

# Comprehensive Lactation Management Centre [CLMC], Visit Report

Institute of Child Health & Institute of Obstetrics &  
Gynecology  
Egmore, Chennai, Tamil Nadu

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NHSRC, MoHFW

## ABSTRACT

*A report on the visit to CLMC Centres of Egmore Medical  
College – Key findings on the Structure, Processes & Outcome*

# Institute of child health (ICH) and Institute of Obstetric & Gynecology

## CLMC Visit - Summary of Key findings

### A. Good practices:

- The CLMC centre had well demarcated areas, which were properly furnished. Out of the CLMCs visited, this one had the best layout (except for restricted entry)
- Group counseling room in the CLMC Centre was properly equipped with TV (for IEC), AC, table and chairs
- The milk expression and collection room ensured privacy by providing semi cabins and curtains between cabins
- They had a soft board where women put up their testimonials about donating milk. This could act as a positive & feel good trigger for other women
- The autoclave room was properly maintained and demarcated
- IEC (posters) on breastfeeding policy was displayed
- The Staff have received training from JIPMER, Puducherry. The staff (not dedicated) was enthusiastic and their interaction with the women was observed to be friendly
- The CLMC gives a '*laddoo*' to every woman who donates her breastmilk, to supplement her nutrition needs, which would contribute to increased lactation. Earlier they used to give a glass of warm milk but had to discontinue that due to lack of funds
- All the necessary components of processing (screening, collection, pasteurization, culture, storage and dissemination) are being followed. However the protocols need to be strengthened and standardized, esp. with regard to pasteurization and culture.

### B. Concerns/Areas of improvement:

- They should have dedicated HR and provide them with proper training. This will improve breastfeeding counseling & support and collection of DHM
- They should get proper equipment, such as laminar air flow, which significantly reduces chances of contamination
- They are using stainless steel containers instead of plastic ones. This is same as Sion Hospital in Mumbai.

- The discard due to positive culture is quite high at 20%.
- Some of the practices that could be contributing to it (as observed) could be lack of restricted entry in the milk processing area, lack of focus on hand hygiene & protocols on sterilization (use of gloves), weak protocols related to pasteurization and storage etc.
- There are no shower areas and women are not asked to shower before donating, as all donor mothers are in house patients. So, at least hand washing and breast wiping should be followed strictly.
- The milk processing room should be a restricted area
- Apart from CLMC, DHM is also collected from other wards, but there are no protocols in place to ensure their proper collection, storage and transfer to the main CLMC
- Due to large load of referral cases, sometimes only infants are admitted here while their mothers may be at home or in some other hospital. The staff in the hospital encourages husband/family members to get milk from the mother and bring it to the hospital. This milk is fed directly to the infant, bypassing the CLMC system as it is seen as autologous donation. Though the staff advise to use sterilized containers, but there is no way to verify if this advice is practiced.
- Also, some mothers engage in informal milk sharing in the wards. A woman may just request another woman to breastfeed her child
- The donor screening and counseling process needs to be strengthened
- There are concerns regarding the pasteurisation and the culture process
  - the 1 ml sample taken out by opening 2 ml bottle post pasteurization, increases the chance of contamination after pasteurization,
  - the opening of bottles to transfer milk is not even done under laminar air flow, which would at least reduce the chances of contamination; and
  - there are concerns that pasteurisation of 200ml and 2ml containers will not be the same. Chances are that the 2ml container will get pasteurized much better than the 200ml container. So, while the sample may come as uncontaminated, it may actually not be true.
- Dissemination of DHM should be done against prescriptions
- Recipient consent should be obtained and properly documented

**Additional specific findings related to Institute of Obstetric & Gynecology (IOG)**

- There was no privacy for women in milk expression and collection area. Neither were there curtains to separate tables, nor was there any restricted entry.

- Two women were expressing milk using the same breast pump simultaneously

### **C. Way Forward**

Apart from improving and strengthening their layout and processes as per CLMC Guidelines (see sub point on 'discard' above), the following measures were identified in conversation with the Neonatologist:

- Ensure restricted entry in the milk processing room
  - More equipment as per the CLMC guidelines. Definitely a laminar air flow
  - More HR, particularly counselors, as currently they are really short staffed. More counselors will help with breastfeeding and DHM counseling
  - If they have more staff, or dedicated staff, they could be open for milk collection for longer hours and not just from 9 am to 2 pm
  - They need training for the staff, especially on pooling, pasteurization and culture samples
  - The practice by the CLMC of asking fathers to bring expressed breastmilk from the mothers (admitted in another hospital or at home) for autologous feeding to her infant admitted in this hospital, needs more assessment and planning.
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# Institute of child health (ICH) and Institute of Obstetric & Gynecology

## CLMC Visit – Full Report

A team from NHSRC comprising Ms. Shivangi Rai and Dr. Aashima Bhatnagar visited Comprehensive Lactation Management Centres (CLMC) at Institute of Child Health and Institute of Obstetrics & Gynecology, Egmore, Chennai on 15<sup>th</sup> – 16<sup>th</sup> 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:

### A. INSTITUTE OF CHILD HEALTH

ICH, Egmore is the first lactation management center of the state established in 2014. The facility has 80 bedded NICU and caters to 2038 patients per annum. The annual collection of Donated Human Milk (DHM) is about 20,380 mL per month from approx. 323 donations per month.

#### 1. Layout

The facility has established a CLMC (currently being called human milk bank) next to NICU on the first floor. Apart from the main CLMC centre, it has milk expression and collection points in the NICU and post natal ward as well. The main CLMC has been divided into following areas: reception area, counselling area, milk expression and collection area, milk processing and storage area and autoclave area.

- Reception area: there is a reception desk where records and registers are also kept
- Counseling area: There was a dedicated counseling area/room with a table and chairs for group counseling. It also had a tv and IEC material for counselling sessions
- Milk expression and collection area:
  - ⇒ There was a room demarcated by curtains for women to express their breast milk. The area has a split AC and music system, but they were both not working at the time of the visit.
  - ⇒ This area had IEC posters on the wall. It also had chart papers, with messages written by mothers who had donated their milk. This testimonial

was a good idea as it personalized the experience and had a feel good factor about donating milk

- ⇒ There was a sink with liquid antibacterial soap for hand washing
- ⇒ There are no shower areas and women are not asked to shower before donating, as all donor mothers are in house patients. Women are asked to wipe their breasts with warm water and cotton before expressing
- ⇒ Breast pumps were available some breast pumps were out of order and need to be repaired or replaced
- ⇒ Silicon bottles and stainless steel bottles were available for collecting and storing DHM
- ⇒ The practice related to gloves and masks were observed to be erratic and inconsistent

- Autoclaving/cleaning room: was properly maintained and demarcated. The autoclave was functioning properly. Though the layout was not as per CLMC guidelines.
- Milk processing room: though the area was demarcated, however, access was not restricted. It was equipped with 2 refrigerator, 2 deep freezers, shaker water bath, induction plate etc. Both pasteurized and unpasteurized milk were stored in different compartments of the same deep freezer.
- Microbiology laboratory: The centre does not have a stand-alone lab only for the Centre's use. The milk samples are sent to the microbiology lab of the hospital for culture.
- Some mothers were expressing milk in the NICU itself. There was however no separate area demarcated for milk expression. The DHM is transferred from here to the CLMC for processing. If women are expressing milk for their own babies in NICU, then they are stored here in stainless steel containers and fed to their babies in the NICU.

## **2. Display of SOPs and checklists:**

- There were no written SOPs available with the centre
- Room wise checklists were not displayed in the centre
- IEC on breastfeeding policy was displayed
- IEC on hand washing and hand hygiene was not displayed

### 3. Equipment:

- The centre did not have adequate nos. of breast pumps (4 electric and 8 manual) and need to procure more. Other equipment were also not as per CLMC guidelines
- Shaker water bath is being used for pasteurizing
- The equipment calibration protocol was not available
- Steel containers were being used instead of bottles as recommended under CLMC guidelines. Even so, they need to buy steel containers of 100ml, as issuing DHM in 200ml containers, can lead to wastage or contamination of DHM.
- They need a laminar air flow

### 4. Human Resource

- HR: 1 neonatologist; 2 nurses (from NICU staff), 1 data entry operator and 1 cleaning staff. There was no dedicated staff for the CLMC. Counseling is being done by inhouse counselor.
- Training: The nurses have received training from JIPMER, Puducherry on lactation counseling and technical know how about counseling.
- The staff of CLMC however has not received any training on operational aspects of CLMC.

### 5. Processes

- Lactation counseling: counseling on breastfeeding does take place but it is not optimum mainly due to shortage of lactation counselors and nurses. According to the nurse, they do focus on establishing breastfeeding as soon as possible, if not within an hour and definitely aim to establish it before the infant is discharged. If a woman does not produce enough milk, then the doctors prescribe 'domperidone' which increases lactation and ayurvedic support is also available. They also give a siddha medicine 'ligyam' to all mothers who have delivered as this also helps in increasing lactation. The counseling for DHM is also rushed for the same reason of lack of adequate or dedicated counselors/nurses. The main message put forwards to mothers are that pumping out their milk with increase their milk production and the altruistic messaging of giving extra milk to babies in dire need of DHM. According to the neonatologist and nurses, the coverage and quality of lactation and DHM counseling will increase by adding more counselors.

- Donor screening and consent: Most women, who donate their breastmilk, have their babies admitted in NICU/SNCU. The CLMC has a donor registration cum consent form. Although the forms are filled out, the emphasis is more on checking for HIV etc., and less on the other conditions or drugs that are contraindicated. As there is a shortage of counselors and nurses, this process may be hurried and mechanical. In interactions with the donor mothers, they did not clearly recall this process or signing the consent form. There should be training on the importance of donor screening and different aspects of ascertaining suitability.
- Testing of donors for diseases: Since, most mothers have had institutional delivery, they already have their medical records with details of testing for HIV, Hep B and Syphilis. If they don't then they are tested for the same.
- Milk expression and collection:
  - ⇒ Collection is from 8 to 11am everyday
  - ⇒ Women do not take a shower before expressing breastmilk. This criterion is relaxed, as most mothers are in house.
  - ⇒ Women are advised to wash their hands with soap and water and to wipe their breasts with warm water and cotton before expressing their milk
  - ⇒ Women who donate breastmilk in CLMCs are given a 'laddoo', which is specially made with nutritious ingredients to boost lactation. The Centre earlier used to give a glass of warm milk to women and according to them it was helpful in increasing milk production. They discontinued with milk because of budgetary constraints.
  - ⇒ The milk is collected in silicon bottles (175ml) and then pooled and transferred to autoclaved stainless steel containers (200ml). The quantity of milk expressed by mothers at a time range from 10 to 100ml. If one woman has expressed between 100 to 200 ml, then they move that milk to a 200ml steel container and store it. The rest of the milk collected is pooled and then divided into steel containers of 200 ml. From 200 ml containers they take out 2ml milk and place it in 2ml steel containers called pilot containers.
  - ⇒ Milk containers are not labeled as per the CLMC Guidelines
  - ⇒ There is one register in the collection room, which records donor details – which woman has donated how much

- Processing (pasteurization, storage and dispensing):
  - ⇒ For 1-2 hours, the collected milk is kept in the fridge and then moved to deep freezer if not to be pasteurized the same day.
  - ⇒ Every day after 11am pasteurization is done by shaker water bath. Both the 200 ml and 2ml pilot container are pasteurized together.
  - ⇒ After pasteurization, the 200ml bottles are moved in deep freezer No. 1. The 2ml bottles are opened and 1 ml milk from it is moved to 1ml culture bottles. After this the remaining 1 ml milk in 2ml pilot container becomes useless.
  - ⇒ After culture report comes, the safe DHM bottles are moved to deep freezer no. 2.
  - ⇒ As per need containers are moved from deep freezer no. 2 to a fridge for 6-7 hours. Then thawing is done by placing the DHM in luke warm water to bring it to 7 degree C. they have kitchen thermometer to check temperature.
  - ⇒ Before dispensing they open the 200ml containers and divide the milk from it, into 30-40ml containers before dispensing as per indents from NICU.

**There are concerns with this process:**

- a) the 1 ml sample taken out by opening 2 ml bottle post pasteurization, increases the chance of contamination after pasteurization,
  - b) the opening of bottles to transfer milk is not even done under laminar air flow, which would at least reduce the chances of contamination; and
  - c) there are concerns that pasteurization of 200ml and 2ml containers will not be the same. Chances are that the 2ml container will get pasteurized much better than the 200ml container. So, while the sample may come as uncontaminated, it may actually not be true.
- Dissemination of DHM: The CLMC gets indents from NICU every day. The indents are made by NICU nurses. The centre sends required DHM containers to NICU. They don't insist on the doctor's prescription.
  - Recipient consent form: The recipient consent forms are not meticulously maintained and this practice needs to be strengthened.

- Some recipient mothers did not remember the process of taking informed consent for receiving DHM for their babies.
- Milk collection at home or other delivery points: some babies are admitted in NICU at this hospital, while their mothers may be in another hospital/delivery point or at home. In that case, if the mothers are lactating, the mothers are asked to express breastmilk at their location and store in sterilized steel containers. The husbands usually bring the milk to the hospital. This milk is usually fed directly to the baby of the mother, without coming into the CLMC. So far around 170 such cases of autologous donations have happened. If this practice has to continue, proper SOPs should be developed and implemented to ensure safety of the milk.
- The nurses also reported that mothers who have insufficient secretion also make informal and personal arrangements with other mothers in the hospital, to breastfeed their babies directly, bypassing the CLMC mechanism.
- Discard: The Centre reported discard due to positive culture to be as high as 20%. The Centre was advised to strengthen its hygiene practices (hand washing, cleaning, sterilization, use of gloves, masks and hair nets etc.), enforce restricted entry in processing room, have written SOPs and checklists for processes, significantly improve their process related to collection and pasteurization, which was quite poor. They were advised to get a lamina air flow, which significantly reduces chances of contamination. Their staff needs training on the processes.

#### **6. Categories of infants given DHM**

- Although the collection of DHM has steadily increased over time, but recently they seemed to have hit a plateau. The Centre did not have latest data on amount collected every day. However, as per old data, the bank collects around 0.5 - 1 litre of DHM every day. They barely manage to meet their needs and on many days they fall short by around 300ml. Then they source DHM from the intramural department, which also has a CLMC.
- The CLMC issues DHM only to babies admitted in the NICU/SNCU of the Hospital. In the past they have given DHM to private hospitals, but they discontinued with that practice and now they only give DHM to other government hospitals, if they have enough in their stocks.

- The profile of infants given DHM include: Pre term, VLBWs & LBWs, sick preterm neonates recovering from illnesses and GI surgeries. They have also issued DHM to abandoned and adopted babies and babies whose mothers have died, but only when they have been admitted in the hospital. In one instance they have issued DHM to an abandoned baby in an orphanage. The Neonatologist informed us that they have more term than preterm babies in their NICU.
- DHM for how long: They usually give DHM till the neonatal period but they also give beyond this period till the babies are admitted. Their aim is to establish lactation in mother's as soon as possible and by the time the babies are discharged.
- Once the babies have attained 1500gms, and if breastfeeding has not been established, then the babies are switched to cow's milk.
- Generally, they don't give DHM to babies post discharge follow up OPDs. After discharge also some mothers have come back with lactation failure and they have given DHM to their babies.

#### **7. Records and Registers maintained:**

- Donor registration and consent form
- Donor registration log book (mother's unique ID no., date of donation, quantity etc.)
- Donation log book (Sl No., date of donation, name of donor, donor location - SNCU or ward, place of donation – SNCU or ward, quantity of milk, bottle id etc.)

#### **8. Views on improvements and scaling up:**

In addition to the suggestions made on improving their layout and processes as per CLMC guidelines (see sub topic 'Discard'), the areas of improvement identified by the neonatologist were:

- They need more lactation counselor/nurses for counseling on breastfeeding and DHM. With the shortfall they are not able to tap into all mothers. If they had more counselors, they would improve both on breastfeeding support as well as increase in DHM.

- The collection points should be decentralized, with plan for cold chain maintenance. For instance at Anganwadi centres or on immunization day etc. Some NGOs are willing to provide support in terms of cold chain and vehicles.
  - There should be more focus on awareness drive to inform general public about donating breastmilk. The State government had carried out some brief awareness drive (television and newspaper slots) and a group of women came to donate every Saturday on a regular basis. These women also started a facebook page talking about their experience and encouraging other women to donate as well.
  - Gradually more CLMCs are being opened up. All CLMCs must have a network arrangement for supplying DHM to one another, if required.
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## **B. INSTITUTE OF OBSTETRICS & GYNEOLOGY**

There is a CLMC established in IOG, Egmore in close proximity to ICH, Egmore. It is a 450 bedded hospital including 80 bedded NICU. The main CLMC is on the same floor as the NICU. They also have DHM collection points in OPD ward and the post natal wards. DHM collected from all the points are sent to the CLMC for processing.

### **1. Layout**

The facility has established CLMC next to NICU on the first floor. The CLMC has been divided into following areas: reception area, milk expression and collection area, milk processing and storage area and autoclave area. Apart from the main CLMC, they also have collection points in the OPD ward and in NICU.

- Reception area: there is a reception desk with donor records and registers
- Milk expression and collection area:
  - ⇒ Women do not take a shower before bath. They are told to wash their hands and breasts with water and Dettol
  - ⇒ This area had no curtains between tables and privacy was compromised
  - ⇒ They had just two breast pumps here
  - ⇒ Some mothers were expressing milk in the NICU itself. There was however no separate area demarcated for milk expression. Mothers express milk in NICU for their own babies as well as for donation.
  - ⇒ The practice related to gloves and masks were observed to be erratic and inconsistent

- Autoclaving/cleaning room was properly maintained and demarcated. The autoclave was functioning properly. Though the layout was not as per CLMC guidelines.
- Milk processing room: area was in a demarcated area; however, access was not restricted. It was equipped with 2 refrigerators, 2 deep freezer, shaker water bath, induction plate etc. Both pasteurized and un pasteurized milk were stored in different compartments of the same deep freezer.
- Microbiology laboratory: The center does not have a stand-alone lab only for the Centre's use. The milk samples are sent to the microbiology lab of the hospital for culture.
- The collection room near OPD ward:
  - ⇒ Around 50-60 women come in OPD (post discharge) for follow up. Out of them around 15-20 agree to donate milk
  - ⇒ No shower room even though women donating milk here are traveling and coming here. The women are just told to wash their breasts by the sink with water and lifebuoy.
  - ⇒ Also did not ensure privacy for women, as again there were no curtains to separate the tables and the male neonatologist just walked in while women were expressing milk and they were very visibly uncomfortable.
  - ⇒ Also, two women were expressing milk using the same breast pump simultaneously
  - ⇒ This collection room had no fridge etc. The milk is collected in steel containers and then sent to the main CLMC centre for processing. But there is no SOP on this entire process. According to the nurse, in OPD ward, DHM is collected from 9:30 to 11am. Thereafter it is sent to main CMC centre

## **2. Display of SOPs and checklists:**

- There were no written SOPs available with the centre
- TV was available for IEC
- There were hardly any written IEC materials on breastfeeding etc.

## **3. Equipment:**

- The centre did not have adequate nos. of breast pumps. Other equipment was also not as per CLMC guidelines.
- Shaker water bath is being used for pasteurizing.

- The equipment calibration protocol was not available.
- Steel containers were being used instead of sterile plastic bottles as recommended under CLMC guidelines.

#### **4. Human Resource:**

- HR: 1 neonatologist; 1 sister in charge, 1 assistant nurse, 2 ANM students (from NICU staff). There was no dedicated staff for the CLMC. Counseling is being done by inhouse counselor
- Training: The nurses have received training on technical aspects of lactation support but are not aware about Gol guidelines on CLMC. The staff of CLMC has not received any training on operational aspects of CLMC.

#### **5. Processes as explained by the nurse in presence of the neonatologist**

- Lactation counseling: Due to shortage of lactation counselors and nurses, lactation counseling for promoting optimum breastfeeding has suffered. The counseling for DHM is also rushed.
- Donor screening and consent: Most women who donate their breastmilk, have their babies admitted in NICU/SNCU. They have a donor registration form cum consent form. There needs to be more emphasis to give proper time to carry out this procedure without any shortcuts. As there is a shortage of counselors and nurses, this process may be hurried. In interactions with the donor mothers, they did not clearly recall this process or signing the consent form.
- Testing of donors for diseases: Most mothers have their medical records with details of testing for HIV, Hep B and Syphilis.
- Milk expression and collection:
  - ⇒ Milk is collected from 2 to 2:30pm everyday
  - ⇒ Mothers do not take a shower before expressing breastmilk. This criterion is relaxed, as most mothers are in house.
  - ⇒ Milk is collected and stored in different bottles with a label with name of woman and date of donation
  - ⇒ These bottles are kept in the fridge overnight
- Processing:
  - ⇒ Next day the milk is taken out of the fridge for thawing. The nurse thaws the milk by pouring hot water on the containers for 15-20 mns.
  - ⇒ After milk becomes warm, the nurse pools milk from 2-3 women in one bottle (150ml).

- ⇒ She then pasteurizes the 150 ml containers in shaker water bath. Total time taken is 60 mns.
- ⇒ After pasteurizing, the nurse lets the container cool to room temperature by placing it in cold water for 20 mns. Once at room temperature, she opens the pasteurized containers and takes out 1 ml sample from each container for culture. The containers are then labeled (by serial no., date of pasteurization, quantity) and stored in deep freezer.
- ⇒ After culture report, she again opens the containers and pours milk in bigger containers of 600ml and again deep freezes it. This means that she probably thaws the milk again. Anyway she was told that this entire process was wrong.
- Dissemination of DHM: The bank gets indents from NICU each day and DHM is issued accordingly. Prescriptions are not really insisted upon. For disseminating, the nurse thaws the 600 ml containers, same way as before. Then again opens the containers to pour milk in smaller containers to issue them to NICU. Concerns were expressed to the doctor that opening a bottle after pasteurization increases the chances of contamination.
- Recipient consent form: The recipient consent forms are not meticulously maintained and this practice needs to be strengthened.
- Discard: The Centre reported discard due to positive culture to be as high as 20%. The Centre was advised to strengthen its hygiene practices (hand washing, cleaning, sterilisation, use of gloves, masks and hair nets etc.), enforce restricted entry in processing room, have written SOPs and checklists for processes, significantly improve their process related to collection and pasteurization, which was quite poor. They were advised to get a lamina air flow, which significantly reduces chances of contamination. Their staff needs training on the processes. They were also advised to at least place curtains between tables in expression room and to restrict entry of male staff in collection rooms.

#### **6. Categories of infants given DHM**

- The bank collects around 0.5 litre of DHM every day. They barely manage to meet their needs and on many days they fall short.
- DHM given only to babies admitted in the NICU/SNCU of the Hospital
- Pre term and LBW babies; sick preterm neonates recovering from illnesses and GI surgeries etc.

- Once the babies have attained 1500gms, and if breastfeeding has not been established, then the babies are switched to cow's milk. They also use human milk fortifiers.
- Generally, they don't give DHM to babies post discharge in follow up OPDs.

#### **7. Records and Registers maintained**

- Donor registration and consent form
- Donor registration log book (mother's unique ID no., date of donation, quantity
- Donation log book (Sl No., date of donation, name of donor, donor location - SNCU or ward, place of donation – SNCU or ward, quantity of milk, bottle id etc.)

#### **8. Views on improvements and scaling up**

Apart from improving and strengthening their layout and processes as per CLMC Guidelines (see sub point on 'discard' above), the Neonatologist identified the following requirements:

- Ensure restricted entry in the milk processing room
- More equipment as per the CLMC guidelines. Definitely a laminar air flow
- More HR, particularly counselors, as currently they are really short staffed. More counselors will help with breastfeeding and DHM counseling
- If they have more staff, or dedicated staff, they could be open for milk collection for longer hours and not just from 9 am to 2 pm
- They need training for the staff, especially on pooling, pasteurization and culture samples
- The practice by the CLMC of asking fathers to bring expressed breastmilk from the mothers (admitted in another hospital or at home) for autologous feeding to her infant admitted in this hospital, needs more assessment and planning.

