CENTRAL LINE ASSOCIATED BLOOD STREAM INFECTION REDUCTION IN THE NEONATAL INTENSIVE CARE UNIT: A QUALITY IMPROVEMENT PROJECT

A DOCTORAL PROJECT

Submitted in Partial Fulfillment of the Requirements

For the degree of

DOCTOR OF NURSING PRACTICE

By

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Central Line Blood Stream Infection (CLABSI) in the Neonatal Intensive Care Unit (NICU) remains a serious health care issue. Although CLABSI reductions have been reported in both the pediatric and adult populations primarily through application of evidence-based practices, research-proven CLABSI reduction practices for the patient in the NICU is lacking. Patients in the NICU are at high risk for CLABSI due to their immature biological systems and need for long-term central line access. Recent reports from multiple learning collaboratives as well as single institutions have demonstrated significant reduction of CLABSI in the NICU. Sustainment of these early successes beyond the initial implementation period has not been widely reported. Although Quality improvement (QI) projects may have initial successes in improving care; very few projects are designed to measure success over time or identify important key factors associated with sustained improvements. Identifying factors associated with improvement sustainment is gaining increased attention across healthcare settings and a much needed next step for optimal patient outcomes.

This single-center QI project evaluated the effect of CLABSI reduction efforts on CLABSI rates over 11-years. All infants admitted to the 45-NICU between 2004 and 2014 who required a central line were included in the project. A steady decline in CLABSI rate was demonstrated. During the sustainment phase of the project (2010-2014), the annual CLABSI rate was reduced by 92% (8.67 vs. 0.65/1000 line days) over
baseline showing a continuing decline beyond the 40% reduction during the intervention phase.

CLABSI rate reductions were associated with important key factors including use of closed infusion systems, reducing central line entries, review and evaluation of events leading to a positive blood culture, regular and ongoing central line insertion and maintenance process audits, and clear and timely communication of QI efforts and results (posting of days-between-CLABSIs, for example) to all health care providers.
TABLE OF CONTENTS

ABSTRACT .......................................................................................................................... iii
LIST OF FIGURES ................................................................................................................. vi
ACKNOWLEDGMENTS .......................................................................................................... vii
BACKGROUND ..................................................................................................................... 1
  Purpose Statement ............................................................................................................. 3
  Supporting Framework ..................................................................................................... 3
REVIEW OF LITERATURE ..................................................................................................... 9
  Overview ........................................................................................................................ 9
  Central Line Associated Blood Stream Infection Pathogenesis ..................................... 9
  Reduced Line Entry ........................................................................................................ 11
  Closed Systems for Central Line Entry ........................................................................ 11
  Sustainment of Improvement ......................................................................................... 12
METHODS ............................................................................................................................ 15
  Study Population .......................................................................................................... 15
  Setting ........................................................................................................................... 15
  Data Collection ............................................................................................................ 17
  Procedures ..................................................................................................................... 18
RESULTS: PROJECT MANUSCRIPT .................................................................................. 20
DISCUSSION ......................................................................................................................... 21
REFERENCES ...................................................................................................................... 23
APPENDIX A: MANUSCRIPT SUBMITTED TO Pediatrics .............................................. 28
APPENDIX B: TABLE OF EVIDENCE ................................................................................. 48
# LIST OF FIGURES

<table>
<thead>
<tr>
<th>Figure</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Conceptual Model to Evaluate Implementation Success</td>
<td>6</td>
</tr>
</tbody>
</table>
ACKNOWLEDGMENTS

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BACKGROUND

Central Line Associated Blood Stream Infection (CLABSI) is a source of significant morbidity in patients in the Neonatal Intensive Care Unit (NICU) (O'Grady et al., 2011). Infection in the preterm infant and the resultant inflammatory cascade that follows, results in an increased incidence of chronic lung disease, retinopathy of prematurity, and prolonged length of stay. Economic costs are also high, with one CLABSI event estimated to add between $16-20,000 in excess hospital costs (Donovan et al., 2013). Finally, premature infants dying as a result of CLABSI is significant with a range in mortality estimated to be 11-31 percent (Wirtschafter et al., 2010).

Although infants in the NICU are considered at highest risk for CLABSI due to their immature body systems and prolonged need for central line access, most experts believe that the majority of CLABSI events in this population are preventable. Successful CLABSI reduction efforts have been reported in both the pediatric and adult intensive care units with reductions as high as 43% and 66% (Fisher et al., 2013; Wirtschafter et al., 2010). The focus of many reduction efforts have been central line care practices (Miller et al., 2010; Pronovost et al., 2006). Successful CLABSI reduction efforts have been reported in the NICU primarily from results of state-wide collaboratives (Fisher et al., 2013; Wirtschafter et al., 2010). These collaboratives not only focus on care practices to reduce CLABSI but also other factors that affect the success of quality improvement projects such as leadership support, communication, and learning culture. Central line care practices associated with CLABSI reduction in adult and pediatric patients are well described in the literature, and have resulted in the formation of care “bundles” (Bundy et al., 2014; Pronovost et al., 2006). Care bundles are a group of
evidence-based interventions that when performed together improve care more effectively than when one intervention is performed alone (Nolan & Berwick, 2006). Important differences exist between premature infants and older populations including fragile and immature skin, long lengths of stay in the NICU, changing biological systems, and impaired immunity that make direct application of adult or pediatric central line care practices problematic. Low birth weight is a specific and significant independent risk factor for the development of CLABSI (Mahieu, De Dooy, Lenaerts, Ieven, & De Muynck, 2001).

Central line care bundles have not been well studied in the premature infant and recent published NICU-specific care bundles (from state-wide collaboratives, for example) contain various and different central line care interventions (Wirtschafter et al., 2010). The evidence supporting central line care bundle items in the NICU patient is not robust resulting in a wide variation in central line care practices.

To further elucidate specific central line care practices associated with CLABSI reduction in the NICU, a quality improvement project was initiated in a tertiary NICU beginning in 2004. The setting is a 45-bed tertiary care NICU that is part of a high-risk perinatal delivery center. The NICU serves as a referral center for all other NICU’s in the community as well as those units in surrounding counties. Complex NICU patients are cared for including infants with extremely low birth weight, complex genetic anomalies, surgical emergencies, and hypoxic ischemic encephalopathy (requiring whole-body cooling). The average daily census is approximately 30 infants; the unit cares for more than 100 very low birth weight infants per year.
Beginning in 2004, the NICU multidisciplinary leadership noted CLABSI was a significant clinical problem. During this time, the CLABSI rate was as high as 25%; or 1 in every 4 patients met the CLABSI criteria. Initial efforts to improve CLABSI rates focused on staff education about CLABSI, hand hygiene, and environmental cleaning. Unfortunately, there was little improvement in the CLABSI rates until the focus turned to central line maintenance practices following a published report describing a closed medication administration practice (Aly et al., 2005). Learning from the results of this report, the quality improvement team focused on central line care practices and increased efforts to reduce line entry using closed central line techniques.

Purpose Statement

The purpose of this DNP project is to review the effect of a practice change project on CLABSI rates in the Neonatal Intensive Care Unit (NICU) and the measures implemented to ensure the sustainability of the practice change in an urban, acute care medical center.

The product of this doctoral work will be a manuscript to be submitted to Pediatrics (see Appendix A). The focus of the manuscript will be the overall effect of a QI project on CLABSI rates in the NICU and the factors associated with sustainment of improvement.

Supporting Framework

The key elements associated with implementation success and sustaining a practice change are varied and frequently not well documented (Wiltsey Stirman et al., 2012). In addition, the presence of strong evidence supporting a clinical practice change does not automatically result in healthcare providers adopting the new information to
transform their practice (Helfrich et al., 2010). Even less is written related to sustaining practice changes, especially over long periods of time. Multiple studies suggest that evidence-based protocols are often partially embraced by healthcare providers and patients receive only a portion of recommended care (McGlynn et al., 2003). Identifying reasons why quality research fails to translate into clinical practice is an ongoing challenge. Increasing attention is focused on understanding what factors support or inhibit implementation of evidence into practice. The purpose of this paper is to examine the facilitators and barriers of initiating and sustaining a practice change related to reducing CLABSI infections in a neonatal ICU within an implementation science framework.

The Promoting Action on Research Implementation in Health Services (PARiHS) framework identifies the necessary key elements that influence the success of a practice change. Developed in the early 1990’s by nurse researchers in the United Kingdom as an application framework describing the process of research utilization in nursing practice, the PARiHS framework identifies various key elements associated with successful change implementation projects. These key factors are grouped into three main elements that are dynamic: evidence, context, and facilitation (Rycroft-Malone, 2004). Each element is rated from low to high, depending upon the presence or absence of factors that support the change. The first key element in the PARiHS framework is “evidence” which is the quality of research, knowledge, and information that serves as the foundation for the change. Additional evidence included is clinical experience, patient experience, and local data (Rycroft-Malone, 2004). In the PARiHS framework, high quality research
is a primary driver of the practice change and is associated with an increased likelihood of successful implementation (Rycroft-Malone, 2004).

The second key element is “context” which refers to the environment or setting of the quality improvement practice and its overall culture regarding implementing change. The PARiHS framework identifies context as a potent influence on the success or failure of the quality improvement project and important organizational factors such as the presence of a learning culture, decentralized decision making, and engagement of transformational leaders to increase the likelihood that practice change can happen (Rycroft-Malone, 2004). Another component added to this element is the consideration of resources such as financial support, personnel time, and equipment (Rycroft-Malone et al., 2004). Quality improvement projects that occur within organizations with a strong learning culture are more likely to be successful.

The final element is “facilitation” which is focused on the role, skills, and attributes of the facilitator of the quality improvement project. In the PARiHS framework, facilitation is less clear than the other two elements; however the person fulfilling this role serves as the primary support for the practice change project (Rycroft-Malone, 2004). The facilitator is often referred to as the change agent or champion of the project and requires a range of skills that are employed based upon the needs of the project. For example, the facilitator may need to work with teams or individuals, provide overall organization to the project, or directly educate care providers.

Planning a successful practice change project requires careful evaluation of the strengths and weaknesses of all three core elements. The elements are dynamic and influence one another, as depicted in Figure 1, which illustrates the strengths and weaknesses of the
practice change project described in this paper. There is not a specific formula to assure a successful practice change project; rather, the interdisciplinary team evaluates and determines interventions needed to strengthen the identified weaknesses (threats) and maximize strengths. Applying the PARiHS framework to this practice change project, the primary key elements of evidence, context, and facilitation were rated and determined to vary in strength from low to medium. However, the interdisciplinary team responsible for implementing the change was successful at capitalizing on the strengths of the elements and mitigating any barriers to ensure the success of the primary outcome of CLABSI reduction. The interdisciplinary team not only met the primary outcome (CLABSI reduction) but also achieved sustainability as the CLABSI rate in this NICU has been at or below than the national average for the past five years.

![Modified PARiHS Framework](image)

*Figure 1.* Modified PARiHS Framework used to evaluate factors associated with successful implementation of this QI project.
In the setting of this project, the weakest element of the PARiHS model was related to the evidence for reducing CLABSI infections in neonates. Although CLABSI reduction efforts were successful in adults and pediatrics (Miller et al., 2010; Pronovost et al., 2006), there was a paucity of strong evidence supporting the majority of central line maintenance practice changes in the NICU at the time this project was initiated. In an effort to strengthen the research basis for change, the interdisciplinary team relied on results of other successful NICU CLABSI reduction efforts published in the literature (Aly et al., 2005; Wirtschafter et al., 2010) and expert opinions to drive clinical practice changes. Finally, the data from intervention activities such as quick cycles of change were immediately fed back to the interdisciplinary team and NICU and shared with all staff in the NICU. Timely sharing of data began to build the research base for successful interventions that reduced CLABSI in the NICU.

The majority of the items within the “context” element were rated medium. Of note, the resources available to the team’s efforts and the organizational culture were medium-high. For example, the hospital provided funds for Performance Improvement team members to participate in a state-wide NICU CLABSI reduction collaborative, which provided monthly conference calls, data tracking and benchmarking, consultation, and every 6 month face-to-face learning sessions. The organizational culture was also rated medium-high as the nurses were eager to participate and evaluate each practice change. This resulted in a quick and broad adoption of all the majority of central line maintenance practice changes.

Finally, the items within the “facilitation” element rated medium. There were key roles identified such as the physician and nurse champion that served as change agents
for the project. These two leaders had the skills, knowledge, and attributes to design, plan, and implement this practice change project. The team was multidisciplinary in nature, involving nurses, physicians, and an infection preventionist (a specially trained Registered Nurse with expertise in infection prevention). As the practice change project moved along the continuum of implementation, team members met regularly to strategize and adjust interventions as needed.

Although the PARiHS framework does not determine one standard formula to assure success, medium ratings in the majority of the key elements appeared to support the success in this practice change project. The two main facilitators assured that any weak items noted were addressed throughout the project implementation.
REVIEW OF LITERATURE

Overview

A review of the literature was conducted and centered on methods to reduce CLABSI in the NICU patient and interventions to insure success and sustainability of a practice change. The following electronic databases were searched for publications relevant to the topics of CLABSI prevention in the preterm infant: PubMed, CINAHL, and Cochrane Library. Key search terms included CLABSI, preterm infant, NICU, central line care, sustainability, and quality improvement. The majority of scholarly and academic journals included were from neonatal and infectious disease. Peer-reviewed journal publications were used and published date range included 1990-2015. The inclusion criteria included NICU patients and articles written in the English language. Exclusion criteria included studies related to adult CLABSI reduction projects.

Pathogenesis of CLABSI

The pathogenesis of CLABSI has been the focus of clinical debate and research studies over the past 35 years. Understanding the mechanism of bacterial contamination of the catheter is an important first step in designing and implementation prevention efforts. In the literature two primary contamination routes are identified: extraluminal and intraluminal. Extraluminal sources include contamination from the skin during insertion of the central line or from the skin surrounding the insertion site (Raad et al., 1993). Intraluminal sources of contamination include the catheter hub, tubing connection, or contaminated infusate (Raad et al., 1993). Extraluminal sources are generally associated with insertion practices and type of skin antiseptic used, site of
insertion (lines placed in the femoral vein are more likely to become infected), and dressing change regimens (Safdar & Maki, 2004).

Intraluminal sources of contamination are important determinants of CLABSI. Early research studies in adults with central lines identified the development of a biofilm within the lumen and at the hub of the catheter, allowing bacteria to easily migrate along the internal surface, significantly increasing CLABSI risk (Raad et al., 1993). As microbiology techniques improved with the ability to identify bacteria via molecular fingerprinting, multiple research studies now have clearly demonstrated that an intraluminal source, specifically the contamination of the catheter hub or hub of any entry port of the central line is the primary source of CLABSI (Bouza et al., 2003; Mueller-Premru, Gubina, Kaufmann, Primozic, & Cookson, 1999; Perez et al., 2014; Safdar & Maki, 2004).

Despite significant immunologic and biological differences, CLABSI pathogenesis via intraluminal sources in neonatal patients appears to be similar to adults (Garland et al., 2008; Mahieu, De Dooy, De Muynck, et al., 2001; Mahieu, De Muynck, De Dooy, Laroche, & Van Acker, 2000). Although the studies are limited in number and very few used molecular fingerprinting to positively identify and compare strains of bacteria, all results demonstrated that the predominate route of contamination was via the catheter hub (Mahieu, De Dooy, Lenaerts, et al., 2001; Mueller-Premru et al., 1999; Salzman, Isenberg, Shapiro, Lipsitz, & Rubin, 1993).

Understanding that the primary method of bacterial contamination and subsequent CLABSI is through the central line hub, the central focus of this change project was to implement central line care practices that reduced catheter hub contamination (through
use of closed systems, further explained below) and entries into the central line. Specifically, changes in medication administration, blood draws, and tubing change were introduced that reduced line entry and potential catheter hub contamination.

Reducing Central Line Entry

Although there are very few research studies specifically describing the reduction of line entries leading to reduced CLABSI, care practices that reduce opportunities to introduce bacteria are prudent. One prospective cohort study tracked the number of catheter manipulations (including tubing changes, blood draws, and medication administration) in 223 neonates (representing 3,470 catheter-days) and the subsequent development of both hub contamination and CLABSI (Mahieu, De Dooy, Lenaerts, et al., 2001). The authors found that there were two catheter manipulations specifically and significantly associated with CLABSI: blood draws (p=0.009) and disconnection of the central line (p=0.002) (Mahieu, De Dooy, Lenaerts, et al., 2001).

Utilizing the results from Mahieu et al. (2001), the practice change at the current institution included implementation of central line care protocols that reduce the number of times the line is entered for medication administration (previously required four separate entries for one medication; reduced to one entry for one medication), for blood culture and other blood draw techniques (previously required three entries to perform, reduced to one entry), and tubing change (previously every 72 hours; increased to every 96 hours).

Closed-Systems for Central Line Care

Closed systems for central lines are systems in which entries to the central line are performed through connectors (often needleless) that are disinfected prior to entry.
Although reducing the accessing of central lines is ideal, completely avoiding access of the central line is not practical for NICU patients. In fact, the lower the birth weight, the more manipulations of the central line occurs (Mahieu, De Dooy, Lenaerts, et al., 2001). When access needs to occur, the most protective manner is utilization of closed systems for all central line care. Although not well studied, closed systems are common interventions used by NICU CLBASI reduction collaboratives as the primary objective of a central lines is to provide access for intravenous fluid and medications (Fisher et al., 2013; Wirtschafter et al., 2010).

Aly and colleagues (2005) reported a 25% reduction in CLABSI events after implementation of a closed medication administration protocol (Aly et al., 2005). The closed medication administration protocol included a novel method of administering medication into the central line that not only reduced line entries but possibly reduced hub contamination and served as a barrier to bacterial migration due to length of tubing and distance from catheter hub. This practice change project utilized the findings from Aly et al. (2005) and implemented a closed medication administration protocol that was modified to utilize the current supplies and equipment.

**Sustainment of Improvement**

There is a paucity of evidence describing sustainability of practice changes and quality improvement results; a recent review identified sustainability of quality improvement practices in severely underdeveloped and much needed area of research (Wiltsey Stirman et al., 2012). Although a large amount of resources and time are dedicated to improving patient outcomes through practice change and quality improvement activities, very few resources are dedicated to assure results are sustained
over time. This practice change project was not designed to consider or formally study sustainability; however, key aspects of sustainability can be identified by the success of this project. For example, this practice change project has sustained reduced CLABSI rates (less than 1 CLABSI/1000 line days) for over 11 years, central line care processes continue to be robust and hard-wired, and key change project team members remain engaged and active in the ongoing efforts to reduce CLABSI in the NICU.

Although quality improvement collaboratives are used widely to spark improvement efforts in the short-term, sustained results are typically not sustained in the long-term or long-term achievements are not measured (Ament et al., 2014). In a recent qualitative case study from the Netherlands, 18 key participants of a successful change project were interviewed and strategies for sustainability were identified: internal audits and feedback on outcomes, small-scale education meetings, reminders, changing the physical structure of the organization, changing care process, delegating responsibility, and using a coordinator (Ament et al., 2014). As part of a state-wide CLABSI reduction effort in Michigan, team members of several intensive care units who had participated noted several key factors for sustainability: continuous feedback of infection data, improvements in the safety culture, a consistent change in the unit’s culture that CLABSI is preventable, involvement of senior leaders of each participating hospital who reviewed data and provided ongoing resources (Pronovost et al., 2010). Finally, a systematic review of 125 studies on sustainability revealed two main findings: partial sustainability is common as most projects did not maintain all change components despite full implementation and participant-level compliance with practice change is enhanced with
ongoing training, audits and feedback, triggers and checklists (Wiltsey Stirman et al., 2012).

Evidence for sustainability is still growing and changing. Based upon the current evidence, this practice change project includes several key factors that enhance sustainability resulting in 11 years of improved patient outcomes. Internal audits of central line care practices and hand hygiene are ongoing and robust, checklists are used and modified as needed in a continuous fashion to assure care processes are hard-wired, new staff are given extensive training and practice in all central line care practices, value-laden and timely data are provided to the staff weekly (in the form of “days-between-CLABSI” postings) and quarterly performance is shared, and key team leaders remain engaged and supportive of the ongoing CLABSI reduction efforts.
METHODS

The proceeding sections describe the study population, setting, measures, specific procedures, and data analysis plan employed during the conduct of the practice change project. Because this practice change project began over 11 years ago, the focus of this paper will be not only on the practice change interventions and process but also on factors contributing to sustainability of the project.

Study Population

The population of focus for this practice change was all infants cared for in the NICU who required placement and care of a central line. Both in-born and transferred infants were included in the sample. The time period was 2004-2014. The Institutional Review Board (IRB) at UCI Medical Center and California State University, Long Beach deemed this activity as QI, non-patient subject research. No ethical concerns were identified.

The device of focus is central lines. Center for Disease Control’s (CDC) definition of a central line was used for this project change. Briefly, the CDC defines central lines as lines with the tip that resides at or close to the heart within a large, central vein such as the subclavian, internal jugular, or femoral (O'Grady et al., 2011). Central lines also include all umbilical lines (both arterial and venous) which are commonly used for patients in the NICU from birth to approximately 10 days of age. In this NICU, approximately 150 lines are placed each year representing over 2000 line days/year.

Setting

The following section describes the setting for this practice change including the NICU and patient population, the nursing staff, and the hospital. The NICU is an urban,
45 bed tertiary NICU that serves as a regional center for critically ill newborns. Attached to a high-risk perinatal delivery center, this NICU cares for over 500 infants per year; 100 of those infants each year are categorized as very low birth weight infants (those weighing less than 1500 grams). A subset of the very low birth weight infant category includes those infants classified as extremely low birth weight (weight less than 1000 grams). The NICU specializes in care of extremely low birth weight infants, caring for more than 80 infants per year within this birth weight category. Extremely low birth weight infants are considered the most at-risk population for CLABSI due to their extremely thin skin, immature body systems, and reduced immune function.

Although premature infants are the primary patient population in this NICU, term infants with various health problems are cared for as well, including those requiring surgical interventions. The NICU cares for approximately 40 plus infants each year who require major surgery for various congenital or acquired surgical emergencies including abdominal wall defects, diaphragmatic hernia, necrotizing enterocolitis, and intestinal atresia.

The NICU employs over 120 Registered Nurses (RN) with varying levels of NICU experience. Almost half of the RN staff is certified in NICU nursing and the majority of the staff has at least 5 years of NICU experience. As a Magnet designated hospital, the nursing staff is encouraged to participate in multiple quality improvement projects, research protocols, and clinical projects focused on improving patient care outcomes.

Finally, the hospital provides an incentive program in which employees are able to receive additional monies if specific clinical goals were achieved. Throughout the
project implementation, the NICU staff adopted CLABSI reduction as a unit-specific incentive goal thereby leveraging NICU staff commitment to CLABSI reduction efforts.

**Data Collection**

This practice change project spanned an 11-year time period, from 2004-2014. Data were collected by project team members including NICU nurses and members of the Infection Prevention department. Data for central line days was collected daily by trained NICU staff during the baseline and active intervention phase and then from the electronic health record during the sustainability phase. Periodic audits of the project records by primary project leaders (RK, CU, and KQ) confirmed the accuracy of the data. The primary outcome measure was mean Central Line Associated Blood Stream Infection (CLABSI) rate.

During the active intervention and sustainability phase, data was collected prospectively and included both process and outcomes measures. Process measures were primarily focused on central line insertion and maintenance practices and included ongoing practice audits (dressing change, tubing change, and access) in which healthcare providers were observed performing care and maintenance procedures of central lines. Baseline measurements were obtained and ongoing audits performed throughout the project. All results were shared with NICU staff as a method to troubleshoot any weak processes as well as to hard-wire those processes working well.

The primary outcome measure was mean CLABSI rate (number of infections/1000 line days), as measured and reported by the CDC’s National Healthcare Safety Network (NHSN). NHSN is the most widely used nosocomial infection tracking system providing data to participating states. In addition to tracking infections, NHSN
also provides risk-adjusted benchmarking of CLABSI rates for various practice settings within hospitals and outpatient clinics.

Days between infections were another method to measure the primary outcome of this practice change. Used to easily display data to staff and as goals for the project, days between infections were graphed as well as posted in common areas within the NICU to assure staff were aware of the status of the CLABSI reduction effort.

Four different checklists (insertion, tubing change, accessing the line, hand hygiene) were developed to audit central line insertion and care practices. These audit tools were developed initially by the interdisciplinary team and subsequently revised and modified in an ongoing manner by the NICU staff and as care processes changed. Audit teams consisted of a variety of NICU RN staff from both day and night shifts. Some audit teams were “secret” observers (accessing the central line, for example) in which the person performing the procedure was not aware that the audit was in process. This was not possible with all audits. For the central line care audits, the goal was to complete between 5-25 audits each month.

The placement of central lines is tracked using a central line log book and the electronic medical record (EMR) for verification. Central line days were collected monthly and used for the calculation of device utilization (DUR) and CLABSI rate per the NHSN reporting guidelines. The Infection Preventionist was responsible for all CLABSI surveillance activities including collating and submitting data to NHSN.

**Procedures**

The CDC CLABSI definition was used throughout this project. Briefly, the CDC defines a CLABSI as a positive blood culture with a central line in place for at least 48
hours and the infection is not due to another source (O'Grady et al., 2011). All positive blood cultures were reviewed by the interdisciplinary team to determine if the CDC CLABSI definition was met. The team leader also reviewed the chart of every patient with a positive blood culture to determine any unusual occurrences such as leakage in the tubing, technical issues with the line (breakage or occlusion alarms), and number of times the line was accessed for medications or blood infusions. Positive blood culture review results were tabulated in an effort to trend any commonalities.

Data analysis was divided into three time periods: 2004-2005 served as baseline data, 2006-2009 active intervention period in which care processes were changed and modified according to results, and 2010-2014 in which care processes were considered hard-wired and activities focused on sustaining the change and maintaining the desired outcome.
RESULTS: PROJECT MANUSCRIPT

A manuscript was created and submitted to *Pediatrics*, the official journal of the American Academy of Pediatrics. *Pediatrics* publishes original research as well as special feature articles and quality reports (reports focused on Quality Improvement projects). The submitted manuscript is located in Appendix A.
DISCUSSION

The results of this QI project provide unique information not only about successful CLABSI reduction in the NICU but also key factors associated with sustainment. Many QI projects are initially successful and demonstrate short-term gains; very few are designed to demonstrate sustainment of early improvements. The idea of sustainability has gathered substantial interest recently and continues to be a significant hurdle in improving outcomes in health care. The QI methods and processes employed in this project may be modified and applied as appropriate in other QI efforts to increase the likelihood that initial improvements will be sustained.

Evaluating this QI project using the PARiHS framework, context and facilitation elements (see Figure 1) were enhanced with specific key activities to ensure success and sustainability. The key activities identified by the project team leaders that enhanced sustainability included central care process audits and clear and timely communication of QI results to staff. Central line care process audits were initiated early in the project and hard-wired into the daily work of staff. The methodology of the audits is an important component; audits were performed by staff and included immediate feedback about performance to the staff being audited. This methodology promoted teamwork between staff members and enhanced the learning culture of the unit. Of note, audits of central line care procedures (both insertion and maintenance practices) has been noted by others as a key factor in sustaining low CLABSI rates (Pronovost et al., 2010; Pronovost, Watson, Goeschel, Hyzy, & Berenholtz, 2015).

Clear and timely communication of QI results to staff is a central component to many QI processes. Multiple avenues were used in this project to communicate results
such as emails of run charts showing interventions across a time line, CLABSI rate compared to national benchmarks, and dashboards. However, the project team leaders found the process of posting “days-between-CLABSI” specifically effective in communicating QI results. Posting weekly days-between-CLABSI provided a simple and effective method to communicate to all team members the current status of the project, was easy to interpret, and became a visible representation of the project. Days-between-CLABSI were not only posted throughout the unit but also included in daily shift huddles, staff meetings, and on the NICU web site.

Consistent with other reports, CLABSI rates in the NICU can be reduced using QI techniques and processes. Sustainment of reduced CLABSI rates was demonstrated over an 11-year period and was associated with important key factors including use of closed infusion systems, reducing central line entries, review and evaluation of events leading to a positive blood culture, regular and ongoing central line insertion and maintenance process audits, and clear and timely communication of QI efforts and results (posting of days-between-CLABSI, for example) to all health care providers.
REFERENCES


APPENDIX A

MANUSCRIPT SUBMITTED TO Pediatrics

Sustainability in Practice: An 11-Year Review of CLABSI Prevention Efforts in the NICU
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Short title: Sustaining CLABSI Reduction in the NICU

Abbreviations:
CLABSI-central line associated blood stream infection
CDC-centers for disease control
IRB-institutional review board
NICU-neonatal intensive care unit
NHSN-national healthcare safety network
QI-quality improvement
RN-registered nurse
UCL-upper control limit
VLBW-very low birth weight

Key Words: sustainability, central line associated blood stream infection, NICU, quality improvement

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Contributors Statement:
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Recent reports from multiple learning collaboratives as well as single institutions have demonstrated significant reductions of Central Line Associated Blood Stream Infection (CLABSI) in the Neonatal Intensive Care Unit (NICU) population \(^1\)-\(^5\). Sustainment of these early successes beyond the initial implementation period has not been widely reported. Although learning collaboratives have been successful driving initial practice changes, few are designed to measure success over time or identify important key factors associated with a sustained CLABSI rate reduction. Recent published reports have demonstrated sustained CLABSI reduction; one study reported reduced CLABSI rates sustained over a 10-year period in adult Intensive Care Units \(^6\) and three studies in the NICU population with varying sustainment time periods \(^5\),\(^7\),\(^8\). This paper describes a Quality Improvement (QI) project demonstrating an 11-year CLABSI reduction effort and identifies key factors associated with our sustained success.

**METHODS**

**Design**

This was a single-center QI project to evaluate the effect of CLABSI reduction efforts on CLABSI rates over an 11-year time span. Evidenced-based practices were implemented and evaluated; no experimental practices or equipment were involved. The Institutional Review Board (IRB) at UCI Medical Center and California State University, Long Beach reviewed this QI project and determined that IRB approval was not required as the project did not meet the definition of human subject research.

**Study Population and Setting**

All infants admitted to the NICU at the University of California, Irvine Medical Center from January, 2004 to December, 2014 who required a central line as part of their
medical care were included in this QI project. The NICU is a 45-bed, tertiary care center. During the project timeline, the NICU had an average daily census of 30; approximately 25% of infants admitted were categorized as very low birthweight (VLBW) and of those infants, almost 60% weighed equal to or less than 1000 grams.

**Intervention**

In response to a significantly higher than expected CLABSI rate when compared to the National Healthcare Safety Network (NHSN) benchmark, a multidisciplinary team was identified to develop an action plan to reduce CLABSI. Team leaders were identified and included a physician champion (CU), a neonatal Clinical Nurse Specialist (RK), and an Infection Preventionist (KQ, beginning 2005). These team leaders recruited NICU staff nurses to form a CLABSI reduction team. The purpose of the team was to evaluate CLABSI incidence in the NICU, participate in available learning collaboratives, engage all healthcare providers in CLABSI reduction efforts, and implement changes in practice that were associated with CLABSI prevention.

Although team leaders were identified and a team was formed, implementation of changes in practice was slow and had limited impact on CLABSI rates; this was most likely due to team logistics and the need to establish QI project tracking and measuring tools. During the baseline period (2004-2005), the CLABSI reduction team participated in one CLABSI reduction learning collaborative (web-based) and primary interventions included the development of methods to measure and report hand hygiene compliance, establishment of baseline measurements of current compliance with central line care, and development of a standardized method of cleaning the immediate patient care
environment (including high-touch areas such as bedside table, IV pumps, and bedside monitors).

The active-intervention phase (2006-2009) included multiple changes in practice for both insertion and maintenance techniques of central lines, participation in learning collaboratives, and use of data collection tools and reporting formats (Table 1). The sustainment phase (2010-2014) was characterized primarily by maintenance activities, minor revisions to care practices as new evidence became available and ongoing reporting of CLABSI rates to staff.
Measures

The project timeline consisted of three main phases: baseline (2004-2005), active intervention (2006-2009), and sustainment (2010-2014). Project team members including NICU nurses and members of the Infection Prevention Department collected the data. Data for central line days were collected daily by trained NICU staff during the baseline and active intervention phase and then from the electronic health record during the sustainment phase. Regular and ongoing audits of the project records by primary project leaders (RK, CU, and KQ) confirmed the data accuracy.

The primary outcome measure was annual, pooled mean (all birthweight groups pooled) CLABSI rate (number of CLABSI divided by total line days). The Centers for Disease Control (CDC)/National Healthcare Safety Network’s (NHSN) surveillance definitions for CLABSI were used throughout the project, including the new, modified definition instituted in 2008. Briefly, the CDC defines a CLABSI as a positive blood culture with a central line in place for at least 48 hours and the infection is not due to another source. In this NICU, approximately 150 lines are placed each year representing over 31,000 line days during the project time period. All positive blood cultures were reviewed by team leaders (RK, CU, and KQ) to verify that the CDC CLABSI definition criteria were met.

A second method to measure the primary outcome was tracking of days-between-CLABSI events (Figure 2). Days-between-CLABSIIs were graphed and posted in common areas within the NICU to inform staff of the ongoing results of the QI project. Early in the project, a goal of 100 days-between-CLABSIIs was established; this goal was
increased incrementally as the project continued and CLABSI reduction efforts became increasingly successful.

Process measures included audits of central line insertion techniques, central line tubing change, central line access for medications, and hand hygiene. Process measurement tools were developed and utilized by the CLABSI reduction team and subsequently revised and modified in an ongoing manner. Audit teams consisted of a variety of NICU Registered Nurses (RN) staff from both day and night shifts. Some audit teams were “secret” observers (evaluating how central lines were accessed and compliance with hand hygiene) in which the person performing the procedure did not know that the audit was in process. This was not possible with all audits. For the central line care audits (tubing change, medication administration) the goal was to complete between 5-25 audits each month. For central line insertion audits, every central line procedure was audited for compliance to the established standard. As part of the implementation of all audits, audit team members were to provide immediate feedback about compliance to the staff member in an effort to promote ongoing learning, team work, identification of missed steps, and improved compliance.

**Key Interventions**

Multiple practice changes were implemented during the active intervention phase of the project and are presented in chronological order in Table 1. Interventions implemented were initially evaluated by the CLABSI reduction team and modifications made to best suit application to our NICU. For example, the use of the closed medication administration system required a re-design to work with the available syringe pumps. Tailoring practices to the unit, staff, and available equipment was an important process
step which increased the likelihood that the interventions were accepted by health care providers inserting and caring for central lines and the tools hardwired within the care processes of the NICU. Education of all NICU staff members was provided with every initiative and ongoing reminders were implemented throughout the project.

Key interventions were reduced central line entries (adoption of the closed medication administration system, modified blood culture procedure, modified blood draws from central line) implementation of closed infusion sets (use of needless-connectors at the hub of all connections) for all central line practices, audits of central line insertion and care practices with immediate feedback, and posting of days-between-infection.

**ANALYSIS**

A statistical process control chart was used to depict annual CLABSI rates, mean CLABSI rates by project phase (baseline, active intervention, sustainment), and Upper Control Limits (UCL) by each project phase (Figure 1). A g-chart was used to evaluate days-between-infection (Figure 2). Differences between baseline and sustainment phase mean CLABSI rate were assessed for significance by an independent t test analyzed by using SPSS version 23 (IBM SPSS Statistics, IBM Corporation, Chicago, IL).

**RESULTS**

Reviewing baseline, active, and sustainment phases, a steady decline in CLABSI rate was demonstrated over the 11-year time span of the project. Overall, the unit’s annual CLABSI rate was reduced by 92% (8.67 vs. 0.65/1000 line days). When compared with the baseline phase (M = 8.12) and sustainment phase (M = 0.95) mean CLABSI rates, there was a statistically significant difference (P = .04, Figure 1). During
the active intervention phase (2006-2009), a 40% CLABSI reduction was noted (5.23 vs 3.08/1000 line days). CLABSI rates continued to decline during the sustainment phase of the project (2010-2014), with a mean CLABSI rate of 0.95/1000 line days. Noteworthy and significant, the CLABSI rate for 2015 is 0.61/1000 line days (data not included in Table 1 or Figure 1), the lowest annual CLABSI rate since the initiation of the project.

Figure 2 (g-chart) demonstrates sustained, increasing days-between-CLABSI over the course of the QI project. In 2007, the first 100 days-between-CLABSI occurred, which marked a major milestone in the project. Beginning in 2010, the unit was CLABSI free for over 200 days for the first time; this represented another major milestone as this was the longest stretch of “zero” CLABSI time span since the inception of the project. Subsequent extended days-between-CLABSI occurred in 2011 (311 days), 2013 (277 days) and 2015, (351 days).

DISCUSSION

To our knowledge, this is the first report of sustained CLABSI reduction over an 11-year period; demonstrating CLABSI reduction in the NICU population is achievable and sustainable. Multiple changes in care processes have been recommended in the literature; however no one clear “bundle” of activities has been identified or standardized for the NICU population. In our experience, several key interventions were associated with a reduction in CLABSI rate including use of a closed medication administration system, detailed review of events leading to a positive blood culture, regular and ongoing central line care process audits, and posting of days-between-CLABSI (Figure 3).

Implementation of a closed medication administration system in early 2006 significantly reduced entries into the central line and was associated with a reduction in
CLABSI events (Figure 3). The closed medication administration system was previously reported to be associated with CLABSI reduction by a single center \(^{10}\), and we subsequently modified the closed medication administration system for use with our equipment and supplies. Along with reducing line entry, the closed medication administration system was easy to use and improved the ability of the nurses to “scrub-the-hub” prior to access (the system resides outside the isolette, providing easy access without disturbing the infant). Since its introduction in 2006, the closed medication administration system has been reconfigured to meet the changes in infusion pumps and infusion tubing systems. Because of its association with CLABSI reduction in this QI project and ease of use, the closed medication administration system continues to be a mainstay for medication administration in our NICU.

Building upon the success of the closed medication administration system, we implemented closed systems for all infusion practices, such as umbilical arterial line access, blood culture draw, and tubing change. Our experience adds to the existing literature that use of closed infusion systems (use of needless-connectors at the hub of all connections) in the NICU as part of a bundle for CLABSI reduction is associated with reduced CLABSI rates \(^{1,2,7,11}\).

In 2007, a positive blood culture evaluation form was developed and utilized by team leaders to determine if the CDC definition for CLABSI was met, identify potential risk factors for CLABSI (such as increased line entry) through retrospective chart review, and identify breeches in central line care (through staff interviews). Results from this evaluation tool were tabulated in an effort to trend any commonalities. Using this form, the project team leaders identified many events that lead to increased line access such as
unplanned flushing of the central line to troubleshoot intermittent occlusion alarms and equipment failures such as cracked IV tubing and leaking. Details of these events were not obtained by chart review but instead were gathered from staff interviews. Occlusion alarms and equipment failure led to increased catheter manipulations and entries. Catheter manipulations have been reported associated with an increased risk of CLABSI. Results from the positive blood culture evaluation form were used to modify and further standardize specific aspects of central line care, increase staff awareness of common equipment failure, and develop central line troubleshooting algorithms.

Although the positive blood culture evaluation form used in this QI project was retrospective, there are components to the completion of the form that are similar to health failure mode and effect analysis (HFMEA), such as staff interviews and identification of risk reduction strategies. HFMEA is a team-based analysis in which vulnerabilities of high-risk processes are identified to minimize risk; a recent report identified the HFMEA process as a strategy to reduce CLABSI events in the NICU. Audits of central line insertion, care, and maintenance practices were another critical intervention associated with CLABSI rate reduction in our unit and a key factor during the sustainment phase. In 2008, the CLABSI reduction team developed and initiated audits of central line insertion, care, and maintenance practices as a method to improve and sustain compliance with evidenced-based practices. Audits have been listed as a key intervention for CLABSI reduction efforts and may be specifically associated with sustainment of low CLABSI rates. An important aspect of the audit process used in this project was to provide timely feedback to the staff about compliance with the audit tool; this methodology served to enhance the staff’s commitment to safety practices,
hardwired practices, and improved compliance rates. Audits continued to be conducted during the sustainment phase of the project and became an important driver of ongoing performance compliance.

Communication about progress toward goals is an important component to successful QI initiatives especially as initial successes begin to wane. As part of our work, team leaders diligently posted days-between-CLABSIs throughout the unit and staff lounge and communicated this data through staff meetings and emails, and to hospital leadership. This became a clear signal to all health care providers in the NICU that the QI project was important and communicated easily and quickly the current status of the project. Displaying days-between-CLABSI continued through the sustainment phase and remains an active part of this QI project.

Although CLABSI reduction has been sustained over 11 years, the unit has not achieved 365 days between-infections or “zero” CLABSI events, as has been reported by others. A few potential reasons may explain this such as our patient profile (skewed toward the infant equal to or less than 1,000 grams) or other unit-specific, unmeasured difference in processes or culture. The youngest and smallest infants have the highest risk for CLABSI events when compared to their older and larger counterparts, making “zero” CLABSI events a challenging goal.

There are several limitations to our report. First, the purpose and design of this QI project was limited to implementation of evidence-based interventions and measuring the effectiveness of those interventions; control of other factors that may affect the primary outcome did not occur. Multiple interventions were implemented simultaneously and the results of this report cannot definitively identify which single
intervention was significantly associated with CLABSI reduction. However, implementing multiple interventions simultaneously or consecutively is consistent with many QI methodologies \textsuperscript{16,17}.

Second, this is a single-center report of an 11-year CLABSI reduction project and lessons learned may not be transferable to other centers. Yet, other centers who continue to struggle in reducing CLABSI rates may benefit from one or more practice changes and processes described in this report. Finally, changes to the CDC definition of CLABSI in 2008 most likely artificially reduced our CLABSI rate during the active intervention phase. One report estimated up to a one-third reduction attributed to this CLABSI definition change (Schulman et al., 2011). Despite the CLABSI definition change, the reported CLABSI reduction in this project remains significant and sustained from the baseline rate.

**Conclusion**

This report provides unique information not only about successful CLABSI reduction efforts but also key factors associated with sustainment. Many QI projects are initially successful and demonstrate short-term gains; very few are designed to demonstrate sustainment of those early improvements over time. The idea of “sustainability” of QI projects has gathered substantial interest over the last decade and continues to be a significant hurdle in improving outcomes in health care. The QI methods and processes employed in this project may be modified and applied as appropriate in other QI efforts to ensure sustainability and optimal patient outcomes.

Consistent with other reports, CLABSI rates in the NICU can be reduced using QI techniques and processes. Sustainment of reduced CLABSI rates was demonstrated over
an 11-year period and was associated with important key factors including use of closed infusion systems, reducing central line entries, review and evaluation of events leading to a positive blood culture, regular and ongoing central line insertion and maintenance process audits, and clear and timely communication of QI efforts and results to all healthcare providers.
Table A1, Practice changes and QI activities by Year

<table>
<thead>
<tr>
<th>Year</th>
<th>CLABSI Number</th>
<th>Line Days</th>
<th>CLABSI Rate (CLABSI #/1000 line days)</th>
<th>Practice Changes Implemented</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>29</td>
<td>3344</td>
<td>8.67</td>
<td>Identified high CLABSI rate and team leaders identified, team forms. Participation in learning collaborative, hand hygiene measurement and report process</td>
</tr>
<tr>
<td>2005</td>
<td>28</td>
<td>3700</td>
<td>7.57</td>
<td>Baseline survey of current central line insertion and care practices, environmental cleaning guidelines developed</td>
</tr>
<tr>
<td>2006</td>
<td>14</td>
<td>2679</td>
<td>5.23</td>
<td>Intralipid days reduced, blood culture draws modified and standardized, closed medication administration procedures implemented, “days-between-CLABSI” posted, hand hygiene audits initiated</td>
</tr>
<tr>
<td>2007</td>
<td>8</td>
<td>3261</td>
<td>2.45</td>
<td>Modified central line tubing change procedure implemented, closed umbilical line draw practices implemented, collaboration procedures for operating room (OR) personnel to maintain central lines established, positive blood culture reviews initiated</td>
</tr>
<tr>
<td>Year</td>
<td>Month</td>
<td>Days</td>
<td>Rate</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>-------</td>
<td>------</td>
<td>------</td>
<td>-------------</td>
</tr>
<tr>
<td>2008</td>
<td>14</td>
<td>2915</td>
<td>4.80</td>
<td>Audits of central line insertion, tubing change, and medication administration practices initiated, parent hand hygiene and infection prevention education initiated, standardized criteria for central line removal initiated</td>
</tr>
<tr>
<td>2009</td>
<td>9</td>
<td>2926</td>
<td>3.08</td>
<td>Resource books for central line tubing set-up developed, central line insertion cart initiated</td>
</tr>
<tr>
<td>2010</td>
<td>2</td>
<td>2214</td>
<td>0.90</td>
<td>Pre-diluted medications dispensed by pharmacy for use with closed medication administration system, ready-to-use sterile saline syringes for closed medication administration system flushing</td>
</tr>
<tr>
<td>2011</td>
<td>2</td>
<td>1854</td>
<td>1.08</td>
<td>Audits of central line care and hand hygiene continued, central line dressing change re-education</td>
</tr>
<tr>
<td>2012</td>
<td>2</td>
<td>2707</td>
<td>0.74</td>
<td>Immediate patient care environment cleaning standardized, audits of central line care and hand hygiene continued</td>
</tr>
<tr>
<td>2013</td>
<td>4</td>
<td>2859</td>
<td>1.4</td>
<td>Audits of central line care and hand hygiene continued</td>
</tr>
<tr>
<td>2014</td>
<td>2</td>
<td>3100</td>
<td>0.65</td>
<td>Audits of central line care and hand hygiene continued</td>
</tr>
</tbody>
</table>
Figure A1

Run chart of CLABSI rate, 2005-2014. Data are presented as mean (all birth weight groups), annual CLABSI per 1000 line days. Upper Control Limit (UCL) is three times the standard deviation (SD). UCL is specific to each phase of the study (baseline, active intervention, sustainment phase). P value indicates significance by independent *t* test.
Figure A2

“Days- between- CLABSI” events in the NICU: solid line represents days-between-CLABSI's and the dotted line is the unit identified goal for that time period.
Figure A3

Key interventions implemented during the active intervention phase of the QI project.
References


## APPENDIX B

### TABLE OF EVIDENCE

**Summary of Studies Including Source of Central Line Associated Blood Stream Infection**

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Design/Key Variables</th>
<th>Sample/Setting</th>
<th>Measurements/Operational Definitions</th>
<th>Findings</th>
<th>Conclusions/Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine the pathogenesis of CLABSI in neonates with PICC’s using molecular microbiological techniques</td>
<td>Prospective, nested cohort study</td>
<td>N= 82 neonates NICU in Milwaukee, WI</td>
<td>Purpose: Test effectiveness of using simulation to teach new protocol for treating cardiac patients with severe acute respiratory failure (SARS)</td>
<td>23 BSI’s in 82 neonates</td>
<td>Majority of CLABSI are CoNS and acquired intraluminal, from catheter hub</td>
</tr>
<tr>
<td></td>
<td>Descriptive</td>
<td></td>
<td></td>
<td>15 (18%) were CLABSI</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Key Variables: BSI, CLABSI</td>
<td></td>
<td></td>
<td>14/15 were CoNS</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10 of those 15 (67%) were intraluminal acquired</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3 (20%) were extraluminal acquired</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 (13%) indeterminate</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Separate analysis from the randomized controlled trial: 9 (22%) of the 41 patients acquired infection from intraluminal route</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Notes: Supports the notion that reduced hub entry is a reasonable intervention leading to reduced CLABSI</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Also supports the “scrub-the-hub” interventions for hub disinfection prior to use</td>
<td></td>
</tr>
</tbody>
</table>
Implement changes to care of central lines in the NICU and compare CLABSI rates pre and post intervention (Aly et al., 2005)

Retrospective, non-experimental, pre/post design.

Key Variables:
IV: Closed Medication Administration System (and other interventions)
DV: CLABSI rates

N=536 inborn (delivered at this site), low birth weight infants placed into two groups.
233/536 were very low birth weight (<1500 grams)

Group 1: n=169, served as the baseline, pre-intervention, 90 VLBW

Group 2: n=367, post-intervention, 143 VLBW NICU in Washington, DC

Number of CLABSI before and after practice change
CLABSI: used CDC definition and per 1000 catheter days
Line Use: ratio of central line days to total patient day

CLABSI rates decreased after practice change, 25% pre-intervention to 2% post-intervention, p<.0001

Closed medication administration technique reduces CLABSI in NICU patients, possibly due to reduced line entry, reduced hub contamination; tubing used for medication administration may act as a barrier to bacteria due to length and reduced direct contact of hub with medications and flush solution

Limitations: Multiple interventions implemented making it difficult to determine which intervention resulted in the reduction of CLABSI, although authors stated the closed medication administration technique was the largest change in practice

Non-randomized, retrospective

Significant differences between groups (Group 2 had more patients, higher birth weight, shorter length of stay, and more infants insured by Medicaid)
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Participants</th>
<th>Key Variables</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Salzman et al., 1993)</td>
<td>Prospective, cross-sectional Descriptive</td>
<td>N=88 NICU patients with central venous catheters NICU in NY</td>
<td>Sepsis: positive blood culture and symptomatic patient Catheter-related sepsis: microorganism recovered from blood culture was identical to organism recovered from catheter hub Hub colonization: any bacterial/fungus growth</td>
<td>35 episodes of sepsis, 28 (80%) met catheter-related definition 45% of the cultures from catheter hubs grew microorganisms 54% of catheter-related sepsis occurred before or simultaneously with contamination of catheter hub</td>
</tr>
<tr>
<td>(Mueller-Premru et al., 1999)</td>
<td>Prospective, cross-sectional</td>
<td>N=49 preterm neonates with a central line in place and with clinical signs of sepsis Divided into 2 groups: Group A: those patients with contaminated stopcocks, N=18 Group B: those patients with sterile stopcocks, N=31</td>
<td>Catheter-related sepsis: microorganisms from blood were the same species as micro-organisms from the catheter tip Catheter hub colonization: &gt;15 CFU growth At time of clinical sepsis presentation, central line was removed and 6 samples taken: 1. Stopcock 2. Swab from skin surrounding central line</td>
<td>49% of the sample had positive blood cultures 63% CLABSI Group A: 72% had positive blood culture (p=0.005), 12 CLABSI (p= 0.0005) CoNS significantly more common organism (p= 0.0005) and typing matched samples from central line tip and stopcock</td>
</tr>
</tbody>
</table>

Notes: only published article detailing medication administration technique associated with reduced CLABSI in NICU patients

Contamination of catheter hub is major portal of entry and may be the pathogenesis of the majority of catheter-related sepsis in this population

Limitations: skin cultures not obtained which would help to determine origin of microorganisms (skin vs. hub)

Notes: First study to demonstrate the hub as a major source for CLABSI

Stopcock contamination is more likely the cause of CLABSI in NICU patients than other sources such as parenteral infusion fluid or skin

Limitations: no control group in which infants had no signs of sepsis and central line removed and same samples obtained; this would have added more rigor
### PICU in Slovenia

3. Tip of central line
4. Intradermal section of the central line
5. Parenteral fluid infusing
6. Blood culture

100% of the catheter tips grew the same organism as those from the stopcock

Group B: 32% had positive blood culture, 3 CLABSI

CoNS less common organism and multi-organism infection common

### Notes: This is an important early study demonstrating the catheter hub, not the skin or infusate as a contributor to CLABSI

| Describe the influence of catheter manipulations on incidence of CLABSI in neonatal patients (Mahieu, De Dooy, Lenaerts, et al., 2001) | Prospective cohort study | N=223 patients representing 357 central lines NICU in Belgium | CLABSI rates: number of infections/total catheter days
CLABSI: clinical signs of sepsis along with positive blood culture
Positive Catheter Hub: 2/4 cultures grew bacteria or fungus
Positive Catheter exit-site: 2/4 cultures grew bacteria or fungus
Catheter Manipulations:
1. Disinfection of hub
2. Connection to infusion line
3. Administration of medication
4. Transfusion of blood products
5. Addition of electrolytes to the line
6. Blood withdrawal
| 17 CLABSI, 4.7/1000 catheter days
Catheter hub positive cultures (p=0.001), extremely low birth weight (p=0.005), and specific catheter manipulations (blood sampling p=0.009; disconnections p=0.002) independent risk factors for CLABSI
| 10,960 catheter manipulations

Specific manipulations to the central line (blood sampling and disconnections) increase the risk of CLABSI; other procedures (heparin and exit site anti-sepsis) are protective against CLABSI

Strongly associated with CLABSI is hub colonization; hub colonization is increased with number of central line disconnections

Limitations: non-randomized or controlled

Notes: first study to examine the number and types of catheter manipulations and association with CLABSI
Serves as background for all interventions aimed at
Describe biofilm present on needleless connectors and compare between two different NC (silver coated and standard) using culture-dependent and culture-independent methods (Perez et al., 2014)

| Describe biofilm present on needleless connectors and compare between two different NC (silver coated and standard) using culture-dependent and culture-independent methods | Descriptive | N=151 needleless connectors collected from 62 adult patients in acute care hospital. Acute care university hospital in Atlanta, Georgia | Positive culture of NC: minimum of 10 CFU/NC | 46% of standard NC grew microorganisms. 59% of sliver coated NC grew microorganisms. No statistical difference in growth between standard and sliver coated NC. CoNS was the most common bacteria noted in both NC. | Most NC are rapidly colonized by a variety of bacteria and there is no difference in biofilm development between standard or silver-coated NC. Limitations: central lines were not analyzed nor blood cultures which would have enhanced the understanding and relatedness of NC biofilm development and clinical infection; number of times NC’s were accessed not tracked. Notes: the study results add to the literature regarding pathogenesis of CLABSI in which catheter hub plays a central role. |

To evaluate the effectiveness of antiseptic barrier cap compared to standard disinfection of heavily contaminated NC (Menyhay & Maki, 2008)

| To evaluate the effectiveness of antiseptic barrier cap compared to standard disinfection of heavily contaminated NC (Menyhay & Maki, 2008) | Prospective, in vitro | N=108 NC (36 from three different manufacturers - Baxter Healthcare, Deerfield, IL; Becton-Dickinson, Franklin, NJ; ICU Medical, San Clement, CA) split into following | Quantitative culture methods | Experimental group (antiseptic barrier cap): 1.6% transmission (p=0.001). CG: 67% transmission. No difference in transmission of bacteria between the three manufacturers of NC. | Antiseptic barrier cap statistically significantly reduced transmission of bacteria when compared to standard disinfection. Limitations: small sample size, limited to one type of bacteria (not biofilm forming), not in vivo study. |
To test the efficacy of a closed-needleless connector (CLAVE) in prevention of CLABSI when compared to a

<table>
<thead>
<tr>
<th>Key Variables:</th>
<th>IV: 2 groups</th>
<th>N=1774 central lines in 352 adult patients who have undergone major cardiac surgical procedures</th>
<th>Hub colonization: bacterial growth &gt; 15 CFU</th>
<th>CLAVE group had a significant reduction in hub colonization (p&lt;0.0001), catheter tip colonization (p&lt;0.0001), and a 46% reduction in CLABSI when compared to CG</th>
<th>Adult patients with a central line undergoing cardiac surgery experienced reduced CLABSI, hub and central line tip colonization with the use of the CLAVE NC</th>
</tr>
</thead>
<tbody>
<tr>
<td>IG: CLAVE NC</td>
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<td></td>
<td>CLABSI: clinical symptoms of sepsis and</td>
<td></td>
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<tr>
<td>CG: COVDV:</td>
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</table>

Notes: conventional disinfection not very effective with NC that are heavily contaminated; although antiseptic caps reduce transmission significantly, adds to cost of care; this study adds to rationale for medication administration techniques that reduced hub entry; would like to see a study with closed medication administration compared to antiseptic caps and compare transmission and/or CLABSI rates.
| conventional open system (COV). (Bouza et al., 2003) | CLABSI, tip colonization, hub colonization, skin colonization | N=865 catheters in 178 patients in the CLAVE group N=909 catheters in 174 patients in the COS Large, metropolitan hospital in Spain | blood culture positive with same bacteria growing on catheter tip Catheter tip colonization: >15 CFU bacteria growth | CoNS most common organism obtained from catheter tip cultures in both groups when compared to no NC. Limitations: population studied was narrow with adult patients undergoing cardiac surgery; other CLABSI interventions were not controlled during the study; did not track numbers of catheter entries |

*Note. BSI= Blood Stream Infection, CDC= Centers for Disease Control, CLABSI= Central Line Associated Blood Stream Infection, CFU=colony forming unit, CoNS= Coagulase-negative staphylococci, CG=control group, COV-Conventional Open System, DV= Dependent Variable, IV= Independent Variable, IG= Intervention Group, NC=needleless connector, PICC= Peripherally Inserted Central Catheter, VLBW= Very Low Birth Weight (<1500 grams).*