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Reducing late-onset neonatal sepsis in very low birthweight neonates with central lines in a low-and-middle-income country setting

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ABSTRACT

Background Late-onset neonatal sepsis (LONS) is a significant contributor to morbidity and mortality in very low birthweight (VLBW) neonates with indwelling central lines. Compliance to central line care bundles is suboptimal in low-and-middle-income country settings. Point of care quality improvement (POCQI) method may be used to improve the compliance gap. We used the POCQI method to achieve an improvement in compliance to central line care bundles with an aim to reduce LONS in a subset of VLBW neonates.

Methods A pre and post-intervention study consisting of three phases was conducted in a tertiary care neonatal intensive care unit. A root-cause analysis was undertaken to find the causes of LONS in VLBW babies with central lines. Multiple change ideas were identified and tested using sequential Plan-Do-Study-Act (PDSA) cycles to address the issue of reduced compliance to the central line care bundles. The change ideas tested in PDSA cycles which were successful were adopted. Compliance to the insertion and maintenance bundles was measured as process indicators. LONS, central line associated bloodstream infections and all-cause mortality rates were measured as outcome indicators.

Results A total of 10 PDSA cycles testing multiple change ideas (staff education, audio-visual aids, supply issues) were undertaken during the study duration. Bundles were not being used in the study setting prior to the initiation of the study. Insertion bundle compliance was above 90% and maintenance bundle compliance increased from 23.3% to 42.2% during the intervention and sustenance phases, respectively. A 43.3% statistically significant reduction in LONS rates was achieved at the end of the study. No effect on mortality was seen.

Conclusion POCQI method can be used to improve compliance to central line care bundles which can lead to a reduction of LONS in VLBW neonates with central lines in situ.

INTRODUCTION

The impact of late-onset neonatal sepsis (LONS) on mortality and morbidity, including adverse neurodevelopmental outcomes and costs of healthcare in very low birthweight (VLBW) infants is well known.[1 2] Increasing survival of premature and lower birth weight babies due to advances in perinatal care has led to a prolonged hospital stay and invasive procedures including central lines in this population of neonates making them vulnerable to LONS.[3–5] The suboptimal compliance to evidence-based measures in low and middle-income countries (LMICs) is known to be one of the causes for high infection rates in such settings.[6–9] The central line-associated bloodstream infection (CLABSI) bundle approach to central line care practices has been proven to be an evidence-based measure for reducing CLABSI/LONS rates in the neonatal intensive care unit (NICU).[10 11] Quality improvement (QI) has improved the central line care practices and brought about a reduction in LONS and CLABSIs, thereby improving the quality of healthcare in NICUs of developed nations.[12–16] Studies from LMIC settings, including India, are few and vary widely due to diverse contextual settings.[17–21] The Point Of Care Quality Improvement (POCQI) methodology developed by WHO has been used in several maternal and neonatal health settings in LMIC settings.[22–24] The current study was planned with an aim to reduce LONS incidence, CLABSI and all-cause mortality among VLBW neonates with central lines in situ by improving compliance to central line insertion and maintenance bundles using the POCQI methodology.

STUDY METHODOLOGY

A prospective pre–post-intervention study was conducted from January 2018 to August 2019 in the Level III NICU of Lady Hardinge Medical College, New Delhi, India, a tertiary care teaching hospital. The hospital has an annual load of about 13 000 deliveries and annual admissions of about 3000 babies in the NICU. The bed occupancy rate ranges from 80% to 125%. VLBW neonates form about 6% of the total annual live births and 25% of the NICU admissions. The doctor:patient ratio in intensive care and high dependency

units is 1:5, and the nurse:patient ratio is 1:6. In the step-down unit, the doctor:patient ratio is 1:10 and nurse:patient ratio is 1:15. Sepsis and VLBW account for nearly half of all deaths in the unit. The study included all VLBW neonates with central lines for more than 48 hours during the NICU stay. The enrolled patients were followed until death or discharge. For the study, the following definitions were used. LONS was defined as the onset of sepsis's signs and symptoms after 72 hours of birth while CLABSI was diagnosed as per the Centre for Disease Control criteria.[25]

The Centre for Disease Control CLABSI Bundle[26] was adapted into a checklist for observing the proper line insertion and maintenance practices. Compliance to central line insertion and maintenance bundle checklists (online supplemental table 1) were used as process indicators in the study. Compliance was reported as a composite statistic, that is, if the staff did not perform even one component of the bundle, it was taken as non-compliant. Compliance scoring was done as the total number of central line procedures where all components of the insertion/maintenance bundles were performed correctly expressed as a percentage of the total number of procedures observed. The compliance scoring was noted and analysed during study phases II (intervention) and III (sustenance) only as the CLABSI bundle was not in routine use during study phase I (baseline). LONS rate calculated as number of LONS episodes per 1000 patient-days, CLABSI rate expressed as CLABSI episodes per 1000 central line days and mortality as mortality per 1000 patient-days were used as outcome indicators.

The study consisted of three predetermined phases (table 1), namely, phase I which consisted of baseline data collection (12 weeks); phase II, the intervention phase (24 weeks); and phase III, a sustenance phase (24 weeks). The duration of the study was planned as per operational convenience. The study used the POCQI method[27] to improve the processes and outcomes of care in the identified study population.

Fish-bone analysis (figure 1) and process flow chart (figuresonline supplemental figure 1a,b) were used to conduct a root cause analysis of the possible causes for LONS and CLABSI in VLBW babies with central lines in our unit. It was observed that there was a lack of awareness among the NICU staff to the importance of the bundle approach and central line bundle components. Improving compliance to the CLABSI bundle required an increase in the awareness of central line care and bundle approach among the NICU staff. To achieve this, the team identified multiple change ideas which were tested using 10 PDSAs which are discussed in table 2.

Sample size and statistical analysis

For a power of 80% with alpha error of 0.05 and assuming a baseline LONS per 1000 patient-days of 5 and a post-intervention reduction by 50% (2.5/1000 patient-days), the required sample size in each phase was 1000 patient-days.

Table 1 Table describing the three phases of the study

Phase	Name of phase	Duration (weeks)	Interventions during the phase
I	Baseline phase	12	► Routine procedures of catheter care and maintenance were observed to gain understanding of the process flow ► Baseline compliance to the central line insertion and maintenance checklists (process indicators) was not obtained as there was no routine policy of following central line insertion and maintenance bundle prior to this study ► Baseline incidence data were collected for the outcome indicators
II	Intervention phase	24	► A QI team was formed comprising resident doctors, nursing supervisors, staff nurses, store in-charge nurse, multipurpose workers and mothers of admitted babies ► Process flow chart and fish bone diagram were used to conduct a root cause analysis and identify factors contributing to LONS in the VLBW babies with central lines in the unit ► Multiple change ideas were developed and tested using short sequential PDSA cycles to enable implementation of CLABSI bundle ► Education sessions for the staff regarding rational use of central lines, proper insertion and maintenance techniques were undertaken
III	Post-intervention/sustenance phase	24	► Low compliance to maintenance bundle was addressed by testing the idea of continuing education among staff and knowledge testing with periodically conducted tests (PDSA 10)

CLABSI, central line associated bloodstream infection; LONS, late-onset neonatal sepsis; PDSA, Plan-Do-Study-Act; QI, quality improvement; VLBW, very low birth weight.

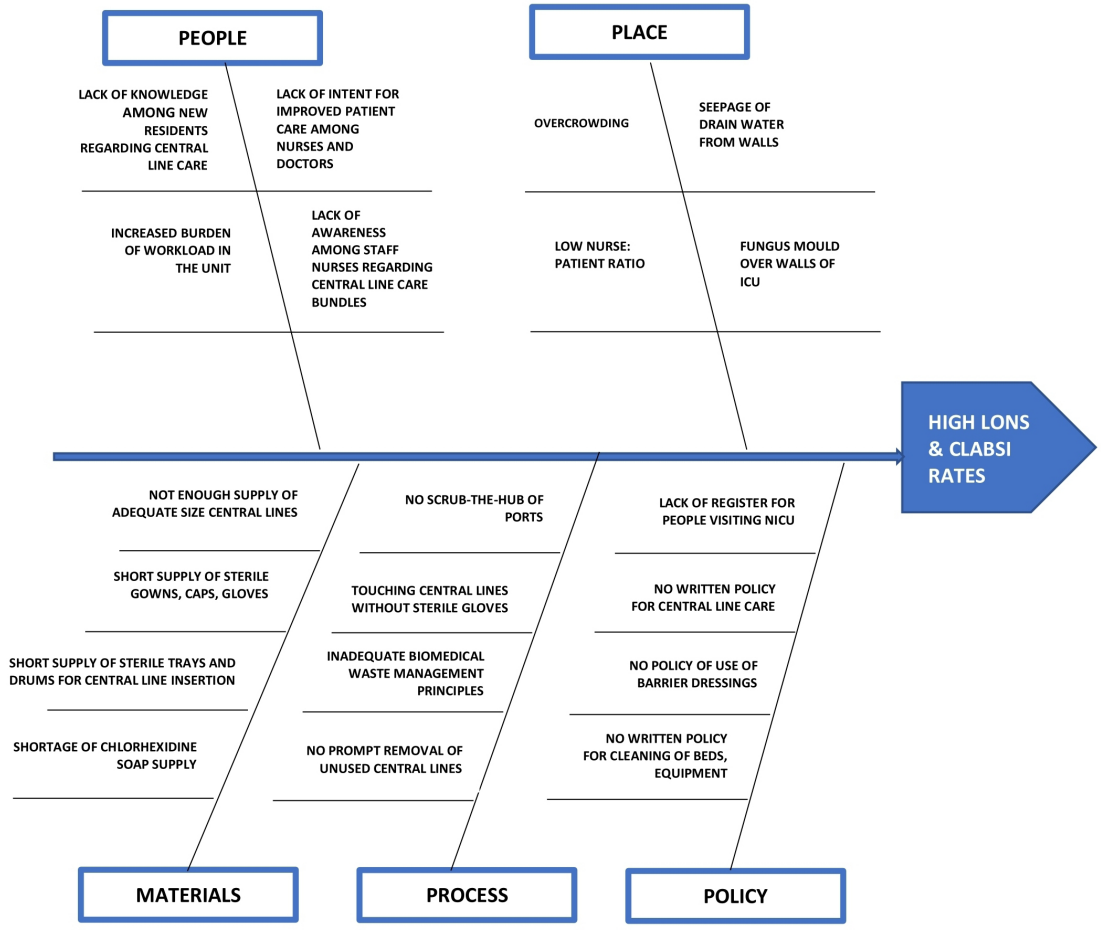

Figure 1 Fish bone analysis.

Data for the process and outcome indicators were collected monthly throughout the study period. Data thus generated were used to develop run charts and control charts (individual and moving range I-MR charts) depicting the different phases of the study. Direct observation and manual re-checking were used for assessing the completeness and accuracy of data.

Data were analysed using standard statistical tests (SPSS software V.20). Continuous variables were described as mean with SD and median with IQR. Parametric data were analysed using Student's t-test and analysis of variance test. Non-parametric data were analysed by the Mann-Whitney U test and Kruskal-Wallis test. Chi-square test or Fisher's exact test was used for categorical variables. Incidence rate ratios, 95% CI and p value were determined for LONS, CLABSI and mortality rate outcomes. The level of significance was set as $p < 0.05$, and all tests of significance were two-tailed.

Approval for the study was taken from the Institutional Ethics Committee. There was no conflict of interest for the authors in the study.

Patient involvement

As the enrolled patients were VLBW neonates, they were not involved in the research's design, conduct, reporting and dissemination plan. The study was related to improving processes of care concerning central line care in NICUs. The results of the study were disseminated through recurring experience sharing sessions among the facility staff.

RESULTS

Out of 774 VLBW babies admitted during the study period, 147 (18.9%) with central lines for more than 48 hours were enrolled. A total of 33 babies in phase I (1002 patient-days) were analysed for outcome indicators; 63 babies in phase II (1834 patient-days) and 51 in phase III (1874 patient-days) were observed for both process and outcome indicators. The baseline characteristics of the enrolled neonates are shown in online supplemental table 2. Babies with Apgar score >7, the median duration of the central line in days, median length of hospital stay and survival of extremely low birthweight (ELBW) babies were significantly more in the third phase of the study. The other variables were not significantly different across the three phases.

Process indicators

A total of 15 out of 63 (23.8%) central line insertion procedures were observed during phase II. Compliance to the insertion bundles was seen in 14 out of the 15

Table 2 Details of the PDSA cycles in the study

PDSA cycle	Change idea tested	PLAN	DO	STUDY	ACT
PDSA cycle 1 in phase II for 3 days	Improving the knowledge of NICU staff regarding CLABSI bundles of NICU staff using a handout in local language which is easily readable	QI team decided to develop and test the ease of use of the CLABSI bundle handout translated in local language (Hindi)	The CLABSI bundle was translated into Hindi (online supplemental figure 3). The QI team members deliberated on the readability and content of the handout in Hindi. Feedback was obtained	Translation in Hindi and obtaining feedback from NICU staff was feasible. However, all of them gave a feedback that Hindi handout was difficult to read and understand as compared with the English handout. September 2018 Mean compliance to insertion bundle: 100% Maintenance bundle: 0% LONS rate: 8.3/1000 patient-days	Hindi handout was discarded and the NICU staff decided to continue using the English handouts. **FINAL ACTION: ABANDONED**
PDSA cycle 2 in phase II for 7 days	To organise focused group discussions for enhancing the knowledge regarding CLABSI bundles among NICU staff	QI team members decided to conduct focused group discussions on CLABSI Bundle and central line care with NICU staff in morning and evening shifts for 7 days (14 sessions)	Handouts of the CLABSI bundle in English were given to all the staff nurses in morning and evening shifts and focused group discussions (FGDs) were conducted by a designated QI team member.	Organising FGDs was partially feasible and difficult to conduct in all morning and evening shifts. Only 3 sessions out of 14 planned were held. The average session length was 20 min. 15/25 staff nurses attended the FGDs. The staff nurses found it difficult to attend the FGDs due to heavy workload in the NICU and difficulty in assembling at one place for a duration of 20 min in each shift	This change idea was adapted to PDSA 3 with an aim to improve the staff attendance and increase the frequency of FGDs. **FINAL ACTION: ADAPTED**
PDSA cycle 3 in phase II for 11 days	Formation of a mobile phone application–based group to increase the number of FGDs conducted to sensitise staff to CLABSI bundle and improve the staff participation	Creation of a WhatsApp group of the QI team and nurses of NICU. This was started by the QI team leader and it was planned to create awareness regarding CLABSI bundle on this group	After creating the group, study material relevant to the topic were shared in the group as per the plan. During the 11 days, 7 virtual FGDs were held on the CLABSI bundles and prevention of LONS and CLABSIs	To study the effectiveness of WhatsApp group–based FGDs, a subject-based questionnaire using SurveyMonkey application was sent to the NICU team on mobile phone before starting FGDs and 7 days after formation of the group. There was an increase in the proportion of correct responses from a baseline of 49% to 90% (online supplemental figure 4a,b) October 2018 Compliance to insertion bundle: 67% Maintenance bundle: 0% LONS rate: 6.5/1000 patient-days	The change idea was adopted as it was feasible, improved participation (all 25 NICU staff participated and 24 took part in the assessments) and led to an objective increase in knowledge of NICU staff to CLABSI bundles. Virtual FGDs were now conducted regularly on a weekly basis. **FINAL ACTION: ADOPTED**

Continued

Table 2 Continued

PDSA cycle	Change idea tested	PLAN	DO	STUDY	ACT
PDSA cycle 4 in phase II for 6 days	To introduce novelty in the discussions and sustain participation of the NICU staff on the WhatsApp group to maintain and sustain interest in staff regarding the concepts of central line care by use of an educational video game	The team leader used a video game on the prevention of hospital-acquired infections with the help of a link from Institute of Healthcare Improvement website (www.ihi.org). This game was disseminated to staff nurses on the WhatsApp group for 6 days. The group members were requested to participate in all the modules of the game and provide feedback. It was felt that introduction of this video game would improve participation and create novelty in the contents of the FGDs	Conducted as per plan	A feedback using the SurveyMonkey application was obtained regarding the feasibility and usefulness of the game. Only 5 out of 25 (20%) nurses were able to complete the game. The major reasons for non-completion were poor internet connectivity and length of the game	The QI team discussed that the video game would need to be adapted by editing its length (reducing number of modules) and re-testing the participation rates and its applicability by the NICU staff. **FINAL ACTION: ADAPTED**
PDSA cycle 5 in phase II for 5 days	To make the educational video game simple to play, easy to load on their phones and easy to use by reducing the length of the video game	The game was shortened by the QI team to 2 modules. The QI team felt that reduction in number of modules would make it easier to load on their phones even with low bandwidth internet connectivity. This would facilitate more staff to participate in the game and remain a part of the virtual FGD sessions	The game was recreated with 2 modules as planned. It was posted on the WhatsApp group for next 5 days. The participants were encouraged to enrol and complete the video game. Feedback was obtained from the staff nurses regarding the ease of use and participation	Feedback regarding the shortened video game was obtained regarding ease of use and participation by SurveyMonkey application. Responses increased from 5/25 (20%) to 18/25 staff nurses (72%). All respondents felt that the video game was easier to use, improved their awareness regarding healthcare infections, created empathy to needs of NICU patients and made them strive for patient safety	The improvement in response and participation as well as the behaviour change noted enabled this idea to be adopted. It was decided by the QI team that this modified video game will now be routinely shared with all the newly posted staff nurses and residents in the NICU. **FINAL ACTION: ADOPTED**
PDSA cycle 6 in phase II for 14 days	It was noted that although insertion bundle compliance was above 80% in the study until now, the maintenance bundle compliance was consistently low (between 30% and 40%). In order to reinforce the components of maintenance bundle in an effective manner to the NICU staff, preparing and showing a video on maintaining asepsis during intravenous fluid/ medication administration through central line was considered	It was planned by the QI team to shoot a short 3 min video on maintaining asepsis during intravenous fluid administration through central lines and show it to all the NICU staff. It was felt that the video would address components of the CLABSI maintenance bundle	With the help of residents and staff nurses from QI team, a 3 min video was shot by team leader on administration of medications and intravenous fluids in an aseptic manner through the central lines. It was shown in 3 different group viewing sessions over 2 weeks consisting of 6 staff nurses in each session Feedback was obtained from the 18 staff who attended the viewing session regarding the usefulness of the video and its accuracy in showing the correct procedure	Feedback was obtained in FGDs on the WhatsApp group. Some minor errors and lack of contextual specificity in the video were noted by the QI team in feedback from NICU staff who viewed the video November 2018 Insertion bundle compliance: 100% Maintenance bundle compliance: 20% LONS rate: 5.8/1000 patient-days	As per the feedback obtained, the video was planned to be reshot to address the concerns raised in the feedback. **FINAL ACTION: ADAPTED**

Continued

Table 2 Continued

PDSA cycle	Change idea tested	PLAN	DO	STUDY	ACT
PDSA cycle 7 in phase II for 15 days	To reshoot and create an educational video of 3 min duration incorporating the suggestions from the NICU staff as per the observations during PDSA 6	The QI team discussed the method to re-shoot and create an educational video of 3 min considering the suggestions by the NICU staff who had viewed the video in PDSA 6	The suggestions as obtained in PDSA 6 were enlisted and incorporated into a video which was re shot by the team. 3 group viewing sessions for the NICU staff were organised. The video was also posted in the WhatsApp group	A positive feedback was obtained in the FGD. The team observed that the reshot video was accurate and contextually valid. They felt this could serve as a powerful educational aid	It was decided by the QI team to organise need-based group viewing sessions periodically for NICU staff and newly posted nurses and doctors. **FINAL ACTION: ADOPTED**
PDSA cycle 8 in phase II for 5 days	As awareness regarding central line care increased in the unit, the team realised that there was a mismatch between the demand and the supply of consumables (sterile gowns) required for sterile central line insertion. The QI team felt that an optimised demand vs supply prediction mechanism was needed to be developed in the NICU	It was decided that one member of the QI team with the help of the nursing in charge of NICU store, would note the daily requirement of sterile gowns in the NICU over the next 2 days and ensure the availability of requisite number of gowns based on the observations thereof. The team felt that this would prevent stock-outs of sterile gowns. The observations were continued over the next 3 days as well	The QI team leader and the nursing in charge of NICU store checked the stock as planned and observed that a total of 10 gowns were required each day. Based on these observations, the nursing in charge of NICU store ensured availability of at least 10 sterile gowns each day. The PDSA was conducted as planned	The QI team met and reviewed the optimised demand vs supply mechanism and concluded that it was feasible in the current setup and was successful in preventing sterile gown stock outs in the NICU December 2018 Insertion bundle compliance: 100% Maintenance bundle compliance: 40% LONS rate: 5.5/1000 patient-days	It was noted by the team that this PDSA cycle ensured adequate supply of sterile gowns and no problems of shortage during procedures in the NICU. The team unanimously agreed to continue with this mechanism monthly and incorporate this as a unit standard operating process. **FINAL ACTION: ADOPTED**
PDSA cycle 9 in phase II for 6 days	80 mm size central lines were in deficient supply leading to the NICU staff substituting 40 mm size central lines in their place. This led to frequent dislodgement and line handling exposing the newborns to risk of LONS and CLABSI. The QI team felt that an optimised demand vs supply prediction mechanism needed to be developed for 80/40 mm size central lines to prevent stock outs	The QI team, the resident doctors of NICU and the nursing in charge of NICU store decided to observe and note the requirement of central lines with the exact size required over next 3 days and indent the required number from the central store on a daily basis. The team felt that this would prevent stock outs of the correct size central lines (40/80 mm)	The PDSA was done as planned	It was noted over the next 3 days that every day at least 3 PICC lines of 80 mm were being used . The team decided to keep a stock of 4 PICC (80 mm) lines daily and keep the stock at all times at this level. January 2019 Insertion bundle compliance: 100% Maintenance bundle compliance: 20% LONS rate: 8.8/1000 patient-days	It was noted by the team that this PDSA cycle ensured adequate supply of 80 mm size central lines. The team unanimously agreed to continue with this mechanism with a monthly review and incorporate this as a unit standard operating process. **FINAL ACTION: ADAPTED**

Continued

Table 2 Continued

PDSA cycle	Change idea tested	PLAN	DO	STUDY	ACT
PDSA cycle 10 In phase III for 6 months (at 6-weekly intervals)	The QI team noted that the compliance to central line maintenance bundles in the initial part of sustenance phase was suboptimal. It was decided to initiate weekly group discussions followed by an evaluation every 6 week regarding central line care for the NICU staff	It was planned by the QI team to use weekly group discussions with NICU staff nurses on WhatsApp as a method to reinforce the importance of the CLABSI bundle followed by an evaluation session conducted every 6 weeks (4 sessions)	Weekly group discussions, sharing of materials and reminders on the WhatsApp group was conducted by the QI team leader over the 6 months and evaluation sessions were conducted (online supplemental table 3) as planned. Compliance rates to maintenance bundle was monitored	There was an increase in average test scores from test 1 to test 4 with a 30% increment between test 4 and test 1. The compliance rate to maintenance bundle improved from mean of 23.3% in phase II to mean of 42.2% in phase III The team noted an improvement in the process and outcome indicators as mentioned below February 2019 (at the beginning of sustenance phase) Insertion bundle compliance: 100% Maintenance bundle compliance: 20% LONS rate: 7/1000 patient-days August 2019 (end of sustenance phase) Insertion bundle compliance: 100% Maintenance bundle compliance: 50% LONS rate: 6/1000 patient-days	This change idea worked successfully in reinforcing the knowledge. The idea was adopted. The QI team subsequently decided to share CLABSI bundle awareness materials and conduct tests periodically on an as-needed basis for the NICU staff especially those who were newly posted in the NICU **FINAL ACTION: ADOPTED**

CLABSI, central line associated bloodstream infection; FGD, focused group discussion; LONS, late-onset neonatal sepsis; NICU, neonatal intensive care unit; PDSA, Plan-Do-Study-Act.

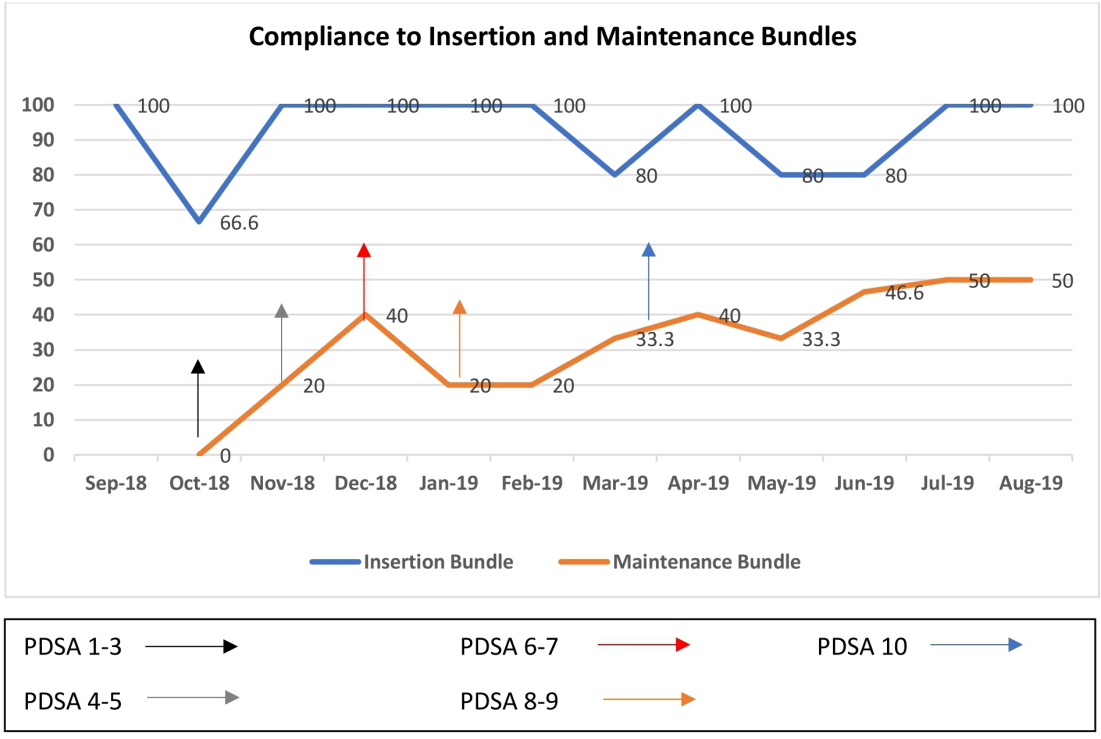

Figure 2 Compliance to insertion and maintenance bundles over the study duration.

(93.3%) observations. In phase III, 30 out of 51 (58.8%) insertions were observed. Compliance to insertion bundle was present in 27 of the 30 observations (90%) (figure 2).

A total of 30 observations were undertaken for the maintenance bundle check in phase II. The compliance with the central line maintenance bundle in phase II was seen in 7 out of 30 observations (23.3%). In phase III, 90 observations were undertaken over 6 months out of which compliance was noted in 38 (42.2%) observations. As compared with phase II, this rise was statistically not significant (p=0.06).

The compliance with the maintenance bundle's components during phase II was calculated using 30 observations over the 63 central lines inserted (450 central line days) during this period. The compliance to hand hygiene and aseptic dressing for the central lines was the highest among the maintenance bundle components (85% compliance), and the scrubbing of the hub was the least performed in the bundle (70% compliance). The compliance to replacement of the dressing when dislodged was 80% and compliance to prompt removal of the line when not in use was 75% (prompt removal defined as the removal of line within 24 hours of having no further indication or baby on enteral feeds 120 mL/kg/day). Changing intravenous infusion sets were done in the unit as per protocol before starting the study; hence, compliance with this component was not studied separately.

Outcome indicators

The mean LONS rate (figure 3) showed a reduction from 12 in phase I to 6.95 per 1000 patient-days in phase II (42% reduction, p=0.0002). In phase III, a further reduction to 6.8 per 1000 patient-days (43.3% reduction, p=0.00016) was achieved compared with phase I.

There was a decline in the mean CLABSI rate per 1000 central line days from 16.04 in phase I to 8.8 in phase II (45% reduction, p=0.676) which subsequently rose to 10.2 in phase III of the study (36.4% reduction, p=0.8) as compared with phase I. The mean mortality rate per 1000 patient-days was 7.4 in phase I, which slightly reduced to 6.25 in phase II (15.5% reduction, p=0.33) and rose to 8.3 in phase III. A 12% increase was observed in phase III (p=0.8) compared with phase I (table 3). I-MR control charts used to analyse the data collected on the outcome indicators (online supplemental figure 2) show a special-cause variation for LONS reduction in the intervention and sustenance phases (tables 3 and 4, figure 3).

It was observed that the incidence of LONS in phase II was 0.58 times that of phase I. The risk of developing LONS was 1.7 times in phase I compared with phase II, which was statistically significant. The CLABSI and all-cause mortality rate did not show a significant reduction (table 4).

DISCUSSION

The current study was conducted to reduce LONS in a tertiary care teaching hospital NICU using POCQI method to improve central line care bundles' compliance. The study led to a 42% reduction in LONS rates from baseline but no significant reduction in the CLABSI or mortality rates in the study subjects in a VLBW population with central lines in situ.

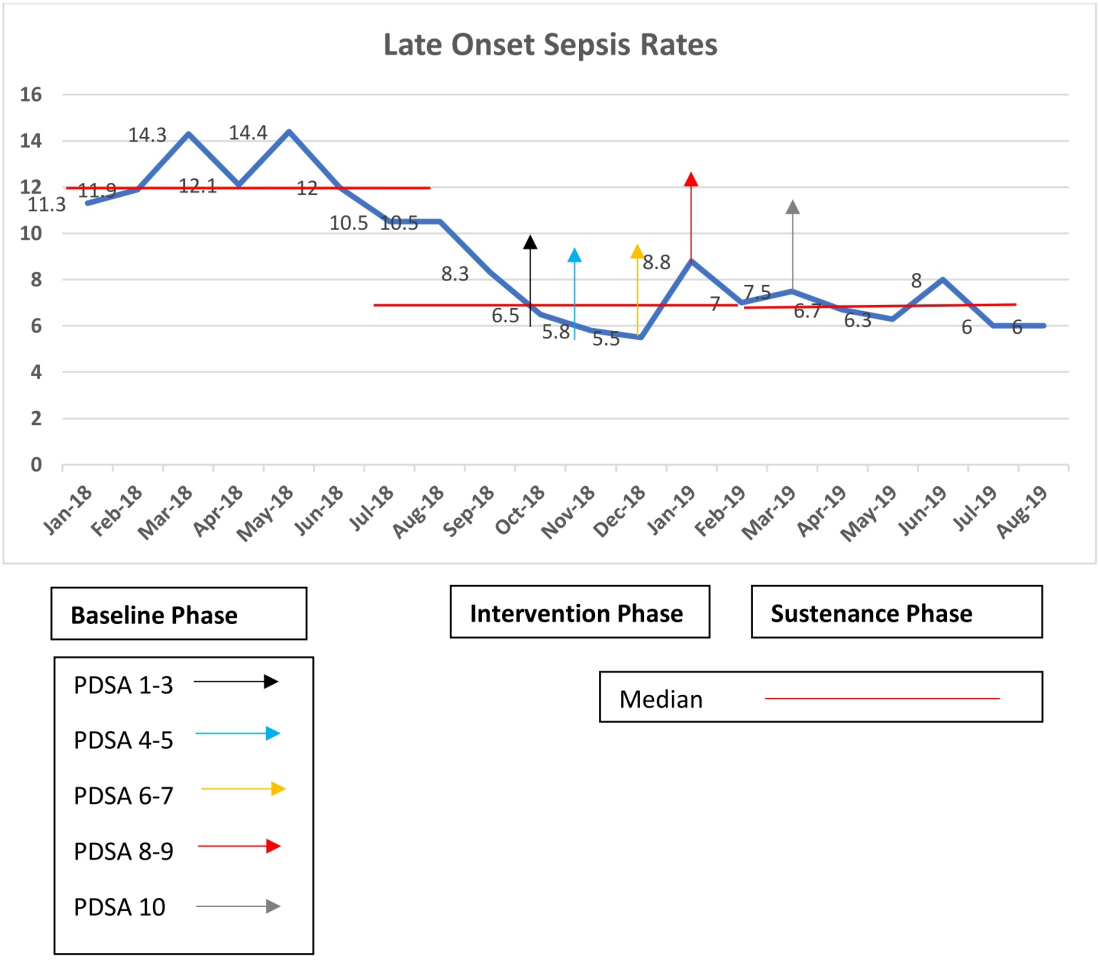

Figure 3 Late-onset sepsis rates over the study duration.

Compliance to the Central Line Care bundles can be linked to multiple root causes as shown in figure 1. The key factors among them being issues related to processes of care, materials and people-related causes. The QI team used the POCQI method to test a series of change ideas focusing on the root causes as mentioned previously. PDSA cycle 1 was conducted to develop and test the ease of use of the CLABSI bundle handout translated in local language (Hindi) from the existing English version. Feedback was obtained from the NICU staff that Hindi handout was difficult to read and understand as compared with the English. Hence, the team continued to use the English handouts. PDSA cycle 2 was done to test the feasibility of focused group discussions for knowledge enhancement of the NICU staff. It was observed that it was difficult to conduct such sessions every day. Hence, this change idea was adapted to PDSA 3. PDSA cycle 3 consisted of creation of a mobile phone application–based group to increase

Table 3 Outcome indicators in the different phases of the study

	Phase I	Phase II	Phase III
Total central line insertions observed	33	63	51
Total central line days	187	450	392
Total no of patient-days	1002	1834	1874
LONS/1000 patient-days	12	6.95	6.8
Total CLABSI episodes	3	4	4
CLABSI rate/1000 central line days	16.04	8.8	10.2
% of LONS accounted by CLABSI	25%	31%	31%
CLABSI/1000 patient-days	2.99	2.17	2.13
Mortality rate/1000 patient-days	7.4	6.25	8.3

CLABSI, central line associated bloodstream infection; LONS, late-onset neonatal sepsis.

Table 4 Incidence rate ratios of outcome indicators in the study

Outcome	Phases	P value	Incidence rate ratio	95% CIs
LONS	Phase II vs phase I	**0.0002**	**0.581**	**0.429 to 0.780**
LONS	Phase III vs phase I	**0.00016**	**0.564**	**0.411 to 0.768**
CLABSI	Phase II vs phase I	0.676	0.55	0.093 to 3.782
CLABSI	Phase III vs phase I	0.8	0.636	0.107 to 4.342
Mortality rate	Phase II vs phase I	0.33	0.84	0.596 to 1.177
Mortality rate	Phase III vs phase I	0.8	1.117	0.809 to 1.539

CLABSI, central line associated bloodstream infection; LONS, late-onset neonatal sepsis.

the number of focused group discussions. A subject-based questionnaire was used to study the effectiveness of this change. There was an increase in the proportion of correct responses from a baseline of 49% to 90%. The change idea was adopted as it was feasible, improved the staff participation and led to an increase in knowledge of NICU staff to CLABSI bundles. Wang *et al* from China used education, feedback and group discussions to implement the bundle and checklist.[28] In PDSA cycles 4 and 5, the QI team created and edited an educational video game consisting of five modules on prevention of hospital-acquired infections. This led to an improvement in participation as well as the behaviour change in the NICU staff. In PDSA cycles 6 and 7, a 3 min video on maintaining asepsis during intravenous fluid administration through central lines was created and subsequently edited by the team. We observed that the audio-visual content developed and tested in PDSA cycles 4–7 enhanced participation and interest in the NICU teams and also led to an increase in their awareness regarding care of central lines. Sinha *et al* used an educational video similar to our study to educate the NICU staff regarding the sterile fluid administration method.[29] Frequent stockouts of essential supplies interfere with routine processes of care and lead to non-adherence to standard guidelines, for example, CLABSI Bundles. In PDSA cycles 8 and 9, we tested and adopted an optimised demand versus supply prediction mechanism to prevent stockout of sterile gowns and size 80/40 mm central lines in the NICU.

Most of the contemporary studies have observed that ensuring compliance to maintenance bundles is the difficult part in the implementation phase.[14 15 20 30–32] Improving the central line care bundle compliance is a resource-intense activity and requires intensive monitoring and mentoring for prolonged periods. The challenges of resources being paramount in LMIC settings become the major bottleneck in implementing the said bundle approach more so during sustenance phases .

We conducted a PDSA cycle during phase III of the study as the compliance to central line maintenance bundles in this phase was found to be suboptimal. We initiated weekly group discussions followed by an evaluation regarding central line care for the NICU staff. As a result of this change, we noted an increase in the compliance to maintenance bundle from a mean of 23.3% in phase II to mean of 42.2% in phase III. Intensive monitoring is required to observe central line insertions and ensure sustained compliance to the central line bundles.[19–21 28 33 34]

Compliance to maintenance bundle is an essential factor in reducing LONS rates in NICU as observed by Kaplan *et al*.[14] NICUs having greater than 90% compliance to maintenance bundle showed nearly 50% reduction in sepsis as compared with those with compliance less than 90%.[14] Compliance to maintenance bundles ranged from 65% to 90% in several studies.[15 30–34] The compliance to maintenance bundles in an Indian study was lower (60%–69%) as compared with Western studies and showed a decrease in the sustenance phase.[20] Interventions in LMIC settings should focus on concurrent improvements directed towards health systems, policies and infrastructure rather than implementing checklists in isolation.[35]

The change ideas tested and implemented by our team using the PDSA approach led to an improvement in the knowledge of NICU staff which translated into increased compliance to insertion and maintenance bundle. Enhanced compliance to the bundles led to an improvement in the outcome indicators of LONS and CLABSI. The reduction in LONS achieved by our intervention was slightly lower than other studies wherein reduction rates for LONS ranged from 44% to 75.6% in a subset of VLBW neonates.[15 16 29 36] A lower rate of reduction seen in our study could have been due to lack of a system-wide implementation at a single setting incorporating minimal interventions over a limited study period.

Contextual factors can significantly affect the study outcomes, as noted by other authors.[7 37] In our study, presence of factors, for example, an unfavourable nurse, doctor:patient ratio, frequent staff rotation, humid and warm weather favouring microbial proliferation, a higher rate of admissions of extremely low birthweight neonates, survival in phase III and overcrowding may have had affected the effect size unfavourably.

There was a decline in mean CLABSI rates across phase I, II by 45%, and III a 36.4% reduction compared with phase I. These reductions were not statistically significant. The possible reasons for a slower decline in the CLABSI rates in our study population are complex to understand. We tried to reduce CLABSI using the same

approach to minimise LONS, that is, by trying to improve the compliance to the adapted version of the central line care bundles. The compliance to maintenance bundle in our research was suboptimal and could have contributed to a lower reduction in CLABSI rates. The bundles used in various studies for CLABSI prevention are difficult to compare with our study due to a difference in method and techniques.[15 16 18 19 37 38] Studies from China, India and Pakistan have reported a much higher reduction in CLABSI rates than our study. A study conducted on 110 VLBW neonates in China[28] by Wang *et al*, using central line bundle guidelines and a standard checklist, achieved a significant reduction in central line infections from 10 to 2.2 infections/1000 catheter days. In another study from India which included 1565 term and late preterm neonates, an 89% reduction in CLABSI and 41% reduction in mortality (both statistically significant) was demonstrated.[20] Using evidence-based interventions, CLABSI prevention package and nurse empowerment, a tertiary care NICU in Pakistan reduced CLABSI rates across all admitted neonates regardless of gestational age by 70%.[21] This study intervention was conducted in a resource-replete setting of Aga Khan University with a very favourable nurse:patient ratio and NICU staffing pattern. None of these studies has evaluated the reduction in CLABSI rates in VLBW neonates as has been done in our study. This per se can explain the lower reductions in CLABSI observed by us. It is reported that reducing CLABSI in VLBW and ELBW neonates are very challenging.[37] In a meta-analysis by Payne *et al* in 2017 on the use of care bundles to reduce CLABSI in neonatal units, a subgroup analysis on VLBW neonates was conducted, revealing an insignificant reduction in CLABSI rate, a finding in conformity with our observations.[39] In addition, it brings forth the importance of a skilled workforce, an essential prerequisite for any successful quality improvement initiative, the need for larger sample size, more interventions and more stringent diagnostic facilities that are often not available in LMIC settings.

Our study did not show any effect on mortality indicators of the study population. Some studies using QI methods for improving compliance to CLABSI bundle have shown mixed results, showing no significant reduction in mortality[21 36 40] in contrast to others[18 20] who have showed a substantial reduction in mortality rates. Mortality in VLBW neonates could be due to multiple causes like extreme prematurity, asphyxia, severe RDS, IVH, BPD, PPHN and pulmonary haemorrhage.[41] To demonstrate the effect of a single intervention on reduction of mortality in a VLBW subset would require a much larger sample size. This can be achieved through a QI collaborative study design with an extended sustenance phase.

There were a few strengths of the study. Our study was done in a LMIC setting in an exclusive cohort of VLBW babies with central lines in situ. The study applied the POCQI methodology to address the problem of LONS among such VLBW neonates by implementing and improving compliance to central line care bundles. The study reports data on compliance with central line care bundles, including compliance with individual components and reports on a sustenance period of 6 months.

Our study had a few limitations. The study was undertaken in a single setting with a limited sample size over a fixed period. A collaborative study design would have yielded a more significant impact and understanding on the effectiveness of POCQI in reducing LONS and CLABSI in VLBW neonates in LMIC settings and is increasingly being regarded as the need of the hour in such settings.[42] A single investigator did the measurements of compliance and data recording. However, this limitation was turned to an advantage as it led to a lack of inter-observer variability and ensured high-quality data capture. Hence, only a limited number of central line insertions and maintenance checklists could be checked for compliance with potential observation bias in the study. There was a periodic rotation of resident doctors and an influx of new nurses who were yet to be trained, which caused periodic fluctuations in the study's asepsis protocols. The organisation of induction sessions addressed this as a standard unit policy. We could not study the impact of the bundle elements' components on the outcomes, cost-effectiveness of implementing checklists, balancing measures, and long-term impact on growth and neurodevelopment.

The study has good generalisability for similar settings as the POCQI methodology has proven to be a useful tool to achieve improvements in processes and outcomes of care in resource-constrained settings.[22 23] POCQI can seed regional QI collaboratives across LMIC settings using QI to improve compliance to evidence-based bundles, thus catalysing better infection control in busy NICUs.[15 16 33 34 38] Studying more extended sustenance periods, cost–benefit analysis of implementing checklists and the impact of individual interventions of bundles could be included in future study designs. Each NICU could form its bundle by selecting the best interventions from such studies relevant to their context for better infection control practices in the units.[43 44] The newer changes in healthcare guidelines and evidence-based interventions could be included as part of the nursing curriculum.[45]

To conclude, the POCQI method is a useful and simple tool to improve healthcare personnel's compliance with evidence-based guidelines in resource-limited settings. It can aid in reduction of NICU infection rates and could be scaled up across similar settings after contextual adaptations.

Contributors VB was involved in the design, data collection, analysis and led the QI team responsible for the implementation of the change ideas. SHS was part of the QI team, was involved in implementation, performed data analysis, interpretation and helped in the drafting of the manuscript. VD designed and conceptualised the study, was part of the QI team, performed data analysis, critically reviewed the manuscript and approved the final manuscript. All authors reviewed and approved the final submission.

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Ethics approval Approved by the Ethical Committee for Human Research, Lady Hardinge Medical College, New Delhi, India.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. All data relevant to the study are included in the article or uploaded as online supplemental information.

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ANNEXURES/ Online supplement

Figure 1a- Process flow chart for central line insertion

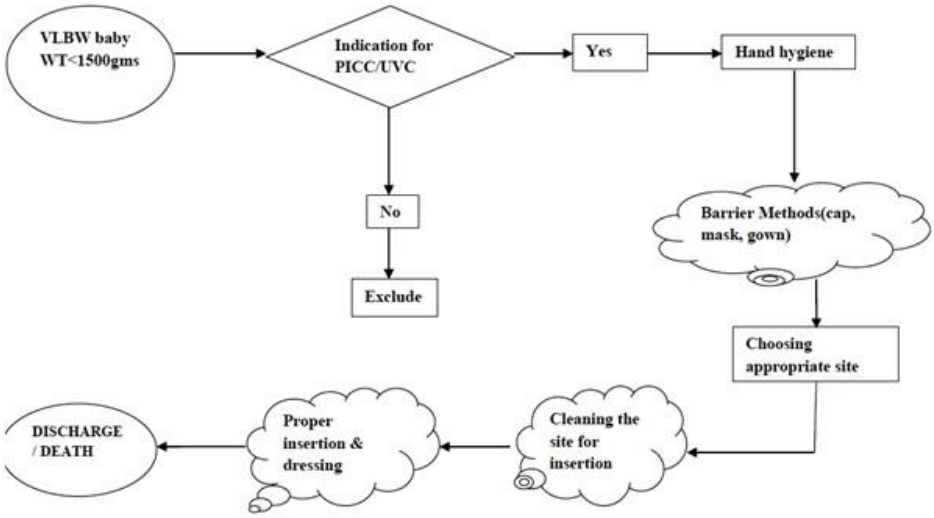


Figure 1b- Process flow chart for central line maintenance

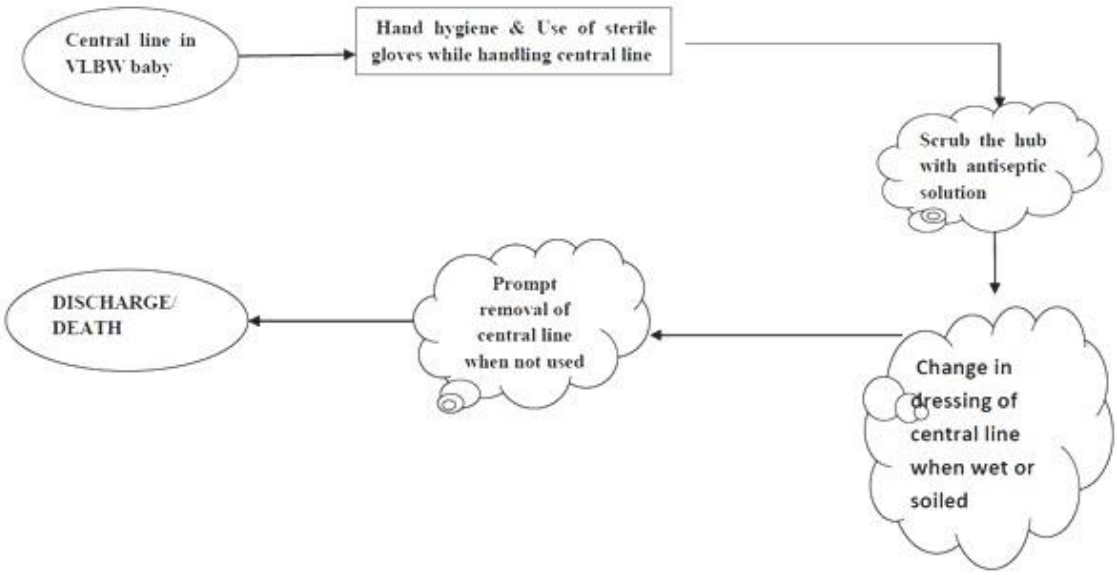


Figure 2- Control chart (I-MR chart) showing the LONS rate/1000 patient days during the study period (UCL- Upper control line, LCL- Lower control line; UCL and LCL correspond to +/- 3SD from mean)

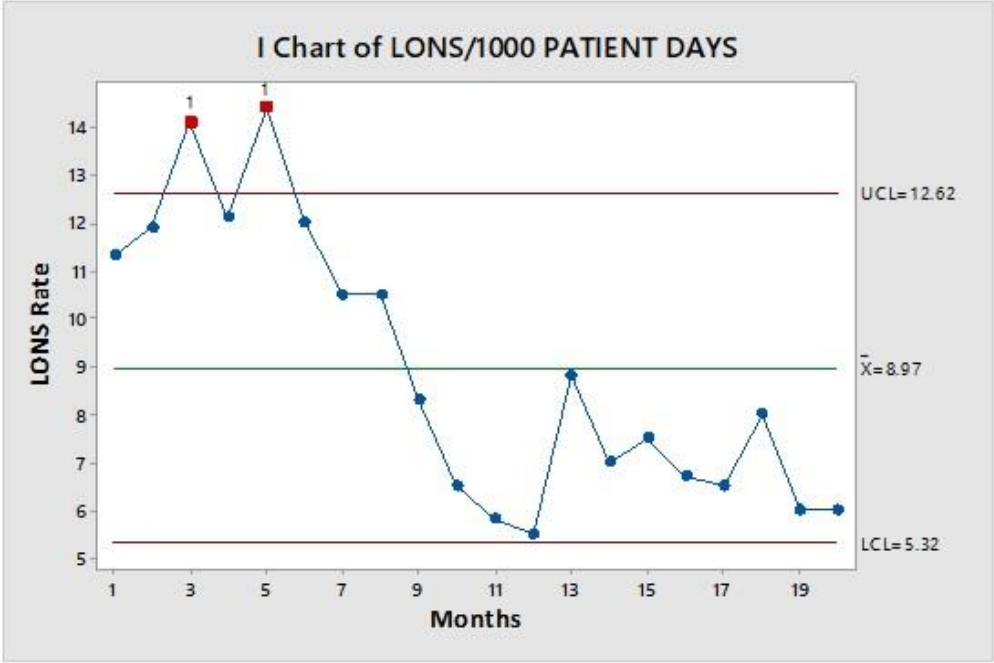
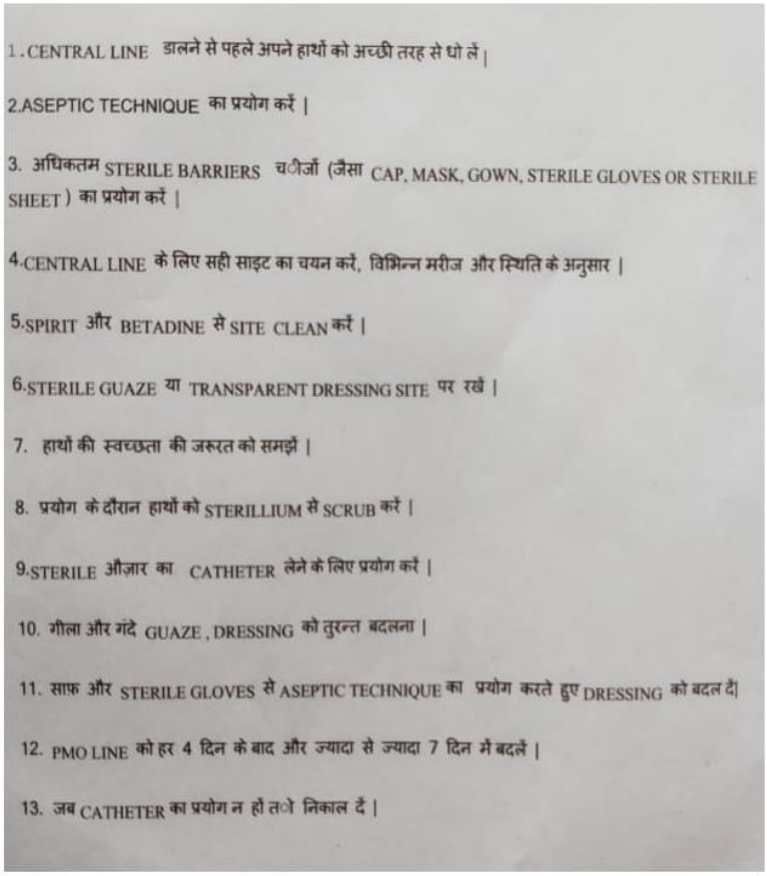


Figure 3- Handout of CLABSI bundle checklist in local language (Hindi)



1. CENTRAL LINE डालने से पहले अपने हाथों को अच्छी तरह से धो ले।

2. ASEPTIC TECHNIQUE का प्रयोग करें।

3. अधिकतम STERILE BARRIERS चीजों (जैसा CAP, MASK, GOWN, STERILE GLOVES OR STERILE SHEET) का प्रयोग करें।

4. CENTRAL LINE के लिए सही साइट का चयन करें, विभिन्न मरीज और स्थिति के अनुसार।

5. SPIRIT और BETADINE से SITE CLEAN करें।

6. STERILE GUAZE या TRANSPARENT DRESSING SITE पर रखें।

7. हाथों की स्वच्छता की जरूरत को समझें।

8. प्रयोग के दौरान हाथों को STERILLIUM से SCRUB करें।

9. STERILE औज़ार का CATHETER लेने के लिए प्रयोग करें।

10. गीला और गंदे GUAZE, DRESSING को तुरन्त बदलना।

11. साफ़ और STERILE GLOVES से ASEPTIC TECHNIQUE का प्रयोग करते हुए DRESSING को बदल दें।

12. PMO LINE को हर 4 दिन के बाद और ज्यादा से ज्यादा 7 दिन में बदलें।

13. जब CATHETER का प्रयोग न हो तो निकाल दें।

Figure 4a- Test responses of health care workers during PDSA 3 **before** creation of WhatsApp group for CLABSI bundle awareness

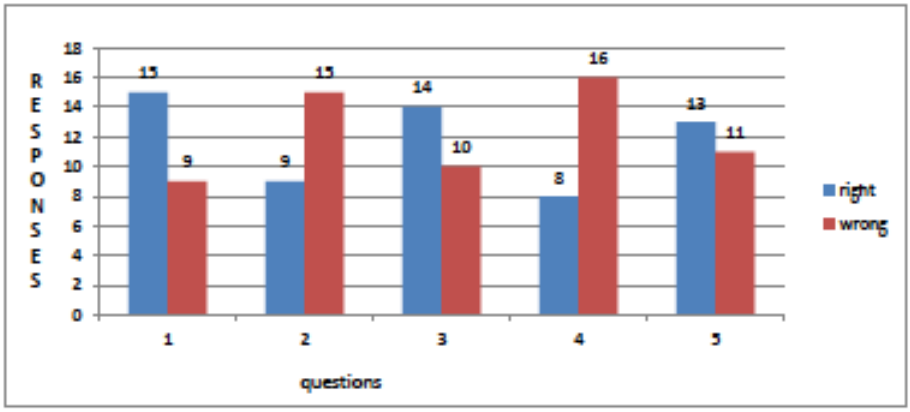


Figure 4b- Test responses of health care workers during PDSA cycle 3 **after** creation of WhatsApp group for CLABSI bundle awareness

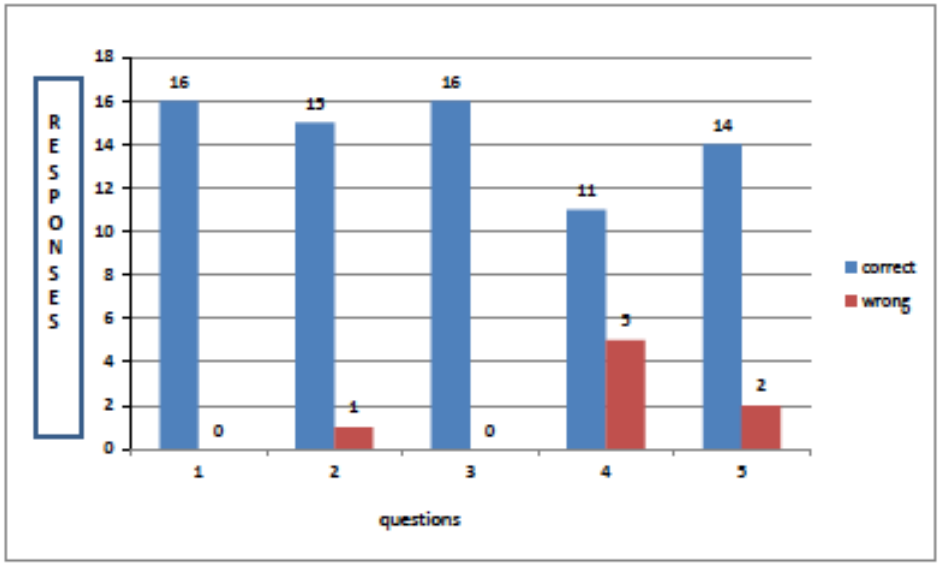


Table 1- Central Line Insertion and Maintenance bundle checklists used in the study [adapted from CDC (26)]

A. Proper insertion practices
a. Perform hand hygiene before catheter insertion b. Adhere to aseptic techniques c. Use maximum sterile barrier precautions (i.e. mask, cap, gown, sterile gloves and sterile body drape) d. Choose best site for catheter insertion to prevent infections and other noninfectious complications based on individual patient characteristics e. Prepare insertion site with chlorhexidine & alcohol. f. Place sterile gauze dressing or a sterile, transparent, semi permeable dressing over insertion site.
B. Proper line maintenance practices
i. Comply with hand hygiene requirements ii. Scrub access ports or hub with friction immediately prior to each use with an appropriate antiseptic iii. Immediately replace dressings that are wet, soiled or dislodged. iv. Perform routine dressing changes using aseptic technique with clean or sterile gloves. v. Change administration sets for continuous infusions no more frequently than every 4days, but at least every 7 days vi. Prompt removal of catheter when not in use.

Table 2- Baseline characteristics of the study population in the three phases of the study

Characteristic	Phase 1 (n = 33)	Phase 2 (n = 63)	Phase 3 (n = 51)	P value
Gender				0.58
Male	18	31	30	
Female	15	32	21	
Gestational age				0.57
< 28 weeks	7	10	10	
28-32 weeks	17	43	32	
33- 36 weeks	9	10	9	
Mean GA in weeks+ standard deviation	30w+4 ± 2w+6	30w+1 ± 2w+3	30w+1 ± 2w+6	0.81 (ANOVA)
Birth weight				0.16
<750gm	2	5	1	
750-999gm	13	12	16	
1000-1249gm	4	19	16	
1250-1500gm	14	27	18	
Mean birth weight+ standard deviation	1115±269gm	1174±263gm	1110±241gm	0.35 (ANOVA)
Weight for GA				0.89
SGA	15	26	23	
AGA	18	37	28	
APGAR at 5min				**0.04**
>7	18	31	39	
< or 7	12	28	11	
< or 3	3	4	1	
Admission temp				0.18
>37.5	1	1	1	
36.5-37.5	20	42	40	
<36.5	12	20	10	
Type of central lines				0.67
UVC	19	33	25	
PICC	12	21	22	
Both	2	9	4	
Median duration of central line days + IQR	5 (4-6)	6 (5-8)	7(6-8)	**0.012**

Median length of hospital stay + IQR	24 (10- 32)	26 (15-40)	31 (21-47)	**0.034**
Central line utilization ratio	0.22	0.25	0.21	0.49
ELBW %	45.5	26.6	33.3	0.17
ELBW survival %	46.7	76.5	82.3`	**0.02**

Table 3- Sample of test questions given to the health care workers for testing

Multiple choice questions
1. While inserting central line, hand hygiene should be done A. Yes B. No
2. Barrier methods used while inserting central line are A. Mask B. Gown C. Head cap D. All of the above.
3. IV port site or hub should be scrubbed with friction prior to its use with antiseptic solution A. Yes B. No
4. PMO lines used for continuous infusions should be changed once in A. 20 hrs B. 24 hrs C. 72 hrs D. 96 hrs
5. Duration of hand wash as per WHO guidelines A. 20 - 40 sec B. 24 - 36 sec C. 30 – 50 sec D. 40 – 60 sec