

## Impact of Quality Improvement Program on Expressed Breastmilk Usage in Very Low Birth Weight Infants

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**Objective:** To improve the usage of expressed breast milk in very low birth weight infants admitted in the neonatal intensive care unit of a tertiary centre in India.

**Methods:** Between April 2015 and August 2016, various Plan-do-act-study cycles were conducted to test change ideas like antenatal counselling including help of brochure and video, post-natal telephonic reminders within 4-6 hours of birth, standardization of Kangaroo mother care, and non-nutritive sucking protocol. Data was analyzed using statistical process control charts.

**Results:** 156 very low birth weight infants were delivered during the study period, of which 31 were excluded due to various reasons. Within 6 months of implementation, the

proportion of very low birth weight infants who received expressed breast milk within 48 hours improved to 100% from 38.7% and this was sustained at 100% for next 8 months. The mean time of availability and volume of expressed breast milk within 48 hours, improved gradually from 73.3 h to 20.9 h and 4.7 mL to 15.8 mL, respectively. The mean proportion of expressed breast milk once infant reached a feed volume of 100 mL/kg/day also improved from 61.3% to 82.3%.

**Conclusion:** Quality improvement interventions showed promising results of increased expressed breast milk usage in very low birth weight infants.

**Keywords:** Antenatal counselling, Breastfeeding, Care bundle, PDSA cycle.

Human milk has immunerable benefits for infants, especially very low birth weight (VLBW) infants [1]. Recent evidence implicate that prematurity related morbidities are closely related to specific critical periods following birth, during which the use of human milk may be most important. In addition, the dose and exposure period of human milk appears critical to confer its benefits [2]. Four well-controlled studies in premature infants have linked the dose of human milk (mL/kg/d) received throughout the Neonatal Intensive Care Unit (NICU) stay with specific health outcomes during or after NICU stay [3-6]. However, the usage of human milk in VLBW infants varies globally and human milk banks are not widely available, especially in resource limited settings. In such a scenario when donor human milk feeding is not available, the only feasible option available to clinicians for optimum nutrition of preterm infants is to make mothers own milk available. Quality improvement (QI) programs through altered clinical behavior and by delivering consistent good practice can improve usage of human milk and therefore improve health outcomes of preterm infants [7]. Interventions such as antenatal consults, lactation counselling, tracking mother's milk supply, staff

education, and other evidence-based bundles have been used to improve usage of human milk [8-13]. However, no QI initiatives have been reported from India focussing on EBM usage in VLBW infants.

In our unit, the usage of expressed breast milk (EBM) in VLBW infants was low, and the proportion of EBM usage of total feeds was only 52% [14], and the availability of first EBM after birth was often delayed for days. This prompted us to start a QI program in our hospital in collaboration with Institute of Healthcare Improvement (IHI), Massachusetts and ACCESS health International, India with an objective to improve usage of EBM in VLBW infants. The specific goals of the project were to obtain EBM in >80% of VLBW infants within 48 hours of admission to the NICU, improve volume of EBM obtained in first 48 hours (by 100%), to decrease the time of availability of first EBM by 20% of baseline and to improve proportion of EBM volume usage by more than 20% of baseline.

### METHODS

The project was carried out in a tertiary-care center with level III B NICU in India from April 2015 to August 2016. The institute does not have a human milk bank and enteral

feeding depends on availability of mother's own milk; in case of unavailability of mother's own milk, preterm formula is used. This project involved the systematic implementation of evidence-based practices utilizing QI strategies and thus did not require Institutional Review Board approval.

Data on all inborn infants with a birth weight of  $\leq 1500$  g admitted to the NICU were included. Driver diagram (**Web Fig. 1**) was developed after internal discussions. The nature of intervention was chalked out by a multi-disciplinary QI team. It consisted of two consultant neonatologists, two neonatology residents, a dedicated lactation counsellor, nurse in charge of NICU and delivery room, four senior NICU nurse with extensive feeding expertise, two improvement experts, and one project manager. This team underwent extensive brainstorming sessions and performed the root cause analysis of less usage of EBM in NICU (**Web Fig. 2.**). The QI team then developed the Care bundles based on evidence based practices distilled from literature search, and agreed upon or modified them for local implementation. A summary of the components of the care bundle is provided in **Web Table 1**. The care bundle consisted of two elements: promotion of early milk expression and ongoing support for lactation and stress management.

In the first phase of the project, from April to June 2015, change ideas were tested by repeated PDSA cycles. Change ideas were modified or discarded based on PDSA ramps. In the first PDSA ramp (**Web Fig. 3**), the change idea of antenatal counselling was developed and tested. Initially antenatal counselling was done in two cases at random and EBM was not available in the first 48 hours in either of them. This idea was discarded. In the second cycle, we developed and tested a standardized format for antenatal counselling in three cases and EBM within 48 hours was available in two of these. The mother who failed to send EBM to the NICU gave the feedback that she forgot about sending EBM. In the third cycle, we added the change idea of giving telephonic reminders to the mother within 6 hours of delivery. We tested these in another four cases and could get EBM within the stipulated time in all cases. In the second phase from mid-June 2015, implementation of these tested change ideas was started while ongoing PDSA were being conducted. The QI team received a feedback from the mothers that a pictorial illustration would help them better to pump EBM, so a brochure and posters were developed and tested in the fourth cycle in July 2015. In the fifth cycle, we added on the change idea of showing videos to mothers during antenatal counselling sessions. The completed PDSA ramp 1 was implemented in August 2015. Similar to PDSA ramp 1, PDSA ramp 2 constituted of three consecutive

PDSA cycles of developing and testing a standardized KMC and NNS protocol followed by its implementation in late August 2015. PDSA ramp 3 constituted of three consecutive PDSA cycles in August to develop and test list-based tracking of mothers. PDSA ramp 4 consisted of another three cycles of daily data entry of EBM status in weight book by nurses, integration of data in excel sheet by residents, followed by Excel-based daily counselling by consultants before it was implemented in September 2015. PDSA ramp 5 consisted of two PDSA cycles on change idea of fortnightly video-based group counselling sessions of mothers in the NICU. PDSA ramp 6 was run in December 2015 and in a planned experimentation design, change ideas of daily team huddle, text messaging and admission brochure were tested.

The improvement activities are described in **Web Box 1**.

**Process and Outcome Measures:** The process measures studied monthly were proportion of mothers counselled ante-natally or post-natally for expression of breast milk and proportion of eligible VLBW infants who received Kangaroo mother care and non-nutritive sucking. The outcomes measures that were evaluated monthly for infants born  $\leq 1500$  g birth weight were percentage of infants who received EBM within first 48 hours of birth, time of availability of first EBM, volume of EBM available in first 48 hours, and volume of EBM vs formula (in %) once infant reached a feed volume of 100 mL/kg/day. The balancing measure was proportion of normal term infants discharged on total breast feeds.

Baseline data of each eligible infant from February 2015 to April 2015 was collected retrospectively from infant's daily milk record. Following April 2015, after initiation of IA program all data was collected prospectively.

**Data analysis:** Data were analyzed using QI charts software. Statistical process control charts called Shewhart's charts were used in our project to evaluate the effectiveness of intervention over time [15-17]. The control limits on the charts (upper and lower) establish the margins within which the measurement will be found approximately 99% of the time. The observed change was considered significant *i.e.* resulting from a special cause variation as per rules for special cause [18]. P statistical process chart was used to examine non-nutritive sucking, Kangaroo mother care, antenatal counseling and percentage of VLBW infants who received EBM within first 48 hours of birth. X-bar chart was used to examine time of availability of first EBM, volume of EBM available in first 48 hours and proportion of EBM once infants reached a feed volume of at least 100 mL/kg/day.

**RESULTS**

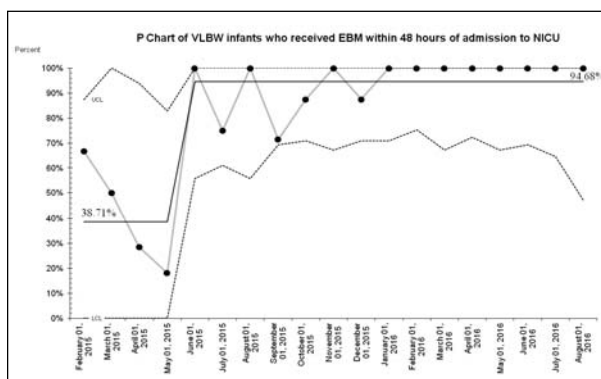
A total of 156 VLBW infants were delivered during the study period, of which 31 were excluded from analysis as their mothers required admission in ICU due to one of the postnatal complications like seizure, shock or severe post-partum bleeding. One hundred and twenty five eligible VLBW infants were finally included for analysis. The mean (SD) gestational age and birth weights of the infants were 29.6 (2.6) weeks and 1094 (243) g, respectively.

The proportion of mothers counselled ante-natally or post-natally for expression of breast milk improved over time and was sustained. The proportion of eligible infants who received Kangaroo mother care and non-nutritive sucking remained above 90% in 12 consecutive data points (**Web Fig. 4**). Before implementation of any component of care bundle, the proportion of VLBW infants who received EBM within 48 hours of birth was 38.7%. Within 6 months of implementation, this improved to 100% and following the most recent interventions, this was sustained at 100% for next 8 months (**Fig. 1a**). The mean time of availability and mean volume of EBM within 48 h, before the implementation phase was 73.3 h and 4.7 mL, respectively. After this phase, the mean time of availability of first EBM steadily declined to 20.9 h and mean volume of EBM obtained within 48 h of birth improved more than three folds to 15.8 mL (**Fig. 1b, 2a**). The mean proportion of EBM once infant reached a feed volume of 100 mL/kg/day also improved from 61.3% to 82.3% (**Fig. 2b**). The balancing measure-proportion of normal term infants discharged on total breastfeeds did not show any significant change during the project.

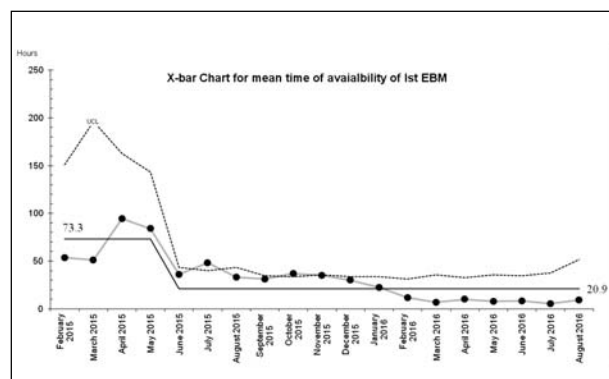
**DISCUSSION**

This quality improvement initiative resulted in increase in proportion of VLBW infants who received EBM within first 48 hours of birth, decreased time of availability of first EBM, increased volume of available EBM in first 48 hours and overall higher consumption of EBM in VLBW infants.

Our results are consistent with other studies that had used similar or different care bundles for achieving higher human milk consumption in VLBW infants [8-13]. Sisk, *et al.* [8] in a study evaluated the impact of lactation counselling on initiation of milk expression and found that counselling mothers of VLBW infants increases the incidence of lactation initiation and breastmilk feeding without increasing maternal stress and anxiety. Murphy, *et al.* [9] implemented similar interventions in addition to tracking of mother’s milk supply and physician education. The median time of first maternal milk expression decreased significantly and there was significant improvement in the proportion of infants receiving exclusive mother’s breast milk at 28 days and at discharge. Spatz, in 2004, recommended 10 steps for promoting and protecting breastfeeding in vulnerable infants [18-19]. The steps involved various aspects of lactation support including assisting the mother with the establishment and maintenance of a milk supply, providing skin-to-skin care (Kangaroo care) and opportunities for non-nutritive sucking at the breast, and providing appropriate follow-up care. Fugate, *et al.* [20] implemented the ten steps in a continuous quality improvement initiative and achieved significant improvements in the percentages of mothers expressing their milk within 6 hours of delivery, infants receiving



(a)



(b)

Arrows denote points of implementation of change ideas; June 2015-Antenatal counselling, reminders, physical help by lactation counsellor; August 2015- KMC/NNS, brochure/videos/postnatal daily counselling and list based tracking; September 2015-excel sheet based daily counselling; October 2015-video based counselling; December 2015-planned experimentation including team huddle.

**FIG. 1** (a) P chart of VLBW infants who received EBM within 48 hours of admission to NICU; and (b) X-bar chart for mean time of availability of first expressed breast milk (EBM).

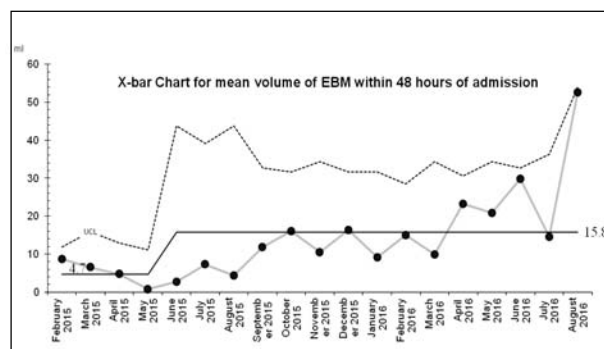
mother's own milk at initiation of feeds, and mothers with a hospital-grade pump at discharge. The findings of QI initiative that we conducted are similar to above published literature.

The care bundles that were used in our QI initiative were tailor-made for our system and upscaled through multiple PDSA cycles before implementation. The use of planned experimentations in choosing some of the care bundles to improve EBM usage is unique to this QI initiative. The outcome measure that improved quickly after implementation was time of availability of first EBM. This happened because the enthusiastic team members would initiate pumping mothers' milk themselves as soon as mother's condition permitted. A dedicated NICU lactation consultant and the NICU nursing team were key members of the team. However, the volume of EBM and proportion of EBM of total feeds not only depended on team member's efforts but also on the commitment of the mothers and physical as well as emotional state. When the time of availability of first EBM consistently came down, we then focussed on outcome measures of improving volume of EBM.

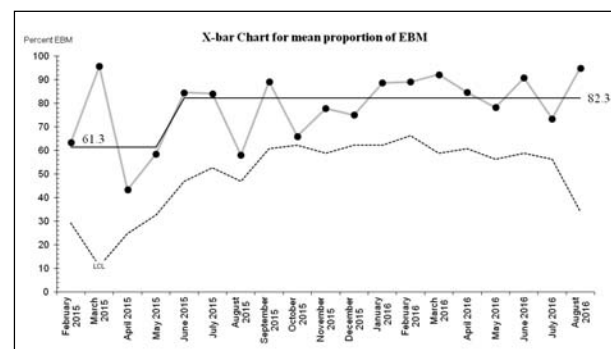
The strength of this QI project is that it represents one of the first few published reports from India to demonstrate the effectiveness of the systematic implementation of QI methods to improve usage of human milk in very low birth weight infants. We used a dedicated lactation consultant to lead the QI improvement project. Nonclinical duties were therefore delegated to ancillary personnel. The improvement project has some limitations. First, the care bundles that were tested in various PDSA cycles were implemented in groups rather than as individual interventions. This potentially limits our ability

to link the interventions with the outcome. This also led us to describe our results in two phases. Phase 1 was the initial phase of the project which had some PDSA testing going on, while phase 2 had both implementation and testing going on concurrently. In our project, as no baseline data was available, historical data was used to create baseline along with first few data points while the project was getting up and running. This is crude but can be useful as chances are that the processes have not been improved much during this start up time frame. Secondly, the outcomes of our study could have been possibly confounded due to constant supervision and monthly reporting of data to IHI from April 2015 to March 2016 but the fact that the results of the study were sustained even after this phase, possibly mitigates this bias. Thirdly, our study was conducted in a level 3B NICU and the study sample was well educated so counselling and implementation of other change ideas could be easier than would be expected in a different set-up. So, some interventions may need to be modified as per the population and local set-up. In addition, although no additional manpower was employed for this QI Project nor was it funded but a replication of similar results may require a dedicated QI team that takes up additional responsibility without compromising other aspects of clinical care unless the entire process is integrated in the system and becomes a culture of the unit.

We conclude that by systematic application of QI methods EBM usage of mother's own milk in VLBW infants can be significantly improved and sustained. Further research should focus on replicating these findings in different settings, further expanding the benefits to all neonates admitted in NICU who require EBM and evaluating the impact of increased EBM, usage



(a)



(b)

Arrows denote points of implementation of change ideas; June 2015-Antenatal counselling, reminders, physical help by lactation counsellor; August 2015- KMC/NNS, brochure/videos/postnatal daily counselling and list based tracking; September 2015-excel sheet based daily counselling; October 2015-video based counselling; December 2015-planned experimentation including team huddle.

**FIG. 2** (a) X-bar Charts for mean volume of first expressed breast milk (EBM) within 48 hours of admission and mean proportion of expressed breast milk (EBM).

#### WHAT THIS STUDY ADDS?

- QI program can be implemented and sustained even in resource-limited settings to improve usage of human milk in very low birth weight infants.

on clinical outcomes such as sepsis, necrotizing enterocolitis, mortality and long term neurodevelopment.

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*Contributors:* AT, NK: conceptualized the project; AT: developed the protocol; AT, PRG: had primary responsibility of patient screening, enrolment and data collection; AT: performed the data analysis; AT: wrote the manuscript; NK, PG: participated in protocol development, supervising enrolment, outcome assessment and in writing the manuscript; AS: participated in planning of project and writing of manuscript.

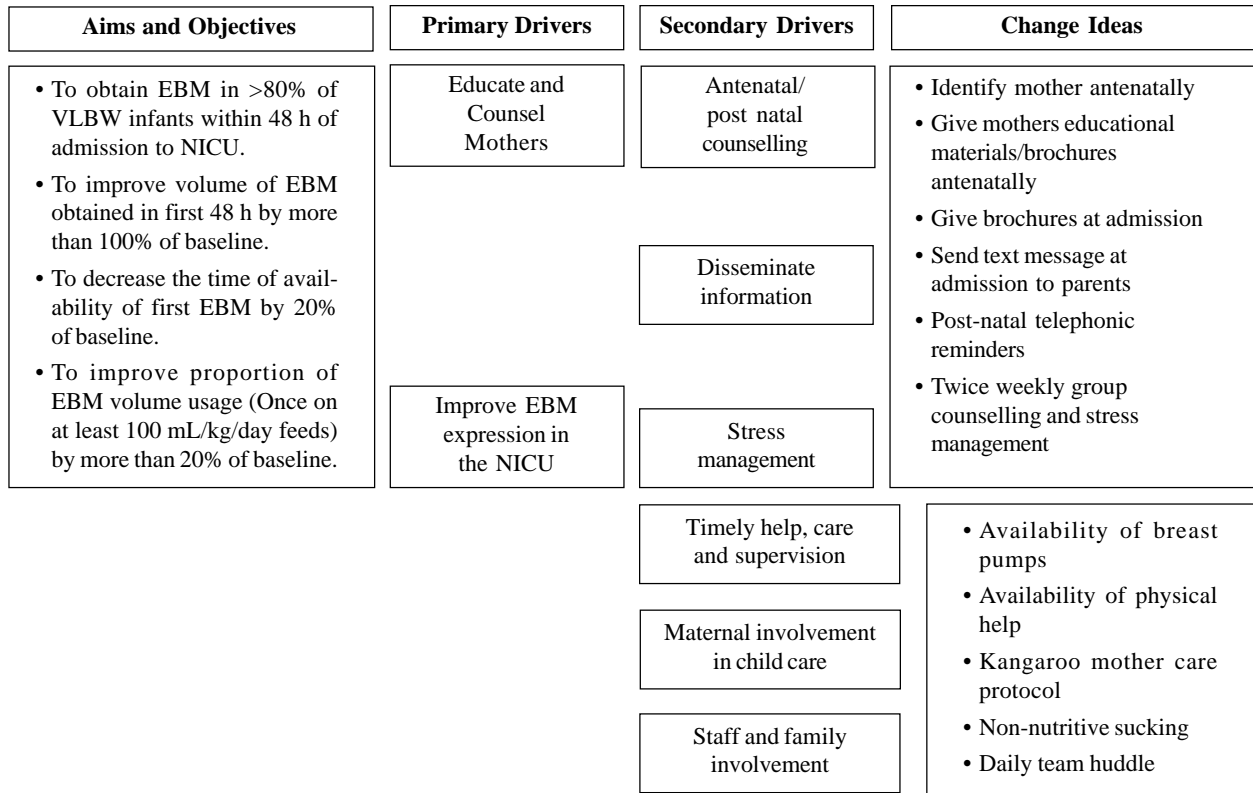
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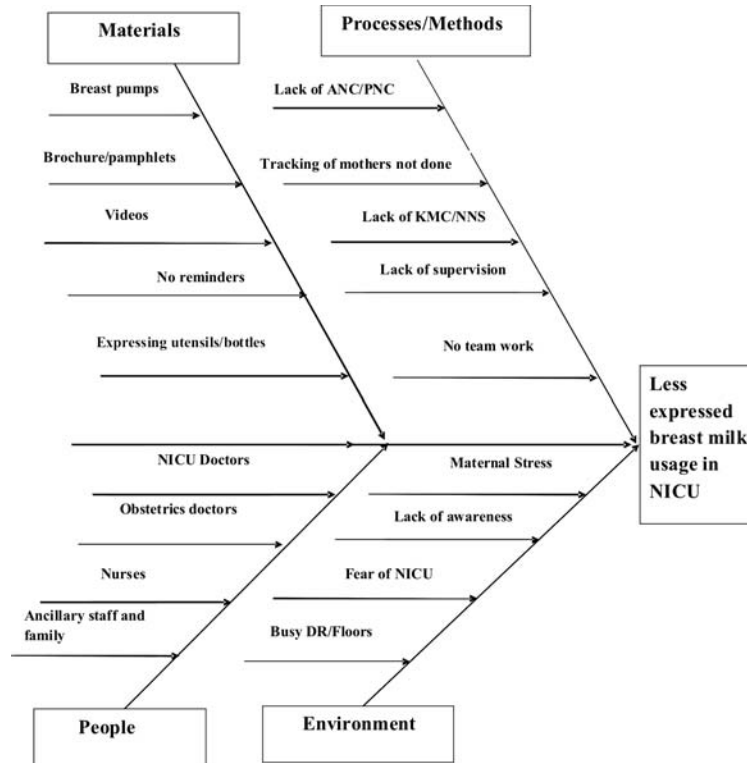
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**Web Box 1** ACTIVITIES FOR QUALITY IMPROVEMENT IN PRESENT STUDY

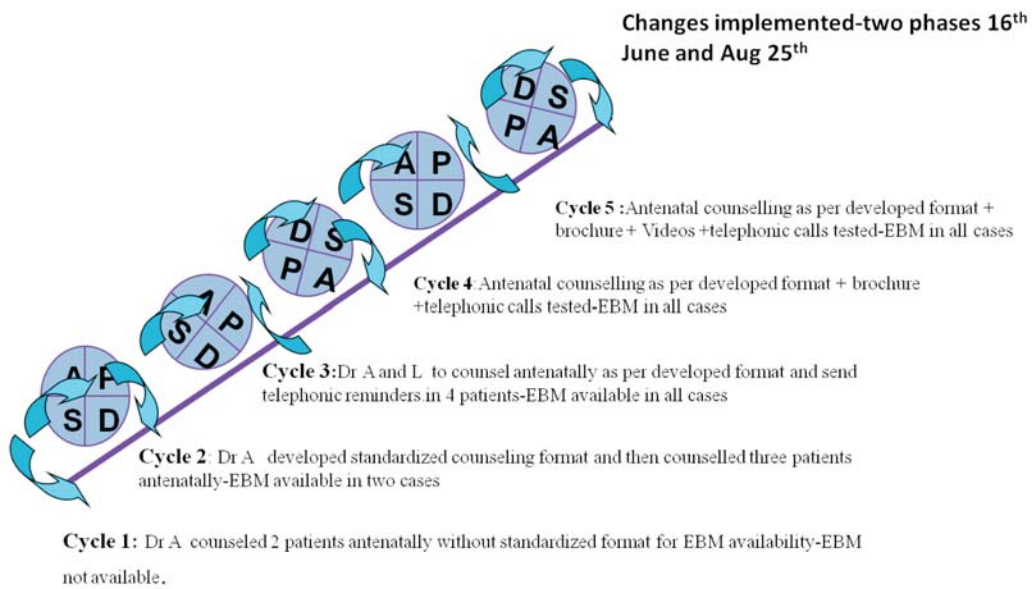
- *Meetings and presentations:* Presentations about improvement project, benefits of expressed breast milk and anticipated hurdles were made to a variety of audience including neonatal and obstetrics residents, nurses, obstetricians and departmental consultants. These presentations also addressed the importance of team work, staff assistance and laid emphasis on common goal of how to get EBM early and in more volume. Administrative bottle necks were discussed and sorted out with the chairs of various departments.
- *Standardized counselling format:* For antenatal counselling of mothers expected to deliver prematurely, a standardized format was developed, to avoid ambiguity during these sessions. Counselling was to be done by members of improvement team-lactation consultant and a neonatologist. The format consisted of greeting the mother, introduction of the team person and specific emphasis on benefits of EBM in decreasing risk of sepsis, necrotizing enterocolitis and improving brain development. The format also contained information about importance of colostrum, recommendations to express milk early, availability of breast pumps, how to send milk to NICU and ended with checking mother's understanding with some random questions. This was developed and tested in the first PDSA cycle before implementation by mid-June 2015.
- *Brochure and posters:* A brochure named "Mom will you do it for me?" was made that contained information about the benefits of breast milk and pictures of how to pump breast milk. It was used during antenatal counselling and in some cases where antenatal counselling had been missed; it was given to the family member during admission of the baby to the NICU. Posters were displayed in the labor rooms and postnatal wards describing the beneficial effects of breast milk, early initiation of breast feeding and expression of breast milk. These were implemented by August end 2015.
- *Videos:* Videos were shown to mothers during counselling sessions informing about benefits of breast milk and its expression. After October 2015, group counselling sessions of all mothers was started fortnightly and videos emphasizing the importance and benefits of breast milk were played in the mothers' room in the NICU.
- *Text messaging and telephonic reminders:* We introduced a system of sending text message at admission of the baby from NICU help line number to parents who delivered a preterm baby. At 4-6 hours after baby's admission, nurse assigned to the baby had to call up the mother via hospital intercom and remind her to send EBM.
- *Standard protocol for Kangaroo mother Care (KMC) and Non-nutritive Sucking (NNS):* Before starting of the project, KMC and NNS were prescribed on random basis by the consultants on rounds. The KMC rates in our unit was 55% and NNS rates was as low as 7.4%. A standard protocol to start KMC and NNS was developed. This was presented and discussed amongst consultants and fellows. After modification based on feedbacks provided, ramps of PDSA cycles were run and this was finally implemented in August 2015.
- *Breast pumps:* The availability of breast pumps was ensured. All pumps in non-working conditions were repaired and new electrical pumps were purchased. Mothers were also encouraged to buy their own breast pumps to express milk at home.
- *Daily logs, list based tracking and team huddle:* The assigned NICU nurse for a baby maintained daily log of volume of EBM available and its time of availability. This helped in providing feedbacks to the improvement team for additional support. The nurse in-charge maintained daily log of infants who were eligible for KMC/NNS and those who actually received them. In addition to these, the team tracked all cases delivered in last 24 hours and maintained an excel sheet of EBM status received by each baby as nil/partial or full EBM. This sheet was used by the consultants during daily routine counselling of the parents. At the end of each day, a system of team huddle was introduced in December 2015, as per which the nurse in charge, lactation consultant and team leader would discuss about each baby's EBM status and difficulty if any encountered.



WEB FIG. 1 Driver diagram.

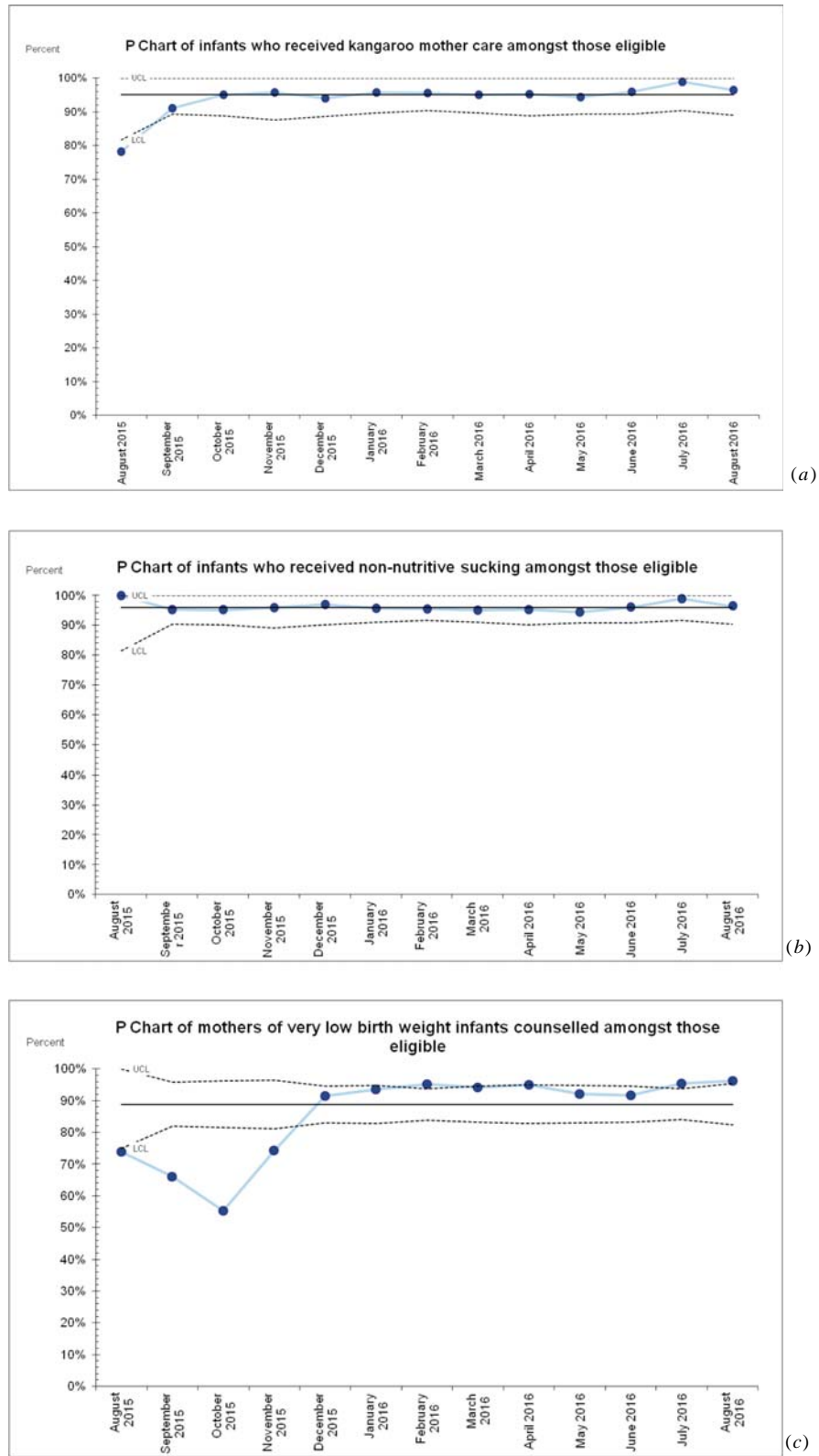


**WEB FIG. 2** Fish bone diagram showing root cause analysis of less EBM usage (ANC/PNC-Antenatal/postnatal counseling, KMC-Kangaroo mother care, NNS-Non-nutritive sucking).



**WEB FIG. 3** PDSA Ramp - 1.





**WEB FIG. 4** (a, b, c). Process measures of kangaroo mother care, non-nutritive sucking and counselling. Arrow indicates time point of standardization of protocols.

**WEB TABLE I** COMPONENTS OF CARE BUNDLE FOR IMPROVING EXPRESSED BREAST MILK USAGE IN VLBW INFANTS

<i>Element</i>	<i>Description</i>	<i>Action required</i>	<i>Staff Involved</i>
1	Promotion of early expression of breast milk	<p><i>Antenatal/Early post-natal</i></p> <ol style="list-style-type: none"> <li>1. Antenatal counselling of mother about benefits of breast milk, how to express breast milk pump availability and how to send milk to NICU</li> <li>2. Give mothers educational brochure in English and local language with pictorials</li> <li>3. Show mothers videos about expression of breast milk</li> <li>4. Counselling of attendants at admission to NICU and giving educational brochure if not given.</li> <li>5. Send text message to mother and father at admission to express and send expressed breast milk.</li> <li>6. Telephonic reminder to mothers/attendants within 2 hours of delivery to send expressed breast milk</li> <li>7. Daily tracking of mothers who delivered in last 24 hours and Staff/Lactation counsellor visit within 24 hours of delivery</li> <li>8. Staff review/lactation consultant review of expression of milk, pump use and volume.</li> </ol>	<ol style="list-style-type: none"> <li>1, 2, 3-Lactation counsellor and resident doctor/consultant-action to be taken before delivery/in missed cases within 4-6 hours of delivery.</li> <li>4-Resident doctor/Consultant and NICU nurse in charge</li> <li>5-Lactation counsellor/nurse in charge</li> <li>6-Bed side nurse</li> <li>7-Data operator/Bedside nurse/Lactation counsellor/resident/Consultant</li> <li>8-Bedside nurse, Lactation counsellor/doctor in charge/consultant on round</li> </ol>
2.	Ongoing support for lactation and stress management	<p><i>Post-natal</i></p> <ol style="list-style-type: none"> <li>1. List Based Daily counselling of all attendants- No EBM/Partial EBM/Full EBM Daily support by kangaroo mother care and non-nutritive sucking if eligible</li> <li>2. Maternal group counselling once every two weeks for stress and lactation management</li> <li>3. Ensure availability of breast pump</li> <li>4. Daily team huddle</li> </ol>	<ol style="list-style-type: none"> <li>1.Consultant on call</li> <li>2.Bedside nurse/Lactation counsellor/resident in charge</li> <li>3.Consultant and Lactation counsellor</li> <li>4.NICU sister in charge/lactation counsellor/ bedside nurse</li> <li>5.Consultant/Lactation counsellor/Data operator</li> </ol>

*VLBW: Very low birthweight; EBM: Expressed breast milk; NICU: Neonatal intensive care unit.*