


# Quality improvement initiative for a sustained increase in human milk donation during the hospital stay

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**To cite:** Jain S, Bansal A, Khurana S, *et al.* Quality improvement initiative for a sustained increase in human milk donation during the hospital stay. *BMJ Open Quality* 2023;**12**:e002133. doi:10.1136/bmjopen-2022-002133

Received 6 October 2022  
Accepted 5 October 2023

## ABSTRACT

**Background** The demand for donors' human milk is much more than the availability of the same due to the myriad challenges faced during the collection process.

**Methods** Baseline milk volume donation done in a human milk bank facility located in tertiary care government institute in a low-middle income country was assessed. It was initially aimed to increase the absolute quantity of milk volume donation by 30% over a period of 6 months, which was subsequently continued following COVID-19 emergence (over another 12 months) along with a particular emphasis on the sustenance of milk donation activities.

**Interventions** Counselling of both the healthcare workers and stakeholders, standardising the timing of milk donation and other policies, equipment in proportion to demand and supply and addition of human resource were done as a multiprong approach to have sustained increase in human milk donation.

**Results** The median control line (MCL) showed a shift of 27.8%; from a baseline of 5032 mL to 6971 mL during intervention phase I comprising of five plan do study act cycles spread over a period of 6 months. During the sustenance phase I even though the monthly collection was non-uniform, there was a further 16% upward shift in MCL to 8122 mL. During the second intervention phase, each component of the Ishikawa diagram was worked on (people, policy, place, procedure) resulting in a more than 100% increase from sustenance phase I taking the MCL to 17 181 mL with an overall increase of 3.41 times from the baseline.

**Conclusion** Dedicated counselling and constant motivation have been conventionally considered as the utmost measure to increase milk volume donation in milk bank. Our study highlights the need to introduce scheduled timings along with sufficient equipment and manpower to overcome the shortage of milk donation in human milk bank facilities.

## BACKGROUND

### Problem description

In-house human milk bank services were started in our centre in September 2016. The centre has a delivery load of 6500–7000 deliveries per year. Of the total delivery load, sick preterm neonates account for around one-third the load with a rapid turnover of approximately 2200–2500 neonates in 25-bedded neonatal intensive unit and 30-bed

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Counselling and education of mother's family and healthcare staff improve breast milk expression and donation.

### WHAT THIS STUDY ADDS

⇒ Use of myriad modes of education and counselling aids, with structured donation time chart while preventing interference with other activities of mothers' childcare, more donation equipment and timing adds to amount of milk donation in a sustained manner.

### HOW THE STUDY MIGHT AFFECT RESEARCH, PRACTICE, AND POLICY

⇒ Human milk donation in a milk bank can be sustained for the demand with multiprong approach.

space for high-risk low birthweight babies. Milk bank was started to decrease the use of formula milk and, wet nursing for a sick delivery load of around 1500 deliveries per year in 16-bedded intensive care unit. With the increase in proportion of sick neonates there was difficulty in ensuring donor human milk (DHM) when it was needed. Moreover, there were issues of over-crowding in milk bank than the available area, waiting time of around 15–45 min before the pump would be available to mother. There was only one full time medical social worker and a part-time lactation councillor; part-time worker for running the pasteurisation cycles, dedicated to milk bank.

There was a need of standardised procedure and policy to have uniformity in availability of mother's milk in accordance with the demand and to ensure the same is sustained on all the days.

### Available knowledge

Since times immemorial wet nursing was being practised with challenges of cross infection. The way ahead to continuously meet the nutritional needs of these preterm infants is well equipped, standardised and self-sustainable human milk banking (HMB)



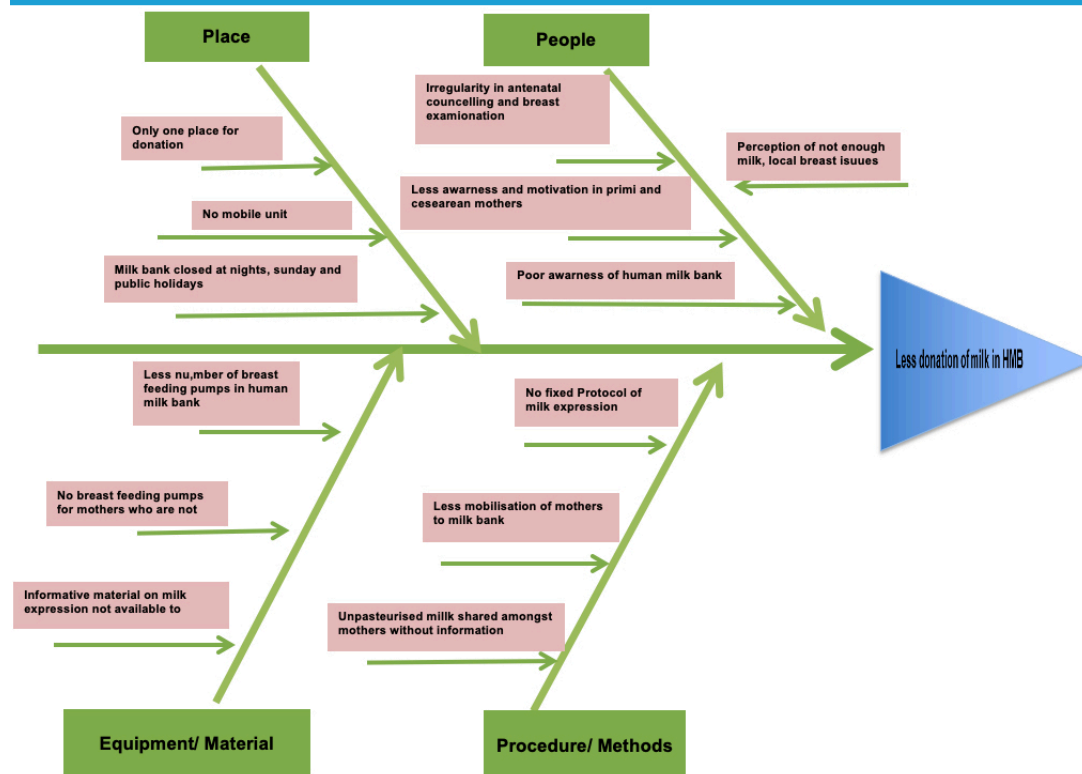
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**Fishbone Diagram: To analyse factors of decreased donation of milk than the demand in HMB**


**Figure 1** Fishbone diagram to analyse factors for decreased human milk donation. HMB, human milk banking.

services.<sup>1,2</sup> To address the same since 1980, the WHO and UNICEF had unanimously recommended and reiterated universal and safe availability of DHM for sick neonates when mothers own milk is not available urging setting up of HMB organisations,<sup>3</sup> such as Human Milk Banking Association of North America (HMBANA), European Milk Bank Association (EMBA), Italian Association of Human Milk Banks (AIBLUD), Global Alliance of Milk Banks and Associations (GAMBA) and Comprehensive Lactation Management Centres (CLMC) by the government of India. The main function of HMB organisations is to act as a reliable repository for surplus pooled and pasteurised DHM under standardised process of selection, collection, screening, pasteurisation and disbursal of DHM.<sup>4</sup>

HMB organisations globally face a varying degree of challenges not only in the form of economic and funding hindrances, but also for the availability of sufficiently trained human resource personnel for safe handling of DHM, professional and compassionate lactational support to donors keeping in view their demographic, sociocultural and religious factors.<sup>4</sup> As per the literature, LMICs share the maximum global burden of low birthweight and preterm births annually; out of which 40%–70% of sick hospitalised neonates are in want of DHM at a given point of time.<sup>5,6</sup> Of all births in India nearly 30%–50% preterm and sick babies in neonatal intensive care units (NICUs) lack access to breastmilk.<sup>7</sup> In a recent cross-sectional survey involving HMB organisations from a LMIC region; more than 60% of the

participating units acknowledged the existent DHM demand–supply gap being faced by their operational milk banking services. DHM has the potential to benefit five million plus babies in India, but the demand is disproportionate to the requirement and when this study was planned there were only 30 HMB organisations in India.<sup>7</sup> Current concern of the HMB organisations in India is limited number of the same in the country with reduced amount of milk donation in these milk banks.<sup>8</sup> This quality improvement (QI) project was initiated with the intent to increase the donation in institutional HMB, to ensure an uninterrupted supply of DHM.

### Specific aim

Initially the study was planned to increase the milk donation by 30% from the baseline (January–June 2019) over a period of 6 months (July–December 2019) and thereafter to check for sustenance of increased donation over next 6 months. However, in view of COVID-19 pandemic onset during the sustenance phase the study was halted and restarted after primary analysis of 6 months, whereby a new set of plan do study act (PDSA) cycles were planned after a period of sustenance check in view of inability to meet the initial aim.

## METHODS

### Context

This QI study was conducted in a tertiary level medical college hospital with level III NICU in North India with 25 intensive care beds, 30 beds for high-risk low

**Table 1** Summary of phase I (post baseline phase I) (figure 1)

PDSA cycle and timeline	Plan	Do	Study (changes in the milk donation volume)	Act
PDSA-1 1–31 July 2019	Counselling of mothers of NICU neonates regarding regular donation of milk in HMB at fixed time periods when maximum mothers could benefit.	Daily counselling at (14:00–15:00 hours) by the resident doctor with frequent counselling of mothers of sick neonates. Poster display on disadvantages of inadequate milk expression.	<i>(It increased from 5812 mL to 7800 mL from baseline of June to first month of intervention).</i>	<b>Adopt</b> the PDSA cycle, and to involve immediate postpartum mothers from CLR for counselling.
PDSA-2 1–31 August 2019	Counselling of early postpartum mothers in CLR nursery along with NICU mothers.	Counselling extended to mothers in CLR nursery. Identifying mothers with local breast problems, engorged breast.	<i>(Milk donation decreased to 4330 mL).</i> <b>Possible causes:</b> less time for counselling at defined hours, individualised counselling reduced. More number of days on which milk bank was closed due to public holidays.	<b>PDSA cycle modified.</b> Plan to involve other personnel in counselling in next PDSA. More focus on mothers who can mobilise.
PDSA-3 1–30 September 2019	Sensitisation of staff who looked after mothers in wards. Involvement of other personnel. Focused counselling and motivation of mothers with good milk output.	Involvement of staff nurses in counselling mothers. Involvement of social worker in counselling. Helping mothers with engorged breast to mobilise early to milk bank.	<i>(Milk donation increased to 6520 mL though the quantity was lesser to beginning of the intervention phase).</i> Some mothers refused donation. Temporary difficulty in keeping a regular track of mothers involved in donation.	<b>Adopt</b> the PDSA cycle. To allay mother's concerns and fears. To keep track of involved mothers in the next PDSA cycle by maintaining a record.
PDSA-4 1–31 October 2019	Increment of catchment area by involvement of mothers of babies admitted in intermediate care nursery, postnatal, new gynae and private wards. Focused counselling of mothers with sore and flat nipples or engorged breasts. Use of IEC means.	Individualised counselling for mothers with local breast issues, formation of dedicated peer groups for helping mothers, encouraging mothers for increasing kangaroo mother care duration and, formation of WhatsApp group to keep track of new mothers (as bundle of care).	<i>(Milk donation increased to 7060 mL from 6520 mL in September).</i> Mothers felt more comfortable in discussing their concerns within peer groups. Time taken in counselling, exceeded allotted time to one group adding to waiting time of another group.	<b>Adopt</b> the PDSA cycle and to decrease waiting time for mothers and to do group counselling in next PDSA.
PDSA-5 1–30 November 2019	To decrease waiting time for mothers coming from areas other than NICU. To club counselling of mothers from various areas.	Designated breast pump for NICU mothers. Group counselling of mothers started. Individual mother counselling abandoned unless person-specific issue.	<i>(Milk donation increased to 7560 mL).</i> Less waiting time for mothers. Easy tracking of new mothers with WhatsApp group, which was also used for motivational messages.	<b>Adopt</b> the PDSA cycle. Continued counselling once in morning hours and in evening hours in all areas.

CLR, clean labour room; IEC, Information, Education and Communication; NICU, neonatal intensive care unit; PDSA, plan do study act.

birthweight babies in postnatal ward and for around 2500 plus high-risk, preterm mother–baby dyad in need of support for human milk. Average nursing strength per shift for patients: nurse was 3:1 in the NICU, 4:1 in

the intermediate care nursery and 15:1 in the wards. A dedicated lactation counsellor and a social health worker were also present in the morning shift on all working days. Unit had three consultant neonatologists, five

**Table 2** Summary of phase II (postsustenance PDSA phase II) (figure 1)

PDSA cycle	Plan	Do	Study	Act
PDSA-6 (1–30 June 2021)	To increase number of breast pumps for stationing with mothers who were not mobile.	Three new breast pumps procured. New breast pumps stationed in wards along with the training of area nursing officers for operation of breast pumps. Three breast pumps kept in HMB for mobile mothers as was in phase I.	Changes in the volume of milk donation with factors behind the same. ( <i>Milk donation raised to 7245 mL but the increase was not substantial.</i> ) Mothers from these areas were concerned about fear of contamination while breast pump usage and had reduced motivational drive due to reduced visits by milk bank staff.	<b>Abandon the PDSA cycle. Actions taken:</b> Reorganise the breast pumps in the milk bank facility. To reorganise the timings of milk donation from various areas.
PDSA-7 (1–31 July 2021)	To reorganise the timings of milk donation from various areas. KMC timings of various areas were noted, and milk donation time preceded it so that both the processes were continued on any given day.	Avoid overcrowding and improve seating arrangement by introducing written schedule for milk expression three times a day. NICU and PNW1: 9:00 hours. Gynae ward and intermediate care nursery: 9:30 hours.	Changes in the volume of milk donation volume with factors behind the same. ( <i>Milk donation increased to 15050 mL</i> ) Milk donation less on weekends due to half working day of staff on Saturdays.	PDSA cycle <b>modified and adapted.</b> Posters along with group counselling of mothers and nursing officers of various areas by HMB staff initiated for staggered timings and motivational messages shared with mothers through job aids.
PDSA-8 (1–31 August 2021)	To improve milk bank functioning facilities over the weekend for improving uniformity in services.	Milk bank timings increased from 13:00 hours to 17:00 hours on weekends.	Changes in the volume of milk donation with factors behind the same. ( <i>Milk donation increased to 17181 mL, MCL figure 2</i> ).	<b>Adopt</b> the PDSA cycle and To alternate duties of lactation counsellor and medical social worker in the HMB over the weekend. To restrict area-wise counselling of mothers before forenoon on weekends and to focus mainly on smooth functioning of milk bank activities post lunch.

HMB, human milk banking; MCL, median control line; NICU, neonatal intensive care unit; PDSA, plan do study act.

fellow residents, three to four junior doctors involved in care of neonates.

### Intervention

To tackle the identified problem, a multidisciplinary QI team was formed. It comprised of one consultant neonatologist, one neonatology fellow resident, one dedicated lactation counsellor, one social worker and experienced staff nurses of respective areas. Neonatologist served as supervisor and coordinated different changes and activities to be performed among members. Fellow neonatology resident worked as a team leader, led meetings and directed activities to achieve goals. Milk bank donation register was maintained by the social worker. The present study followed the WHO Point of Care Quality

Improvement (POCQI) model. The study was conducted in three phases.

### Observation phase (January 2019–June 2019)

Total milk donation per month during the 6 months period was calculated from the milk bank register maintained prospectively by a social worker, which formed the baseline data. Baseline milk donation was 5030 mL/month. A root cause analysis was done by means of a fishbone diagram (figure 1), to delineate possible contributing factors of inadequate milk donation.

The QI team identified various causes for decreased milk donation in the milk bank namely lack of awareness among mothers regarding donation, use of unprescribed non-pasteurised donor milk, less mobilisation of mothers

**Table 3** Activities done in the intervention phase and sustenance phase to increase donation of milk in HMB

Phase of QI and activity	Target areas and structure of activities
<b>Intervention phase</b>	<b>Target areas: mainly related to policy and population</b> <b>Structure: how, where and when</b>
Counselling of mothers and family Involvement of staff nurses Involvement of medical social worker	<ul style="list-style-type: none"> <li>▶ In NICU, extended in phasic manner to clean labour room, wards and step-down ICU</li> <li>▶ Counselling in group with individualised focus on those with local breast issues and increased frequency in those with caesarean section</li> <li>▶ Proven aids for group counselling with posters, videos were used along with scaling to use of social media in form of WhatsApp group media</li> <li>▶ Staff nurses of all the areas were taught in a structured manner for counselling the mothers and family</li> <li>▶ Social worker was trained for breastfeeding counselling using various modes of communication in a structured manner</li> </ul>
<b>Sustenance phase</b>	<b>Target areas: adding of equipment and human resource improvising in policy and population parameters</b>
Equipment Policy Policy and Human resource	<p>New breastfeeding pumps were procured. The timetable was prepared for visit of mothers to HMB to decrease the waiting time and non-interference with kangaroo care timings</p> <p>Timings of milk bank services were increased with additional, adjustable work hours of human resource</p>
HMB, human milk banking; NICU, neonatal intensive care unit.	

and waiting period for mothers during milk expression in a milk bank. Some mothers had surplus milk output and they even donated it to others but felt reluctant to come to the milk bank for donation due to the above-mentioned reasons. Lack of awareness of milk expression benefits, and scarcity of professional counselling skills among healthcare personnel also compounded towards aggravating the existing problem. Also, it was found that personalised individual counselling was missing in primiparous mothers and those who underwent caesarean section, as these mothers are at higher risk of delayed establishment of lactation beyond the initial 48–72 hours.

#### Intervention phase (July 2019–December 2019)

All healthy postpartum mothers admitted in the hospital and willing to donate their breast milk were included after a written informed consent. They were screened for HIV, Venereal Diseases Research Laboratory (VDRL), Hepatitis B and Hepatitis C and reviewed for medication intake contraindicated during breast feeding. A patient information sheet was provided in the vernacular language containing the basic details of the mother and the baby. The QI team then decided to perform multiple sequential PDSA cycles to tackle the identified problems. The elements of these PDSA cycles included dedicated regular education and counselling of mothers, skilled training and robust involvement of healthcare workers, use of information, education and communication means such as posters, video recordings, focused group discussions, informal peer group meetings, multimedia-WhatsApp group formation and education of mothers towards possible adverse effects of unpasteurised donor milk usage. These changes were tested and modified as a part of PDSA cycles. Changed ideas were then adopted, adapted or abandoned, depending on

their feasibility and outcomes. Summary of these PDSA cycles is described in [table 1](#).

#### Sustenance phase

To check the sustainability of QI project, the amount of milk donated from January 2020 onwards was planned to be recorded prospectively by medical social worker over a period of 3–6 months, however in view of onset of COVID-19 pandemic in the region led to ongoing policy changes in the milk bank collection processes. Hence, this phase was not considered as representative of post QI project sustenance phase.

The data were collected for milk collection from January 2021 onwards, once restrictions related to COVID-19 admissions were modified. The study had to be halted during the COVID-19 pandemic (onset of first wave) in the region; due to separate SOPs followed for COVID-19 infection as per the hospital policies keeping in view the need for social distancing and segregation policies. In view of the inability to meet initial Specific, Measurable, Achievable, Relevant, Time bound (SMART) aim over first 6 months period after baseline assessment, a new set of PDSA cycles ([table 2](#)) were planned after a period of sustenance check.

#### Study of the intervention

The intervention team led the monthly meetings and reviewed the collection of milk. During each meeting along-with discussion of progress of PDSA cycles, it was planned to identify and involve hospital areas from where fewer postpartum mothers came forward for milk donation and to tackle the problems that they were facing ([table 3](#)).

## Process measures

The process measure was the total amount of milk donated per month, number of postpartum mothers coming from individual hospital area for donation, amount of milk donated by mothers with regard to maternal characteristics such as mode of delivery, parity, maternal age, duration of hospital stay and infant characteristics like birth weight and gestational age.

Outcome indicators were to percentage increment in milk donation and identification of maternal and/or infant characteristics that might have affected the milk donation.

## Data analysis

Data were collected on the patient information sheet and transferred to the excel sheet. The continuous analysis was done on a QI Macros chart (statistical process control software package plugin for Microsoft Excel for Lean Six Sigma) to evaluate the trend of increase/decrease in the donation of milk per month in the milk bank.

## Ethical considerations

The present study was conducted after taking approval from institutional ethical committee.

## RESULTS

During the observation, implementation and sustenance phase data collected prospectively by lactation counsellor was entered into excel and process control charts were created to analyse effect of PDSA cycles (figure 2)

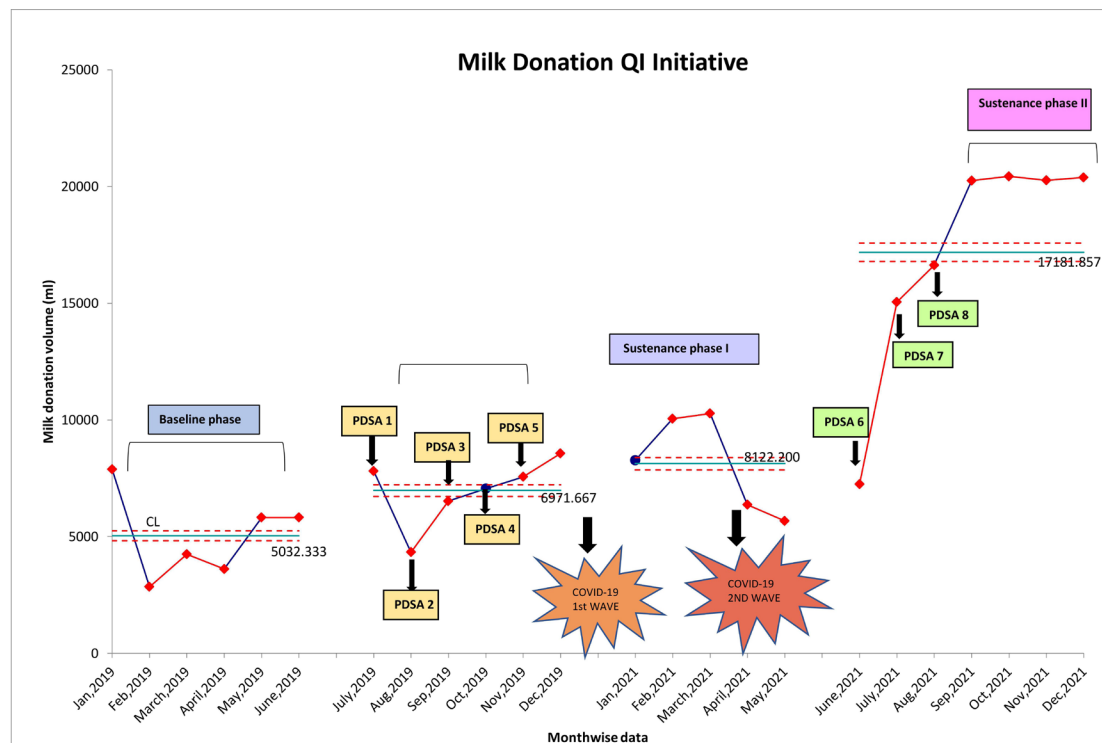
## Observation vers intervention phase

Total milk donation in the observation phase was 30 182 mL; 5030 mL/month ( $\pm 1831$ ) and an average of 167 mL/day which increased gradually during the intervention phase to 41 830 mL, which is around 6971 mL/month ( $\pm 1465$ ) and an average of 227.2 mL/day. Trend of milk donation per day in each month, total milk donation in each month and applied PDSA cycles have been depicted in table 1. Total increment during phase I of the study was 27.8% against a target of 30%.

## Intervention vers sustenance phase

In the sustenance phase, there was a continuous increment in the milk donation, which was 8260 mL (266 mL/day) in January 2021. The amount of milk collected from January 2021 to May 2021 (figure 2) was 8122 mL as per median control line (MCL), hence showing the sustainability of phase I activities. There was a decline during month of April to May 2021 in view of resurgence of COVID-19 second wave. It was therefore planned to procure more portable breast milk pumps to avoid overcrowding in HMB.

During PDSA cycles phase II, the amount of milk donated during the month of August 2021 was 16 630 mL, as compared with 5640 mL in the month of May 2021, prior to PDSA cycle phase II implementation, with MCL shift from 8122 mL to 17181 mL, an increment of double the initial volume that is, 2.1 times over a period of 12 months.



**Figure 2** Milk bank QI statistical process control chart during baseline, intervention and sustenance phase. PDSA, plan do study act; QI, quality improvement.

During sustenance phase number of mothers who donated milk had decreased in phase I to 117 and increased in phase II to 530; but increase in milk volume was 28% more in intervention phase and 210% more in sustenance phase II.

## DISCUSSION

Our results are consistent with other studies, which have also shown a positive impact of counselling on milk expression. In a study conducted by Sisk *et al* to determine the effect of lactation counselling on maternal stress and anxiety level and the amount of milk expression, it was found that 85% of women in the formula feeding group started expression of breast milk without any increment in the maternal stress or anxiety level.<sup>9</sup> Other studies concluded educating participant mothers about benefits of milk donation and so they felt more motivated and reported increased milk production.<sup>10</sup> In the current study, counselling was done using myriad modes like audio-video, charts, WhatsApp group of mothers, individualised to special need mothers, counselling of nurses and milk bank staff in all areas, which sensitised them to human milk bank, benefits of milk expression, resulting in increased milk expression and donation. Mothers waiting time in milk bank was reduced to nil with increase in breast milk pump and clarity on their timing to come for milk expression.

There are data from North India on improving milk expression in first 7 days of postnatal age, whereby education and sensitisation of healthcare workers using videos, webinars, teamwork, rewards of good work and sensitisation of the family for early and nocturnal milk expression has shown improvement in human milk expression from 12.5% to 80%.<sup>11</sup> Another study conducted in South India had shown an increase of 65% in exclusive human milk feeding from 44% of baseline with Mother Baby Friendly Initiative model. Structured capacity building, training of staff, behaviour modification with proven aids, conducive infrastructure and equipment improved exclusive human milk intake in babies during the hospital stay. In this study, Pooled Donor Human Milk (PDHM), after milk donation, and KMC were part of intervention and not the sole intervention.<sup>12</sup> Total increment following phase I and phase II PDSA cycle was 3.41 times from the baseline targeting education of healthcare staff and family, human resource, equipment, policy modification using structured time frame of activities.

The major *strength* of this QI initiative was that no extra space and healthcare personnel were employed for improving functioning of HMB facilities, and all the domains of Ishikawa diagram were targeted to sustain the milk donation to 2.11 and then 3.4 times the baseline value.

*Limitation* of the study was that socioeconomic and demographic factors were not analysed. These factors too have influence on milk donation practices. Outcome of

increased donation in the form of neonatal outcome at discharge was not studied objectively.

## CONCLUSION

The authors conclude that the QI initiative following repeated cycles of adapting, adopting and abandoning PDSA cycles based on local challenges and targeting major domains of policy, population, equipment and human resource in the form of targeted counselling of mothers using myriad modes, relocation of breast pumps for ease of use and readjustment of milk donation and milk bank operational timings served as a major tool in donation of milk in institutional HMB and sustain the same effectively.

**Acknowledgements** The authors would like to thank all the nursing staff of NICU, intermediate care nursery, labour room nursery and postnatal ward who played a major role in counselling of mothers. We would also like to pay our special regards to the lactation counsellor, and social worker who went an extra mile not just in maintaining records and gave dedicated counselling but also eagerly accepting to work extra hours on weekend to improve the services of HMB. Lastly all the mothers who had donated milk in the milk bank, without whom this study could have not been possible.

**Contributors** The study was designed by SJ, it was carried out by AB. During the sustenance phase, SK helped in PDSA cycles. Training of the staff and team mates was done by SJ and DC. SK helped in finalising the manuscript. All the authors contributed to finalising the study and manuscript. SJ is the guarantor.

**Funding** Publication of this article is made open access with funding from the Nationwide Quality of Care Network.

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Ethics approval** Study was approved by institutional ethics committee.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data sharing not applicable as no datasets were generated and/or analysed for this study. All data relevant to the study are included in the article or uploaded as supplementary information. Data available on request due to privacy/ethical restrictions.

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