

Reducing Neonatal Central Line Infections with the Implementation of a Maintenance Bundle

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Abstract

Problem: Central line-associated bloodstream infections (CLABSIs) were identified as a concern in a large academic-level IV NICU, as evidenced by CLABSI rates exceeding the standardized infection ratio (SIR) for four of ten quarterly reports. To reduce CLABSIs in the neonatal population, government agencies recommend bundled interventions. **Purpose:** This quality improvement (QI) initiative aims to implement a central line maintenance bundle adapted from The Joint Commission's central line checklist for the neonatal population to eliminate CLABSI rates and promote safety through early identification of central venous catheter (CVC) management needs. **Methods:** A central line maintenance bundle was adopted over a 15-week implementation period. To achieve process measure goals, in-person education sessions, module-based instruction on bundle components, and aseptic non-touch technique (ANTT[®]) were utilized, unit champions were prepared, and daily chart audits were conducted. Nurses completed the central line bundle by scanning a QR code linked to REDCap during night and day shifts. Nurses (n=148), attending (n=15), and fellows (n=4) were educated on the central line bundle. **Results:** Approximately 1,057 central-line days were observed during the 15-week CVC maintenance bundle implementation period. Following implementation, central line bundle compliance increased to an average of 34% during day shifts and 15% during night shifts. When looking at individual bundle components, the results indicate 58.3% compliance with the assessment of the line during interdisciplinary rounds, 99.6% compliance for the use of disinfecting Curoc caps, 90.7% compliance for maintaining dressing integrity and prompt dressing changes, 99.7% compliance for tubing labeling, and a 50.7% adherence to ANTT[®]. CLABSI rates decreased by 100% compared to quarterly data before implementation. **Conclusion:** Implementation of the CVC maintenance bundle enhances standardization in central line care, facilitating early recognition of CVC-related clinical needs and mitigating the risk of CLABSIs.

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Keywords: Central line-associated bloodstream infection (CLABSI), Neonatal Intensive Care Unit (NICU), Central venous catheters (CVC), Aseptic Non-Touch Technique (ANTT), Quality Improvement (QI), Bundle

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Reducing Neonatal Central Line Infections with the Implementation of a Maintenance Bundle

Newborns admitted to the Neonatal Intensive Care Unit (NICU) frequently require the placement of central venous catheters (CVCs), such as umbilical venous catheters (UVCs), umbilical artery catheters (UACs), and peripherally inserted central catheters (PICCs). These CVCs are essential for delivering medications, fluids, parenteral nutrition, and monitoring vital signs in critically ill neonates. However, the use of CVCs also carries a significant risk of central line-associated bloodstream infections (CLABSIs).

The Centers for Disease Control and Prevention (CDC) defines CLABSI as a primary bloodstream infection (BSI) in a patient who had a central line within 48 hours of the BSI development and is not related to an infection from another site (2011). Although there has been an eight percent reduction in CLABSI standard infection ratios (SIRs) nationwide, the NICU still grapples with a high burden of CLABSIs, leading to increased morbidity and mortality (Centers for Disease Control and Prevention [CDC], 2021). Furthermore, CLABSIs impose a significant financial burden of approximately 2.3 billion dollars on the United States healthcare system annually (Savage, 2018). As a result, government agencies such as the CDC and the Agency for Healthcare Research and Quality (AHRQ) recommend the implementation of CVC insertion and maintenance bundles as crucial interventions to lower CLABSI rates in the neonatal population.

In an urban Level-IV NICU, a review of CLABSI rates from April 2020 to September 2022 revealed that CLABSI rates exceeded the standardized infection ratio (SIR) in four out of ten quarterly reports. A root cause analysis, illustrated in Figure 1B, highlights the necessity for standardized CVC care guidelines and identifies compromised sterility during tubing and fluid changes as a contributing factor to CLABSI rates. The purpose of this quality improvement (QI) initiative was to implement a central line maintenance bundle adapted from The Joint Commission's central line checklist for the neonatal population to eliminate CLABSI rates and promote safety through early identification of CVC

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management needs. The CVC maintenance bundle, centered on a daily assessment checklist, interdisciplinary evaluations of line necessity during rounds, and the implementation of Aseptic Non-Touch Technique (ANTT) during fluid changes, was implemented to potentially eliminate or drastically reduce CLABSI rates in the neonatal population.

Available Knowledge

The literature strongly supports the use of maintenance bundles in preventing CLABSIs, as detailed in Table 1A. Notably, research by Bierlaire et al. (2021), Payne et al. (2018), Schmid et al. (2018), Taylor et al. (2017), and Hamza et al. (2022) underscores the feasibility and reliability of employing bundles for preventing CLABSI. These studies exhibit a standardized approach to bundle components and implementation design, a key factor contributing to their successful outcomes.

For instance, Bierlaire et al. (2021) reported a substantial reduction in CLABSI rates, from 8.4 to 1.8 infections per 1000 CVC days, using insertion, dressing, and maintenance bundles. Payne et al. (2018) and Schmid et al. (2018) conducted systematic reviews and meta-analyses, focusing on the efficacy of care bundles in reducing CLABSI in infants with CVCs when compared to standard care. Their findings revealed a statistically significant decrease in CLABSI rates with the implementation of bundles. Similarly, Taylor et al. (2017) and Hamza et al. (2022) adopted a quasi-experimental design to investigate the impact of checklists on CLABSI rates, resulting in a 41 percent and 59.5 percent reduction in CLABSI rates.

Notably, Clare and Rowley (2018), Khurana et al. (2018), Shettigar et al. (2021), and Taylor et al. (2017) integrated ANTT as a bundled or standalone intervention to standardize CVC care and monitor its impact on Healthcare Acquired Infections (HCAs). The results from these studies demonstrated enhanced compliance and a reduction in HCAs from 26 per 1000 patient days to 8 per 1000 patient days.

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The evidence synthesis, presented in Table 2A, encompasses one Level-I randomized control trial, seven Level-III studies, and two Level-V studies, with quality ratings spanning from A to C. This synthesis also provides a comprehensive overview of the evidence-based bundle components implemented in each study.

The primary process goal is to utilize a maintenance bundle, incorporating a daily checklist, interdisciplinary CVC assessments, and the integration of ANTT for tubing and fluid changes for all patients with CVCs. Outcome measures will assess education, utilization, and completion of the maintenance checklist, along with adherence to ANTT, utilizing data extraction and randomized audits. In line with the objectives of this quality improvement (QI) project, the overarching goal is to employ the maintenance bundle with the aim of eradicating CLABSI incidents in the urban Level-IV NICU.

Rationale

The QI initiative was guided by the Promoting Action on Research Implementation in the Health Services (PARIHS) framework, which views successful implementation as a synergy of evidence, context, and facilitation (Bergström et al., 2020). Initial evidence analysis, detailed in Tables 1A and 2A, underpins the first framework component. Context, encompassing the intervention's application setting, involves understanding unit culture to tailor implementation strategies. Successful bundle implementation was monitored through data collection and randomized audits. Facilitation, the process enhancing implementation likelihood, was achieved by delineating roles, providing education, emphasizing CVC bundle necessity, and equipping staff with the skills and resources for implementation (Ward et al., 2017).

Methods

Context

The implementation setting was a tertiary center with a high-risk obstetrics unit and a Level-IV NICU. The NICU was a high-volume, high-acuity unit with approximately 1,700 deliveries and 800

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neonates admitted annually. Depending on acuity, the unit was typically staffed with 25 registered nurses caring for one to three patients. Notably, two-thirds of the nursing staff possessed less than two years of clinical experience. Despite their relative inexperience, these nurses demonstrated an openness to adopting a CVC maintenance bundle aimed at reducing the risk of infections associated with CVCs.

The NICU's process of educating new graduates in CVC care was subjective and contingent upon the trainer. Due to the absence of standardized guidelines, variability existed in the training approaches, underscoring the potential advantages of standardized protocols in care provision. Moreover, the high influx of new graduates may have contributed to burnout among senior preceptors, potentially compromising the thoroughness of CVC care education [and contributing to the CVC care deficiencies identified during the initial root cause analysis].

There was a need to utilize maintenance bundles and checklists for the daily assessment of CVCs. Prior to implementation, CVC practices included hourly line documentation by the bedside RN in the line assessment and daily care flowsheet, 24-hour sterile fluid changes, and needleless valve changes every 96 hours. While these processes were in place, further standardization and implementation of evidence-based infection prevention strategies were imperative to reduce rates of CLABSIs in neonates with central lines.

Figure 4 B outlines the pre-implementation or "current process." Institutional policies and guidelines were available for inserting CVCs, although these policies were general, non-specific to the NICU population, and often difficult to find on the institution's intranet. There was an evident necessity for standardized policies and guidelines on maintenance and aseptic techniques tailored specifically to the NICU population.

Intervention

A central line maintenance bundle was introduced and operational from September 5th, 2023, through December 10th, 2023. This comprehensive bundle encompassed a daily central line checklist

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sourced from the Joint Commission and customized for the neonatal population (Figure 3C). Key elements within this bundle encompassed standardized maintenance procedures, daily interdisciplinary assessments of the CVC, and the implementation of ANTT during fluid and tubing changes (Table 3A).

The educational phase was conducted from August 28th, 2023, through September 4th, 2023. Dissemination of knowledge pertaining to the central line bundle was achieved through a combination of modules, email communications, and in-person demonstrations. A noteworthy contribution to this endeavor was the ANTT module, generously provided by Stephen Rowley, the clinical director and ANTT originator, specifically for staff education. In addition to these resources, optional in-person sessions were conducted a week prior to implementation to enhance comprehension of bundle components and ANTT. Pre- and post-assessments were conducted to evaluate the effectiveness of both the module and in-person sessions in enhancing staff members' learning. To demonstrate comprehension of ANTT, staff needed to attain a score of 80 percent or higher on the post-module examination. Further fortifying the educational aspect, the project lead recorded an instructional video illustrating the correct ANTT method, which was subsequently shared with NICU RNs after gathering feedback and obtaining approval from infection control and prevention prior to distribution.

After the educational phase, staff members showcased their understanding of the importance of implementing the maintenance bundle through consistent completion of daily maintenance CVC checklists, active participation in daily CVC assessments during rounds, and careful execution of fluid and line changes while ensuring asepsis. Adherence to the central line maintenance bundle was emphasized as a mandatory requirement for all neonates with CVCs during this QI initiative. The initiation of the bundle process occurred when a CVC order was entered into the patient's electronic health record (EHR) (refer to Figure 5B). Subsequently, the bedside RN was responsible for the completion of the central line checklist, active participation in rounds for presenting CVC-related information, and the execution of ANTT during fluid and tubing changes. Each bedside computer was equipped with a QR code, granting

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RNs easy access to the central line bundle checklist to directly input data into Research Electronic Data Capture (REDCap) (Figure 3C).

To facilitate the successful implementation of this QI project, a team consisting of nurses, attending physicians, nurse practitioners, and infection preventionists was strategically assembled. Each team member's role and responsibilities were tailored to their individual skills and positions, as outlined in Table 4A. Furthermore, the implementation strategy was fortified by adopting Bringham ABCDE strategies and tactics, as delineated in Table 5A. These encompassed securing formal commitments, delivering performance feedback, adjusting incentive structures, identifying and nurturing champions, scheduling bi-weekly meetings, conducting audits, and providing online education, among other strategic initiatives.

Measures

The collection and analysis of data in QI initiatives require the use of structured, process, and outcome measures, as outlined in Table 6A. The structural objectives for this QI project encompassed the establishment of a maintenance bundle endorsed by stakeholders and the interdisciplinary team, which had to be achieved by July 2023. Existing evidence underscored the effectiveness of bundled interventions and checklists in preventing CLABSIs; however, validated tools tailored for NICUs were unavailable. To address this gap, the maintenance checklist tool was adopted from the Joint Commission's daily central line maintenance checklist, a well-validated and reliable resource, and modified with the latest evidence for NICU use (See Table 3A and Figure 3C). Structure measures included the following goals: achieving 100% completion of bundle education and attaining a score of 80% or higher on the post-test with data obtained through REDCap audits.

To monitor the process goals of maintaining an 80% compliance rate for adhering to bundle documentation and ANTT procedures, daily evaluations included data collection on the number of active CVCs and the number of completed central line maintenance checklists during day and night shifts. The

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project lead exclusively oversaw data collection to ensure uniformity, completeness, and data accuracy. Additionally, randomized observational audits of ANTT were conducted once a week by either the project lead or designated champions. These audits entailed the utilization of a validated audit tool (Figure 2C) generously provided by Stephan Rowley. Audits were utilized to monitor compliance and provide staff reeducation on the correct ANTT technique. The outcome measure was assessed bi-weekly in collaboration with the NICU's infection preventionist, as detailed in Table 4A.

The significance of ongoing assessment of implementation facilitators and barriers was recognized, and these discussions were held regularly during bi-weekly meetings with team members, champions, and staff to drive process improvements. A foundation of open and constructive communication within the team enabled the effective addressing of obstacles that arose during and after implementation. Furthermore, to ensure that all staff had the opportunity to contribute, the project leader's contact information was provided for feedback, particularly if they were unable to attend meetings. In commitment to transparency and keeping staff well-informed, pertinent information was made accessible via email, and weekly huddles were conducted. Feedback from stakeholders played a crucial role in guiding process adjustments. As part of this commitment to improvement, data and run charts were utilized, as well as MDs, to help promote CVC discussions on rounds.

Ethical Considerations

The completion of the Collaborative Institutional Training Initiative (CITI) program and the Health Insurance Portability and Accountability Act (HIPAA) training modules ensured the unwavering adherence to ethical principles throughout the QI project. Prior to implementation, diligent submission and approval were obtained for the project by the University of Maryland School of Medicine (UMSOM) Institutional Review Board (IRB), classified as a non-human subject's research determination by the Human Research Protection Office (HRPO).

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The project was guided by the essential ethical principles of beneficence, nonmaleficence, autonomy, and justice. Importantly, the project posed no discernible threat of physical or psychological harm, with a commitment to ensuring equal benefit to all neonates from the intervention. To safeguard participant confidentiality, robust measures were employed, including participant de-identification and the use of REDCap, a secure and HIPAA-compliant database for data collection.

The project was conducted with unwavering honesty and integrity, reflecting the dedication to ethical standards. With a clear focus on achieving the previously outlined structure, process, and outcome goals, it was anticipated that the implementation of the central line maintenance bundle would significantly reduce CLABSI rates among neonates with CVCs, leading to a substantial decrease in associated morbidity and mortality.

Results

The NICU introduced the central line maintenance bundle over a 15-week period, observing approximately 1,057 central-line days. The initiative began with a focused educational phase, including staff modules, email communication, and in-person demonstrations to ensure readiness. Notably, 86 percent of staff completed the education module, while 14 percent were pending completion (Figure 1D). An instructional video on proper ANTT was created to enhance staff comprehension. The implementation timeline saw an evolution in staff understanding and practice as they adapted to the central line maintenance bundle. Central line bundle compliance data revealed noteworthy progress, with an average increase of 34 percent compliance during day shifts and 15 percent during night shifts (Figure 2D).

The adherence to the central line bundle is depicted in the run chart, as shown in Figure 2D, which displays the average compliance rates for both day and night shifts over a span of 14 weeks. For day shift compliance, a considerable number of runs appear both above and below the median, totaling four runs. This pattern indicates random variation, typical in a stable process. The run chart exhibits a

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shift, demonstrated by six consecutive data points above the mean, observed between weeks three and eight. This shift signified an improvement in compliance levels compared to the mean, indicating an improvement in care practices during this period. The data did not reveal any discernible trends, but two astronomical points of 100 percent compliance, potentially influenced by the project lead incentivizing staff engagement with the central line bundle were of note. For night shift compliance, numerous runs are observed, with data points crossing the median four times. While such variability can be expected in a stable process, a trend of six points consistently falling below the median suggests a gradual deterioration over time. An astronomical data point indicating 100% compliance aligned with a project champion's involvement in supporting staff with checklist completion. In the context of this QI initiative, it is essential to note that, despite observed trends and runs in the data, the intended goal of achieving and maintaining 80% compliance was not achieved.

Specific components of the bundle exhibited varying levels of compliance: 58.3 percent for CVC assessment during interdisciplinary rounds, 99.6 percent for Curoc caps use, 90.7 percent for maintaining dressing integrity and initiating prompt dressing changes, 99.6 percent for tubing labeling, and 50.7 percent for ANTT adherence. Notably, the implementation of the central line maintenance bundle corresponded to a remarkable 100 percent reduction in CLABSI rates during the 15-week implementation period (Figure 3D).

Several contextual elements interacted with the intervention, including the high volume and acuity of the NICU, which necessitated tailored approaches for successful implementation. Furthermore, the level of nursing staff experience played a pivotal role in their willingness to embrace and comply with the central line maintenance bundle.

Observed associations within the NICU indicated a strong correlation between staff education and improved compliance with the bundle components. Enhanced compliance with the central line

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maintenance bundle may have been associated with a substantial reduction in CLABSI rates, demonstrating the intervention's direct impact on the outcome measure.

The intervention also yielded unintended yet positive consequences, including an enhanced understanding of aseptic techniques, improved interdisciplinary collaboration, and more effective practices in caring for CVCs. However, challenges arose, including initial resistance to change and difficulties in data collection for ANTT attributed to a high acuity level and project champions being involved in orienting new graduates. Nevertheless, the intervention fostered increased awareness of the importance of infection prevention and contributed to fostering a culture of safety within the NICU.

Despite overall improvements in compliance, gaps in bundle compliance data were noted, primarily attributed to staff turnover, variations in documentation practices, and the absence of the checklist in the EHR, which may have posed a barrier and increased resistance to documentation. Therefore, while the initial results are promising, the QI project acknowledges the need for further analysis to assess the sustainability of these improvements and their enduring impact on patient outcomes.

Discussion

The implementation of a bundled approach to enhance CVC care demonstrates feasibility in reducing the risk of CLABSI among neonates, aligning with existing literature findings. However, despite concerted efforts, the project fell short of achieving the targeted 80 percent adherence to the CVC checklist, with only 35 percent adherence on day shift and 15 percent adherence on night shift. Adherence rates were notably higher during the day shift compared to the night shift. The enhanced compliance during day shifts is likely attributable to the heightened presence of the project lead and champions, who provided reminders and incentives for the completion of the checklist. Various interventions were introduced to enhance compliance, including TigerConnect reminders and incorporating notes into nursing handoffs. Following the implementation of reminders in nursing

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handoffs, a discernible upward trend in compliance was observed for both day and night shifts.

Nonetheless, the intervention led to increased utilization of the CVC checklist, reflecting progress in integrating standardized protocols into practice. Beyond adherence metrics, the project yielded significant benefits, including heightened awareness of aseptic techniques, enhanced interdisciplinary collaboration, and more effective CVC care practices.

While a comprehensive financial analysis was not explicitly outlined, the potential cost savings associated with CLABSI prevention through improved CVC care warrant consideration. The Return on Investment (ROI) may manifest through reduced healthcare costs, including expenses related to extended hospital stays and additional treatments for CLABSI.

Moving forward, sustaining these improvements will necessitate ongoing training, reinforcement of protocols, and fostering a culture of adherence to best practices. These include the incorporation of the CVC checklist and ANTT education into new graduate orientation, integration of checklist components into a newly designed central line rounding QI initiative, inclusion of CVC maintenance education into yearly nurse competencies, and integration of components of the CVC maintenance bundle into the unit's central line rounding protocol. Collaboration with the clinical educator to develop formal competencies and guidelines for ANTT is currently being discussed.

Comparing the QI project results with findings from other publications underscores the challenges and successes encountered in CVC care improvement initiatives. While this QI project echoes the feasibility of bundled approaches in reducing CLABSI risk, the variability in adherence rates and the gap between anticipated and observed outcomes highlight the nuanced nature of implementation in real-world clinical settings. Consistent with findings in the literature, a significant reduction in CLABSI rates was observed during the implementation period. Prior to implementation, there were two incidences of CLABSI, whereas none were reported during the 15-week implementation period.

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Several factors contributed to the observed discrepancies and limitations. High patient acuity, coupled with a significant proportion of new graduate RNs, introduced complexities in adherence to protocols. Variations in documentation practices and challenges with data collection, including generating EHR reports, further compounded these issues. Difficulty in obtaining ANTT audits stemmed from challenges related to project champion availability, unit size, and the necessity for unit-wide adoption of formal competencies. Efforts were made to mitigate these limitations, yet inherent biases and imprecisions in project design, methods, and measurement may have influenced internal validity.

Conclusion

In conclusion, this QI project underscores the significance and potential of bundled approaches in enhancing CVC care within real-world clinical settings. The observed improvements in adherence to protocols and interdisciplinary collaboration hold significant value for enhancing healthcare delivery, quality, safety, and patient outcomes. Despite encountered challenges, the project's strengths lie in its demonstrated efficacy in reducing CLABSI rates, with the potential for substantial ROI through cost savings and improved patient outcomes. Moreover, the project's sustainability efforts, including integration into new graduate orientation programs and central line rounding initiatives, suggest a likelihood of continued adherence to best practices. Moving forward, the implications for practice are vast, emphasizing the importance of ongoing QI initiatives to optimize CVC care. Future research endeavors should build upon these findings, exploring strategies to enhance CVC care further while considering contextual factors and lessons learned from implementation efforts.

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Appendix A

Table 1A

Evidence Review Table

<p>Citation: Arnts, I., Schrijvers, N., Flier, M., Groenewoud, J., Antonius, T., & Liem, K. (2015). Central line bloodstream infections can be reduced in newborn infants using the modified Seldinger technique and care bundles of preventative measures. <i>Acta Paediatrica</i>, 104(4), e152–e157. https://doi-org.proxy-hs.researchport.umd.edu/10.1111/apa.12915</p> <p>Level: III-C</p>					
Purpose or Hypothesis	Type of Evidence and Research Design	Sample (population, size, setting)	Intervention Procedures	Primary Outcome/Measures	Results Conclusions
<p>The purpose of this study was to address the gap in knowledge to identify whether care bundles of preventative measures reduce central line-associated bloodstream infections (CLABSI) in peripherally inserted central catheters (PICC) using the modified Seldinger technique.</p>	<p>Research: Prospective, observational cohort study</p>	<p>Setting: Tertiary-level- 17-bed neonatal intensive care unit (NICU)</p> <p>Eligible Participants: All newborn infants between 24 and 42 weeks of gestation, with an indwelling PICC inserted using the Seldinger technique.</p> <p>Exclusion Criteria: Newborn infants with a PICC placed at a different facility, indwelling time of less than 24 hours, infants on extracorporeal membrane oxygenation treatment.</p> <p>Pre-intervention period: total of 43 patients with a total of 45 PICC lines and 463</p>	<p>Observation Period: Recorded the clinical characteristics of gestational age and birthweight, the reason for line insertion, age at insertion, insertion location, indwelling time, the reason for removal, and CLABSI signs for 48hrs after line removal. No changes were made in material, policies, and hygiene procedures. Medical staff and nursing were aware of this observation period.</p> <p>Intervention Period: Implementation of preventative bundle including sharing the</p>	<p>Dependent Variable: CLABSI defined as “at least one of the following clinical signs- fever, hypothermia, apnea or bradycardia- with no other recognized cause than the PICC”.</p> <p>Dependent Variable Measure: The dependent variable was measured through laboratory confirmation via culture. An assessment for interrater reliability was not performed.</p>	<p>Statistical Results: Laboratory-confirmed CLABSI was 12.9 per 1000 catheter days in the pre-intervention period and 4.7 per 1000 catheter days in the postintervention period ($p=0.09$). Findings were not found to be statistically significant, although it may have indicated a declining trend in CLABSI.</p> <p>Conclusion: Insertion skill and introduction of care bundles significantly reduced the CLABSI incidence in PICCs inserted using the</p>

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		<p>catheter days</p> <p>Post-intervention period: total of 82 patients with a total of 88 PICCs and 858 central line days</p>	<p>analysis of the pre-intervention period with the NICU team; introduction of an insertion -checklist; adapting the existing protocols for insertion procedure, with mobile screens, temporary closure of entrance to the unit in question and sharper protocols for hand hygiene, disinfecting the catheter hub and hygiene protocols during the insertion procedure and standard daily assessment by both nursing and neonatologists to determine whether the PICC was still required.</p> <p>Postintervention Period: Utilization of the same material, techniques, and observation list as the pre-intervention period, but the procedures were updated as described in the bundle</p>		<p>modified Seldinger technique.</p>
<p>Citation: Kaufman, D. A., Blackman, A., Conaway, M. R., & Sinkin, R. A. (2014). Nonsterile glove use in addition to hand hygiene to prevent late-</p>					

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Level: I-C

Purpose or Hypothesis	Type of Evidence and Research Design	Sample (population, size, setting)	Intervention Procedures	Primary Outcome/Measures	Results Conclusions
<p>Hypothesis: Hand hygiene followed by nonsterile glove use prior to all patient and intravenous (central or peripheral) catheter contact will result in decreased late-onset infections or NEC</p>	<p>Prospective, unmasked, randomized clinical trial</p>	<p>Sampling Technique: Non-probability sampling</p> <p>Eligible Population: Infants inborn or outborn with a birthweight of less than 1000g or gestational age of less than 29 weeks and were less than 8 days old.</p> <p>Setting: Level IV NICU- Urban academic medical center in the south Atlantic region of the United States.</p> <p>Excluded: Infants greater than 7 days old, infants on contact precaution and infants >1000g or >29weeks gestation</p> <p>Accepted: 124 infants eligible for study participation</p> <p>Control: 61 infants. 1/6 lost due to contact isolation</p> <p>Intervention: 63 infants.</p>	<p>Control Procedures: hand hygiene alone</p> <p>Intervention Procedures: Nonsterile glove use after hand hygiene. Signs were placed on a stand at the bedside indicating group assignment and protocol.</p>	<p>Primary Outcome:</p> <p>Infection</p> <p>Last-onset invasive infection (>72 hours after birth) defined as “one or more episode per patient of BSI, urinary tract infection, meningitis, and/or NEC associated with clinical signs and symptoms of infection and treated with antimicrobials”.</p> <p>Necrotizing Enterocolitis (NEC) defined as “stage II or greater using the modified bells criteria”.</p>	<p>Statistical Results:</p> <p>Late-onset infection was 32% in the intervention group and 45% in the control group (P=.13)</p> <p>There were 52% fewer gram-positive blood stream infections in the intervention group than in the control group (P=.03)- statistically significant</p> <p>CLABSI were reduced by 64% in the intervention group compared to the control group (P=.01)- statistically significant</p> <p>Conclusion</p> <p>This study demonstrates that nonsterile glove use after hand hygiene prior to patient and line contact is associated with fewer gram-positive blood stream infections, CLABSI. The prevention of late-onset infections did not reach clinical significance.</p>

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		<p>3/63 lost dues to contact isolation</p> <p>Power Analysis: Based on a type I error rate of .05 or less and at least 80% power-power analysis not met.</p>		<p>Urinary tract infection as defined as “growth of 10,000 or more CFU/mL”.</p> <p>CLABSI defined as “detection of one or more blood cultures of any organism including coagulase-negative staphylococcus organisms, and the presence of a central line within 72 hours in the absence of another source of infection”.</p> <p>Outcome Measure: The dependent variable was measured by diagnostic testing (culture).</p>	
<p>Citation: Bierlaire, S., Danhaive, O., Carkeek, K., & Piersigilli, F. (2021). How to minimize central line–associated bloodstream infections in a neonatal intensive care unit: a quality improvement intervention based on a retrospective analysis and the adoption of an evidence-based bundle. <i>European Journal of Pediatrics</i>, 180(2), 449–460. https://doi-org.proxy-hs.researchport.umd.edu/10.1007/s00431-020-03844-9</p> <p>Level: III-C</p>					
Purpose or Hypothesis	Type of Evidence and	Sample (population, size, setting)	Intervention Procedures	Primary Outcome/Measures	Results Conclusions

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	Research Design				
The aim is to assess the impact of new central line, insertion, dressing, and maintenance bundles on the rate of CLABSI and catheter-related complications.	Prospective, quasi experimental study	<p>Eligible Population: Term and preterm neonates, hospitalized in the NICU for more than 48 hours, and a central line in place.</p> <p>Excluded: Term or preterm infants with congenital heart disease</p> <p>Setting: Level III, 24-bed academic NICU</p> <p>Accepted: 430 neonates. 241 neonates in the preintervention period and 189 in the intervention period.</p> <p>Pre-intervention Period: 101/241; lost due to lack of central line. Total of 140 participants.</p> <p>Intervention Period: 76/189 lost due to lack of central line. Total of 113 participants.</p>	<p>Pre-intervention Period: 9-month observational period.</p> <p>Intervention Period: Implementation of material based on the latest international recommendations and updating central venous catheter bundles.</p> <ol style="list-style-type: none"> 1) Hand hygiene: Several education sessions were held to highlight the importance of hand hygiene 2) Central line material and sterile dressing changes: Development of sterile dressing checklists to ensure uniformity in practice. Cyanoacrylate glue used at the insertion site, Stat-lock and transparent dressing used for securement. 3) Drug preparation and 	<p>Primary Outcome: CLABSI rates</p> <p>Secondary Outcome: Catheter-related complications, defined as “thrombosis and rupture or dislocation of the catheter”.</p> <p>Outcome Measure: Measured via diagnostic testing (culture).</p>	<p>Statistical Results: There was a significant reduction of CLABSI ($P < 0.05$) during study period two versus study period one. Decreased rate of CLABSI (8.4 to 1.8 infections per 1000 central venous catheter (CVC) days, $p = 0.02$;) as well as decreased catheter-related complications (47 to 10, $p < 0.007$).</p> <p>The relative risk of CLABSI calculated in comparing group two versus group one was 0.28 (95% CI 0.085–0.95).</p> <p>Data analyzed neonates with a gestational age < 32 weeks, the relative risk of CLABSI comparing group two to group one was 0.08 (95% CI 0.01–0.6).</p> <p>Conclusion: The implementation of updated central line bundles based on evidence-based practice</p>

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			<p>administration: Development of a new bundle requiring nurses to wear sterile gloves and mask when preparing any drug or infusion. Used 70% isopropyl alcohol impregnated caps.</p> <p>4) Prompt/timely catheter removal: Encouraged removal of central lines as soon as enteral nutrition reached 120 mL/kg/day</p> <p>5) Creation of an effective checklist: central line insertion and maintenance checklists</p> <p>6) Specialized team: Education sessions regarding insertion and maintenance of lines were held for all residents and nurses by the team.</p>		<p>are imperative for the reduction of CLABSI in the NICU. Implementation of new evidence was associated with reduction in CLABSI rates in the study.</p>
<p>Citation: Payne, V., Hall, M., Prieto, J., & Johnson, M. (2018). Care bundles to reduce central line-associated bloodstream infections in the neonatal unit: a systematic review and meta-analysis. <i>Archives of Disease in Childhood -- Fetal & Neonatal Edition</i>, 103(5), F422–F429.</p>					

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https://doi-org.proxy-hs.researchport.umd.edu/10.1136/archdischild-2017-313362					
Level: III-B					
Purpose or Hypothesis	Type of Evidence and Research Design	Sample (population, size, setting)	Intervention Procedures	Primary Outcome/Measures	Results Conclusions
The purpose of this study is to assess the evidence for the efficacy of care bundles to reduce CLABSI in infants with indwelling central lines in the NICU, compared with standard care, and determine which bundled elements were most used.	Systematic review and meta-analysis	<p>Search Strategies: MEDLINE, CINAHL, and EMBASE databases were searched from January 2010- January 2017. The Cochrane Library, Web of Science, Zetoc and Ethos were searched for additional studies and reference lists of relevant articles were searched.</p> <p>Eligible Studies: Studies investigating the effect of a care bundle and were performed in the NICU of any care level. Studies must include central line insertion and maintenance bundles.</p> <p>Excluded Studies: Studies that investigated single intervention, were performed in adult or pediatric populations, or focused on a specific pathogen outbreak were excluded. Studies not</p>	The Newcastle-Ottawa scale was used to assess the quality of the included articles. The mean score across the studies was seven. SQUIRE reporting framework was used to assess the QI studies.	<p>Primary Outcome: The number of CLABSIs per 1000 central line or patient days</p> <p>Secondary Outcome: To identify the frequency with which bundled technical and non-technical elements were used</p>	<p>Statistical Results: Meta-analysis revealed a statistically significant reduction in CLABSIs following the introduction of care bundles (rate ratio=0.40 (CI 0.31 to 0.51), $p<0.00001$), which equates to 60% reduction in CLABSI rate</p> <p>Conclusion: There is a substantial body of quasi-experimental evidence to suggest that care bundle elements are effective in specific settings.</p>

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		<p>published in English, and conference abstracts, were excluded.</p> <p>Included Articles: 24 studies were eligible for inclusion</p> <p>PRISMA: A flow diagram was included in the systematic review which provided a detailed screening process for the selected studies.</p> <p>Power Analysis: N/A</p> <p>Heterogeneity: There was no statistical heterogeneity among the studies, with I²=0%.</p>			
<p>Citation: Schmid, S., Geffers, C., Wagenpfeil, G., & Simon, A. (2018). Preventive bundles to reduce catheter-associated bloodstream infections in neonatal intensive care. <i>GMS Hygiene and Infection Control</i>, 13, 10. https://doi-org.proxy-hs.researchport.umd.edu/10.3205/dgkh000316</p> <p>Level: III-C</p>					
Purpose or Hypothesis	Type of Evidence and	Sample (population, size, setting)	Intervention Procedures	Primary Outcome/Measures	Results Conclusions

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	Research Design				
Evaluate the available studies on the use of preventative bundles for the prevention of CLABSI in NICUs	Systematic review of cohort studies and interrupted time series.	<p>27 studies were included in the analysis.</p> <p>Search Strategy: A literature search was performed in PubMed using the key words “central venous line, neonatal intensive care, prevention, prevention bundle, central line-associated bloodstream infection” and included secondary citations found in these articles and surveys to find clinical studies published according to peer-review procedure in Medline-listed scientific journals between 2002 and 2016.</p> <p>Eligible Studies: contained precise information on the most important aspects of infection prevention when inserting or handling central venous lines in neonates. Required method of diagnosing CLABSI, endpoint definitions and the effect of the preventative strategy on the CLABSI rate in %, and CLABSI incidences per 1,000</p>	<p>Analyzed elements of preventative bundles:</p> <ul style="list-style-type: none"> ▪ Hand hygiene ▪ Feedback of surveillance findings and compliance rates to treatment team ▪ Clinical indication and limitation of indwelling ▪ Skin Antisepsis ▪ Empowerment of staff ▪ Reviewing compliance, checklists, daily goals ▪ Maximum barrier precaution when inserting central lines ▪ Dressing changes ▪ Change of infusion system ▪ Provision of necessary medical devices and products on a trolley 	<p>The systematic review analyzed the individual components in a preventative bundle.</p> <p>Primary Outcome: CLABSI rates</p> <p>Outcome Measure: The change in CLABSI rates with the implementation of the intervention</p>	<p>Conclusion: A significant reduction of CLABSI was found in 17 of the 27 studies. Results support the use of preventative bundles</p> <p>Statistical Results: The pooled relative risk for eight studies comparing before and after implementation of preventative bundle was 0.58 (95% CI=0.50-0.67) with moderate heterogeneity. Egger’s tests for symmetry (–2.16; 95% CI –3.17 to –1.15; P=0.002) are indicating a possible publication bias</p> <p>Metanalysis of seven studies shows a pooled rate ratio of 0.55 (95% CI 0.47-0.66; P<0.0001). Possible publication bias.</p>

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		<p>hospitalization days, or CLABSI incidences per 1,000 treatment days.</p> <p>Included Studies: Experimental study, monocenter retrospective surveillance studies, and prospective cohort studies.</p> <p>Power Analysis: N/A</p> <p>No prospective randomized controlled studies were published on the use of preventative bundles in the NICU during search timeframe.</p>	<ul style="list-style-type: none"> ▪ Specialized teams ▪ Pre-assembled flushing syringes ▪ Disinfection of catheter hub and other injection/connection points 		
<p>Citation Taylor, J. E., McDonald, S. J., Earnest, A., BATTERY, J., Fusinato, B., Hovenden, S., Wallace, A., & Tan, K. (2017). A quality improvement initiative to reduce central line infection in neonates using checklists. <i>European Journal of Pediatrics</i>, 176(5), 639–646. https://doiB-C-org.proxy-hs.researchport.umd.edu/10.1007/s00431-017-2888-x</p> <p>Level: III-B</p>					
Purpose or Hypothesis	Type of Evidence and Research Design	Sample (population, size, setting)	Intervention Procedures	Primary Outcome/Measures	Results Conclusions

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<p>The study was performed to determine the impact of checklists on central line infections</p>	<p>Prospective Quasi-experimental design</p>	<p>Setting: Urban level IV NICU</p> <p>Eligible Participants: Inborn or outborn infants in the NICU with a central venous catheter in place.</p> <p>Excluded Criteria: Infants were excluded if transferred from a different facility with a CVC and positive for infection 48 hours of arrival</p> <p>Pre-intervention Phase: 159 infants required CVC with a total of 248 CVCs inserted</p> <p>Post-intervention Phase: 160 infants required CVC with a total of 261 CVCs inserted</p>	<p>Pre-intervention Phase: Information collected retrospectively from May 2013 to April 2014. All clinical records of infants who has a CVC were assessed using set criteria.</p> <p>Post-intervention period: CVC data was collected and analyzed on an ongoing basis with the checklists in place. Insertion and maintenance checklists were assessed for compliance daily.</p>	<p>Primary Outcome: CLABSI defined as “Isolation from an organism from at least one peripheral blood culture. Coagulase negative staphylococcus must not be mixed or contain other skin flora and two or more signs of infection must be present and signs and symptoms are not related to an infection at another site and treatment with antibiotic therapy for ≥5 days and a CVC in situ or within 48 h post removal”.</p> <p>Suspected CLABSI defined as “No positive blood culture obtained, and two or more signs of infection must be present, and signs and symptoms are not related to an infection at another site and treatment with antibiotic therapy for ≥5 days and a CVC in situ or within 48 h post removal”.</p> <p>Outcome Measure: Primary outcome</p>	<p>Statistical Results: The pre intervention phase, there were 23 infants (15.8%) born between 23 and 25 weeks and in the post intervention phase, there was an increase to 37 infants (23.1%); however, this was not statistically significant (p value 0.568)</p> <p>Overall definite CLABSI rates declined by 41%, from 13.8 definite CLABSIs per 1000 central-line days to 7.8 definite CLABSIs per 1000 central-line days.</p> <p>Interrupted time series analysis noted no statistical significance in the change in post intervention slope despite the reduction in infection (may be due to small number of central line infections).</p> <p>There was significant change in mean levels in the post intervention phase for definite infections (coefficient crude -0.01015; 95% CI -0.01980–0.00051, p value 0.039)</p>
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				measured via diagnostic testing (culture) and signs of infection	Conclusion: Use of checklists, supported with education and feedback, significantly reduced CLABSI in the NICU.
<p>Citation: Hamza, W. S., Hamed, E. A.-T. M., Alfadhli, M. A., & Ramadan, M. A.-M. (2022). A multidisciplinary intervention to reduce central line-associated bloodstream infection in pediatrics and neonatal intensive care units. <i>Pediatrics & Neonatology</i>, 63(1), 71–77. https://doi-org.proxy-hs.researchport.umd.edu/10.1016/j.pedneo.2021.08.010</p> <p>Level: III-B</p>					
Purpose or Hypothesis	Type of Evidence and Research Design	Sample (population, size, setting)	Intervention Procedures	Primary Outcome/Measures	Results Conclusions

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<p>The aim of this study is to reduce CLABSI rate through adoption of standardized quality improvement interventions.</p>	<p>Quasi-experimental study utilizing pre-post intervention design.</p>	<p>Setting: The study was conducted between January 1, 2015, and March 31, 2017, in two pediatric and neonatal intensive care units.</p> <p>Eligible Participants: one or more central line catheter inserted for more than two days</p> <p>Post-intervention Phase: 998 central lines were monitored until they were discharged or transferred to another department/hospital</p>	<p>Phase one: Pre-intervention, included a retrospective analysis of the surveillance records of 12 months from January 1-December 31, 2015, to establish a baseline CLABSI rate.</p> <p>Phase two: January 1- March 31, 2016, was for establishing a quality improvement multidisciplinary intervention which composed of 12 elements. A checklist was created, and piloted, necessary changes were made. Continuous auditing, infection rates, and audit results were discussed with the multidisciplinary team monthly.</p> <p>Phase three: A post-intervention period for 12 months (April 1, 2016- March 31, 2017); to follow up the intervention's implementation and collect all the filled bundle checklist, to calculate CLABSI rate per 1000 central line days and to compare between the pre- and post- intervention periods.</p>	<p>Outcomes: CLABSI rates, device utilization, and compliance for each element</p> <p>Outcome Measure:</p> <ol style="list-style-type: none"> 1) CLABSI rate "calculated by dividing the total number of CLABSI by the total number of central line days and multiplying the results by 1000. In the pre- and post- intervention phase". 2) Device utilization ratios "calculated by dividing the total number of central line days by the total number of patient-days". 3) Compliance calculated with a "special form divided the total number of 	<p>Statistical Results: CLABSI rate significantly reduced by 59.5% from 7.5 to 3.0 per 1000 catheter days, and the duration of use of the central line decreased from 21.3 to 9.9 -11.0- 3.2 days (P < 0.05)- statistically significant.</p> <p>Conclusion: The implementation of a multidisciplinary quality improvement strategy, including central line insertion and maintenance care bundle, dedicated IV team, education, and feedback, effectively lowered the rate of CLABSI in pediatric and neonatal ICUs.</p>
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				patient days compliant to the given element by the total number of patient days examined for the same element and multiplying by 100”.	
<p>Citation: Shettigar, S., Somasekhara Aradhya, A., Ramappa, S., Reddy, V., & Venkatagiri, P. (2021). Reducing healthcare-associated infections by improving compliance to aseptic non-touch technique in intravenous line maintenance: A quality improvement approach. <i>BMJ Open Quality</i>, 10(Suppl 1), e001394. https://doi.org/10.1136/bmjog-2021-001394</p> <p>Level: V-A</p>					
Purpose or Hypothesis	Type of Evidence and Research Design	Sample (population, size, setting)	Intervention Procedures	Primary Outcome/Measures	Results Conclusions
The aim of the study is to improve	Quality improvement initiative	Setting: Tertiary care NICU Size: 143 neonates and 897 patient days.	PDSA Cycle 1: Information dissemination via in-person teaching sessions twice	Outcome Measure: HCAI as defined by an a clinical or microbiologically	Overall improvement in compliance to ANTT principles in the intravenous line maintenance followed a

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compliance with ANTT in intravenous line maintenance in neonates admitted to the NICU to reduce HCAI by 50% over six months.		<p>Eligible Participants: Patients with CVC's</p>	<p>weekly and WhatsApp messages once daily. Audits for compliance with aseptic technique and data of HCAI were obtained.</p> <p>PDSA Cycle 2: Continuing education sessions twice weekly. Outcome and process measures were displayed in the form of run charts, and scrub-the-hub education was disseminated via video demonstrations.</p> <p>PDSA Cycle 3: Principles of ANTT were incorporated into the onboarding unit education.</p> <p>PDSA Cycle 4: Compliance with aseptic technique was studied by the audits preformed twice a week.</p>	<p>confirmed bloodstream infection, meningitis, or pneumonia as defined by the German neonatal nosocomial infection surveillance system.</p> <p>Process Measure: Compliance with individual aseptic techniques.</p>	<p>gradual decrease in HCAI in the unit from 26 per 1000 patient days to 8 per 1000 patient days (median) over nine months.</p>
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Citation: Khurana, S., Saini, S. S., Sundaram, V., Dutta, S., & Kumar, P. (2018). Reducing Healthcare-associated Infections in Neonates by Standardizing and Improving Compliance to Aseptic Non-touch Techniques: A Quality Improvement Approach. *Indian Pediatrics*, 55(9), 748–752.

Level: V-A

Purpose or Hypothesis	Type of Evidence and Research Design	Sample (population, size, setting)	Intervention Procedures	Primary Outcome/Measures	Results Conclusions
The objective of the study is to standardize and	Quality improvement initiative	<p>Setting: Tertiary-care neonatal unit</p> <p>Size: 6929 procedures were</p>	<p>Phase 1: Prospective data collection for type and frequency of various</p>	<p>Outcome Measure: Change in compliance to ANTT for most frequently performed procedures.</p>	<p>Significant improvement in compliance to ANTT practices was observed, specifically in use of</p>

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improve compliance with Aseptic non-touch technique for commonly performed procedures in the NICU and study its impact on HCAI.		performed on 60 neonates during 399 patient-days. Eligible Participants: All resident doctors and nurses working in neonatal unit were subjects for assessment of compliance to ANTT. All admitted neonates staying in hospital for more than 48 hours were subjects for HCAI data collection.	procedures performed on all admitted neonates during first 10 days of life. Phase 2: ANTT audit tool was utilized to gather baseline information on procedural practices in the unit. Phase 3: Formation and dissemination of SOPs and guidelines. Phase 4: Re-audit using ANTT based tool and audit of compliance to procedure specific ANTT based SOPs were conducted in each clinical area to check change in compliance rates.		procedure tray/ trolley (16% to 49%, P=0.001), iv hub scrubbing (0% to 60%, P=0.001), local skin cleaning (33% to 67%, P=0.004), personal protective equipment use (55% to 80%, P=0.02) and disposal (27% to 51%, P=0.03), use of non-touch technique (50% to 70%, P=0.001) and reduction in key part contamination (45% to 31%, P=0.03). A modest decrease in HCAI rates was seen in the short period of observation after implementation.
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Citation: Clare, S., & Rowley, S. (2018). Implementing the Aseptic Non Touch Technique (ANTT®) clinical practice framework for aseptic technique: A pragmatic evaluation using a mixed methods approach in two London hospitals. *Journal of Infection Prevention, 19*(1), 6–15.
<https://doi.org/10.1177/1757177417720996>

Level: III-B

Purpose or Hypothesis	Type of Evidence and Research Design	Sample (population, size, setting)	Intervention Procedures	Primary Outcome/Measures	Results Conclusions
The primary aim of this study is to determine whether standardizing aseptic	Quasi-experimental study utilizing pre-post intervention design.	Setting: Two London Hospitals Size: 49 participants Eligible Participants: - Participants must be	Phase 1: Pre-implementation evaluation of ANTT using an observational audit tool (Group A) Phase 2: Post-Implementation Evaluation	Outcome Measure: Improvement in compliance with the implementation of ANTT.	Mean compliance with competencies was 94%; each component of practice was improved over baseline: hand hygiene = 63% (P<0.001); glove use =14% (P<0.037); Key-Part

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<p>technique for invasive IV procedures, using ANTT, increases staff compliance with infection prevention actions designed to achieve safe and effective aseptic technique.</p>		<p>licensed RNs. Must be competent in performing intravenous therapy and or intravenous cannulation.</p>	<p>of ANTT using an observational audit tool (Group B) Phase 3: Participant opinion of the adoption of the ANTT standard approach to aseptic technique using self-report questionnaire (Group B- Post implementation) Phase 4: Structured interviews with key stakeholders associated with the implementation and maintenance of ANTT (separate from Group A or B)</p>	<p>protection=54%(P<0.001); non-touch technique = 45% (P < 0.001); Key-Pam cleaning = 82% (P < 0.001); and aseptic field management = 80% (P < 0.001). Additionally, in the preceding 12 months prior to implementation. There were 54 reported cases of MRSA, 80% of which were bacteremia's from central lines. 20 months following the intervention there were zero MRSA catheter-related bloodstream infections reported.</p>
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Table 2A*Evidence Synthesis*

Project Title: Reducing Neonatal Central Line Infections with the Implementation of a Maintenance Bundle			
JHNEBP Model Level	Total Number of Sources	Author and Quality Rating of each study	Synthesis of Findings
Level I Experimental study · Randomized Controlled Trial (RCT) · Systematic review of RCTs with or without meta-analysis	1 (Prospective, unmasked, RCT)	Kaufman et al: C	This study found nonsterile glove use after hand hygiene prior to patient and line contact is associated with fewer gram-positive blood stream infections, CLABSIs. This article was utilized to highlight the importance of diligent hygiene practices in decreasing the incidence of central line infection in the neonatal population. No additional RCT study used in evidence review for comparison.
Level II Quasi-experimental studies · Systematic review of a combination of RCTs and quasi-experimental studies, or quasi-experimental studies only, with or without meta-analysis			
Level III Non-experimental study · Systematic review of a combination of RCTs, quasi-experimental, and non-experimental studies, or non-experimental studies only, with or without meta-analysis · Qualitative study or systematic review of qualitative studies with or without meta-synthesis	7 (Quasi-experimental, observational, and systematic review with meta-analysis)	Arnts et al: C Bierlaire et al: C Hamza et al: B Payne et al: B Taylor et al: B Schmid et al: C Clare & Rowley: B	Schmid et al. (2018) and Payne et al. (2018) systematic reviews with meta-analysis found a significant reduction in CLABSI rates with the implementation of preventative bundles. Schmid et al. (2018) bundle components focused on hand hygiene, indication and limitation of line, skin antisepsis, maximum barrier precaution when inserting central lines, staff empowerment, compliance, checklists, daily goals, dressing changes, change of infusion systems, disinfection of catheter hubs, and specialized teams. In comparison Payne et al. (2018) similarly identified

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		<p>skin preparation, hand hygiene, education and training, checklists, auditing, and feedback as bundle components in the literature review.</p> <p>Bierlaire et al. (2021) implemented a bundle focused on the following aspects: hand hygiene, central line material and sterile dressing care, drug preparation and administration, timely removal of line, creation of effective checklist and creation of a specialized team. Hamza et al. (2022) performed a study focused on the pediatric and neonatal ICU. Implementation checklists focus on a designated central line team, use of sterile dressing, hand hygiene, skin antisepsis, daily assessment, and site section. Bierlaire et al. (2021) and Hamza et al. (2022) found the implementation of preventative central line bundles in accordance with the most up to date evidence-based practice decreased CLABSI rates.</p> <p>Taylor et al. (2017) performed a literature review focused on preventative measures for central line infections. Like Payne et al. (2018) and Schmid et al. (2018) hand hygiene, skin asepsis, maximal sterile barriers were identified as insertion precautions. For prevention and maintenance Taylor et al. (2017) identified aseptic non-touch technique, disinfection of catheter hub/ports, administration set management, prompts CVC removal and education as important components. Results identified that poor dressing management, contamination of the catheter hubs or lack of asepsis during fluid line changes are serious risk of introducing infection. An emphasis is made on developing protocols on best available evidence.</p>
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			<p>Arntns et al. (2015) saw overall decreased CLABSI rates per 1000 catheter days with preventative bundles but did not find statistical significance.</p> <p>Clare and Rowley (2018) implemented and evaluated compliance with ANTT, while also assessing its impact on HCAI. The finding suggested that improved compliance with ANTT was directly correlated with decreased MRSA HCAs.</p>
<p>Level IV Opinion of respected authorities and/or reports of nationally recognized expert committees/consensus panels based on scientific evidence</p>			
<p>Level V Evidence obtained from literature reviews, quality improvement, program evaluation, financial evaluation, or case reports · Opinion of nationally recognized expert(s) based on experiential evidence</p>	<p>2 Multicenter Quality Improvement Study</p>	<p>Shettigar et al: A Khurana et al: A</p>	<p>Shettigar et al. (2021) and Khurana et al. (2018) integrated ANTT as a standalone intervention to standardize CVC care and monitor its impact on HCAs. The results from these studies demonstrated enhanced compliance and a reduction in HCAs from 26 per 1000 patient days to 8 per 1000 patient days.</p>
<p>Overall Quality Rating w/rational and Recommendation: B; Neonatal sepsis is associated with increased morbidity and mortality and prolonged hospitalization with substantial additional healthcare costs (Payne et al., 2018). There is a significant body of evidence that suggest central line bundles reduce CLABSI rates in the NICU. However, it is not clear what bundle elements are most effective in specific settings. The evidence review reveals the statistically significant drop in CLABSI rate with implementation of updated bundles in accordance with the most up to date evidence-based practice. Additionally, implementation of bundle components was not documented to have any risk or adverse effects. There is good and consistent evidence that warrants a practice change.</p>			
<p>Recommendations Based on Evidence Synthesis</p> <ul style="list-style-type: none"> • Strong, compelling evidence, consistent results: solid indication for a practice change. • Good and consistent evidence – practice change 			

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- Good but conflicting evidence: questionable indication for practice change; consider risk/benefit analysis.
- Little or no evidence: no indication for practice change

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Table 3A*Supporting Evidence for Central Line Checklist*

Critical Steps	Articles with supporting evidence
The need for the line was assessed during rounds?	<ul style="list-style-type: none"> • Schmid, S., Geffers, C., Wagenpfeil, G., & Simon, A. (2018). Preventive bundles to reduce catheter-associated bloodstream infections in neonatal intensive care. <i>GMS Hygiene and Infection Control</i>, 13, 10. https://doi-org.proxy-hs.researchport.umd.edu/10.3205/dgkh000316 • <i>Central Line-associated Bloodstream Infection (CLABSI) HAI CDC</i>. (2019, April 19). https://www.cdc.gov/hai/bsi/bsi.html • Vachharajani, A. J., Vachharajani, N. A., Morris, H., Niesen, A., Elward, A., Linck, D. A., & Mathur, A. M. (2017). Reducing peripherally inserted central catheters in the neonatal intensive care unit. <i>Journal of Perinatology</i>, 37(4), Article 4. https://doi.org/10.1038/jp.2016.243 • <i>Recommendation Summary NICU: CLABSI Guidelines Infection Control CDC</i>. (2022, February 3). https://www.cdc.gov/infectioncontrol/guidelines/nicu-clabsi/recommendations.html
Open injection ports are covered with Curoc Disinfecting Caps?	<ul style="list-style-type: none"> • O’Connell, S., Dale, M., Morgan, H., Carter, K., & Carolan-Rees, G. (2021). Curoc™ Disinfection Caps for the Prevention of Infection When Using Needleless Connectors: A NICE Medical Technologies Guidance. <i>Applied Health Economics and Health Policy</i>, 19(2), 145–153. https://doi-org.proxy-hs.researchport.umd.edu/10.1007/s40258-020-00602-8 • <i>Central Line-associated Bloodstream Infection (CLABSI) HAI CDC</i>. (2019, April 19). https://www.cdc.gov/hai/bsi/bsi.html
Insertion site free from infection (redness, warmth, irritation)?	<ul style="list-style-type: none"> • Weston, V. (2019). Assessment for Catheter Function, Dressing Adherence and Device Necessity. In N. L. Moureau (Ed.), <i>Vessel Health and Preservation: The Right Approach for Vascular Access</i> (pp. 219–233). Springer International Publishing. https://doi.org/10.1007/978-3-030-03149-7_17

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Dressing is intact and labeled properly?	<ul style="list-style-type: none"> • Schmid, S., Geffers, C., Wagenpfeil, G., & Simon, A. (2018). Preventive bundles to reduce catheter-associated bloodstream infections in neonatal intensive care. <i>GMS Hygiene and Infection Control</i>, 13, 10. https://doi-org.proxy-hs.researchport.umd.edu/10.3205/dgkh000316 • Weston, V. (2019). Assessment for Catheter Function, Dressing Adherence and Device Necessity. In N. L. Moureau (Ed.), <i>Vessel Health and Preservation: The Right Approach for Vascular Access</i> (pp. 219–233). Springer International Publishing. https://doi.org/10.1007/978-3-030-03149-7_17
Was the dressing changed today?	<ul style="list-style-type: none"> • <i>Central Line-associated Bloodstream Infection (CLABSI) HAI CDC</i>. (2019, April 19). https://www.cdc.gov/hai/bsi/bsi.html
Fluids, drips, and tubing changed within the last 24 hours and labeled appropriately (time, date, initial)?	<ul style="list-style-type: none"> • Savage, T., Hodge, D. E., Pickard, K., Myers, P., Powell, K., & Cayce, J. M. (2018). Sustained Reduction and Prevention of Neonatal and Pediatric Central Line-Associated Bloodstream Infection Following a Nurse-Driven Quality Improvement Initiative in a Pediatric Facility. <i>Journal of the Association for Vascular Access</i>, 23(1), 30–41. https://doi.org/10.1016/j.java.2017.11.002
Antiseptic Non-touch technique performed during tubing/fluid changes.	<ul style="list-style-type: none"> • Khurana, S., Saini, S. S., Sundaram, V., Dutta, S., & Kumar, P. (2018). Reducing Healthcare-associated Infections in Neonates by Standardizing and Improving Compliance to Aseptic Non-touch Techniques: A Quality Improvement Approach. <i>Indian Pediatrics</i>, 55(9), 748–752. • Clare, S., & Rowley, S. (2018). Implementing the Aseptic Non Touch Technique (ANTT®) clinical practice framework for aseptic technique: A pragmatic evaluation using a mixed methods approach in two London hospitals. <i>Journal of Infection Prevention</i>, 19(1), 6–15. https://doi.org/10.1177/1757177417720996

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Table 4A*Site Team*

Team Member Name/Credentials/Title	Responsibilities
1. Member 1	<ul style="list-style-type: none"> ○ Project Leader ○ Gather support and resources for project implementation. ○ Recruit super users ○ Manage project: develop project plan and timeline, set goals. ○ Oversee data collection. ○ Arrange meetings with stakeholders
2. Member 2	<ul style="list-style-type: none"> ○ Guide staff education roll out. ○ Guide tracking of compliance ○ Contribute to formation of bundle contents.
3. Member 3	<ul style="list-style-type: none"> ○ Provide feedback and ideas throughout project. ○ Assist with data collection/analysis. ○ Provide contact information for stakeholders
4. Member 4	<ul style="list-style-type: none"> ○ Assist with data collection and analysis
5. Member 5	<ul style="list-style-type: none"> ○ Assist with tracking compliance. ○ Assist with education roll out. ○ Assist with IT
6. Member 6	<ul style="list-style-type: none"> ○ Assist with education roll out. ○ Assist with tracking compliance
7. Member 7	<ul style="list-style-type: none"> ○ Assist with education roll out. ○ Assist with tracking compliance

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Table 5A*Bingham Strategies and Tactics*

Action to Achieve Goals (Bingham ABCDE strategies and tactics)	Goal the Action will Achieve
<p>Accountability</p> <ul style="list-style-type: none"> • <u>Obtain formal commitment</u>: Identify key partners and their role within the quality improvement project. Obtain written commitment of those individuals to fulfill set tasks. Obtain written commitment from registered nurses to complete documentation of maintenance bundle once a shift. • <u>Obtain and use patients/consumers and family feedback</u>: Provide a platform for constructive feedback on maintenance bundle and two-person aseptic technique. • <u>Provide performance review</u>: Provide productive feedback to nursing staff on performance of bundle documentation and aseptic techniques. • <u>Revise professional roles</u>: Alter professional roles within the QI project as needed achieve timeline laid out in the Gantt Chart. 	<ul style="list-style-type: none"> • The NICU will create a maintenance bundle agreed on by the multidisciplinary team by July 2023. • 100% of nursing staff complete the education modules assigned for the maintenance bundle and aseptic technique by September 2023.
<p>Buy-In</p> <ul style="list-style-type: none"> • <u>Alter incentive structure</u>: Empower nursing staff to complete shift documentation in the flowsheet and achieve compliance in two-person sterile fluid changes. Those who are complaint will receive a thank you note and treat. Project superusers will be reminded that their participation demonstrates staff engagement and is beneficial to induce in their yearly performance reviews. 	<ul style="list-style-type: none"> • The NICU will achieve 80% compliance in maintenance bundle documentation by December 2023. • NICU staff will achieve 100% completion of education material by October 2023. • 80% of staff will perform aseptic technique during fluid and tubing changes without breaching sterility.
<p>Collaboration/Communication</p> <ul style="list-style-type: none"> • <u>Identify and prepare champions</u>: Identify project champions to help aid in implementation and re-education of staff on bundle components and aseptic technique. Champions will be trained prior to the QI implementation. Champions will assist with chart and observational audits. • <u>Meetings</u>: Schedule bi-weekly meetings with stakeholders, sponsor, and CSR to discuss barriers and facilitators to implementation. Hold a unit meeting for available staff to discuss project details, outline timeline, and discuss project goals/outcomes. • <u>Share information in a public and transparent manner</u>: Display pre-implementation data along with project details and goals at nursing stations, 	<ul style="list-style-type: none"> • The multidisciplinary NICU team will create a maintenance bundle by August 2023. • 100% of nursing staff complete the education modules assigned for the maintenance bundle and aseptic technique by September 2023. • The NICU will achieve 80% compliance in maintenance bundle documentation by December 2023.

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<p>breakroom, and on unit bulletin boards. Also, place information on weekly huddles.</p> <ul style="list-style-type: none"> • <u>Remind clinicians</u>: Send out emails to staff as a reminder to complete education and maintenance bundle. • <u>Develop a formal implementation blueprint</u>: Share implementation plan/ timeline with sponsor and CSR for approval. Use the blueprint as a tool to guide implementation. 	<ul style="list-style-type: none"> • 80% of staff will perform aseptic technique during fluid and tubing changes without breaching sterility. • NICU staff will achieve 100% completion of education material by October 2023.
<p>Data</p> <ul style="list-style-type: none"> • <u>Complete audits and provide feedback</u>: each week, collect and summarize key performance data. Share data with staff and provide constructive feedback for improvement. • <u>Assess for readiness and identify barriers and facilitators</u>: Utilize validated survey tools to assess staff readiness, facilitators, and barriers. 	<ul style="list-style-type: none"> • NICU staff will achieve 100% completion of education material by October 2023. • The NICU will achieve 80% compliance in maintenance bundle documentation by December 2023. • 80% of staff will perform aseptic technique during fluid and tubing changes without breaching sterility.
<p>Education</p> <ul style="list-style-type: none"> • <u>Provide on-line education</u>: educational material will be required for completion by the staff. Once completed staff will still have access to material for reference. • <u>Use tests</u>: Once staff have completed education to complete the module a post-test is administered to assess understanding of material. RN may take the assessment three time. • <u>Develop and distribute educational material</u>: toolkits and cheat sheets will be accessible at the nursing station for easy reference. Reminders and weekly reminders will be posted in the huddle for staff to review. 	<ul style="list-style-type: none"> • NICU staff will achieve 100% completion of education material by October 2023. • The NICU will achieve 80% compliance in maintenance bundle documentation by December 2023. • 80% of staff will perform aseptic technique during fluid and tubing changes without breaching sterility

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Table 6A*Measurement Plan*

Measures		
Project Goals	Measure Pre-Implementation	Measure During Implementation
Structure		
1. The NICU will create a maintenance bundle agreed on by the multidisciplinary team by August 2023.	Maintenance bundle accessible in EPIC/REDCap (yes/no)	Maintenance bundle accessible in EPIC/REDCap (yes/no)
2. The project lead and key stakeholders will meet with ANTT representatives and acquire guidelines and E-learning modules by August 2023.	Guide for ANTT accessible in NICU specific guidelines (yes/no)	Guide ANTT technique accessible in NICU specific guidelines (yes/no)
3. NICU staff will achieve 100% completion of education material by October 2023.	Numerator: Number of nurses who completed education. Denominator: Total number of nurses	Numerator: Number of nurses who completed education. Denominator: Total number of nurses
Process		
1. The NICU will achieve 80% adherence to maintenance bundle documentation.	Numerator: Number of 12-hour nursing shifts demonstrating 100% adherence in central line maintenance bundle documentation. Denominator: Total number of 12-hour nursing shifts audited	Numerator: Number of 12-hour nursing shifts demonstrating 100% adherence in central line maintenance bundle documentation. Denominator: Total number of 12-hour nursing shifts audited
2. The NICU will achieve 80% adherence to the ANTT technique.	Numerator: Number of 12-hour nursing shifts demonstrating 100% adherence to two-person aseptic techniques. Denominator: Total number of 12-hour nursing shifts audited	Numerator: Number of 12-hour nursing shifts demonstrating 100% adherence to two-person aseptic techniques. Denominator: Total number of 12-hour nursing shifts audited
Outcome		
1. Zero documented central line associated blood stream infections.	Numerator: Number of line infections	Numerator: Number of line infections

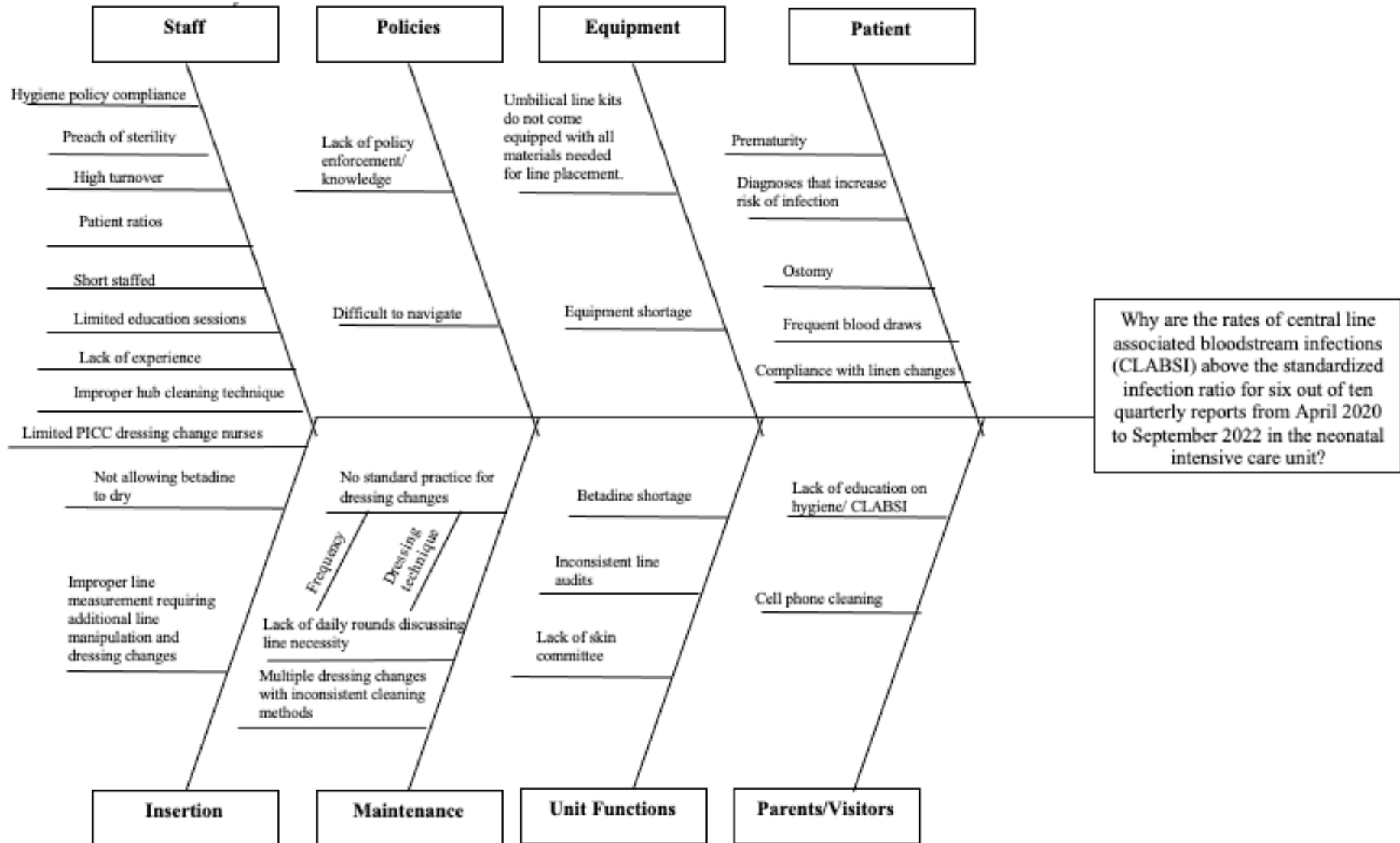
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	Denominator: Total number of central line days (the number of days when patients could develop an infection)	Denominator: Total number of central line days (the number of days when patients could develop an infection)
Measurement Plan		
Project Goals	Data Collection Procedures (who, how, when)	Name of Data Collection Tool
NICU staff will achieve 100% completion of education material by October 2023.	Who: Project Lead How: Passing with an 80% or higher on the post-module assessment When: Weekly	Staff Education (UMMS U) Education
The NICU will achieve 80% adherence to maintenance bundle documentation.	Who: Project Lead How: Random chart audit When: twice a week	Adherence to Documentation
The NICU will achieve 80% adherence to two-person aseptic technique.	Who: Project Lead & Champions How: Observational audits When: 1-2 times weekly.	ANTT Auditing Tool
Zero documented central line associated blood stream infections	Who: Project lead, infection specialist How: Quarterly infection reports When: Monthly	Quarterly Report

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Appendix B

Figure 1B
Fishbone Diagram

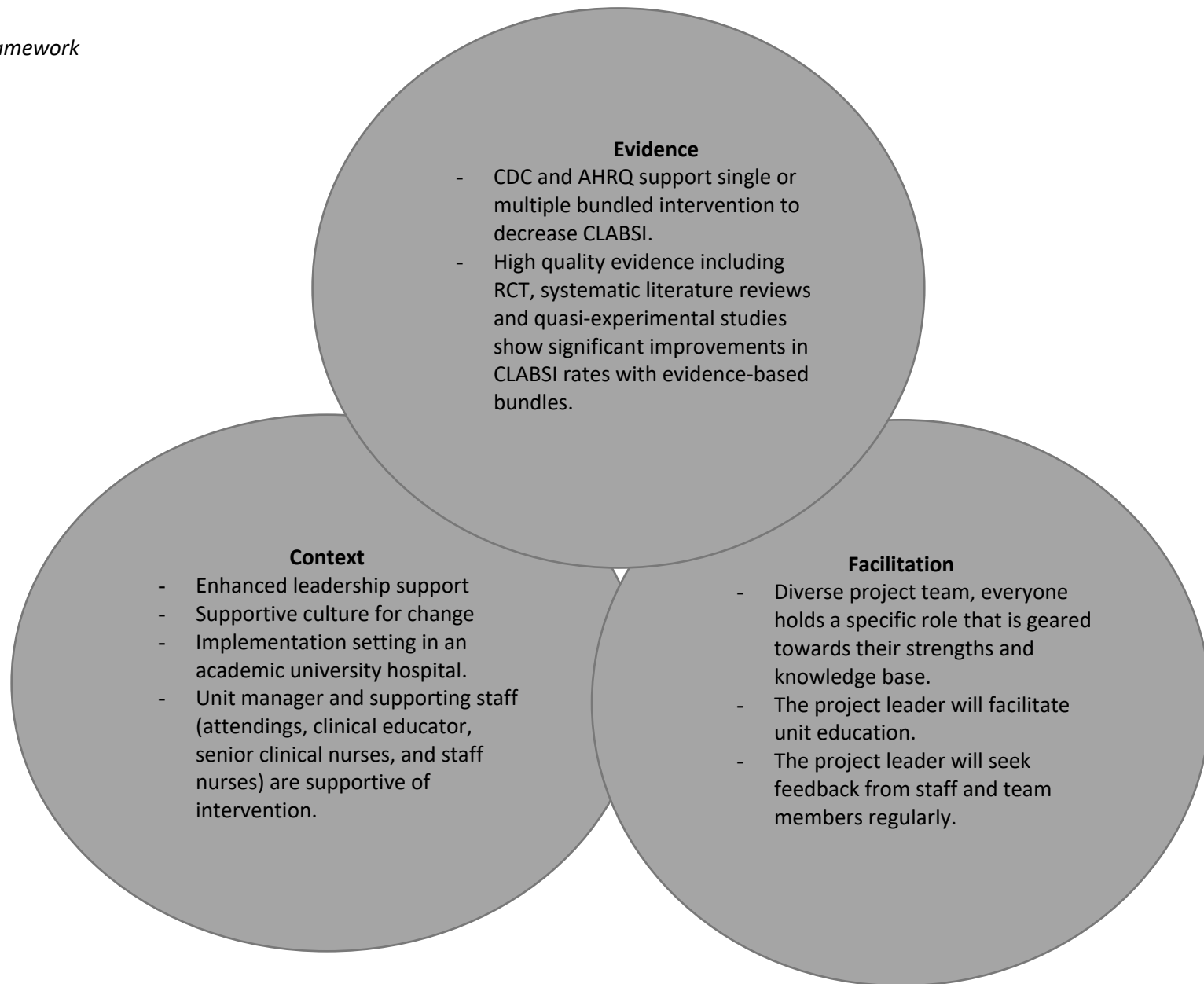


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Figure 2B*Framework Original*

Note: Hack, T. F., Ruether, J. D., Weir, L. M., Grenier, D., & Degner, L. F. (2011). Study protocol: Addressing evidence and context to facilitate transfer and uptake of consultation recording use in oncology: A knowledge translation implementation study. *Implementation Science*, 6(1), 20. <https://doi.org/10.1186/1748-5908-6-20>

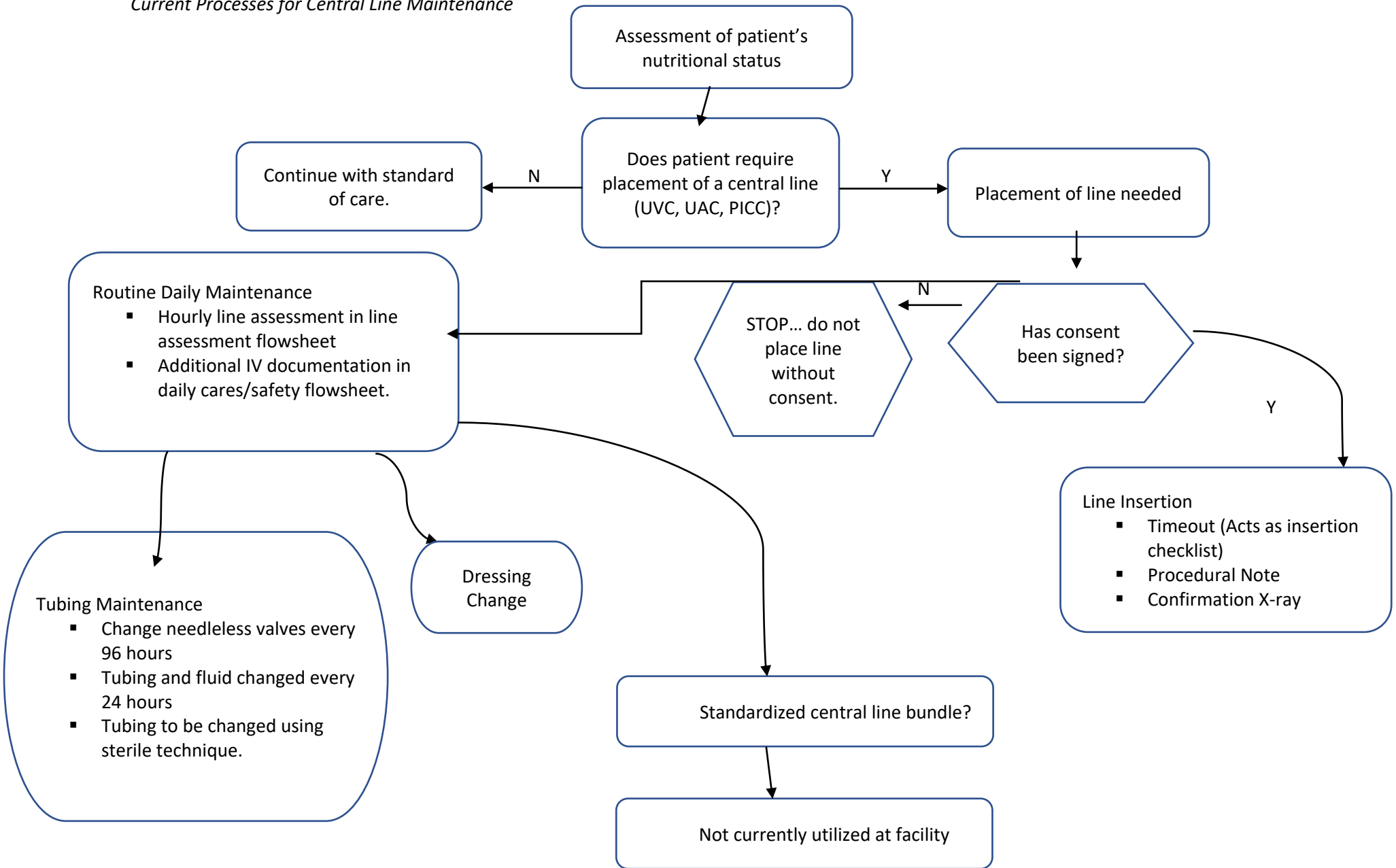
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Figure 3B*Project Framework*

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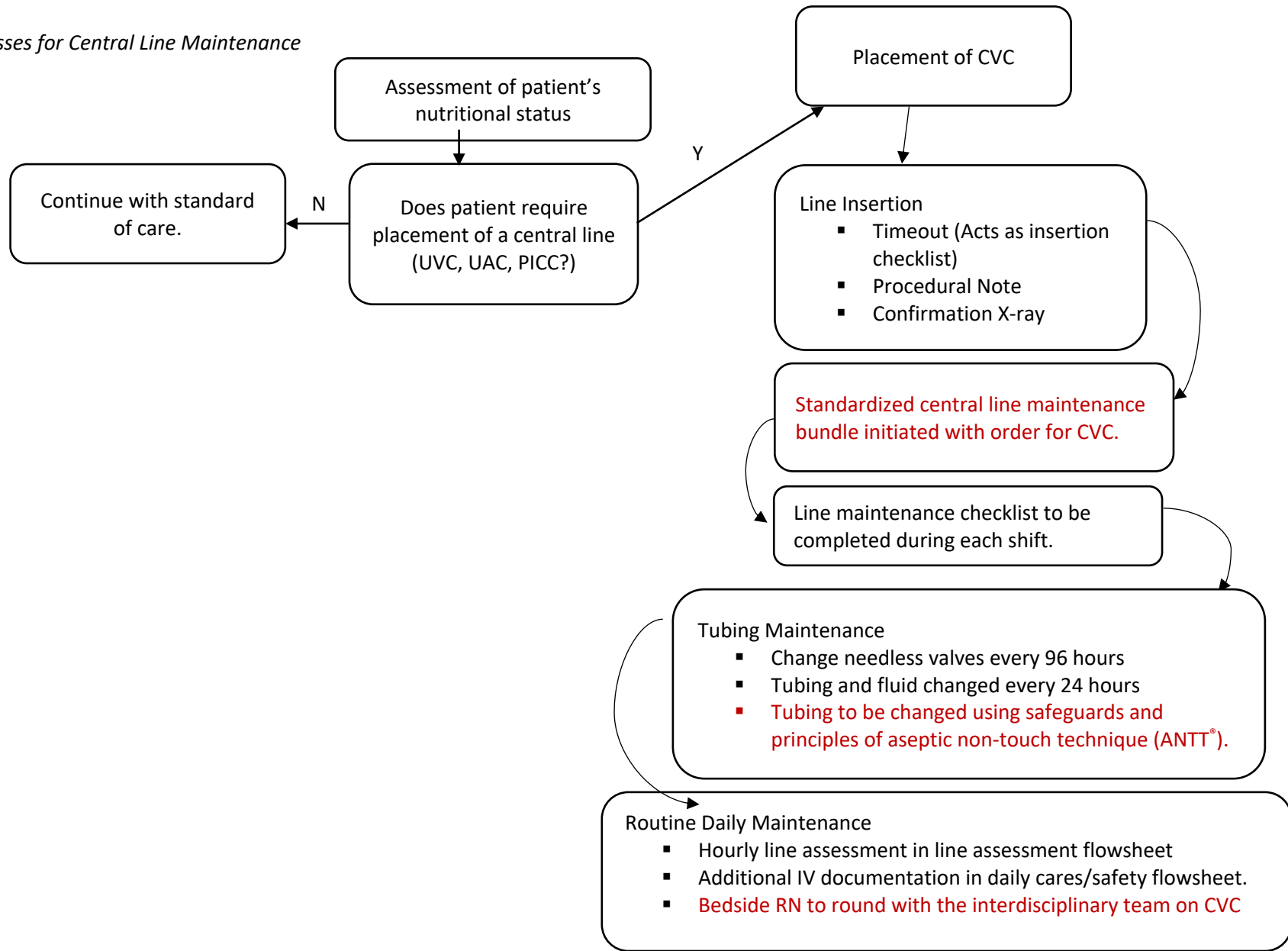
Figure 4B

Current Processes for Central Line Maintenance



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Figure 5B
Proposed Processes for Central Line Maintenance



Appendix C

Figure 1C
Education Auditing Tool

Reducing Central Line Associated Blood Stream Infections in the Neonatal Intensive Care Unit with The Implementation of a Central Line Bundle
Page 1


Education

Record ID _____

Staff Member _____

Is the education module completed? Yes
 No

Did the staff member receive an 80% or greater on the post-module assessment? Yes
 No

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Figure 2C*ANTT Audit Tool***ANTT® Audit Tool**

Page 1

Please complete the survey below.

Thank you!

 Todays Date _____

 Project Week

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15

 Auditors Name _____

 Procedure Setting?

- Hospital
- Community
- Patient Home

 Procedure Observed

- Peripheral IV Drug Administration
- Central Venous IV Drug Administration
- Administration Set Change

 Ask the Healthcare Worker what the aim of the technique is

- Clean
- Aseptic
- Sterile
- Other

 From start-to-finish of the procedure, please tick the quality of each hand-cleaning episode by ticking the type of hand-cleaning technique used (including drying time).

- 0
- 1
- 2
- 3
- 4
- 5
- 6

(Please select the number of times the observed RN washes their hands for < 10 seconds throughout the fluid change.)

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Page 2

From start-to-finish of the procedure, please tick the quality of each hand-cleaning episode by ticking the type of hand-cleaning technique used (including drying time).

- 0
 1
 2
 3
 4
 5
 6

(Please select the number of times the observed RN washes their hands for >20 seconds throughout the line change.)

Type of glove used?

- Sterile
 Non-sterile gloves
 No gloves

Were the gloves contaminated during the procedure?

- Yes
 No

How were the gloves contaminated?

What type of aseptic field was used?

- None
 Paper tray
 Metal tray
 Plastic Tray
 Trolley
 Sterile drape
 Non-sterile drape
 (Select all that apply.)

Was an aseptic field contaminated?

- Yes
 No

If you answered yes to the above question, how?

Was the procedure tray disinfected according to local policy?

- Yes
 No
 (Was the procedure tray cleaned with Oxivir and allowed 60 seconds to dry?)

For IV therapy, were IV Hubs disinfected effectively?

- Yes
 No
 Not Applicable
 (Did the observed RN "scrub the hub" for 10-15 seconds?)

When not in use, were ALL equipment Key-Parts* protected at all times during the procedure?

- Yes by sterile packaging or packaging
 No

Were equipment Key-Parts touched at all by the Health Worker's hands or gloved hands?

- Yes
 No

Were equipment Key-Parts touched at all by any equipment, containers, surfaces etc.?

- Yes
 No

At the end of the procedure were hands cleaned immediately after glove removal?

- Yes
 No

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Page 3

Ask the Health Worker what type of technique they used
(Don't show the options)

- Sterile technique
- ANTT
- Clean technique
- Non-touch technique
- Aseptic technique

Ask the Health Worker what factors they considered
when selecting the type of clean, aseptic or sterile
technique they used (Don't show the options) (Tick all
that apply):

- Patient age
- Immunosuppression
- None: the technique is mandated
- Procedure difficulty
- Patient's disease

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Figure 3C
Central Line Daily Checklist

Daily Central Line Maintenance Checklist

Page 1

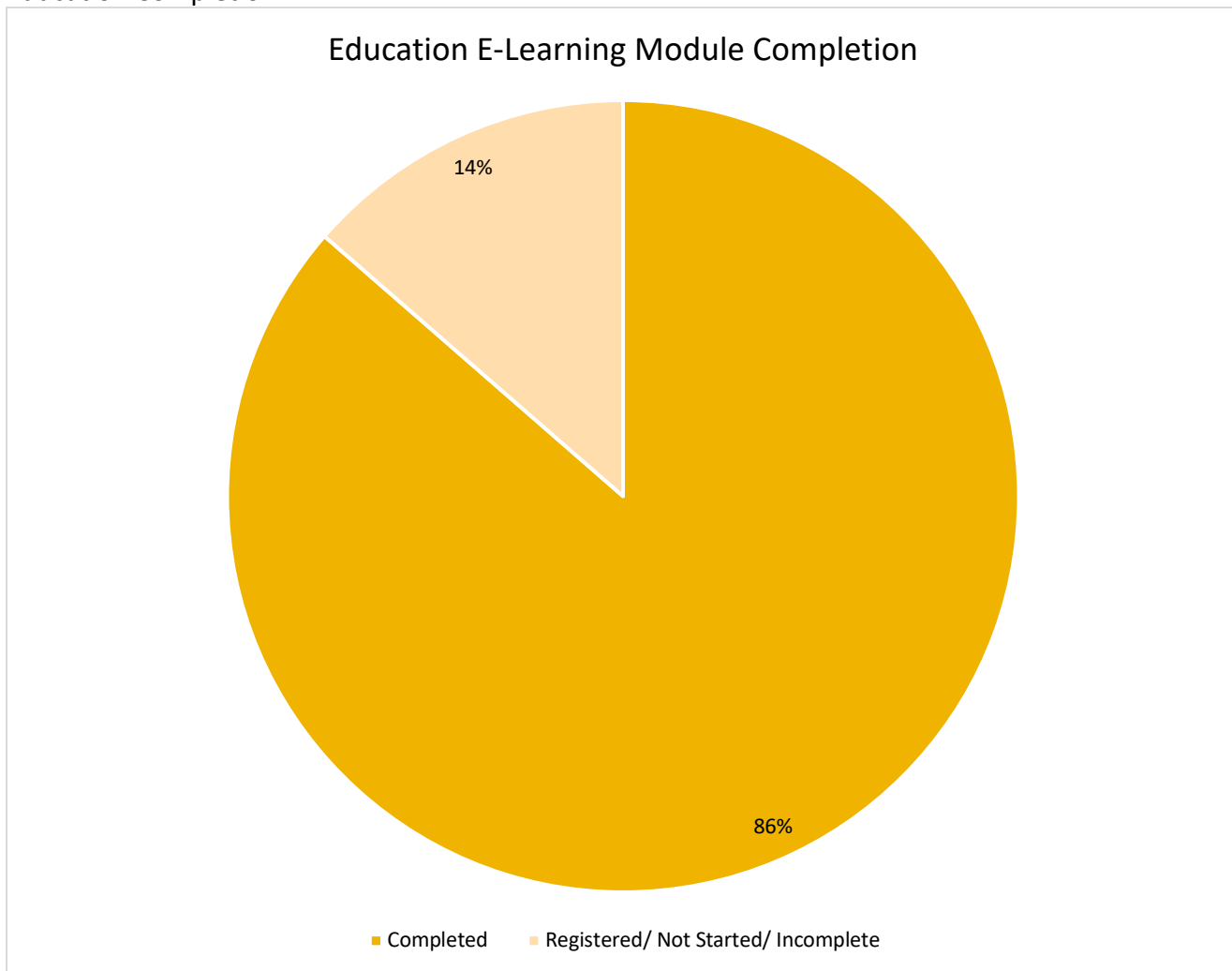
Please complete the survey below.

Thank you!

Patient MRN	_____
Shift	<input type="radio"/> Day Shift <input type="radio"/> Night Shift
Was the need for line assessed during interdisciplinary rounds?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Nurse did not attend rounds <input type="checkbox"/> N/A (Please select N/A if you are completing this checklist on night shift.)
Open injection ports are covered with Curois Disinfecting Caps?	<input type="checkbox"/> Yes <input type="checkbox"/> No
The dressing is intact, dated, timed, and initialed?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If you selected no to the previous question. Was the dressing changed?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Fluids, drips, and tubing changed within the last 24 hours and labeled appropriately (time, date, initial)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Aseptic Non-touch Technique (ANTT®) performed correctly during tubing and fluid changes and without breach in aseptic technique?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Please provide additional comments and concerns for the patient's central line below.	_____

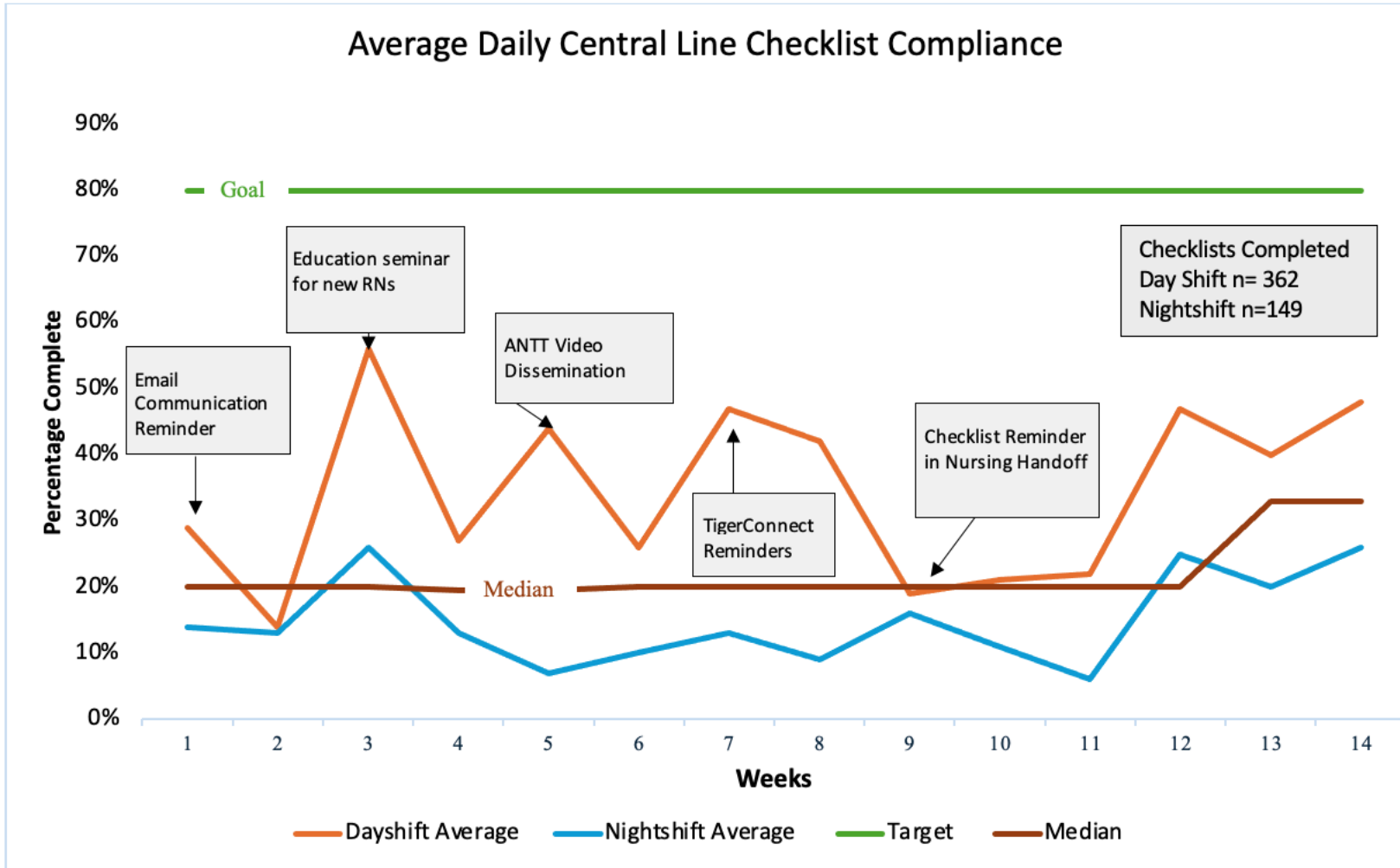
Appendix D

Figure 1D
Education Completion



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Figure 2D
Average Daily Compliance with Central Line Checklist



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Figure 3D*Confirmed CLABSIs*