

ORIGINAL ARTICLE

A statewide quality improvement collaborative to reduce neonatal central line-associated blood stream infections

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Objective: The objective of this study was to reduce central line-associated blood stream infections (CLABSIs) among 13 collaborating regional neonatal intensive care units by 25%. We tested the hypothesis that change could be attributed to the quality improvement collaborative by testing for 'special cause' variation.

Study Design: Our prevention project included five features: (1) leadership commitment, (2) potentially best practices, (3) collaborative processes, (4) audit and feedback tools and (5) quality improvement techniques. Baseline (1 January 2006 to 30 August 2006) data were compared with the intervention (1 September 2006 to 30 June 2007) and post-intervention (1 July 2007 to 30 December 2007) periods and analyzed using statistical process control (SPC) methods.

Result: We detected special cause variation, suggesting that the collaborative was associated with reduced infection rates, from 4.32 to 3.22 per 1000 line days (a 25% decrease) when comparing the baseline with the follow-up period.

Conclusion: The collaborative's process was associated with fewer infections. SPC suggested that systematic changes occurred. The remaining challenges include sustaining or even further reducing the infection rate.

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Introduction

Health-care-associated infections, and in particular, central line-associated blood stream infections (CLABSIs) are an important cause of increased morbidity and mortality in hospitalized patients. These infections are increasingly recognized as preventable life-threatening adverse events,^{1,2} even among neonates who may be more biologically at risk for these infections than older infants or adults.^{3,4} Although primary prevention consists of avoiding line insertion, this is often not feasible in premature and critically ill neonates.⁵ However, secondary prevention strategies, emphasizing improved techniques and clinician education for inserting and maintaining vascular lines, are very feasible in neonates. Because prevention strategies have been shown to be successful, payers, both governmental and private, have proposed withholding payment for the occurrence of CLABSIs, as part of a program to decrease the incidence of preventable 'never events'.⁶

Multi-site quality improvement (QI) collaboratives are one effective way of gaining provider attention and organizational focus on implementing clinically proven 'best practices'.^{7–12} In these collaboratives, clinicians from several sites are introduced collectively to a set of best practices, as well as the methods for implementing change (QI methods). Site variation is a great advantage in QI collaboratives because it enables sites to learn from one another's data and implementation experiences as well as from their own. The aim of QI collaboratives is to improve outcomes at the collaborative level, recognizing that sites will vary at baseline in their processes and outcomes and, later, their ability to affect change over time will reflect how local context affects their implementation processes.

Recognizing the need to improve perinatal health outcomes, California has developed structures to support such collaboratives. Beginning in 1997, the California Department of Health Care

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Services' program for children with special health-care needs, California Children's Service (CCS), assumed the role of working to improve the quality of infant health care by partnering in the development of the California Perinatal Quality Care Collaborative, a statewide perinatal consortium that identifies desired outcomes and promotes best perinatal–neonatal practices through the development and dissemination of 'toolkits' (a compendium of documents to aid adoption of best practices).¹³ In 2006, CCS joined with the California Children's Hospital Association to further develop and expand the implementation strategy of the California Perinatal Quality Care Collaborative Nosocomial Infection Prevention Toolkit as part of a statewide neonatal QI collaborative to reduce the rate of CLABSIs within the regional neonatal intensive care units (NICUs) of the association members.

We report the results of this QI collaborative with respect to whether the collaborative met its clinical goal of reducing CLABSIs by 25% in the 13 participating NICUs. In addition to measuring the clinical significance of the collaborative, we also tested the effect of the collaborative, using statistical process control (SPC) methods, that is, we tested the hypothesis that the CLABSI rate showed special cause variability temporally associated with the timing of the intervention.

Methods

Setting

The 13 collaborating regional NICUs included all eight of the Children's Hospitals in the state, four of the five University of California Hospitals and one large regional center of a multi-site hospital system. Regional NICUs, as defined by CCS standards regulations, provide mechanical ventilation and major surgery without restriction, but only variably provide on-site extracorporeal membrane oxygenation and cardiac surgery for all serious malformations (equivalent to levels 3B and 3C of the American Academy of Pediatrics).¹⁴ Eight of the 13 NICUs have related delivery services; their average outborn admission rate was 39% during the study period. NICU size ranged from 23 to 84 beds and patient days in 2007 ranged from 7665 to 29 565. In 2007, these units constituted 68% of the beds in all CCS-approved regional NICUs and provided 71% of NICU patient days reported to CCS. Their aggregate patient days were 196 005 (central line days 59 182) in 2006 and 203 670 (central line days 73 077) in 2007.

Study design

We designed a prospective interventional cohort study that included all patients admitted to the collaborative's NICUs between 1 September 2006 and 31 December 2007 and compared these patients with historical controls from the first eight months of calendar 2006. We specified three periods: baseline (January to August 2006), intervention (September 2006 to June 2007) and post-intervention (July to December 2007).

Measures

The primary outcome measure was the self-reported laboratory-confirmed CLABSI rate per 1000 central line days, stratified by four birth weight groups, using conventions described by the Centers for Disease Control and Prevention (CDC).¹⁵ In a neonate, a central line, as defined by the CDC, refers to an intravascular catheter introduced either through the umbilical artery or vein and any others that terminate at or close to the heart or in one of the great vessels that is used for infusion, withdrawal of blood or hemodynamic monitoring. These guidelines were followed with one exception: axillary, rather than rectal, temperatures were the accepted standard for monitoring neonatal temperature, and 'out of normal range' values were only considered abnormal when confirmed with a second reading. The collaborative chose not to use the 'clinical sepsis' criteria to define a CLABSI event because of difficulties anticipated in ensuring their consistent application. These self-reported rates are vetted by the infection control department of each hospital, whose personnel have completed the CDC National Healthcare Safety Network-sponsored trainings on classifying and reporting infectious events.

Baseline NICU organizational practices and subsequent organizational performance improvement were assessed using an assessment tool^{16,17} administered to a convenience sampling of the leadership teams of each NICU, before and after implementation. The self-reported ratings were aggregated by unit and by organizational dimensions (not shown). Each team also performed an overall intervention self-assessment upon the project's conclusion, using the scale for assessing collaboratives of the Institute of Healthcare Improvement (IHI).¹⁸

Interventions

Our improvement program included five interventions: (1) develop leadership commitments, (2) describe 'potential best practices', (3) develop collaborative processes between members, (4) develop audit and feedback processes and (5) teach quality improvement techniques.

Obtain leadership commitment

We obtained strategic commitment, support and sponsorship from the executives of the California Children's Hospital Association, the statewide leadership consortium of children's hospital executives, and CCS, the major authorizer of services to children with special needs. The executives of each children's hospital monitored results and helped their NICU leadership teams obtain resources and align objectives. We obtained NICU commitment by ensuring that teams included representation of the physician, nursing and infection control leadership and staff.

Describe care processes

The description of 'potential best care practices' was iterative and based upon group consensus because, unlike 'bundles' produced

for 'adult' patients, there have not as yet been any neonatal CLABSI prevention 'bundles' promulgated by professional societies. The Nosocomial Infection Prevention Toolkit, 2003 edition, of the California Perinatal Quality Care Collaborative was used as our foundation document (the 2003 Toolkit is no longer available online, as it has been superseded by the 2007 version, available at <http://www.cpqcc.org>). Its development, in turn, was influenced significantly by the literature reviews and experiences of California's participants in the NIC/Q 2000 project.^{19,20} After an updating of the literature through early 2007 and discussions of emerging issues, the collaborative worked to specify greater detail about each of the processes of interest: diagnosis of a CLABSI, hand hygiene and vascular access device insertion and maintenance processes. Three Ishikawa diagrams, also termed 'fishbones' or 'cause and effect' diagrams, were developed to reflect the hypothesized inter-relationships of these factors in contributing to the reduction of CLABSIs (see Figures 1–3). On-going discussions supported the continuing evolution of potential best practices knowledge and techniques as the members shared their own and newly published experiences.

Develop collaborative processes

The project was initiated in September 2006, with separate kick-off meetings in Southern and Northern California, respectively. Project aims and approaches were addressed and basic methods for performing QI projects were described. Organizational assessments of each NICU, current medical and nursing practices for preventing CLABSIs and current means for data monitoring were assessed (see below). The project team and participants conducted biweekly

conference calls to identify and motivate prioritization of initiatives, develop consensus about data definitions and collection procedures, exchange knowledge about 'best practices' and exchange ideas on 'best implementation' practices. The project team visited each NICU to provide tailored, real-time clinical and administrative 'consulting' about their individual challenges and barriers. Mid-course collaborative meetings brought participants together again to review their progress, describe implementation problems, share techniques and approaches and reassess future priorities. The final project meeting included all participants and focused on lessons learned, opportunities for improvement, project assessment, as well as a presentation and celebration of the attained results attended by the senior leadership of California Children's Hospital Association and many of its members and state legislators.

These meetings and phone calls were importantly supplemented by a listserv and a password-protected web site for sharing data and documents. All contacts encouraged these NICUs to identify and share their observations, processes, materials and practical suggestions.

At the unit level, project teams assessed their individual needs, established priorities and worked to achieve their own individual objectives, whether related to medical/nursing practices, organizational support or operational effectiveness. Thus although all sites shared the same outcome goals of reducing/eliminating CLABSIs, the approaches to reach that goal varied among the sites. This allowed each site to focus on its highest internal needs while also expanding the number of interventions tested and shared within the entire collaborative.

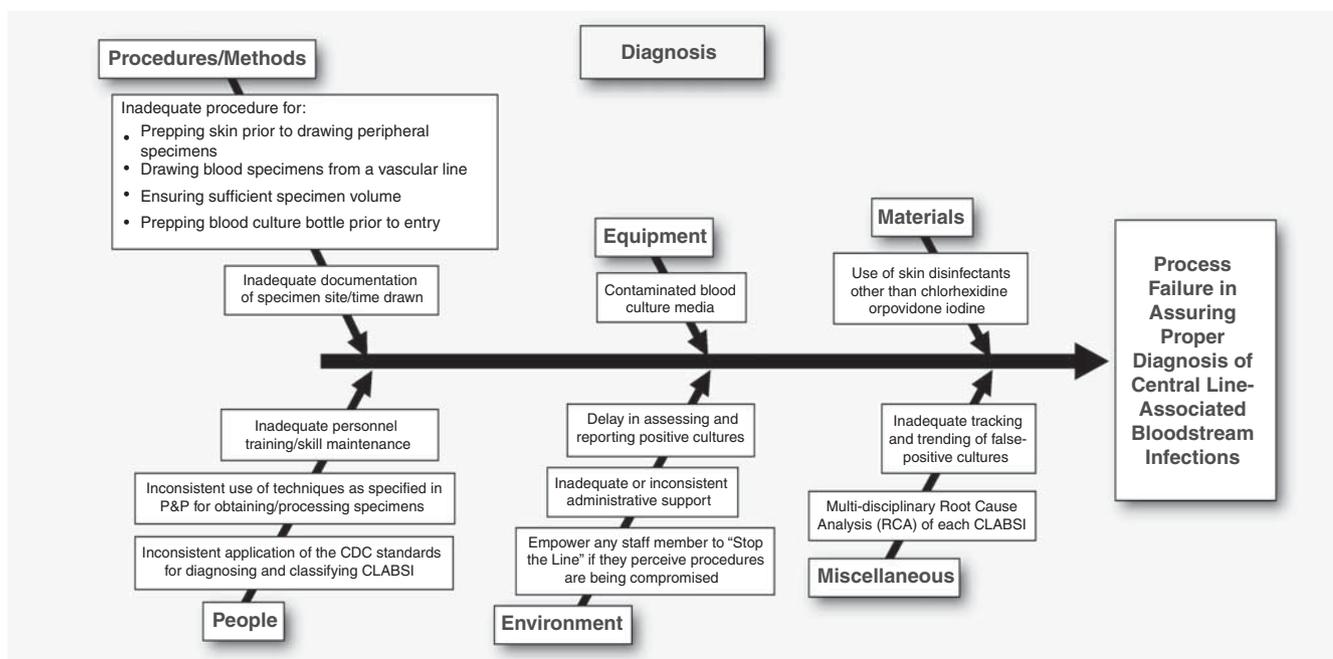


Figure 1 Ishikawa diagram of the central line-associated blood stream infection diagnosis process.

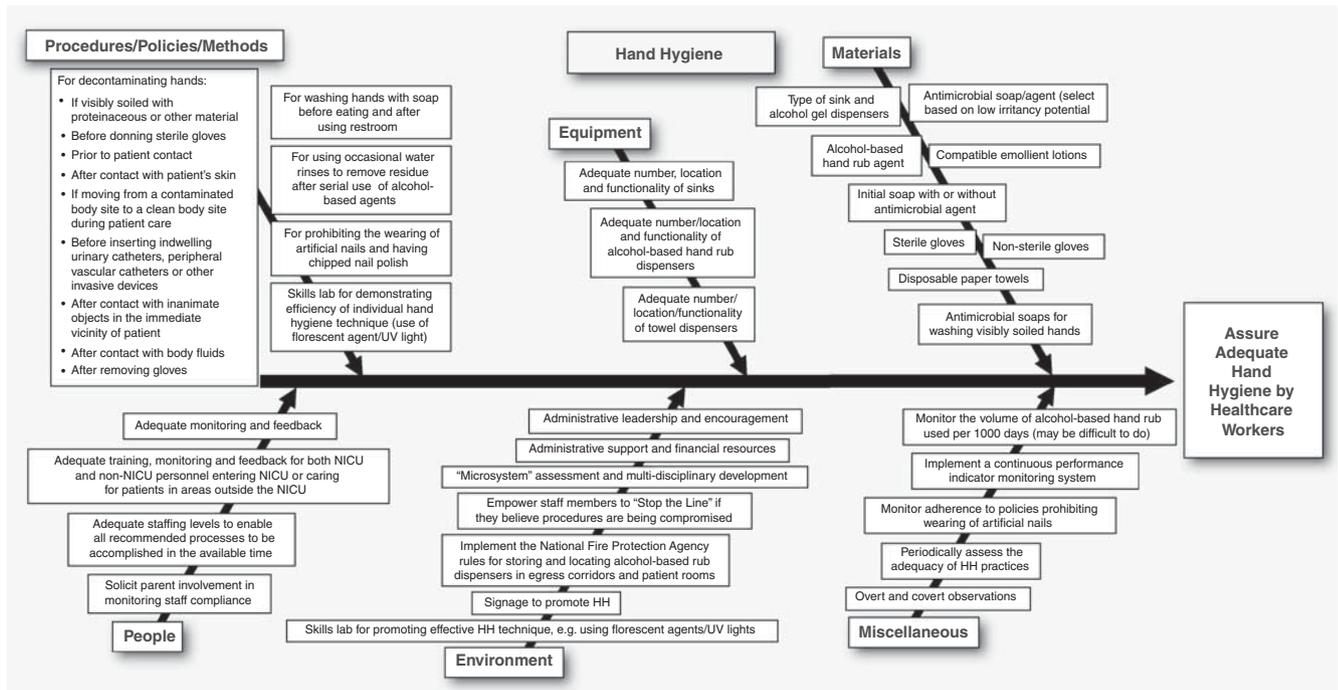


Figure 2 Ishikawa diagram of the hand hygiene process.

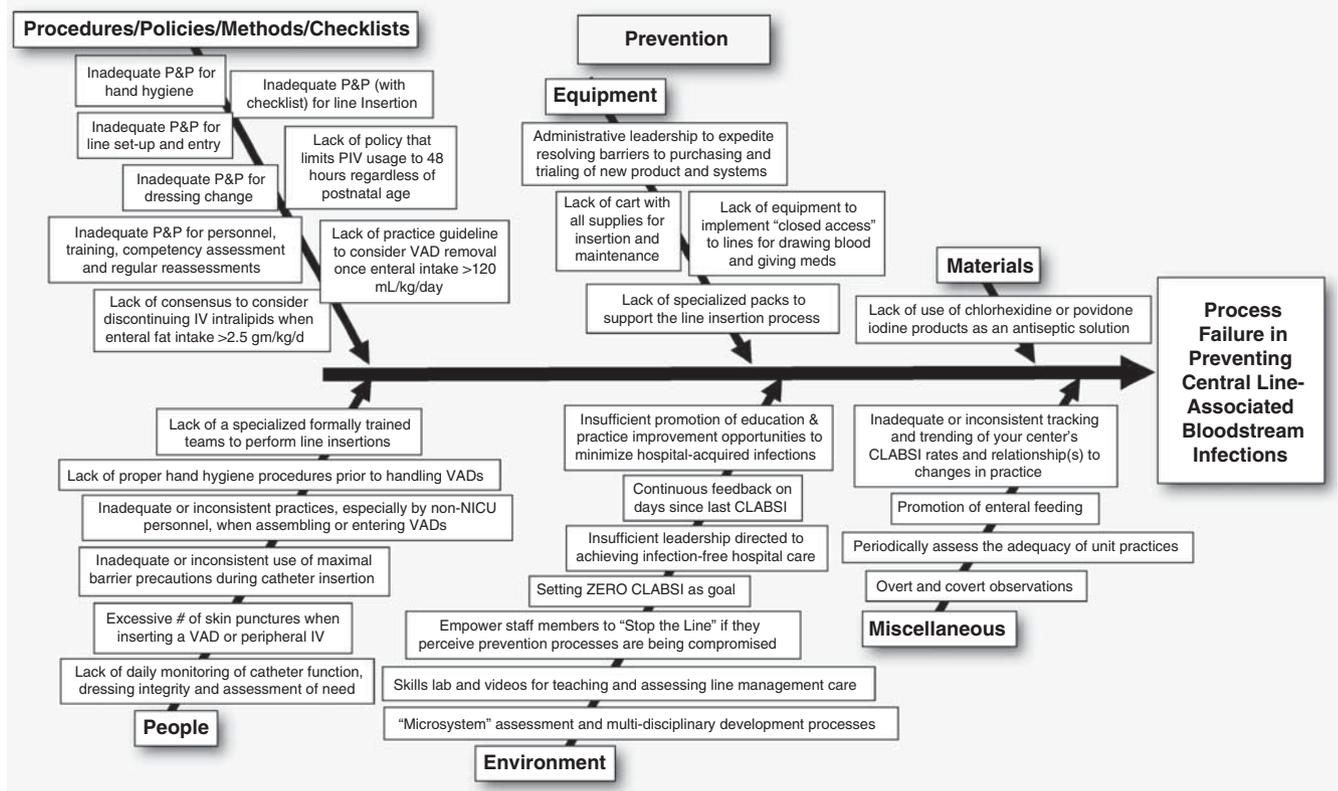


Figure 3 Ishikawa diagram of the central line-associated bloodstream infection process.

Develop audit and feedback process

Each center audited and reported its implementation activities using the nosology implicit to the fishbones described above.

In addition, minutes from the mid-course and final project meetings and phone calls were used to identify the practices that attendees planned to implement in their NICUs as a result of the

information that they obtained at meetings. Measures of hand hygiene, line set-up and line entry processes were collaboratively developed and adopted by many members. All members implemented means to periodically provide feedback to their staffs about process measures and SPC charts of their own CLABSI rates, as well as encouraged their staffs to announce daily the number of days since the last CLABSI in their NICU. The combined results of the collaborative were distributed monthly and discussed on both the conference calls and at meetings.

Teach unit quality improvement techniques

NICU teams were taught how to use the unit assessment tools to reflect on their organizational practices and performance. Site-specific agenda and action plans were developed. We emphasized implementation of reflective practices associated with high-reliability organizations, that is, those that sustain high-quality services, such as staff empowerment to halt care processes whenever safety concerns are perceived, increased staff communication and immediate fact gathering about and timely reflection upon any adverse event occurrence.²¹

Analysis and interpretation

Analysis was designed to detect significant change in the overall collaborative CLABSI rates by comparing the rate per 1000 line days in the baseline period to that in the intervention and post-intervention periods. Because we measured the universe of all line days and all CLABSIs, as opposed to a sample of these, no inferential statistics were calculated.

To determine whether the collaborative was associated with systematic change in outcomes, we used SPC methods.²² Variation is inherent in all processes and thus produces variations in outcomes. SPC has been used for decades in manufacturing to quantify and understand variation in manufacturing process and outcomes. According to SPC theory, there are two types of variation: common cause and special cause. Common cause is the random variation inherent in any production process. A system that shows only common cause variation is said to be stable. Special cause variation is variation attributable to a specific, identifiable factor causing instability in the process. One can think of our collaborative as a 'production process' for generating CLABSI-free line days, with CLABSIs corresponding to 'defects' resulting from the production process. We used Shewhart control charts to monitor the CLABSI rate monthly over time for the collaborative. Specifically, we used U-charts, which are appropriate for count data with varying opportunities for nonconformities, for example CLABSIs per 1000 line days. Following standard practice, we calculated the centerline (\bar{u}) as the sum of the CLABSIs ($\sum c$) divided by the sum of the 1000 line days ($\sum n$). The U-chart is based on the Poisson distribution for which three -Sigma upper control limits and lower control limits are calculated using the following formula:

$\bar{u} \pm 3 * \sqrt{\bar{u}/n}$.²³ We calculated the initial centerline and control limits from the baseline period.

We used standard industry criteria to determine whether the observed variation in CLABSI rates was due to common cause or special cause.²² These include: the presence of a single point outside the control limits, a run of eight or more points in a row above (or below) the centerline, six consecutive points increasing or decreasing, or two out of three points near a control limit. Therefore, we decided *a priori* that, when any of these criteria were present and coincided with the intervention, we would conclude that the collaborative had produced special cause variation. We then recalculated the centerline and control limits from the point of the special cause variation forward.

Results were calculated for the entire cohort and for subgroups of those who were <1500 g, very low birth weight (VLBW), and for those >1500 g, reasoning that the latter infants were more likely to have had central lines because of surgical problems and thus were clinically different than the VLBW infants (correlation coefficient between each NICU's aggregate central line days in those >1500 g birth weight and surgical volume was 0.82).

Project financing

The project was administered by the California Children's Hospital Association with financing by individual hospital assessments and financial and in-kind support by the CCS.

Institutional review

This project was conceived, designed and implemented with the sole purpose of quality improvement, and for this reason no review by an institutional review board was sought.²⁴ All data collected were part of the usual and routine clinical care. Data submitted to and analyzed by the project's leadership, for example, the total number of infections per month and total number of line days per month in each NICU, contained no patient identifiers. In addition, each NICU was asked to identify its own greatest need for improvement in the processes of preventing CLABSIs. No directives were given to any unit regarding what it needed to work on; however, once an area for improvement was identified, suggestions for improvement were shared with the unit. Each unit was free to adopt or not adopt those suggested changes.

Results

When compared with the baseline period, CLABSI rates for all birth weights cohort fell 25%, from 4.32 to 3.22 infections per 1000 line days, during the follow-up periods. In a population exposed to approximately 73 000 line days, this translates to approximately 75 fewer infections in 2007 when compared with 2006.

Figure 4a shows the CLABSI rates before, during and after the collaborative intervention. According to our *a priori* rules, we note special cause variation (eight points in a row below the centerline),

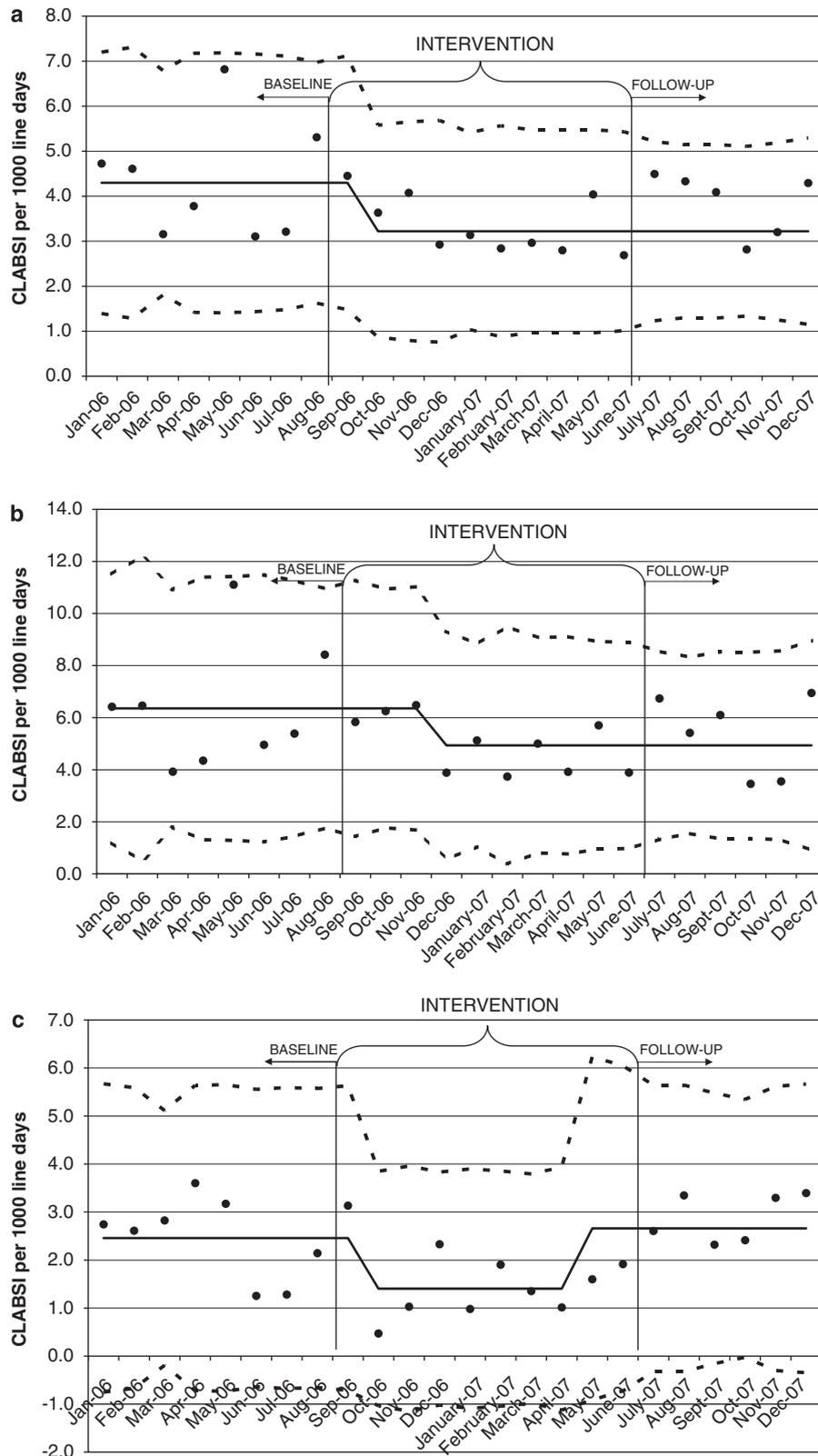


Figure 4 (a) California Children’s Hospital Association (CCHA)-California Children’s Service (CCS) neonatal intensive care unit (NICU) collaborative: observed central line-associated blood stream infection (CLABSI) rates among all birth weights combined, 2006 to 2007. Centerline (solid line) and upper and lower control limits (dashed lines) were calculated using the method described by McCarty.²³ (b) CCHA-CCS NICU collaborative: CLABSI rates among infants with birth weights ≤ 1500 g, 2006 to 2007. Centerline (solid line) and upper and lower control limits (dashed lines) were calculated using the method described by McCarty.²³ Reprinted with permission from Schulman.³² (c) CCHA-CCS NICU Collaborative: CLABSI rates among infants with birth weights > 1500 g, 2006 to 2007. Centerline (solid line) and upper and lower control limits (dashed lines) were calculated using the method described by McCarty.²³

beginning in October 2006, the month after the intervention began. The centerline and control limits were therefore recalculated, showing the resulting downward shift in CLABSI rates. The variability from month to month in the CLABSI rate seems to decrease from baseline to intervention period, with 7 of the 10 intervention months falling very close to the intervention period average, and five of those months in a row falling below the average.

To examine whether these improvements were sustained, we compared the population of VLBWs with >1500 g birth weight. Figure 4b shows the CLABSI rate control chart for the VLBW babies. As with the overall chart, this segment shows a special cause variation beginning in December 2006. Moreover, although there is some increasing scatter during the follow-up period, this is not a strong enough shift to suggest a rising CLABSI rate.

Figure 4c shows the CLABSI rate for those infants with birth weights >1500 g. Again, there is special cause variation beginning in October 2006. However, in this study the follow-up picture is different, with another special cause variation (eight points in a row above the recalculated centerline) beginning in May 2007. In the case of the larger babies, it seems that the improvements in CLABSI preventions have not been sustained.

The hypothesized processes involved in CLABSI prevention and reporting are specified in the fishbones shown in Figures 1–3. Examples of these processes include retrospective root cause analysis of each infection, adequate systems for maintaining closed vascular lines, ensuring real-time compliance with unit policies and procedures and staff training to prevent an infection's occurrence. In aggregate, the fishbones define our current consensus on best practices. When used as a means of documenting the practices of the participants at the start of and changes during the project, the fishbones describe the dissemination and adoption process. By monitoring those ideas that seemed to gain support during the meetings of the collaborative, the fishbones provide an objective description of the value of collaborative meetings over and above the other means of disseminating process ideas, such as peer-reviewed publications or presentations at scientific meetings. Initially, members concentrated on implementing technical aspects of the recommended practices: revising and improving hand hygiene processes and products; selecting and implementing 'closed' vascular access devices; initiating standardized methods for infusion tubing assembly using aseptic or sterile technique; changing the agent used for skin antisepsis to chlorhexidine gluconate; methods and antimicrobial agents to use for cleaning needleless connectors before entry, daily monitoring of all central line dressings and daily determination of line necessity; and ensuring timely, complete data collection and analysis. Later, the emphasis changed to those items that were related to complex social initiatives: 'Stop the line' (empowering anyone within the NICU to pause a process if they perceived potentially harmful

deviations from established procedure), immediate fact gathering about potential breaks in line management processes whenever a positive blood culture was reported and initiation of staff communication about the numbers of days since the last infection.

Organizational practice and performance assessments by each NICU were informally obtained and were used as a means to stimulate reflective discussion of these topics. The post-intervention organizational dimension scores showed the greatest increases in items related to organizational support, process improvement and results, education and training and sharing information with providers, all reflective of the project's immediate emphasis.

IHI collaborative assessment scoring was performed at the conclusion of the project. All NICUs reported improvement: two described the effect as 'improvement', four as 'significant improvement' and six as 'sustainable improvement' (IHI collaborative assessment statements are shown for scores 3.5 to 4.5 on a scale from 1 to 5¹⁸).

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- 3.5 *Improvement*: Some improvement in outcome measures, process measures continuing to improve, PDSA test cycles on all components of the change package, changes implemented for many components of the change package.
 - 4.0 *Significant improvement*: Most components of the change package are implemented for the population of focus. Evidence of sustained improvement in outcome measures, halfway toward accomplishing all of the goals. Plans for spreading the improvement are in place.
 - 4.5 *Sustainable improvement*: Sustained improvement in most outcomes measures, 75% of goals achieved, spread to a larger population has begun.
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Abbreviation: PDSA, plan-do-study-act.

Discussion

Large improvement collaboratives are often organized using the leadership-dominated methodology described by IHI.²⁵ In this project, the IHI method was supplemented with the shared motivational and learning processes incorporated into the California Perinatal Quality Care Collaborative Toolkit approach for disseminating evidence-based practices¹³ and the organizational assessment and development methodology for enhancing unit functioning.²⁶ Reflecting our less prescriptive approach, individual units set their own implementation agenda based on their locally perceived needs in both the technical and social aspects of the change. Our approach placed great emphasis and value on local context: 'When you have seen one NICU, you have seen one NICU'. Thus, although the technical interventions were broadly similar, their introduction and usage reflected the varying conditions and players within each of the complex social systems of these NICUs. The importance and validity of an individualized, local approach to clinical improvement is supported by the extensive experiences reflected upon by Berwick²⁷ and by Bate *et al.*²⁸

Nelson *et al.*^{17,26} have highlighted the importance of the individual clinical service unit (described by them as a 'clinical

microsystem') as the primary social unit in which change takes place. They have developed methods for assessing microsystem performance across 10 dimensions and described pathways for these microsystems to remedy performance challenges. In our project, the NICU leadership performed their own assessments, often as an open discussion on how to grade their own performance. They were then free to devise and implement staff development activities as they deemed fit. Although only informally addressed, the value of using these tools derived from their ability to cause reflective conversations to take place.

Our project has generated many observations reflective on the collaborative processes at the heart of every QI effort. Strategic collaboration by state-level payers and provider organizations clearly affected agenda setting at the individual center level. This QI effort became a priority. Hospital administration support was manifest both in mobilizing resources and gaining recognition for the participants, including supporting NICU 'celebrations' when interval goals, such as reaching 100 days since the last infection, were met.

Hospital leadership affected tactical collaboration within their organizations. For example, many NICUs related how leadership interest was translated into improved collaboration between departments and services within their hospital (such as better working relationships were developed with anesthesia, radiology and infection control departments). At the operational level, QI efforts are collaborative and interdisciplinary within each NICU. Fundamentally, improvements in CLABSI rates revolve around the safe application of complex technology by many individuals over often-long periods of hospitalization, during which any specific dysfunction can have harmful effects.

Sustainability is a significant hurdle in every QI effort. The birth weight-specific analysis showed that the CLABSI rate decrease was sustained only in the VLBW population. However, further progress even in this population can be made in two ways. First, the variability within individual sites and between sites can be further reduced. Second, the collaborative as a whole will need to continue to evolve and implement new strategies. In the case of infants >1500 g, gains did not last, suggesting the need to better understand other variables affecting infectivity, such as varying severity of illness, post-surgical wound effects and delays in achieving full enteral nutrition.

Sustainability was more clearly shown in the Michigan project in which gains lasted at least 18 months.² This is in contrast with the finding that 85% of QI projects are not sustainable (M Bisagnano (chief operating officer of the IHI), personal communication). Features that would seem to favor sustainability include: the development of a culture of safety, incorporation of new work flows and materials into revised competency training and assessment processes, use of readily apparent process and outcomes measures that immediately advertise loss of organizational focus, continuing celebration of

success and continuing evaluation of adverse events for further QI opportunities. For example, when individual units reported rate spikes, they responded with reinforcement of hand hygiene practices and re-education about line management procedures.

Lessons learned about the specific techniques to decrease CLABSI events are encapsulated in our proposed 'bundle' (see Tables 1A and 1B). The bundle uniquely describes the administrative context within which the actual medical and nursing processes take place. It has been updated to include the 2009 CLABSI definition amendments promulgated by the CDC in place of the definitions applicable in 2007.²⁹ It describes the need for continuing hospital and NICU leadership; it emphasizes the need to enhance the safety climate within the NICU; and it addresses the need to systematically review each positive blood culture event for improvement opportunities (Blood Stream Infection evaluation form, available at <http://www.dhcs.ca.gov/provgovpart/initiatives/nqi/Documents/BSIEvalForm6-08.pdf>, last accessed 25 August 2008).

We chose SPC methods rather than a single-group pre- and post-test design to describe the progress of the collaborative. This choice reflects the sense of the QI community that the basic assumption for the use of inferential statistics—that sampled data are drawn from a stable population—is absent in dynamic care settings, such as the NICU. CLABSI events occur in a background of iterative production processes subject to secular changes (as, for instance, induced by this project) and by variable individual performance, which results in variation in outcomes. SPC is designed to accurately characterize such variation over time—to discriminate signal from noise, how much of a change must occur for it to 'mean something' and to indicate whether the systems perform predictably or not.³⁰ Researchers and practitioners often use SPC data display to evaluate performance and guide change.³¹

We note several shortcomings in this study. First, we do not have a randomized control group and hence cannot rule out alternate explanations for the change in CLABSI rates. Nevertheless, our control charts show special cause variation shortly after the introduction of the collaborative. Second, our analysis does not indicate which NICUs, or which elements of the intervention, were responsible for the observed changes. For the purposes of our study, both of these questions are interesting but not central. The intent of the collaborative was to reduce the overall CLABSI rate among the participating NICUs; the intent of the SPC analysis was to determine whether the collaborative was associated with systematic change (special cause variation) in the CLABSI rate. With regard to which elements of the intervention were associated with change, further research is necessary. Third, our baseline and follow-up periods were shorter than desirable for SPC purposes. Although 20 or so points are ideal, we felt it more important to begin the collaborative work and have only eight points in the baseline than to wait for a year to accrue more baseline data (and more CLABSIs). Further, no special cause variation was apparent during

the baseline period, easing concerns that the system might not be stable at baseline. As for the follow-up period, the CDC definition of CLABSIs changed in January 2008, and this makes it impossible to continue to gather follow-up data points using comparable definitions.

Conclusion

CLABSI rates for the 13 participating NICUs fell 25%, compared with baseline, after our collaborative was initiated, which translates to approximately 75 fewer infections per year. As CLABSIs are associated with substantial morbidity and costs, we suggest that this

Table 1A Central line-associated blood stream infection prevention bundle-part A

<i>Performance expectations</i>	<i>Considerations</i>
<i>Insertion</i>	
1. Maximum sterile barrier precautions utilized	Cover entire infant with sterile drapes or as much as affords safe observation. Recommend staff wear face mask when within 3 feet of sterile field
2. Skin disinfected with chlorhexidine (CHG) or povidone iodine (PI)	Apply over 30 s (15 s when 3.15% CHG/alcohol) and allow to dry (exception aqueous CHG)
3. Dedicated team for placement and maintenance	Insertion training course, including sterile technique, hand hygiene, use of maximum sterile barrier precautions, proper skin disinfection Educational competencies for all aspects of care
4. All supplies required for the procedure should be available at the bedside before catheter insertion	
5. Hand hygiene standards met	
6. Insertion checklist used	Standardize critical elements of line insertion Ensure staff observers are skilled in monitoring elements of sterile technique
7. Staff empowered to stop non-emergent procedure when sterile technique not followed	
<i>Maintenance</i>	
<i>Assessment and site care</i>	
1. Daily assessment and documentation of catheter need included as part of multidisciplinary rounds and review of daily goals	When catheter used primarily for nutritional purposes: Consider removal when infant reaches $>120 \text{ ml kg}^{-1}$ per day enteral nutrition Consider discontinuing lipids when infant reaches $>2.5 \text{ g kg}^{-1}$ per day of enteral fat intake
2. Review dressing integrity and site cleanliness daily	Change PRN using sterile technique and CHG or PI for skin antisepsis
<i>Tubing, injection ports, catheter entry</i>	
1. Use 'closed' systems for infusion, blood draws and medication administration	May use manufactured or improvised closed system. If stopcocks are used, port(s) are capped with swabable needleless connector(s). Define consistent practice to be used when accessing catheters
2. Assemble and connect infusion tubing using aseptic or sterile technique. Configure tubing consistently for each type of vascular access device (VAD).	Sterile technique ideally includes sterile barrier for tubing assembly and wearing of face mask, hat, sterile gloves and two staff members performing connection to central catheter. Aseptic technique includes clean barrier for tubing assembly and wearing clean gloves
3. Scrub needleless connector using friction with either alcohol or CHG/alcohol swab for at least 15 s before entry. Allow surface to dry before entry.	
4. Clean gloves for all VAD entries and hand hygiene used before and after glove use	Standard precautions
5. Use pre-filled, flush containing syringes wherever feasible	Higher risk of contamination when flush withdrawn from another container by a nurse
7. Staff empowered to stop non-emergent procedure when sterile technique not followed	

Table 1B Central line-associated blood stream infection prevention bundle-part B

<i>Administrative leadership</i>	<i>Considerations</i>
<ol style="list-style-type: none"> 1. Demonstrable administrative involvement in and support for achieving zero healthcare-associated infections 2. Engage staff with feedback: <ul style="list-style-type: none"> Posting days since last central line-associated blood stream infection (CLABSI) Posting CLABSI rates 3. Perform investigation and analysis of each CLABSI 4. Surveillance activities of critical processes related to sustaining the gains: <ol style="list-style-type: none"> a. Hand hygiene b. Adherence to unit catheter management and entry standards c. Monitor patient processes off unit for bundle compliance d. Unit personnel support for the 'Stop the Line' safety culture 5. Competent trained personnel to perform specialized maintenance activities 	<p>Annotate CLABSI rates with descriptions and dates of practice changes.</p> <p>Celebrations of successes</p> <p>Begin process ASAP and within 24 h of CLABSI notification. Review opportunities for system improvements after each event</p> <ol style="list-style-type: none"> a. Capture 50 HH observations/month/activity using consistent observers. b. As above initially, then smaller volume less frequently. c. Prospectively establish and maintain bundle compliance with off unit service departments, for example, operating rooms (anesthesiology and pediatric surgery), radiology suite (radiology). d. Empower staff to stop intervention at any time when technique is being breached <p>Consider specialized team for dressing changes, catheter repair, catheter clearance of blockage</p>
<i>CLABSI diagnosis and classification</i>	
<ol style="list-style-type: none"> 1. Two or more blood cultures drawn on separate occasions from separate sites, following skin disinfection with povidone iodine (PI) or chlorhexidine (CHG), within 48 h of each other, that is, blood from at least two blood draws were collected within 2 days of each other 2. The diagnosis of a laboratory-confirmed (LC) catheter-associated BSI (CLABSI) can only be made in the absence of another clinically appreciated infectious focus, the presence of one or more positive blood cultures and one of the following three criteria being met: <ul style="list-style-type: none"> criteria 1, at least one blood culture growing a recognized pathogen (see Considerations); or criteria 2, at least two blood cultures growing a recognized contaminant (see Considerations) and the presence of one (or more) clinical signs of generalized infection (either fever $>38^{\circ}\text{C}$ (see Considerations), chills or hypotension; or criteria 3, age <1 y: at least two blood cultures growing a recognized contaminant (see Considerations) AND at least one of the following: fever ($>38^{\circ}\text{C}$ core), hypothermia ($<36^{\circ}\text{C}$ core), apnea or bradycardia <p>See: http://www.cdc.gov/nhsn/PDFs/pscManual/pscManual_current.pdf</p> 	<p>One culture may be from a central line site when a second peripheral site is not feasible, taking into account circumstances such as vessel accessibility, pain and the infant's clinical status.</p> <p>The recommended neonatal culture volume is >1 ml</p> <p>Recognized pathogens are those not named as common skin contaminants. Common skin contaminants: diphtheroids (<i>Corynebacterium spp.</i>), <i>Bacillus spp</i> (not <i>B. anthracis</i>), <i>Propionibacterium spp.</i>, coagulase-negative staphylococci (including <i>S. Epidermidis</i>), viridans group streptococci, <i>Aerococcus spp.</i>, <i>Micrococci spp.</i></p> <p>The collaborative recommends that axillary temperatures should be considered as a screening method; axillary temperatures $<36.0^{\circ}\text{C}$ ($<96.8^{\circ}\text{F}$) should be tentatively labeled as 'hypothermia' and axillary temperatures $>38.0^{\circ}\text{C}$ ($>100.4^{\circ}\text{F}$) should be tentatively labeled as fever. Because of the variability in axillary temperature readings, the presence of an elevated or hypothermic temperature will only be termed confirmed when there have been at least two consecutive abnormal axillary measurements or one abnormal axillary and one abnormal rectal (or other core) measurement.</p>

reduction is clinically meaningful. Although we did not have a randomized control condition, we conclude, based on the SPC methodology, that our collaborative was associated with special cause variation, that is, a systematic change, in the CLABSI rate. Our multidimensional intervention emphasized leadership engagement, comprehensive content and QI tools and unit culture development. Although we cannot state with absolute certainty that our collaborative intervention was the only cause associated with the decrease in CLABSIs, nor the exact mechanism of the intervention, it is clear that reducing CLABSIs in NICUs is possible. Further improvement in infection prevention will require an even more comprehensive

understanding of the technical and organizational factors related to the risk of infection.

Conflict of interest

The authors declare no conflict of interest.

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Appendix

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