
10. DoCUMENTATIoN		

10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hardcopy and soft-copy) of: 1. User, technical and maintenance manuals to be supplied in English/ Hindi language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals (original and copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection. Satisfactory certificate for any existing installation from government hospital.
10.2	Recommendations for maintenance	List of important spares and accessories, with their part numbers and cost.
11. NoTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	1. Contact details of manufacturer, supplier and local service agent to be provided. Any Contract (AMC/CMC/ad-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	2. NA

5. REFRIGERATOR

MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)		
Version no. :		1.0
Date:		July 6, 2016
Done by : (name/institution)		HCT/NHSRC
Name and Coding		
GMDN name		Refrigerator
GMDN code(s)		NA
General		
1. USE		
1.1	Purpose	A device which is artificially kept cool and used to store food and drink.
1.2	Used by	All Departments.

MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)
Technical
2. TECHNICAL CHARACTERISTICS

2.1	Technical characteristics (specific to this type of device)	1. Should be frost free Refrigerator. 2. Should have a capacity of 300L. 3. Should have EEC 4-star rating or above. Should have inbuilt protection for voltage fluctuation or to be supplied with external stabilizer of adequate KVA capacity.
2.2	User's interface	Automatic/Semi-Automatic
2.3	Product Safety Features	Continuous recording for full traceability
2.4	Software and/or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	Dimension of internal self and weight carrying capacity will be defined locally Shelving should be compatible with the size of bottle.
3.2	Weight (lbs, kg)	NA
3.3	Configuration	Refrigerator only without freezer component
3.4	Noise (in dB)	NA
3.5	Heat dissipation	Inbuilt temperature control module.
3.6	Mobility, portability	
4. ENERGY SoURCE (electricity, UPS, solar, gas, water, Co_2 ....)		
4.1	Power Requirements	Power Supply: 220-240Vac, 50-60HZ Power Supply.
4.2	Battery operated	No
4.3	Tolerance (to variations, shutdowns)	Tolerance for 10% voltage fluctuations.
4.4	Protection	Earthing for installation site, fuse for the machine.
4.5	Power consumption	NA
5. ACCESSoRIES, SPARE PARTS, CoNSUMABLES		
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	List of all accessories, spare parts and consumables with rates and commitment of availability till the end life of the machine to be shared by the supplier.
Bidding/Procurement Terms/Donation Requirements		
6. ENVIRoNMENTAL AND DEPARTMENTAL CoNSIDERATIoNS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust ...)	1. Operating condition: Capable of operating continuously in ambient temperature of 0 to 50°C and relative humidity of 15 to 90% in ideal circumstances. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50°C and relative humidity of 15 to 90%.

6.2	User's care, Cleaning, Disinfection and Sterility issues	To be detailed by the manufacturer
MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)		
7. STANDARDS AND SAfETY		
7.1	Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type);Local and/or international	1. All the electrical and measuring devices of CE standard. 2. All electrical cables & connections will be fire and chemical resistant.
8. TRAINING AND INSTALLATIoN		
8.1	Pre-installation requirements: nature, values, quality, tolerance	1. Availability of 15-amp socket; (TYPE D). 2. Safety and operation check before handover.
8.2	Requirements for sign-off	Certificate of calibration and inspection from the manufacturer.
8.3	Training of staff (medical, paramedical, technicians)	NA
9. wARRANTY AND MAINTENANCE		
9.1	Warranty	3 years but 5 years on compressor
9.2	Maintenance tasks	To be included in State Equipment Maintenance Program
9.3	Service contract clauses, including prices	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached.
10. DoCUMENTATIoN		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hardcopy and soft-copy) of: 1. User, technical and maintenance manuals to be supplied in English/ Hindi language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals (original and copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Satisfactory certificate for any existing installation from government hospital.
10.2	Recommendations for maintenance	List of important spares and accessories, with their part numbers and cost.
11. NoTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	1. Contact details of manufacturer, supplier and local service agent to be provided. 2. Any Contract (AMC/CMC/ad-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	3. Any warning signs would be adequately displayed.

6. DEEP FREEZER

MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)		
Version no. :		1.0
Date:		July 6, 2016
Done by : (name/institution)		HCT/NHSRC
Name and Coding		
GMDN name		Deep Freezer

MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)		
GMDN code(s)		NA
General		
1	USE	
1.1	Purpose	A vertical deep freezer to store the milk
1.2	Used by	The machine is to be used in human milk banks.
Technical		
2 TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	⊙ 250L hard top double door (preferred) with hinges, lockable preferred. ⊙ Manage temperature between –20°C to –22°C ⊙ Capacity to cool 15 litres water in assorted sizes (50 to 200 ml plastic/glass bottles) at 10°C to –20° C in 24 hours ⊙ PUF insulated steel sheet sandwich construction ⊙ Provision to fix 5 baskets to store bottles. ⊙ Freezer should be lockable. ⊙ Audio Visual high and Low temperature alarms. ⊙ Stainless Steel Interior. ⊙ Castors free easy mobility. ⊙ Compatible Voltage Stabilizer (2 kVA) of standard Brands/ISI Mark. ⊙ Temp. Thermostat regulator. ⊙ Temp. Indicator Lamp. ⊙ Digital temperature control and LED door display and systems monitoring and reporting technology. ⊙ Epoxy covered SS metallic e external case. ⊙ Strong, moulded, chemically resistant abs interior. ⊙ The height between two sliding racks should be approximately 15 cm with proper provision to hold milk bottles of 50-200 ml
2.2	User's interface	Automatic/Semi-Automatic

2.3	Product Safety Features	1. Automatic control of temperature. 2. Automatic flow diversion. Continuous recording for full traceability.
2.4	Software and/or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Configuration	NA
3.4	Noise (in dB)	NA
3.5	Heat dissipation	Inbuilt temperature control module
3.6	Mobility, portability	
4. ENERGY SoURCE (electricity, UPS, solar, gas, water, Co_2 ....)		
4.1	Power Requirements	Power Supply: 220-240Vac, 50-60HZ Power Supply.
4.2	Battery operated	No

MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)		
4.3	Tolerance (to variations, shutdowns)	Tolerance for 10% voltage fluctuations.
4.4	Protection	Earthing for installation site, fuse for the machine.
4.5	Power consumption	NA
5. ACCESSoRIES, SPARE PARTS, CoNSUMABLES		
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	NA
Bidding/Procurement Terms/Donation Requirements		
6. ENVIRoNMENTAL AND DEPARTMENTAL CoNSIDERATIoNS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust ...)	Operating condition: Capable of operating continuously in ambient temperature of 0 to 50°C and relative humidity of 15 to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection and Sterility issues	To be detailed by the manufacturer. To be installed 1 ft. away from the wall.
7. STANDARDS AND SAfETY		

7.1	Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/ or international	1. All the electrical and measuring devices of CE standard. 2. All electrical cables and connections will be fire and chemical resistant.
8. TRAINING AND INSTALLATIoN		
8.1	Pre-installation requirements: nature, values, quality, tolerance	1. Availability of 15-amp socket; (TYPE D). Safety and operation check before handover.
8.2	Requirements for sign-off	Certificate of calibration and inspection from the manufacturer
8.3	Training of staff (medical, paramedical, technicians)	NA
9. wARRANTY AND MAINTENANCE		
9.1	Warranty	3 years or 5 years on compressor
9.2	Maintenance tasks	To be included in State Equipment Maintenance Program.
9.3	Service contract clauses, including prices	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached.
10. DoCUMENTATIoN		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hardcopy and soft-copy) of:- 1. User, technical and maintenance manuals to be supplied in English/ Hindi language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals (original and copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Satisfactory certificate for any existing installation from government hospital.
10.2	Recommendations for maintenance	List of important spares and accessories, with their part numbers and cost
MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)		
11. NoTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	1. Contact details of manufacturer, supplier and local service agent to be provided. 2. Any Contract (AMC/CMC/ad-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning signs would be adequately displayed.

7. HOT AIR OVEN

MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)	
Version no. :	1.0

Date:		July 6, 2016
Done by : (name/institution)		HCT/NHSRC
Name and Coding		
GMDN name		HOT AIR OVEN
GMDN code(s)		NA
General		
1. USE		
1.1	Purpose	Hot air ovens are electrical devices which use dry heat to sterilize. They can be operated using a thermostat to control the temperature. Their double walled insulation keeps the heat in and conserves energy, the inner layer being a poor conductor and outer layer being metallic. There is also an air filled space in between to aid insulation. An air circulating fan helps in uniform distribution of the heat. These are fitted with the adjustable wire mesh plated trays or aluminium trays and may have an on/off rocker switch, as well as indicators and controls for temperature and holding time.
1.2	Used by	The machine is to be used in human milk banks/laboratories.
Technical		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device) Temp Required 121°C	1. Should be operated on 230V, 50Hz single phase AC supply and having temperature ranging between 50–200ºC. 2. Should be made of double walled chamber -Inner made of stainless steel SS 304 grade and powder coated outer surface. 3. Should provide with three heating elements on three sides of the equipment for uniform temperature on all shelves. 4. Should be provided with air circulating fan. 5. Should provide with a variable microprocessor based digital temperature controller with digital display and thermometer should be provided separate. 6. Should have a minimum chamber size of (LxBxH) 450x450x450 with 2 stainless steel trays with holes. 7. Should provide with air ventilations.
2.2	User's interface	Automatic/Manual
2.3	Product Safety Features	⊙ Hot air oven making use of dry heat for sterilizing of articles. ⊙ Features thermostat based controls for temperature. ⊙ Digitally controlled interface for maintaining of the temperatures.

MEDICAL DEVICE SPECIfICATIoN
(Including Information on the following where relevant/appropriate, but not limited to)

		⊙ Features double-walled construction. ⊙ System designed to hold in heat as well as bring reduction in energy output. ⊙ Double walled construction with inside from stainless steel as well as outside made available in mild steel finish. ⊙ Superior quality enamel paint as well as glass wool insulation support provided between two walls that provides for maximum thermal efficiency. ⊙ Silent hot air blower support that provides for uniform air movement as well as improved temperature distribution. ⊙ Featuring polished 304 grade stainless steel interior that provides for corrosion resistant usage as well as long lasting operation support. ⊙ Thermostat based safety device support. ⊙ Digital temperature controller cum indicator support.
2.4	Software and/or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Configuration	NA
3.4	Noise (in dB)	NA
3.5	Heat dissipation	Inbuilt temperature control module.
3.6	Mobility, portability	
4. ENERGY SoURCE (electricity, UPS, solar, gas, water, Co_2 ....)		
4.1	Power Requirements	Power Supply: 220-230Vac, 50HZ Power Supply.
4.2	Battery operated	No
4.3	Tolerance (to variations, shutdowns)	Tolerance for 10% voltage fluctuations.
4.4	Protection	Earthing for installation site, fuse for the machine.
4.5	Power consumption	NA
5. ACCESSoRIES, SPARE PARTS, CoNSUMABLES		
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
Bidding/Procurement Terms/Donation Requirements		
6. ENVIRoNMENTAL AND DEPARTMENTAL CoNSIDERATIoNS		

6.1	Atmosphere/Ambiance (air conditioning, humidity, dust ...)	NA
6.2	User's care, Cleaning, Disinfection and Sterility issues	To be detailed by the manufacturer
MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)		
7. STANDARDS AND SAfETY		
7.1	Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/ or international	1. All the --electrical and measuring devices of CE standard. 2. All electrical cables and connections will be fire and chemical resistant.
8. TRAINING AND INSTALLATIoN		
8.1	Pre-installation requirements: nature, values, quality, tolerance	1. Availability of 15-amp socket; (TYPE D). 2. Safety and operation check before handover.
8.2	Requirements for sign-off	Certificate of calibration and inspection from the manufacturer.
8.3	Training of staff (medical, paramedical, technicians)	NA
9. wARRANTY AND MAINTENANCE		
9.1	Warranty	3 years
9.2	Maintenance tasks	To be included in State Equipment Maintenance Program.
9.3	Service contract clauses, including prices	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached.
10. DoCUMENTATIoN		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hardcopy and soft-copy) of:- 1. User, technical and maintenance manuals to be supplied in English/ Hindi language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals (original and copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Satisfactory certificate for any existing installation from government hospital.
10.2	Recommendations for maintenance	List of important spares and accessories, with their part numbers and cost;
11. NoTES		

11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	1. Contact details of manufacturer, supplier and local service agent to be provided. 2. Any Contract (AMC/CMC/ad-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning signs would be adequately displayed.

8. AUTOCLAVE

fLASH STERILIzER wITH TRoLLEY	
Version no.:	1
Date:	5/12/2014
Done by: (name/institution)	HCT/NHSRC

fLASH STERILIzER wITH TRoLLEY		
Name and Coding		
GMDN name		Flash Sterilizer with trolley
GMDN code		NA
General		
1. USE		
1.1	Clinical purpose	Used for sterilization of unwrapped equipment at 132°C for three to ten minutes using steam.
1.2	Used by clinical department/ ward	Operation Theatre
Technical		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. 18–23 litres table-top model. 2. No utility connection other than drainage and electricity. 3. In-built dryer. 4. Constructed of 304 or 316 stainless steel 5. Automatic cycle control with printer
2.2	User's interface	Manual
2.3	Software and/or standard of communication (wherever required)	Stages should be displayable.
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	As per capacity
3.2	Weight (lbs, kg)	Max:900 gm
3.3	Capacity	18 to 20 litre
3.4	Noise (in dBA)	Noise-free

3.5	Heat dissipation	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism
3.6	Mobility, portability	Table with castors and brakes
4. ENERGY SoURCE (electricity, UPS, solar, gas, water, Co_2...)		
4.1	Power Requirements	Recharging unit: Input voltage- 220V-240V AC, 50Hz
4.2	Battery operated	Yes
4.3	Tolerance (to variations, shutdowns)	NA
4.4	Protection	Earthing for installation site, fuse for the machine.
4.5	Power consumption	NA
5. ACCESSoRIES, SPARE PARTS, CoNSUMABLES		
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	1. Trays-2 nos
Bidding/Procurement Terms/Donation Requirements		
6. ENVIRoNMENTAL AND DEPARTMENTAL CoNSIDERATIoNS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust...)	1. Operating condition: Capable of operating continuously in ambient temperature of 10 to 40°C and relative humidity of 15 to 90% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50°C and relative humidity of 15 to 90%.

fLASH STERILIzER wITH TRoLLEY		
6.2	User's care, Cleaning, Disinfection & Sterility issues	1. Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required.
7. STANDARDS AND SAfETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/ or international	1. Should be FDA/CE/BIS approved product. 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements (or equivalent BIS Standard) 4. Shall meet internationally recognised for Electromagnetic Compatibility (EMC) for electromedical equipment: 61326-1. 5. Certified to be compliant with IEC 61010-1 ,IEC 61010-2-40 for safety.
7.2	Local and/or international	Manufacturer/supplier should have ISO 13485 certificate for quality standard.
8. TRAINING AND INSTALLATIoN		

8.1	Pre-installation requirements: nature, values, quality, tolerance	1. Availability of 15 amp socket. 2. Safety and operation check before handover.
8.2	Requirements for sign-off	Certificate of calibration and inspection from the manufacturer.
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance. 2. Advanced maintenance tasks required shall be documented.
9. wARRANTY AND MAINTENANCE		
9.1	Warranty	3 years
9.2	Mantenance tasks	1. Maintenance manual detailing. 2. Complete maintenance schedule.
9.3	Service contract clauses, including prices	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached.
10. DoCUMENTATIoN		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hardcopy and soft-copy) of: 1. User, technical and maintenance manuals to be supplied in english/ hindi language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals (original and copy) to be provided; 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection.
10.2	Other accompanying documents	List of important spares and accessories, with their part numbers and cost;
11. NoTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided. Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning signs would be adequately displayed.

9. ICE BOX WITH COLD GEL PACK

MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)	
Version no. :	1.0
Date:	July 6, 2016
Done by : (name/institution)	HCT/NHSRC
Name and Coding	
GMDN name	Ice box with cold gel pack.
GMDN code (s)	NA
General	

1. USE		
1.1	Purpose	Ice box is portable air conditioning system without the need of electrical power. It is used with cold gel packs to maintain the cold chain of milk during the transport.
1.2	Used by	The ice box is to be used in CLMCs.
Technical		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Insulated box for refrigerated samples: Insulated box made of PVC or HDPE with minimum 3 mm inner & outer wall thickness with insulation of polyurathine foam having foam density of 38-42 Kg/ cubic metre. The product stored at 4°C should not rise by more than 1°C in 24 hours at ambient temp of 40°C. The box should pass the drop test of 1.5 metre. 2. Insulated box for frozen samples: Insulated box made of PVC or HDPE with minimum 3 mm inner & outer wall thickness with insulation of polyurathine foam having Foam Density of 38-42 Kg/ Cubic Meter. The product stored at -18°C temp should not rise by more than 1°C in 24 hours at ambient temp of 40°C. The box should pass the drop test of 1.5 metre.
2.2	User's interface	Manual
2.3	Product Safety Features	
2.4	Software and/or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	10" x 13" x 18"
3.2	Weight (lbs, kg)	10 lbs
3.3	Configuration	NA
3.4	Noise (in dBA)	NA
3.5	Heat dissipation	NA
3.5	Mobility, portability	
4. ENERGY SoURCE (electricity, UPS, solar, gas, water, Co_2 ....)		
4.1	Power Requirements	NA
4.2	Battery operated	No
4.3	Tolerance (to variations, shutdowns)	NA

MEDICAL DEVICE SPECIfICATIoN (Including Information on the following where relevant/appropriate, but not limited to)		
4.4	Protection	NA
4.5	Power consumption	NA

5. ACCESSoRIES, SPARE PARTS, CoNSUMABLES		
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
Bidding/Procurement Terms/Donation Requirements		
7. ENVIRoNMENTAL AND DEPARTMENTAL CoNSIDERATIoNS		
7.1	Atmosphere/Ambiance (air conditioning, humidity, dust ...)	NA
7.2	User's care, Cleaning, Disinfection and Sterility issues	To be detailed by the manufacturer.
7.3	Standards and Safety	
7.4	Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/ or international	Insulation thickness should be minimum 50 mm.
8. TRAINING AND INSTALLATIoN		
8.1	Pre-installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Certificate of inspection from the manufacturer.
8.3	Training of staff (medical, paramedical, technicians)	NA
9. wARRANTY AND MAINTENANCE		
9.1	Warranty	NA
9.2	Maintenance tasks	To be included in State Equipment Maintenance Program
9.3	Service contract clauses, including prices	NA
10. DoCUMENTATIoN		
10.1	Operating manuals, service manuals, other manuals	User manuals to be supplied in English/Hindi.
10.2	Recommendations for maintenance	NA
11. NoTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	NA

11.2	Recommendations or warnings	NA

10. OTHER EQUIPMENT SPECIFICATIONS

A. SHAKER WATER BATH

fUNCTIoN

Bottles/containers filled with liquid/fluid will be submerged in the water bath chamber of the instrument. The temperature of water bath can be controlled at a particular temperature as well as the shaker speed can also be controlled at a particular speed to maintain a uniform temperature at every parts of the bottle fluid.

SPECIfICATIoNS

- It will contain a micro-processor controlled temperature regulator, an electronic timer device and a shaker speed controller.
- The temperature of water bath can be maintained at 62.5 degree Centigrade during the process by adjusting the micro-processor controlled temperature regulator.
- It should have a digital temperature indicator showing the bath temperature.
- There should be a system with which the shaker speed can be controlled.
- The bath chamber must accommodate at least 12–15 polypropylene-make bottles of height 10 cm and 5.5 cm diameter.
- Bottles will be submerged during the process; the water level can be adjusted manually.
- The bottles can be placed on removable stainless steel tray houses and fitted with lotus clamps.
- The inner chamber and outer body should be made of stainless steel.
- It should have a welded stainless steel construction CE marking.
- The instrument will work in the power supply of 230 V 50Hz single phase.
- Free delivery & installation and on site demonstration & training are required to be provided.
- **warranty:** One-year warranty from the date of installation.

BINoCULAR MICRoSCoPE	
Version no. :	1
Date:	5/12/2014
Done By: (Name/institution)	HCT/NHSRC
GMDN name	Binocular Microscope
GMDN Code	NA
General	
1. USE	

1.1	Clinical Purpose	Binocular microscope is simply a microscope that lets the viewer use both eyes. The microscope has 2 eye lenses. The development of the double eye piece microscope was adapted to reduce the eyestrain and muscular strain that typically results from traditional microscopes.
1.2	Used by clinical department/ ward	Clinical labs.

BINoCULAR MICRoSCoPE		
Technical		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Body-Single mould sturdy stand, inclined Binocular body 30 °, 360º rotatable head. 2. Eyepieces-Highest quality 10 X/20mm wide angle anti fungus field eyepiece. One with pointer. Diopter adjustment must be present on both eye pieces. 3. Objectives-Parfocal, antifungus coated 4x, 10x, 40x and 100x (oil immersion) with semi planner achromatic correction. Objective should be well centered even if their position on turret is changed. 4. Optical system-Infinity corrected. 5. Stage - Double plate rackless horizontal mechanical stage preferably 100 x 140 mm with fine vernier graduations designed with convenient coaxial adjustment for slide manipulation preferably through 30 x 70 mm double slide holder. 6. Sub stage-Abe condenser focusable, continuously variable iris diaphragm 7. Illuminator-Built-in LED light source with white light with intensity control and LED life of more than 10, 000 Hrs. 8. Finish-A durable textured acid resistant finish. 9. Battery backup : minimum 1 Hour. 10. Nose piece: Backward tilted revolving nose piece suitable to accommodate four objectives with click stop and rubber grip. 11. Focusing: Coaxial coarse and fine focusing knob, capable of smooth, fine focusing movement sensitivity; minimum: 300 micron; focusing stop for slide safety.
2.2	User's interface	Manual
2.3	Software and/or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Capacity	NA
3.4	Noise (in dBA)	NA
3.5	Heat dissipation	NA
3.6	Mobility, portability	Portable

4 ENERGY SoURCE (electricity, UPS, solar, gas, water, Co_2 ....)		
4.1	Power Requirements	Input voltage- single/3-phase
4.2	Battery operated	No
4.3	Tolerance (to variations, shutdowns	NA
4.4	Protection	Should have over-charging cut-off with visual symbol.
4.5	Power consumption	Less than 2 W.
5. ACCESSoRIES, SPARE PARTS, CoNSUMABLES		
5.1	Accessories(mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)	Should provide with wooden storage box, dust cover, immersion oil.

BINoCULAR MICRoSCoPE		
Bidding/Procurement Terms/Donation Requirements		
6. ENVIRoNMENTAL AND DEPARTMENTAL CoNSIDERAToNS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	1. Operating condition: Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	1. Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required.
7. STANDARDS AND SAfETY		
7.1	Certificates (premarket, sanitary, ..); Performance and safety standards (specific to the device type); Local and/ or international	1. Should be FDA/CE/BIS approved product. 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements (or equivalent BIS Standard) 4. Certified to be compliant with IEC 61010-1, IEC 61010-2-40 for safety
7.2	Local and/or international	Manufacturer / supplier should have ISO 13485 certificate for quality standard.
8. TRAINING AND INSTALLATIoN		
8.1	Pre-installation requirements: nature, values, quality, tolerance	1. Availability of 5 amp socket; 2. Safety and operation check before handover;
8.2	Requirements for sign of	Certificate of calibration and inspection from the manufacturer

8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance; 2. Advanced maintenance tasks required shall be documented
9. wARRANTY AND MAINTENANCE		
9.1	Warranty	3 years
9.2	Maintenance tasks	1. Maintenance manual detailing; 2. Complete maintenance schedule;
9.3	Service contract clauses, including prices	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached;
10. DoCUMENTATIoN		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hardcopy and soft-copy) of:- 1. User, technical and maintenance manuals to be supplied in English/ Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals (original and copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection
10.2	Other accompanying documents	List of important spares and accessories, with their part numbers and cost;
BINoCULAR MICRoSCoPE		
11. NoTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/ad-hoc) to be declared by the manufacturer;
11.2	Recommendations or warnings	Any warning signs would be adequately displayed

B. BOTTLE SEALER

fUNCTIoN

Specifically designed to avoid leakage of tank water into the breast milk bottle during the heating and cooling cycles of the breast milk pasteurization process. Sealing the breast milk bottles insures that mother's breast milk retains its sterilization properties, and that no leakage occurs in the bottle while the milk pasteurization process takes place in the heating/cooling cycles, and after the breast milk is stored for later usage.

SPECIfICATIoN

This equipment is intended to seal metal foiled wafer inside the capped containers. Heating takes place in the metal foil and conducts heat to its plastic coating and subsequently causes the container material to melt and fuse. Pressure is normally applied to the joint by means of the torque exerted by the screwed cap and it is obviously essential that the foil coating is compatible with the particular material.

The package should consist of the induction heating generator and hand applicator.

C. WASHER & THERMAL DISINFECTOR

SPECIfICATIoNS

1. Single door Washer Disinfector with Thermal Disinfection & Cleaning, in a single closed system. Front loader with LCD Display. Thermal disinfection should be carried out at more than 90˚ C.
2. Washer shall be able to wash instruments, trays, bottles, dishes etc.
3. The washer Disinfector should be microprocessor/PLC based with pre-set programs as well as option of at least 3 customize programs for cleaning and disinfection. Indicators for operation and programming of current cycle status and alarms (audio/video), program running date & time, error messages etc. RS 232 port for printer connection to monitor and validate washing phases
4. Should have at least 1 automatic Dispenser pumps for liquid cleaning agents/acidic agents.
5. Should have powerful circulation pump for efficient cleaning of the instruments.
6. Washer Disinfector should be made from high grade stainless steel AISI304. The wash chamber should have rounded corners & self-cleaning tank for easy cleaning & drainage.
7. Electrical door lock, Program failure check, audio/video alarms, should have sensors for temperature monitoring and control.
8. Cold & Hot water connections. Electrical connection: 240V 1N 50Hz 3.5kW.
9. The system should be ergonomic and user friendly.
10. The system should be ISO; European CE or US FDA certified & also comply with EN ISO 15883.-1 & EN ISO 15883.-2. Company should have a Local Service Centre in India.
11. All the consumables like detergents, neutralizer, door gasket, printer paper etc. should be quoted separately which will be freeze for next 10 years.
12. The system should be supplied with consumables like detergent, neutralizer and salt for water at least 500 cycles
13. The system should be supplied with at least 1 wash basket, 2 wash arms, Racks for washing of at least milk bottles.
14. The built-in water softener optional provides optimal cleaning effectiveness.
15. Basket volume at least 40 litre.

D. PH METRE

SPECIfICATIoN

	pH Mode	mV Mode
Range	0.00 to 14.00 pH	0 to ±1999 mV
Resolution	0.01 pH	± 1 mV
Accuracy	0.01 pH ± 1 digit	1 mV ± 1 digit

Input Impedance	10^{12} Ohms
Temperature Control	0 to 100°c Manual
Display	3.5 digit LED display with auto polarity & decimal
Calibration	Two buffers calibration (manually) 7pH & 4pH Or 9.2pH
Power Requirement	230V A.C ± 10%, 50Hz single phase
Environment	230V AC ± 10% 50Hz
Dimensions	205 x 65 x 130mm (Aluminum powder coated cabinet)
Weight	1.5kgs (Approx.) including accessories
Standard Accessories	PH Electrode, Stand, Rod, Clamp, Buffers, Dust Cover & Manual

E. LABEL PRINTER (Water Proof)

FUNCTION: Required for printing the labels and marking the bottles with pasteurization batch number, and expiry date.

SPECIfICATIoN

- Should produce high resolution Labels.
- Should print more than 60 Labels per minute.
- Resolution of 300x600 dpi.
- Should be supplied with 100 compatible labels with the following specifications:
- Labels should be water proof.
- Can be peeled off easily.
- Size around 100 mmx 25 mm
- Can also be written with hand written labels with permanent markers.

11. LIST OF OTHER EQUIPMENT

- Steel sink
- Air Conditioner
- RO system
- Room thermometers
- Computer/laptop with internet facility and printer
- Hand dryer
- Provision of Music/Television
- Facility for drinking water to mother

APPENDIX

6

Record Keeping Formats

1. Donor record

S. no.
Date and time
Donor registration number (unique ID as prepared by the CLMC/MCTS/AADHAR)
Donor's Full name
Age of the donor's baby
Result of serological testing
Name of the attending lactating support staff
Signature of the donor
Signature of the Lactation Support Staff

2. Milk refrigeration records

S. no.
S. no. of the container
Volume
Date and time of refrigeration
Date and time of collection
Site of collection
Fit for use: yes/no

3. Milk pooling records

S. no.
Date and time of pooling
Batch no.
S. no. of containers
Date and time of thawing
S. no. of containers in the batch
Total volume
Total containers

4. Milk pasteurization records

Date and time
Batch no.
Volume
Heat treatment and time
Post-pasteurisation report
Fit for use: yes/no

5. Dispensing record

S. no.
Site of use
Batch no.
S no. of container
Volume
Date of time and dispatch
Date of expression
Date of pasteurization
Delivered by
Received by

6. Temperature log book for refrigerator and freezer (separate registers should be maintained for each)

S. no
Date
Time
Temperature
Corrective steps take in case of deviation
Signature of in-charge

7a. Label on the container of pasteurized DHM

Unique ID of mother
Volume of Milk
Name and address of the lactation management centre
Batch no
Expression date
Freezing date
Thawing date
Thawing time

Result of pre-pasteurization testing
Date of post-pasteurization testing
Result of post-pasteurization testing
Expiry date
Date of issue
Place of issue

7b. Label on the container of mother's own milk

Unique ID of mother
Volume of Milk
Name and address of the lactation management centre
Batch no
Expression date
Freezing date
Thawing date
Thawing time
Expiry date
Date of issue
Place of issue

8. Label on the container of pasteurized DHM (heterologous donation)

Name of the product
Total volume
Unique ID for the mother
Batch no:
Date of donation
Age of child- to know whether pre term/term milk
Date of freezing
Date of pasteurization
Date and time of thawing?
Expiry date
Results of serological testing
Required temperature
Info on any visible signs of deterioration

national Guidelines on Lactation Management Centres in Public health Facilities

Place & date of issue

9. Label on the container of homologous donation

Name of the product
Total volume
Unique ID for the mother
Batch no:
Date of donation
Age of child- to know whether pre term/term milk
Expiry date
Required temperature
Info on any visible signs of deterioration
Place & date of issue

10. Deep freezer register

Date
S. no. of the container
Volume
Status: Raw/pasteurized/awaiting serological report
Date and time of pasteurization
Post-pasteurisation report
Freezing date
Expiry date
Date and time of thawing

11. Culture report register

Date

Date	Sl No./Batch No.	Reason for discard	Signature of technician

Batch no. of samples sent for culture

Laboratory
Date of report received
Details of report
Fit for use: yes/no
Signature of in-charge

12. Daily feeding record of the recipient

Date
Registration no. of recipient
Mother’s name
Volume of milk fed to recipient
Time of feeding
Name of staff feeding milk
Batch no. of milk

13. Discard Register

ANNEXURE 1

1 Checklist for Pre-requisites for Establishing Lactation Management Centres

ANNEXURES

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I. Pre-requisites for Establishing Comprehensive Lactation Management Centre (CLMC)				
S. No.	**Parameter**	**Status Tick (√) Yes or No**		**Remarks**
		Yes	No	
1	Early breastfeeding is a practice **for all deliveries,** irrespective of normal or assisted deliveries.			
2	Practice breastfeeding for babies born by Caesarean Section deliveries.			
3	Demonstrate efforts to **provide IYCF counseling** at each contact with mother-newborn dyad such as ANC clinic, delivery, post neonatal follow up, routine immunization, IPD and OPD.			
4	Practice **feeding with breast milk** and not artificial feeds for: Sick babies Preterm babies Low birth weight babies Cleft palate HIV mother			
5	Practice the policy of bedding in of babies and not separate babies from mothers at any point of time.			
6	Compliant with provisions of IMS Act 2003 and must not indulge in promotion of artificial infant formula feed.			
7	Delivery rate is at least 10,000 babies annually.			
8	Have 20 bedded NICU along with SNCU			
9	Case load of sick newborns	_____ _____ (Average number of Sick newborns admitted per annum)		
10	Have provision for admitting mothers of out-born babies close to NICU/SNCU			
11	Have adequate space i.e. 350 Sq. Mt. for establishing CLMC, preferably in close proximity of the neonatal units (NICU/SNCU)			

I. Pre-requisites for Establishing Comprehensive Lactation Management Centre (CLMC)				
S. No.	**Parameter**	**Status Tick (√) Yes or No**		**Remarks**
12	Full time neonatologist/pediatrician and part time microbiologist available			
13	Have laboratory facility for testing for Hep B, C (Optional), Syphilis/VDRL and HIV 1 and 2			
14	A dedicated refrigerator for storing human milk is available at SNCU			
15	Need assessment for establishing CLMC has been carried out by SPMU nominated officials			

ANNEXURE

2

Indicative Budget Estimate Details for Establishing CLMC and LMU

II. Pre-requisites for Establishing Lactation Management Unit (LMU)				
S. No.	**Parameter**	**Status Tick (√) Yes or No**		**Remarks**
		Yes	No	
1	Early breastfeeding is a practice **for all deliveries,** irrespective of normal or assisted deliveries			
2	Practice breastfeeding for babies born by Caesarean Section deliveries			
3	Demonstrate efforts to **provide IYCF counseling** at each contact with mother-newborn dyad such as ANC clinic, delivery, post neonatal follow up, routine immunization, IPD and OPD			
4	Practice **feeding human breast milk** and not artificial feeds for: Sick babies Preterm babies Low birth weight babies Cleft palate HIV mother			
	Practice the policy of bedding in of babies and not separate babies from mothers at any point of time			
5	Compliant with provisions of IMS Act 2003 and must not indulge in promotion of artificial infant formula feed.			
6	Case load of sick newborns	_____ (Average number of Sick newborns admitted per annum)		
7	At least 12 bedded SNCUs			
8	Have adequate space i.e. 160Sq Mt. for establishing CLMC, preferably in close proximity of the neonatal units (NICU/SNCU)			
9	A dedicated refrigerator for storing human milk is available at SNCU			
10	Need assessment for establishing CLMC has been carried out by SPMU nominated officials			

1. Indicative list of Budget estimate details for CLMC					
Heads	**Essential**	**Desirable**	**Unit Cost (INR)**	**Units Needed**	**Total Cost (INR)**
fixed Cost					
Infrastructure: Built up area at least 350 Square Metres					
Construction, renovation or minor civil work	*		Variable		Variable
Equipment					
Pasteurizer	*				
Automated imported/indigenous pasteurizer (the cost will vary according to the size)			3,00,000 (indigenous)/ 21,00,000 (imported)	1	3,00,000 (indigenous) /21,00,000 (imported)
Shaker water bath	*		60,000	1	60,000
Vertical Laminar air flow	*		1,00,000	1	1,00,000
Horizontal Laminar air flow (Bio-safety Cabinet)	*		1,00,000	1	1,00,000
Deep Freezer	*		50, 000	4	200,000
Refrigerator	*		30,000	3 (Minimum)	90,000
Microscope with oil immersion lens	*		10,000	1	10,000
Shaker Incubator		*	20,000	1	20,000
Lab Incubator	*		10,000	1	10,000
PH Meter	*		2,500	1	2,500
Bunsen burner	*		500	1	500
Analytical Balance	*		20,000	1	20,000
Hospital grade Electric Breast Pump	*		1,80,000	6 (Minimum)	10,80,000
Extra Re-usable Lactation sets supplied to be used with Breast pumps	*		3000	30	30,000
Containers Polypropylene (BPA Free)	*		100	150	15,000
Bottle sealer with Foil for sealing bottles	*		5,000	1	5,000
Printer and water proof labels	*		5,000	1	5,000

1. Indicative list of Budget estimate details for CLMC					
Heads	**Essential**	**Desirable**	**Unit Cost (INR)**	**Units Needed**	**Total Cost (INR)**
Stainless steel strainer	*		500	4	2,000
Stainless steel wire mesh basket	*		1,500	5	7,500
Glass beaker/Flask (1 litre) for pooling	*		300	6	1,800
Cleaning and sterilizing equipment	*				
Steel scrub station	*		35,000	4	1,40,000
Stainless steel table (4 x 2 Sq. Ft.)	*		5,000	5	25,000
Dishwasher	*		30,000	1	30,000
Kitchen Basket (steel/plastic)	*		3,000	1	3,000
Hot air oven	*		35,000	2	70,000
Bench top autoclave (automated)	*		80,000	2	160,000
Heat sealer Machine with cutter	*		1,500	1	1,500
Bucket trolley	*		7,000	2	14,000
Folding laundry trolley	*		1,000	2	2,000
Multi- Function Janitor	*		15,000	1	15,000
Dustbins (Stainless steel)	*		1,500	8	12,000
Mop set with 360° rotating pole and steel bucket	*		2,500	1	2,500
Medical ice box - gel packs	*		10,000	2	20,000
furniture					
Cupboard	*		10,000	3	30,000
Chairs	*		1,500	10	15,000
Donor room sofa (5 seats)		*	25,000	1	25,000
Tables	*		7,000	2	14,000
Miscellaneous items - reception counter, fixed cupboards, baby cradle, lockers, staff garment cabinet, wheel chair etc.		*	30,000		30,000

office Utility Items					
Curtains	*		500	5	2,500
Gowns	*		300	10	3,000
Dustbins	*		500	1	500
Communication Equipment and Computer					
Computer	*		35,000	1	35,000
Printer	*		8,000	1	8,000
Intercom	*		5,000	1	5,000
other Electronic Machines					
Air conditioner	*		30,000	4	120,000
Exhaust Fan	*		1,500	4	6,000
Ceiling Fan	*		2,000	4	8,000
RO water system	*		20,000	1	20,000
Generator	*		100,000	1	100,000
Geyser for hot water	*		8,000	5	40,000
LED television with a DVD player		*	25,000	1	25,000
Music System		*	10,000	1	10,000
Drinking water machine	*		12,000	1	12,000

1. Indicative list of Budget estimate details for CLMC					
Heads	**Essential**	**Desirable**	**Unit Cost (INR)**	**Units Needed**	**Total Cost (INR)**
oNE TIME fIXED CoST					**30.62 lakhs approx. (with indigenous pasteurizer)**
One time fixed cost for desirable items: 1.1 lakhs approx. **Note:** Washer & Disinfector may be considered as desirable equipment instead of dishwasher.					
Recurring Expenses Per Annum					
Containers Polypropylene (BPA Free)	*		100	150	15,000
Extra Reusable Lactation sets supplied to be used with Breast pimps	*		3,000	12	36,000
Stationary (Record and registers etc.)	*				2,400
Other cleaning equipment (Broom and stick with bucket and dust pan, Dust mop, water mop, window wiper, microfiber cloth, squeeze sponge, sponge mop, colour coded garbage can, bucket, brush and stainless steel dustbins etc.)	*		15,000		15,000
Dress, rubber gloves, gum boots for hygiene helpers	*		3,000	4 sets	12,000
Toilet cleaning requirements (separate rubber gloves, shoes, toilet brush)	*		2,000		2,000
Soap and other cleaning agents	*		1,000	12	12,000
Laboratory reagents including culture Media Nutrient Agar and CLED agar) and Petri dish (e.g. 300 per month @ Rs. 10 per pc)	*		5,000	12	60,000
Staff items (Gloves, mask, cap, apron, lab coat, gown etc.)	*		25,000	-	25,000
Electricity and water	*		Variable		Variable
Analysis of samples	*		Variable		Variable
Maintenance cost of equipment (part of AMC)	*		5,000	12	60,000
Miscellaneous items (Curtains, cup, saucer, glasses, baskets, mugs etc.)			10,000	-	10,000
Contingency @5%					12,500
ANNUAL RECURRING CoST					**2. 62 lakhs approx.**

Human Resources Per Annum					
fULL TIME HR					
CLMC Manager	*		30,000	1	360,000
CLMC Technician	*		18,000	1	216,000
Lactation Support Staff	*		15,000	5	900,000
PART TIME HR					
Microbiologist	*		As per State Norm	1	
Hygiene helper	*		As per State Norm	3	

2. Indicative list of Budget estimate details for LMU					
Heads	**Essential**	**Desirable**	**Unit Cost (INR)**	**Units Needed**	**Total Cost (INR)**
Infrastructure Built up area: 160 Sq. Mts.					
Construction, renovation or minor civil work	*		Variable		Variable
Equipment					
Refrigerator	*		30,000	1	30,000
Deep freezer	*		50,000	1	50,000
Hospital grade Electric Breast Pump	*		1,00,000	3 (Minimum)	3,00,000
Extra Reusable Lactation sets supplied to be used with Breast pimps	*		3,000	15	45,000
Containers Polypropylene (BPA Free)	*		100	75	7,500
Bottle sealer with Foil for sealing bottles	*		5,000	1	5,000
Printer and water proof labels	*		5,000	1	5,000
Stainless steel strainer	*		500	2	1,000
Stainless steel wire mesh basket	*		1,500	2	3,000
Cleaning and sterilizing equipment	*				
Steel scrub station			35,000	2	70,000

Stainless steel table (4*2 Sq. Ft)			5,000	3	15,000
Dishwasher			30,000	1	30,000
Kitchen Basket (steel/plastic)			2,000	1	2,000
Hot air oven			30,000	1	30,000
Bench top autoclave (automated)			60,000	1	60,000
Heat sealer Machine with cutter			1,500	1	1,500
Bucket trolley			7,000	1	7,000
Folding laundry trolley			1,000	1	1,000
Multi- Function Janitor			15,000	1	15,000
Dustbins (Stainless steel)			1,500	5	7,500
Mop set with 360^0 rotating pole and steel bucket			2,500	2	5,000
Medical ice box - gel packs	*		10,000	2	20,000
furniture					
Cupboard	*		6,000	3	18,000
Chairs	*		1,500	6	9,000
Donor room sofa (5 seats)		*	25,000	1	25,000
Tables	*		7,000	2	14,000
Miscellaneous items - reception counter, fixed cupboards, baby cradle, lockers, staff garment cabinet, wheel chair etc.		*	10,000		10,000
Communication Equipment and Computers					
Computer	*		25,000	1	25,000
Printer	*		5,000	1	5,000
other Electronic Equipment					
Air conditioner	*		30,000	3	90,000
Ceiling Fan	*		1,500	3	4,500
2. Indicative list of Budget estimate details for LMU					

Heads	Essential	Desirable	Unit Cost (INR)	Units Needed	Total Cost (INR)
Exhaust Fan	*		1,500	3	4,500
Geyser	*		6,000	3	18,000
Music System	*		10,000	1	10,000
Drinking water machine	*	*	12,000	1	12,000
office Utility Item					
Curtains	*		500	5	2,500
Gowns	*		300	10	3,000
oNE TIME fIXED CoST					**9.60 Lakhs Approx.**
Recurring Expenses Per Annum					
Record registers	*		1,000		1,000
Containers Polypropylene (BPA Free)	*		50	150	7,500
Extra Reusable Lactation sets supplied to be used with Breast pumps	*		3,000	6	18,000
Stationary	*				2,500
Other cleaning equipment (Broom and stick with bucket and dust pan, Dust mop, water mop, window wiper, microfiber cloth, squeeze sponge, sponge mop, colour coded garbage can, bucket, brush)	*		7,000	-	7,000
Dress, rubber gloves, gum boots for hygiene helpers	*		2,000	3	6,000
Toilet cleaning requirements (separate rubber gloves, shoes, toilet brush)	*		3,000	-	3,000
Soap and other cleaning agents	*		1,000	12	12,000
Staff items (gloves, mask, cap, apron, lab coat etc.)	*		10,000	-	10,000
Electricity and water	*		Variable	-	Variable
Maintenance cost of equipment (part of AMC)	*		3,000	12	36,000
Curtains	*		1,000		1,000
Miscellaneous items (cup, saucer, glasses, baskets, mugs etc.)	*		2,000	-	2,000

Contingency @ 5%					5,300
Annual Recurring Cost					**1.11 Lakhs Approx.**
Human Resource					
Lactation Support Staff (Full time)			15,000	2	360,000
Hygiene Helper (Part time for 2 hrs for morning and afternoon shifts)			As per State norm	2	

national Guidelines on **Lactation Management Centres** in Public health Facilities

ANNEXURE

3

Registration and Consent Form for the Donor

(The form should be printed and filled in local language)

1. Registration Form

(Confidential)

1. Date: _____/_____/_____
2. Donor registration number: ..... (This should be linked to the hospital registration number)
3. Name of the donor: .....
4. Address:.....

   .....
5. Phone no.: .....
6. Age of the donor: .....
7. Age of her child: .....
8. Name of collection centre: .....
9. Name of referring doctor: .....
10. Check List for Taking Medical History of the Mother
    a. Any acute illness: Yes/No
    b. Past illness/chronic disorders: Yes/No
    c. Medications being taken (if any)
    d. Any organ transplant or blood transfusion in past 12 months: Yes/No
    e. High risk behaviour for HBV, HIV, HCV and venereal diseases: Yes/No
    f. Consumption of illegal drugs, tobacco products, alcohol or nicotine: Yes/No
11. Breast examination:
    a. Mastitis: Yes/No

Name of the donor	
Age	
Witnesses (please state two)	1) 2)
Signature	
Date and time	

b. Local skin lesions: Yes/No

c. Others: .....

12. Active herpes simplex or chicken pox infections: Yes/No

13. Received viral vaccine like rubella, measles, mumps vaccination in past one month: Yes/No

14. Received varicella vaccination in the past 3 months: Yes/No

15. Had Rubella or Chicken Pox infection in the household in the past one month: Yes/No

16. Child thriving well: Yes/No

17. Laboratory reports

a. HIV I and II: Positive/Negative

b. Hepatitis B: Positive/Negative

c. VDRL: Positive/Negative

Name and Sign of the Counsellor

Sign of the donor

2. Consent Form

I have been counselled about (a) breastfeeding, (b) advantages of breastfeeding for the baby and the mother (c) use of donor human milk by lactation management centres. I have also been informed that if I donate milk as per the guidelines, I will still have adequate milk to meet my baby's needs.

I have been informed of the following in the language known to and understood by me:

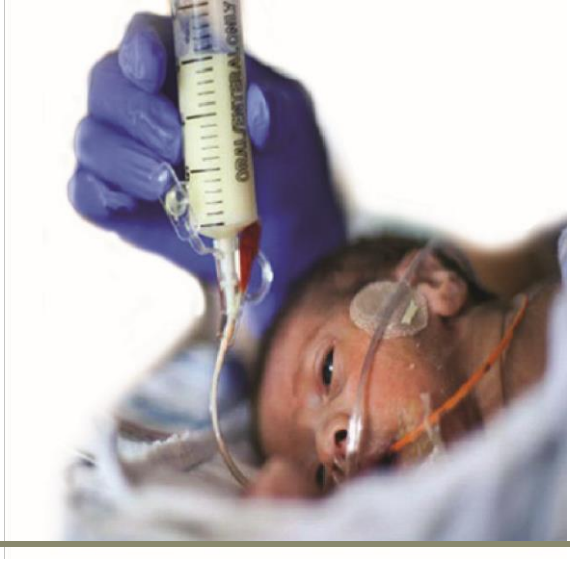
1. donated milk will be used for vulnerable babies irrespective of their religion and will not be used for commercial purposes.
2. for ensuring safety of the donated milk, I will have to provide medical history and undergo physical examination and screening for HIV 1 & 2, Hepatitis B and Syphilis
3. all information pertaining to my medical status and status of donation will be strictly confidential and will be shared on a 'need to know basis' only.
4. donation of milk is voluntary and I can withdraw my consent for further donation of milk at any time.
5. I will get no incentive whether in cash or kind, for donating milk
6. information on safe expression and storage of breast milk.

On the basis of the above information provided to me, I hereby give my consent for donating my breastmilk by signing this form without any coercion or undue influence and after satisfying my queries and doubts.

ANNEXURE

4

Consent Form for the Recipient



(This form should be printed and filled in local language)

I have been informed about (a) breastfeeding, (b) advantages of mother's milk for nutrition, growth and development of the baby as compared to other types of milk as well (c) donor human milk provided by the Comprehensive Lactation Management Centre (CLMC) for my baby for fulfilling the nutritional requirement.

I have been informed that adequate precautions are taken to make the milk disease free and quality is assured. However, still some diseases can be transmitted to the recipient. The CLMC follows strict guidelines to ensure that safest possible milk is provided. I have also been informed that the donors are healthy mothers who have been screened; the milk is pasteurised and checked for bacterial growth.

After understanding relevant details and clearing my doubts, I am willing to use this milk for my baby.

I have been explained all these in the language known to me and I am signing this form without any pressure or coercion.

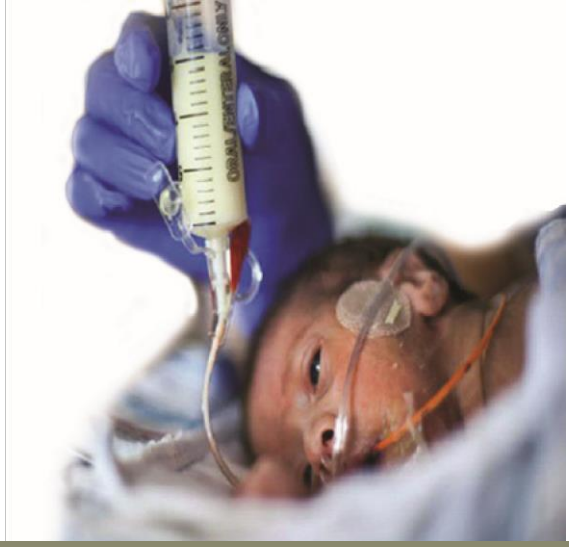
1) Name of the facility:

Name of the recipient/hospital registration number	
Age and gender	
Name of relatives and relationship with them	
Witnesses (please state two)	1) 2)
Signature	
Date and time	

ANNEXURE

5

Monitoring and Evaluation Form



2) Name of the surveyor:

3) Date:

4) Score:

Guidelines	Met	Not Met	Comments
Organisation			
Written procedures and protocols that meet the minimum standards as in guidelines			
Administrative structure meets the guidelines			
Donor Selection			
Evidence that potential donors are screened verbally			
Evidence that potential donors have completed written health screening as per the guidelines			
Evidence that potential donors are instructed to report all infections			
There is a written record that documents that each donor has been screened for HIV 1 and 2, Hepatitis B, VDRL within 6 months before milk donation			
Serological testing is done by a certified laboratory and donors are excluded if any positive results on a diagnostic/confirmatory serological test are received			
In case where Hindi is not a primary language for the donor applicant and she indicates that a translator is required, the CLMC will make efforts to offer a translator to help with screening process			
Donor Education and Procedures			
Donors are given verbal/written instructions covering: 1. Technique for milk collection following Hygiene Protocols 2. Hand washing			

Guidelines	Met	Not Met	Comments
3. Bathing/washing the breast 4. Handling milk containers			
Evidence of donor consent			
Procedures			
A detailed procedure manual is available to the personnel for lactation management centre all the time			
Evidence of disaster plan covering emergencies affecting DHM quality. These plans should include how to protect milk in case of power outage, and notification plans for staff in case of inability to dispense milk			
Provision of automatic switch of equipment to generator/UPS/inverter facility in case of temporary power failure			
Building and Facilities			
The milk processing building and structure will of suitable size, construction and design to facilitate maintenance and sanitary operations for milk processing purposes			
Provide sufficient place for placement of equipment and storage of materials			
Are constructed in such a manner that the floors, walls and ceiling can be adequately cleaned			
No pest is allowed in any area of the lactation management centre. Effective measures are taken to exclude pests from the processing areas and to protect against contamination of milk by pests.			
Only designated staff have access to freezers used for lactation management centre			
Equipment			
Equipment manual is available to the lactation management centre personnel all the time			
Evidence of disaster plan covering emergencies affecting DHM quality. These plans should include how to protect milk in case of power outage, and notification plans for staff in case of inability to dispense milk			
Refrigerators are monitored by means of recording thermometers or are equipped with temperature sensitive alarms. The temperature should be maintained at 4°C with brief fluctuations secondary to opening doors			
Freezers are monitored by means of recording thermometers or are equipped with temperature sensitive alarms. The temperature should be maintained at –20°C with brief fluctuations secondary to opening doors (not above –18°C).			
There is evidence that storage and processing equipment calibrated every 6 months as per the manufacturer's directions.			
All equipment cleaned and maintained according to manufacturer's instructions.			
Milk Analysis and Handling			
Milk is gradually thawed in a manner that it prevents the milk from reaching room temperature.			

Guidelines	Met	Not Met	Comments
Pooling of the milk is conducted under clean conditions			
A sample is taken from each pool of milk for bacteriological screening using sterile technique			
Confirmation of negative serological test			
Aliquots of milk are pasteurised by heating to 62.5°C for 30 minutes and rapidly cooled to 4°C.			
Milk temperature and bath temperature are recorded and monitored.			
The containers are sealed by air tight lids			
Milk is promptly labelled and frozen for storage			
Pasteurised milk is stored in separate freezer or different pre-defined shelf of same freezer			
Milk Dispensing			
The lactation management centre has a written plan of how to dispense milk on priority basis to those in greatest need			
The milk is dispensed on a first-in, first-out basis			
Record Keeping			
A system of tracking DHM from donor to recipient should be maintained			
The labelling should be done as specified in the guidelines			

ANNEXURE

6

The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 and as Amended Act in 2003

This Act provides for the regulation of production, supply and distribution of infant milk substitutes, feeding bottles and infant foods with a view to the protection and promotion of breastfeeding and ensuring the proper use of infant foods and for matters connected to it. It extends to the whole of India. It also lays the responsibility of health workers and of the government to provide accurate information to people. Following are the basic provisions of the IMS Act.

THE IMS ACT PROVISIONS

IMS Act is violated if any baby Food Company, its distributor or supplier, or any person

1. Promotes any food by whatever name, for children up to two years.
2. Promotes use of infant foods before the age of six months.
3. Advertises by any means--television, newspapers, magazines, journals, through SMS, emails, radio, pamphlets etc.
4. Distributes the product or samples to any person
5. Contacts pregnant or lactating mothers using any person.
6. Gives any kind of inducements like free gifts, tied sales, to anyone.
7. Distributes information and educational material to mothers, families etc. (They can give educational material to health professionals like doctors, nurses etc. provided it has information prescribed in clause 7 of the IMS Amendment Act, 2003. The education material should have only factual information and should not promote the products of the company).
8. Gives tins, cartons, accompanied leaflets of these products having pictures of mothers or babies, cartoons or any other such images to increase salability.
9. Displays placards, posters in a hospital, nursing home, chemist shop etc. for promoting these products.
10. Provides direct or indirect inducements to health workers.
11. Demonstrates to mothers or their family members how to feed these products. However, a doctor can demonstrate this to the mother.
12. Gives benefits to doctors, nurses or associations like IAP, IMA, NNF etc., for example, funds for organizing seminars, meeting, conferences, contest, fee of educational course, sponsoring for projects, research work or tours.
13. Fixes commission of employees on the basis of volume of sales of these products.

HIGHLIGHTS OF THE ACT

- Prohibits all persons from any kind of promotion of infant milk substitutes, infant foods or feeding bottles.
- Prohibits the advertisement of infant milk substitutes and feeding bottles to ensure that no impression is given that feeding of these products is equivalent to, or better than, breastfeeding.
- Prohibits providing free samples and gifts to pregnant women, mothers of infants and members of the families.
- Prohibits donation of free or subsided supplies of products for health care institutions and prohibits incentives and gifts to health workers.
- Prohibits display of posters at health care facilities/hospitals/health centres.
- The Act also prescribes that all labels of IMS/Infant food, must say in English and local, languages that breastfeeding is the best. Also, the labels must not have pictures of infants or women or phrases designed to increase the sale of the product.
- Prohibits any contact of employers manufacturing and distributing company with pregnant women, even for providing educational material to them.

PENALITIES FOR CONTRAVENTION

Violations of the Act attract imprisonment for up to three years and/or fine up to Rs. 5000.

Penalty with regard to the Label on container or quality of infant milk substitute, feeding bottle and infant food is punishable with imprisonment up to 6 month extended to 3 years and fine at least Rs. 2000.

WHAT HEALTH SERVICE PROVIDERS CAN DO

- Seek correct and scientific information about breastfeeding, feeding bottles and infant foods.
- Understand the hazards of using infant milk substitutes.
- Create awareness on promotion and protection of breastfeeding.
- Report violations to the right authorities. Inform/publicize addresses and names of organizations where you can report violations.

A. Immunosuppressive drugs

Azathioprine	❑ Avoid breastfeeding cyclosporine
	❑ Avoid breastfeeding

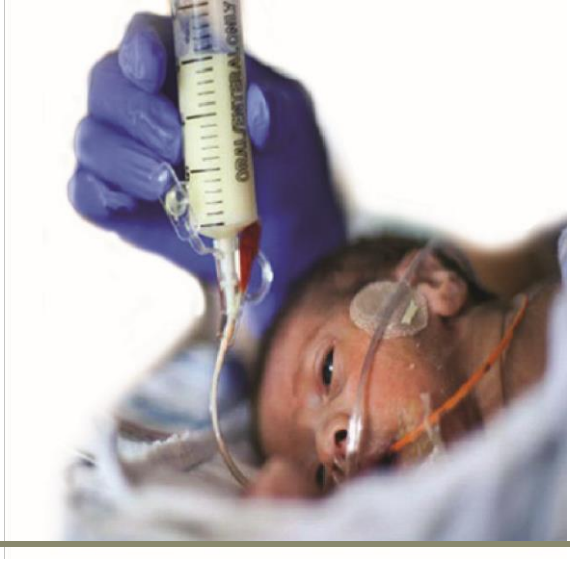
B. Cytotoxic drugs General information: Breastfeeding is contraindicated when a mother has to take a drug which belongs to this category:

Asparaginase	❑ Avoid breastfeeding
Bleomycin	❑ Avoid breastfeeding
Chlorambucil	❑ Avoid if possible
Chlormethine	❑ Avoid breastfeeding
Cisplatin	❑ Avoid breastfeeding

ANNEXURE

7

List of Contraindicated drugs for milk donation



Cyclophosphamide	❑ Avoid breastfeeding
Cytarabine	❑ Avoid breastfeeding
Dacarbazine	❑ Avoid breastfeeding
Dactinomycin	❑ Avoid breastfeeding
Daunorubicin	❑ Avoid breastfeeding
Doxorubicin	❑ Avoid breastfeeding
Etoposide	❑ Avoid breastfeeding
Fluorouracil	❑ Avoid breastfeeding
Levamisole	❑ Avoid breastfeeding
Mercaptopurine	❑ Avoid breastfeeding
Methotrexate	❑ Avoid breastfeeding
Procarbazine	❑ Avoid breastfeeding
Vinblastine	❑ Avoid breastfeeding
Vincristine	❑ Avoid breastfeeding

C. Hormones and Antihormones

Tamoxifen	❑ Avoid breastfeeding

D. Drugs used in palliative care: The Committee recommended that all drugs mentioned in the WHO publication *Cancer pain relief: with a guide to opioid availability*, second edition 1996 be considered essential. The drugs are included in the relevant sections of the model list, according to their therapeutic use, e.g. analgesics.

E. Anti-parkinsonism Drugs

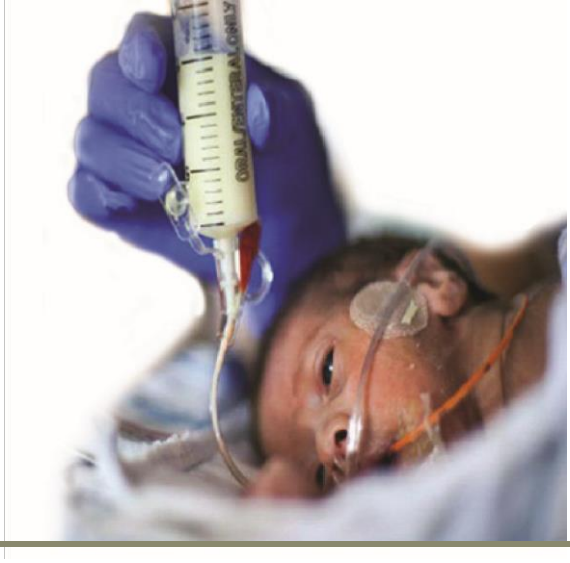
Levodopa + Carbidopa	❑ Avoid if possible. (**Levodopa** may inhibit lactation)

f. Amiodarone

G. Lithium

H. Radio Pharmaceuticals

I. Retinoids



ANNEXURE

8

References

J. Anti-cancer drugs

K. Androgens

L. Aspirin in large doses

M. Chloramphenicol

N. Estrogens

o. Ergotamine P.

Iodine

Q. Metformin

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Notes

Notes

Ministry of health & Family Welfare
Government of india
nirman Bhavan, new delhi

VALUE ADDED COURSE

Human Milk Banking Course and PECO 12

List of Students Enrolled (November 2019- December 2019)

Final Year MBBS Student			
Sl. No	**Name of the Student**	**Roll No**	**Signature**
1	AARTHI.A	U16MB251	Aarthi .A.
2	ABILASHA.K	U16MB252	Abilasha. K.
3	ABITHA RAJLIN J.S	U16MB253	Abitha Rajlin
4	ADAPALA PRIYANKA	U16MB254	Adapala priyanka
5	ADHITHAYA RAJ .N	U16MB255	Adhithya raj. N.
6	AJAY .N	U16MB256	Ajay N
7	AKSHYA .R	U16MB257	
8	ALLARI KARTHIK ABHIROOP	U16MB258	
9	AMAL ASHOK	U16MB259	Amal Ashok.
10	AMIRTHAVARSHNI .R	U16MB260	
11	ANANYA SHARMA	U16MB261	Ananyasharma
12	ANGALAKUDURU DEEPCHAND	U16MB262	Angalakuduru Deepchand.
13	ANJAN BANERJEE	U16MB263	
14	ANWESHA CHATTERJEE	U16MB264	
15	ARCHANA .A	U16MB265	Archana. A.
16	ARCHITHA.A	U16MB266	Architha. A.
17	ARIVUMATHI .R	U16MB267	Arivumathi .R
18	ARJUN.S	U16MB268	Arjun. S.
19	ASHVANTH KUMAR .A	U16MB269	Ashvanth Kumar. A
20	ASMITHA S.V	U16MB270	

Dr Karuppaiah Pandi

RESOURCE PERSON

ASSISTANT PROFESSOR
DEPARTMENT OF PAEDIATRICS
SRI LAKSHMI NARAYANA INSTITUTE OF
MEDICAL SCIENCES

Dr Sivaprakasam

CO-ORDINATOR

PAEDIATRICS HEAD
DEPT. OF PAEDIATRICS
SRI LAKSHMI NARAYANA INSTITUTE OF
MEDICAL SCIENCES
OSUDU, PUDUCHERRY

SRI LAKSHMI NARAYANA INSTITUE OF HIGHER EDUCATON AND RESEARCH

Aastha. A
V16MB257

HUMAN MILK BANKING COURSE

QUESTIONS

Course Code: PECO 12

1. What is PDHM?

   Pasteurised Donor Human Milk

2. Who started the first milk bank in India and where?

   Dr. Armeda Fernandez in SION hospital, Mumbai

3. Who are the primary beneficiaries of PDHM?

   High risk newborns admitted in the NICU.

4. What is the minimum required area for a milk bank?

   300 square feet.

5. What is the method of heat treatment of donor milk to eliminate potential pathogens?

   Pretoria Holder pasteurization method.

6. Recommended temperature and duration in the above method?

   62.5 deg celsius for 30 mins

7. What is the temperature in a deep freezer to store milk in a milk bank?

   -30 deg celcius

8. Which method is used to sterilize articles needed in the milk bank?

   Hot air oven/ Autoclave

9. Say true or false: Pooled milk from various donors can be used in a milk bank.

   False

10. What is CLMC?

    Comprehensive Lactation Management Centre.

Sri Lakshmi Narayana Institute of Medical Sciences

Affiliated to Bharath Institute of Higher Education & Research

(Deemed to be University under section 3 of the UGC Act 1956)

CERTIFICATE OF MERIT

This is to certify that _____ABITHA RAJLIN J.S___U16MB253_____ has actively participated in the Value Added Course on *Human Milk Banking Course* held during December 2019- Jan 2020 Organized by Sri Lakshmi Narayana Institute of Medical Sciences, Pondicherry- 605 502, India.

Dr. Karuppaiah Pandi
RESOURCE PERSON

Dr. Sivaprakasam
COORDINATOR

Sri Lakshmi Narayana Institute of Medical Sciences

Affiliated to Bharath Institute of Higher Education & Research

(Deemed to be University under section 3 of the UGC Act 1956)

CERTIFICATE OF MERIT

This is to certify that _____AJAY N___U16MB256_____ has actively participated in the Value Added Course on *Human Milk Banking Course* held during December 2019- Jan 2020 Organized by Sri Lakshmi Narayana Institute of Medical Sciences, Pondicherry- 605 502, India.

Dr. Karuppaiah Pandi

RESOURCE PERSON

Dr. Sivaprakasam

COORDINATOR

Student Feedback Form

Course Name: Human Milk Banking Course
Subject Code: PECO12

Name of Student: Aarthi. A Roll No.: U16MB001

We are constantly looking to improve our classes and deliver the best training to you. Your evaluations, comments and suggestions will help us to improve our performance

Sl. NO	Particulars	1	2	3	4	5
1	Objective of the course is clear				✓	
2	Course contents met with your expectations				✓	
3	Lecturer sequence was well planned					✓
4	Lectures were clear and easy to understand				✓	✓
5	Teaching aids were effective				✓	
6	Instructors encourage interaction and were helpful					✓
7	The level of the course					✓
8	Overall rating of the course	1	2	3	4	5

** Rating: 5 – Outstanding; 4 - Excellent; 3 – Good; 2– Satisfactory; 1 - Not-Satisfactory*

Suggestions if any:

nil.

Date: 18.11.2019.

Signature

Date: 03.01.2020

From

Dr. Sivaprakasam. V
Professor and Head,
Department of Pediatrics,
Sri Lakshmi Narayana Institute of Medical Sciences
Bharath Institute of Higher Education and Research,
Chennai.

Through Proper Channel

To

The Dean,
Sri Lakshmi Narayana Institute of Medical Sciences
Bharath Institute of Higher Education and Research,
Chennai.

Sub: Completion of value-added course: Human Milk banking

Dear Sir,

With reference to the subject mentioned above, the department has conducted the value-added course titled: Human Milk Banking from December 2019 to January 2020 for 20 final year MBBS students. We solicit your kind action to send certificates for the participants, that is attached with this letter. Also, I am attaching the photographs captured during the conduct of the course.

Kind Regards,

Dr. Sivaprakasam

PAEDIATRICS HEAD
DEPT. OF PAEDIATRICS
SRI LAKSHMI NARAYANA INSTITUTE OF
MEDICAL SCIENCES
OSUDU, PUDUCHERRY

Encl: Photographs

PECO 12 –Human Milk Banking Course, December 2019