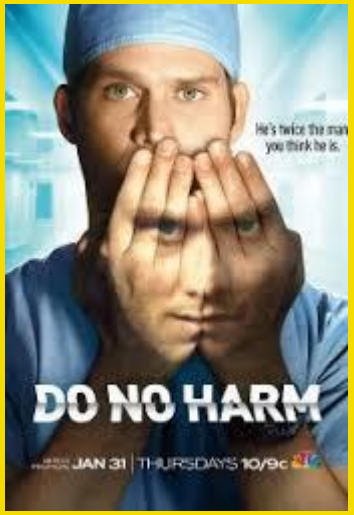
Assuring Quality in a Comprehensive Lactation Management Centre



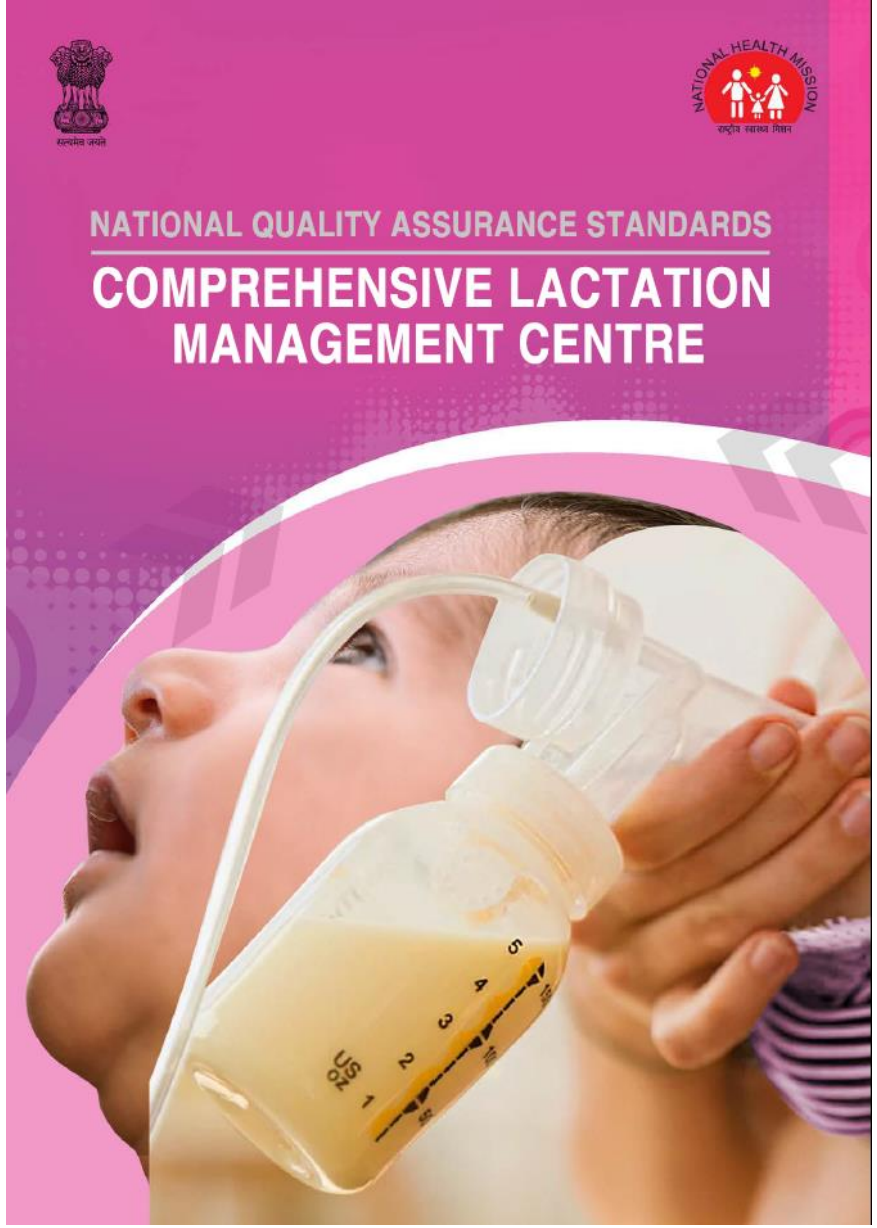
Primum non nocere

FIRST DO NO HARM

FIRST safer care together
DO NO HARM

Why Have Quality Assurance In A CLMC ?

- **Food safety particularly important for vulnerable babies receiving DHM**
- To ensure high-quality processed human milk is consistently provided to recipients
- To ensure that CLMC operations adhere to the National Quality Assurance Standards as stated in the national guidelines.
- **What could cause a risk to the quality of donor milk?**
- Identifying "Hazards" : biological, chemical or physical agent in/or condition of food with the potential to cause an adverse effect on the health of consumer
- **What needs to be done to ensure high-quality donor milk?**



https://qps.nhsrcindia.org/sites/default/files/2023-03/CLMC-Module.pdf

- Standards organized around **8 area of concern :**
- Service Provision, Patient Rights, Inputs, Support Services,Clinical Services, Infection Control, Quality Management and Outcome.
- 30 standards
- 90 measurable elements
- 350 checkpoints in the assessment tool to ensure quality of care in milk bank as well as concerned departments viz. postnatal wards, SNCUs, KMCs, mother & babies OPD etc

Components Of Quality Assurance

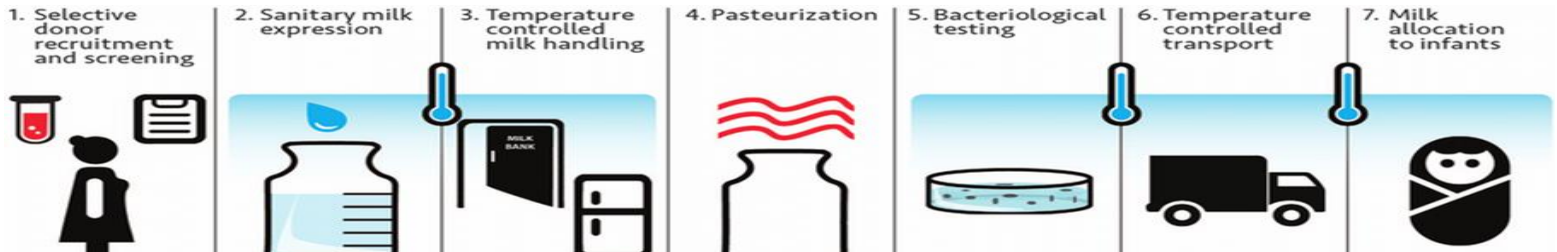
- Quality Assurance team
- HACCP processes
- Good Manufacturing Practices
- Standard operating procedures
- Completed and accurate documentation and registers
- Documentation of equipment checks and services
- Training and reference materials
- Donor records
- Audit records and action plan

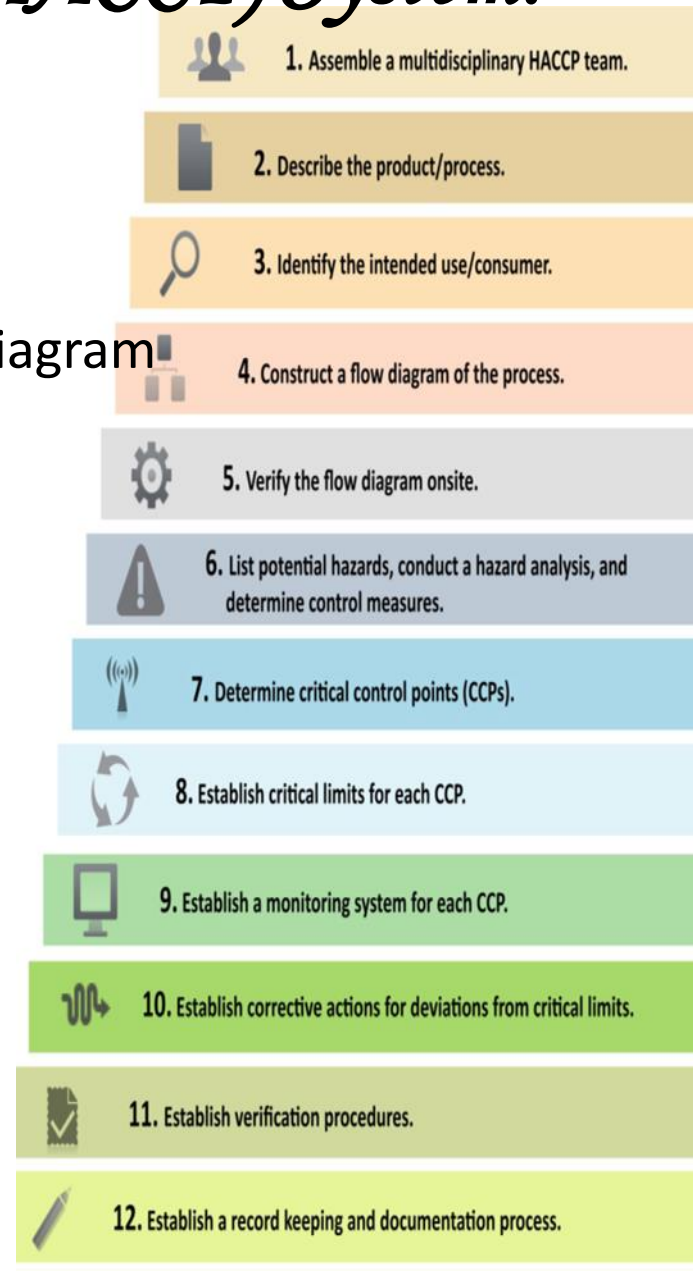
Quality Assurance Team

1. Neonatologist/Pediatrician
2. CLMC Manager
3. Microbiologist
4. Lactation nurse
5. Dispensing center(NICU) sister in-charge
6. Infection control team

What is Hazard Analysis, Critical Control Points (HACCP) System?

- Internationally recognized system used in food industry to identify and reduce hazards during food processing
- Detailed analysis of steps of the food production process with flow-diagram
- List potential hazards & identify Critical Control Points (CCP)
- Define critical limits for each CCP (safety range)
- Define a monitoring system for each CCP
- Define corrective actions in case of exceeding the critical limits
- Establish a system to register the procedures and to keep the data
- Verify and revise periodically the procedures

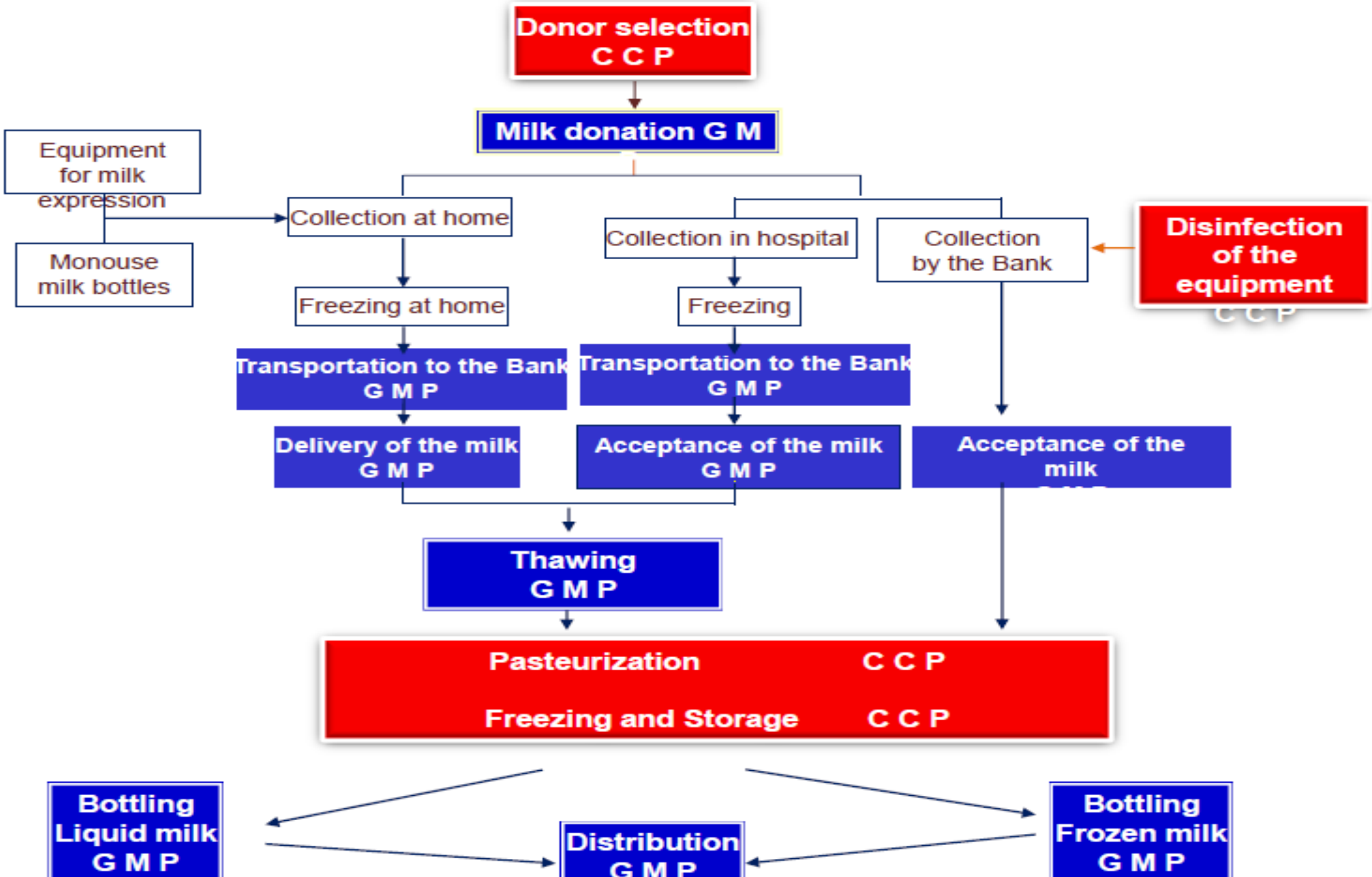




Good Manufacturing Practices (GMP): Definition

- GMP identify the phases of the production process which do not contain critical points,

  but require monitoring
- Includes:
- Minimum sanitary and processing requirements ensure production of safe, high-quality foods.
- **Design** and facilities of the HMB
- Food safety **training** for all staff & Personnel hygiene,
- Equipment disinfection
- Hygienic processing of DHM
- GMP is part of quality assurance and quality control and is a prerequisite for implementation of a HACCP food safety system


Donor selection
C C P
Milk donation G M
Equipment for milk expression
Monouse milk bottles
Collection at home
Collection in hospital
Collection by the Bank
Disinfection of the equipment
C C P
Freezing at home
Freezing
Transportation to the Bank
G M P
Transportation to the Bank
G M P
Delivery of the milk
G M P
Acceptance of the milk
G M P
Acceptance of the milk
Thawing
G M P
Pasteurization C C P
Freezing and Storage C C P
Bottling Liquid milk
G M P
Distribution
G M P
Bottling Frozen milk
G M P

Benefits of HACCP Certification

Improve Compliance level with applicable statutory and regulatory food safety requirements.

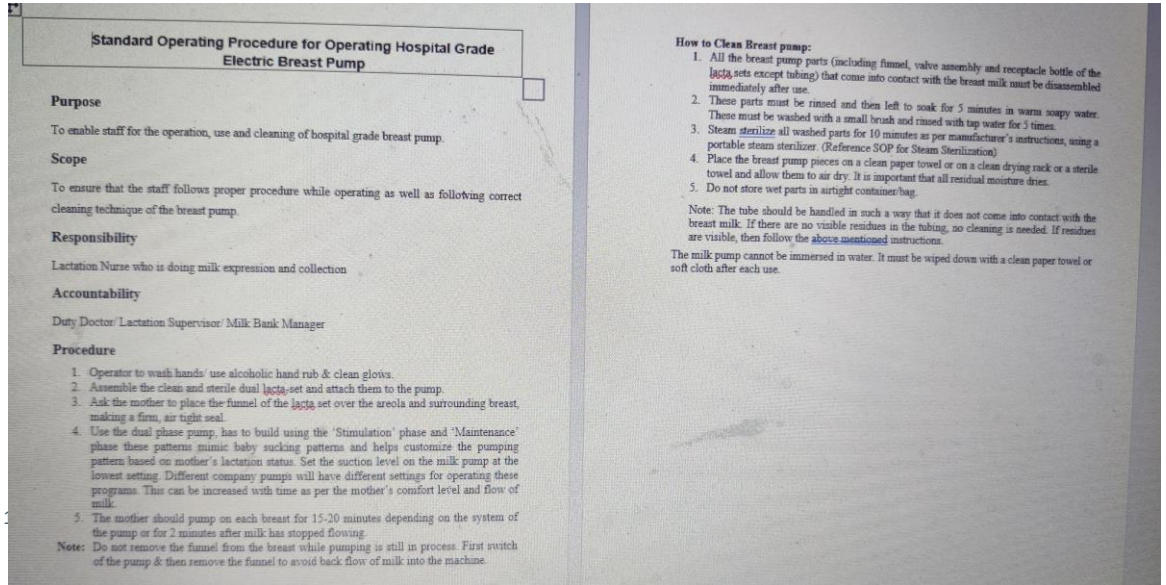
Can Conduct Internal Audit based on HACCP System.

Minimize the food safety hazards.

Improve the confidence of end user.

What are standard operating procedures (SOPs)?

- SOPs are a list of all critical procedures laid down to assure workers correctly carry out all routine operations.
- SOPs are designed to achieve uniform performance, quality output, and efficiency, while also reducing miscommunication and failure to comply with regulations.
- Operating procedures and guidelines encompass protocols, quality control systems, safety regulations, and required technical skills.



Standard Operating Procedure for Operating Hospital Grade Electric Breast Pump

Purpose

To enable staff for the operation, use and cleaning of hospital grade breast pump.

Scope

To ensure that the staff follows proper procedure while operating as well as following correct cleaning technique of the breast pump.

Responsibility

Lactation Nurse who is doing milk expression and collection

Accountability

Duty Doctor/ Lactation Supervisor/ Milk Bank Manager

Procedure

1. Operator to wash hands/ use alcoholic hand rub & clean gloves.
2. Assemble the clean and sterile dual lacta set and attach them to the pump.
3. Ask the mother to place the funnel of the lacta set over the areola and surrounding breast, making a firm, air tight seal.
4. Use the dual phase pump, has to build using the 'Stimulation' phase and 'Maintenance' phase these patterns mimic baby sucking patterns and helps customize the pumping pattern based on mother's lactation status. Set the suction level on the milk pump at the lowest setting. Different company pumps will have different settings for operating these programs. This can be increased with time as per the mother's comfort level and flow of milk.
5. The mother should pump on each breast for 15-20 minutes depending on the system of the pump or for 2 minutes after milk has stopped flowing.

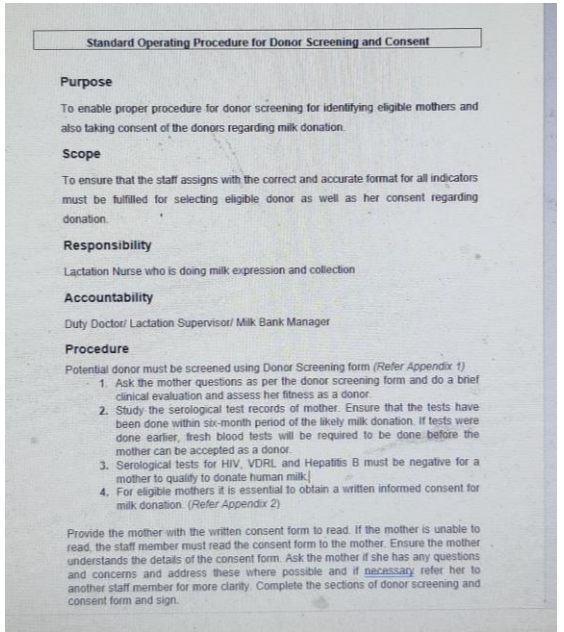
Note: Do not remove the funnel from the breast while pumping is still in process. First switch of the pump & then remove the funnel to avoid back flow of milk into the machine.

How to Clean Breast pump:

1. All the breast pump parts (including funnel, valve assembly and receptacle bottle of the lacta sets except tubing) that come into contact with the breast milk must be disassembled immediately after use.
2. These parts must be rinsed and then left to soak for 5 minutes in warm soapy water. These must be washed with a small brush and rinsed with tap water for 3 times.
3. Steam sterilize all washed parts for 10 minutes as per manufacturer's instructions, using a portable steam sterilizer. (Reference SOP for Steam Sterilization)
4. Place the breast pump pieces on a clean paper towel or on a clean drying rack or a sterile towel and allow them to air dry. It is important that all residual moisture dries.
5. Do not store wet parts in airtight container/bag.

Note: The tube should be handled in such a way that it does not come into contact with the breast milk. If there are no visible residues in the tubing, no cleaning is needed. If residues are visible, then follow the above mentioned instructions.

The milk pump cannot be immersed in water. It must be wiped down with a clean paper towel or soft cloth after each use.



Standard Operating Procedure for Donor Screening and Consent

Purpose

To enable proper procedure for donor screening for identifying eligible mothers and also taking consent of the donors regarding milk donation.

Scope

To ensure that the staff assigns with the correct and accurate format for all indicators must be fulfilled for selecting eligible donor as well as her consent regarding donation.

Responsibility

Lactation Nurse who is doing milk expression and collection

Accountability

Duty Doctor/ Lactation Supervisor/ Milk Bank Manager

Procedure

Potential donor must be screened using Donor Screening form *(Refer Appendix 1)*

1. Ask the mother questions as per the donor screening form and do a brief clinical evaluation and assess her fitness as a donor.
2. Study the serological test records of mother. Ensure that the tests have been done within six-month period of the likely milk donation. If tests were done earlier, fresh blood tests will be required to be done before the mother can be accepted as a donor.
3. Serological tests for HIV, VDRL and Hepatitis B must be negative for a mother to qualify to donate human milk.
4. For eligible mothers it is essential to obtain a written informed consent for milk donation. *(Refer Appendix 2)*

Provide the mother with the written consent form to read. If the mother is unable to read, the staff member must read the consent form to the mother. Ensure the mother understands the details of the consent form. Ask the mother if she has any questions and concerns and address these where possible and if necessary refer her to another staff member for more clarity. Complete the sections of donor screening and consent form and sign.

Suitable SOP components for a Lactation Management Unit

- Donor screening and consent
- Operating electric breast pump
- Sterilization of lacta sets & milk containers
- Milk collection at hospital setting
- Milk expression at home
- Transportation of donor human milk from collection centre to processing centre
- Thawing of DHM
- Pooling & Labelling of DHM
- Procedure for pasteurized DHM
- Storage of donor human milk
- Procedure for discard
- Procedure for recipient prioritization & distribution
- Procedure for hygiene and housekeeping

Completed And Accurate Documentation And Registers

All milk bank processes to be documented as per National CLMC guidelines 2017.

All HACCP deviations encountered, corrective steps taken , monitoring done to ascertain corrections should be properly documented.

Tracking and tracing of all donor milk fed to an infant must be possible to trace back to its treatment record as well as original donor mother / donor pool for safety of DHM and for medico legal purposes.

AMC/ CMC for all equipment in the CLMC with periodic calibration for quality assurance.

Thank You!