Comprehensive Lactation Management Centre [CLMC], Visit Report
Lokmanya Tilak Municipal General Hospital [LMMTC], Sion Hospital, Mumbai, Maharashtra

NHSRC, MoHFW

ABSTRACT

A report on the visit to CLMC of LMMTC, Sion Hospital, Mumbai – Key findings on the Structure, Processes & Outcome

Lokmanya Tilak Municipal General Hospital [LMMTC], Sion Hospital

CLMC Visit - Summary of Key findings

A. Good practices:

- The Centre which was established in 1989, was the first ever Milk Bank of Asia, let alone India.
- Nearly 3000 to 5000 babies benefit from the services of this CLMC every year.
- Nearly 800 to 1200 liters of human milk each year is received and fed to sick and vulnerable babies admitted in the NICU
- The milk processing and storage area in the CLMC was very well maintained and had the necessary equipment. In fact, of the centres visited, it was the only one, which strictly followed restricted access and infection control measures in the processing and storing room.
- The CLMC displayed the processes protocol charts as given in the GOI CLMC Guidelines
- The CLMC also provides training to other newer CLMCs in Bombay.

B. Areas of concern:

- The main CLMC is used as a processing, storing and dispensing unit for DHM. It does not have any reception, counseling room, or milk expression and collection area/room.
- There are collection rooms in wards, from where the DHM is collected and then sent to main CLMC for processing, storing and dispensing. These rooms neither have proper layout nor have required equipment.
- They are very short staffed and as a result comprehensive counseling and support for breastfeeding and donating breastmilk is not optimum.
- There is not enough IEC or posters or aids for lactation counseling
- The documentation related to donor screening and counseling and donor and patient consent forms are weak.

C. Issues:

- The CLMC Centre does not want to use plastic bottles and are of the opinion that it should not be mandated by law. They have been using stainless steel containers and haven't found any problems with it. They are doing research to generate evidence that there is not much variance in quality of DHM stored in stainless steel containers as compared to plastic bottles.

- The CLMC Centre is not keen to use imported fully automatic pasteurisers as they are too expensive and their repairs are expensive and difficult to carry

out. The chances of human error in shaker water bath can be minimized by proper and repeated training to staff for carrying out the pasteurization process. However, they are in talks with some domestic company, which is developing indigenous and much cheaper fully automatic pasteurisers. If the tests show that it is effective, they would rather use these pasteurisers.

- The CLMC thinks that there should not be a blanket ban on research in DHM. Only that research in DHM should be banned which is done from the point of view of commercialization and profiting. Otherwise, no CLMC centre will be able to carry out any research whatsoever.
- The CLMC does home based collection of DHM. They see this as a natural progression as a CLMC centre grows and matures and they have been functioning since 1989. They have around 60 women on their record who express and store their breastmilk at their homes, as per the instructions of the CLMC and on fixed days of week, a vehicle goes and collects the DHM and brings them to the CLMC, where the home collected DHM gets logged in separately. Detailed information is in the report and at Annexure 5.

D. Way Forward

- Plan the layout better. Have adequate and clearly demarcated spaces for counseling & donor screening; milk expression and collection area with proper nursing station; arrangement for privacy for women donating their breastmilk etc.
- Make SOPs for collection of DHM in wards and its transfer to the main CLMC
- Have dedicated HR for CLMC, especially lactation counselors/ trained nurses. This has been identified as the single biggest factor in ensuring that we meet the objectives of CLMC and breastfeeding programs of GOI, i.e. to increase the rates of early breastfeeding. This is also necessary for improving counseling for DHM.
- Provide proper and regular trainings to existing CLMC staff
- The Centre believes that the government should set up CLMCs in several medical colleges and district hospitals and there should be a network between them for DHM, in case of shortfall in one centre. There are many CLMCs being set up in Mumbai and they hope to establish a networked relationship with them.

Lokmanya Tilak Municipal General Hospital [LMMTC], Sion Hospital

CLMC Visit – Full Report

A team from NHSRC comprising Ms. Shivangi Rai and Dr. Aashima Bhatnagar visited Comprehensive Lactation Management Centres (CLMC) at LMMTC, Sion Hospital, on 18th April 2019. The visit was made with a twofold objective: a) to understand the functioning of the centre, scope of its operations and learn about the challenges encountered and discuss ideas for way forward; and b) to ensure that the actual functioning of the CLMCs, their experience and contexts, informs the drafting of the CLMC Bill. Facility wise findings observed during the visit are placed below:

LMMTC, Sion Hospital

Since, this is not only India's but Asia's first milk bank, we had an engaging conversation with Dr. Jayshree Mondkar, Neonatalogist and HOD, about the inspiration behind the milk bank and the journey so far. With the aim of procuring an emergency supply of human milk for the newborn babies, Dr Armida Fernandez pioneered the establishment of Asia's first Human Milk Bank (HMB) at Sion Hospital, Mumbai. In November 1989. She was inspired by the milk banks in Brazil and wanted to do something similar in Mumbai. After Dr. Fernandez, Dr. Mondkar has been running the HMB/CLMC for several years. When they started they followed the protocols laid down in the HMBANA Guidelines and now they also ascribe to the GOI's CLMC Guidelines, which was issued in 2017. She says, "More the mother expresses her milk; more is generated in the breast". So usually when a baby suckles on its mother's breast, it stimulates the production of more milk, and there is always some surplus amount, which is not required by the baby. It is this surplus amount, which can be donated by the lactating mother without compromising on her own baby's requirements.

Nearly 3000 to 5000 babies benefit from the services of this CLMC every year. Nearly 800 to 1200 liters of human milk each year is received and fed to sick and vulnerable babies admitted in the NICU. The donors are mostly women who are in the neonatal ward of the hospital. However, more recently, a few women who might afford private hospital care have also started coming forward to donate their surplus breastmilk.

Dr Jayashree Mondkar elaborated that right from the beginning, they had stringent donor screening and testing requirements to ensure the safety of the donated milk. She said, "We approve of only those mothers to be prospective donors who are free from infections and communicable diseases, have a *physically fit body***,** are not on any medications, have appropriate haemoglobin, are not an addict and most important are willing to donate".

Dr Mondkar believes that financial compensation for contributing the milk should not be encouraged as it may lead to poorer women depriving their own children of the milk to earn some spare cash.

Following the guidelines laid down by Human Milk Banking Association of North America, the bank takes utmost care in handling the donated milk which varies from 50 ml to 300 ml per donor. All donated milk collected usually during the day hours is first tested for harmful microorganism.

Dr Mondkar explained the whole process of collecting, pasteurising and storing of the milk in sterilised steel containers. The milk is stored at -20º centigrade in freezers and can last upto six months. "But with 14000 deliveries the stored milk lasts hardly for two weeks. We collect 1200 litre of milk yearly but even that falls short,"

1. **Layout**
    - The main CLMC centre is situated in the first floor, not very close to the NICU.
    - The layout is not as per the CLMC Guidelines as it has none of the following- reception, counseling or IEC room, milk expression collection room, microbiology lab, shower, washrooms etc.
    - The main CLMC Centre is mostly used as a processing, storage and dispensing unit for DHM. The collection points for DHM are in the wards. From there the DHM is brought to CLMC Centre for processing, testing, storing and dispensing.
    - However, out of the centers visited, it had the best processing and storage area. The entry was restricted. There was proper use of masks and gloves. There was proper hygiene and infection control protocols being followed at least in this area.
    - The milk expression and collection area in the wards were very basic. There is no separate area for counseling and for milk expression. There was no AC or music system etc.

2. **Display of SOPs and checklists:**
    - There were no written SOPs available with the centre
    - Checklists were not displayed in the centre
    - IEC on breastfeeding was displayed
    - IEC on hand washing and hand hygiene was not adequately displayed in several places

3. **Equipment:**
    - The Centre had electric breast pumps but they needed more. The CLMC centre was properly equipped with fridge, deep freezers, laminar air flow etc.
    - They take out samples for culture only under a laminar air flow, as it really reduces the chance of contamination.
    - They used a water shaker bath for pasteurizing by holder's method and not a pasteurizer. They don't think that there should be insistence on buying an imported pasteurizer and that the shaker water bath is good enough. They are doing a research study to establish that the quality of DHM does not vary upon using a shaker water bath or pasteurizer. However, they do admit that there are more chances of human error related issues in using the shaker water bath. But proper training and quality control can take care of that.

4. **Human Resource**
    - HR is also not as per the CLMC Guidelines
    - They don't have dedicated lactation counselors or a CLMC Manager etc. They desperately need more counselors/trained nurses. Dr. Mondkar says that if we want to scale up the rates of early breastfeeding and increase donation of breastmlk, then we need to have a significant number of lactation counselors in the CLMCs.

5. **Processes**
    - Counseling – the counselors in CLMC mostly counsel for motivating women to donate breastmilk and not that much on breastfeeding per se. Lack of dedicated counselors or enough nurses has been identified by the Neonatologist and staff, as the reason for inadequate comprehensive counseling and its coverage
    - Donor screening – The donor screening and informed consent form procedure is rushed. It is mostly limited to checking the records for HIV. There needs to be more training on a comprehensive donor screening and its documentation. There needs to be equal emphasis on checking for other conditions or drugs that may be contraindicated or act as temporary disqualification from donating, as per the guidelines.
    - Collection and pooling - Milk is collected in steel containers. The Centre thinks that the plastic bottles are expensive and don't have that much advantage over the steel containers. They are doing a research on this issue. The milk is pooled before pasteurization.
    - Pasteurization - The milk is thawed by placing it in room temperature water for about 2 hours. Then the milk is transferred in steel containers of different sizes. The containers are then placed in the shaker water bath.

- Culture - They take out samples for culture under laminar air flow, to minimize chances of contamination and send to the microbiology lab of the hospital. Result comes in 2 days. If culture comes positive, they discard the whole batch. They sometimes get culture reports as positive for ASB Bacteria. They did not have proper data on discard due to positive culture. But said that the discard is not more than 5%
- Storage - Post pasteurization storage is done in deep freezers. The deep freezer has two compartments: pre and post pasteurization compartments
- Recipient consent form: The recipient consent forms are not meticulously maintained and this practice needs to be strengthened.

6. Home Based Milk Collection

Sion hospital has around 60 mothers who voluntarily donated milk in 2018. These are usually mothers from the community who come to know about Sion hospital milk bank through online search or through peer to peer information sharing. These mothers are called longitudinal donors as they continue to donate for over period of time.

Information re hygiene and sterilization given to women include:
On call mothers are oriented on the collection process and instruction on maintaining temperature while storing the milk. There is information on the process to storing milk on the hospital website as well. See the document on their website at Annexure A.

How do they do the screening of women for HIV etc., if they were not admitted in the hospital and are just volunteering to donate milk?
Strict adherence to eligibility criteria is followed. Donors are asked to submit their blood tests reports. If the span of reports is more than 6 months they are asked to redo the test and submit the reports. These are filed at the department.

What is the cold chain arrangement in the vehicle that goes to collect? Does it collect daily?
Hospital does milk collection twice a week on fixed days. On these days the pickups are coordinated by the dept staff. The milk is collected in ice box with ice packs to maintain cold chain.

What is the mechanism to ensure that the DHM collected from homes is perfectly logged in to the system and not diverted? (malpractice fears)
The collection is always communicated to the HOD and she is well informed of all the activities. Separate logs for milk collected from external donors are

maintained in the register for external donors, along with contact details of the mother.

Is there clear demarcation of home collected DHM from facility collected DHM right from registering to processing to dispensing. Can a particular feed even to a baby be traced back to home based DHM?
Yes. The external donor milk bottles are coded as "EX" followed by bottle number. This label with external donor code can be tracked back to the donor. Single mother milk is only pooled together and given number for easy tracking.

7. Categories of Infants given DHM:

- The CLMC issues DHM only to babies admitted in the NICU/SNCU of the Hospital.
- The profile of infants given DHM include: Pre term, VLBWs & LBWs, sick preterm neonates recovering from illnesses and GI surgeries.
- They usually give DHM till the neonatal period but they also give beyond this period if necessary but only till the babies are admitted. They aim is to establish lactation in mother's as soon as possible and by the time the babies are discharged.
- They do not give DHM to other hospitals, whether private or public.

8. Records and registers

They maintain all necessary records and registers. However, the label and the format of the registers needs to be standardized in accordance with GOI Guidelines.

9. Views on way forward/ improvement and scaling up:

- Plan the layout better. Have adequate and clearly demarcated spaces for counseling & donor screening; milk expression and collection area with proper nursing station; arrangement for privacy for women donating their breastmilk etc.
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