Cover Page

Institution:

University of California, Irvine Medical Center
101 The City Drive
Building 56, Suite 700
Orange, CA 92868
URL: http://www.ucirvinehealth.org/

Contact Person:

Shruti Gohil, MD, MPH
Associate Medical Director, Epidemiology & Infection Prevention
Assistant Professor, Division of Infectious Diseases
101 The City Drive
Building 56, Suite 700
Orange, CA 92868
Email: skgohil@uci.edu
Phone Number: 714.456.5221.
Mobile Number: 347.675.0571

Title of Submission:

Use of Standardized Central Line Insertion Site Assessment (CLISA) Score Reduces Localized Inflammation and Central Line-Associated Bloodstream Infection (CLABSI)

Area of Focus:

Patient Safety, Quality Improvement

Brief Statement, Douglas G. Merrill, MD MBA, Chief Medical Officer and Senior Associate Dean for Quality and Safety, UC Irvine Health:

Central Line Associated Bloodstream Infections (CLABSIs) are a recognized high risk for the most severely ill patients undergoing inpatient and outpatient therapy for cancer, immune system disorders, severe infections and inadequate nutrition. Long recognized nationally as an innovative force for infection prevention, the members of the Departments of Infectious Disease and Epidemiology and Infection Prevention at UC Irvine Health created an ingenious means of insuring standardized and regular assessments and interventions to protect patients from infections of their central venous access lines, the Central Line Insertion Site Assessment (CLISA) Score. The process was created in a multidisciplinary fashion, including students, Nursing, resident physicians and nationally recognized infectious disease faculty. CLISA was trialed and validated as effective, as you will read below. As a consequence, it is now being promulgated in the scientific literature and will therefore likely improve and save the lives of thousands of patients in the healthcare delivery systems in which it is adopted. Part of my excitement in supporting this effort for your consideration of CLISA as worthy of a Vanguard Award is that it will bring the CLISA system to the attention of many more hospitals and clinics, increasing the likelihood that it will benefit many more patients. I hope you will enjoy reading about this work as much as I have observing it. Thank you for your consideration.

Executive Summary

Central Line Associated Bloodstream Infections (CLABSIs) represent a major, preventable hospital-acquired infection. Nearly 72,000 CLABSIs occur annually, with up to 25% resulting in mortality. Progression of locally inflamed/infected insertion sites accounts for nearly 40% of central line-associated bloodstream infections (CLABSIs). UC Irvine Medical Center (UCIMC) developed and implemented a novel central line insertion site assessment score (CLISA) to standardize assessment of insertion sites for early identification of localized infection and prompt removal of high-risk lines (Figure 1). Since implementation, the number of lines with CLISA 3 (severe erythema/purulence) decreased from 40 (10%) to 14 (4%) post-intervention ($p<0.01$) and CLABSIs decreased from 19 (0.52/1000 line-days) to 13 (0.37/1000 line-days) post-intervention. The CLISA score enabled a programmable primary prevention strategy to standardize insertion site assessment across providers and to decrease localized infections that can progress to CLABSI. This strategy engaged multiple stakeholders, integrated communication between nurses and physicians, streamlined documentation to impact meaningful action, and has helped shift our culture towards prevention. The CLISA Score has been presented at national conferences, including the Infectious Diseases Society of America (IDSA) and the Society for Healthcare Epidemiologists of America (SHEA).

Background

CLABSIs are a major cause of preventable healthcare-associated infections, sepsis, and death. Over 250,000 CLABSIs occur annually, with an attributable mortality of up to 25% and added healthcare costs of $36,000 per event. While many approaches to reduce CLABSIs are focused on practices during central line insertion, less attention has been given to daily assessment of line site appearance, line necessity, and/or timely removal of central lines at high risk for infection. Prior to CLISA, there was no structured way to categorize insertion site appearance and no clear directive on what clinicians should do when they found signs of inflammation or infection; furthermore, communication between nurses and doctors about the condition of central lines was not uniform or consistent. These issues resulted in delayed recognition of inflamed or infected central line insertion sites, delayed removal of high risk lines, and greater risk for progression to CLABSIs.

Intervention

Our goal was to improve early detection, to decrease the rate of localized inflammation at the central line insertion site, and to ultimately decrease the rate of CLABSIs. Paralleling the strengths of the Braden Score for assessing pressure ulcers, we developed the CLISA tool to standardize visual assessments of CVC sites and define recommended actions (Figure 1). The CLISA tool provides a simple and trainable scoring system ranging from 0 (normal insertion site appearance) to 3 (overt localized insertion site infection with purulence or severe erythema). Each score is accompanied by specific recommendations on actions to be taken, such as physician visualization of the line and request for line removal and replacement. The creation of a scoring tool allowed us to embed nursing documentation of line site appearance into the physician's progress notes and alert physicians on patients with central lines at high risk for infection. For patients with CLISA Scores ≥ 2, physicians were required to (1) attest to a plan for removal or replacement of the central line or (2) document the medical reason why removal was not possible.

Central Line Insertion Site Assessment (CLISA) Scoring

Score	Category	Description
0	**Normal Appearance**	- Skin is flesh-colored - No erythema, localized swelling, or drainage
1	**Minimal Erythema**	- **Skin at insertion site with erythema < 3mm radius** - Drainage/crusting scant and non-cloudy, if present* - No localized swelling at insertion site
2	**Advancing Erythema**	- **Skin at insertion site with erythema 3-6mm radius** (or increase in erythema over 24 hours) - Localized swelling at insertion site may be present - Drainage/crusting is non-cloudy, if present*
3	**Severe Erythema *OR* Purulence**	- **Purulent (cloudy) drainage/crusting AND/OR** - **Erythema >6mm or rapid worsening in size/brightness** - Focal swelling at insertion site (common, not required)** - Erythema common with purulence, but not required
NV	**Insertion site not visible**	Assessment not possible due to obscured line insertion site. Skin that is visible appears normal.

*Bleeding without erythema excluded
**Specifically related to insertion site. Not intended to refer to anasarca or limb swelling.

Figure 1: Central Line Insertion Site Assessment (CLISA) Score.

Implementation of this intervention required a paradigm shift among clinicians to think preventatively about device associated infections. Previous to our intervention, clinicians removed central lines only when patients showed signs or symptoms of active infection (e.g., fever, bacteremia, and sepsis) or when no longer needed; this is still national practice. In order to implement our preventative strategy to recognize and remove high risk lines before a CLABSI occurs, our intervention required several system-wide efforts and strong leadership commitment to CLABSI prevention and patient safety.

(1) We conducted a photo-survey project to demonstrate the scope of the problem.
(2) We identified our highest performing inpatient units (lowest CLABSIs) and determined their threshold for action when evaluating clinical appearance of central line insertion sites.
(3) We finalized the CLISA Scoring Tool with input from stakeholders across the institution: nursing, critical care physicians, hospitalists, nursing educators, peripherally inserted central catheter (PICC) team members, unit leaders from specialized care areas (oncology, burn unit), and infection prevention.
(4) We tested the scoring tool by measuring agreement of CLISA scores between 4 healthcare workers (6 pairs) at various levels of medical and nursing training but who had minimal training with the CLISA tool. After assessing 85 lines together, the inter-rater reliability (IRR) of clinicians who had minimal training with the CLISA tool showed good agreement (Spearman's R 0.70-0.80).
(5) We engaged our Information Technology department to program and build the automated alerts for dwell time as well as CLISA scoring within nursing flowsheets and physician notes. This step was critical to ensure proper documentation, alerting, and compliance with recommended actions.
(6) Once finalized the CLISA score was presented to physician and nursing leadership, who endorsed its implementation.
(7) We then began a facility wide educational campaign that included nursing educator training, grand rounds presentations, lectures, and a computer-based training course educating all inpatient faculty/staff.

Challenges

The primary challenges in this intervention centered around educating our healthcare workers on the metrics of prevention and shifting the culture of medical assessment toward prevention. These challenges were addressed by institutional leadership demonstrating a strong commitment to patient safety and quality and creating an environment in which a culture of prevention was encouraged. We also used a computer-based training program that provided education on the causes of CLABSIs and how they can be prevented.

While the CLISA Score was enthusiastically supported by nursing staff, physician engagement and appropriate response to high risk lines identified by nursing was more difficult to engender. In some instances, physicians failed to remove lines despite several days of documented high risk insertion site appearance. Because the CLISA Score was embedded in the medical chart as a discrete field, we were able to build an electronic report that alerted our infection prevention team to any patient who had a sustained CLISA $\geq$ 2 without line removal. The infection prevention team and medical director would review each of these patients and call the nursing and physician teams to intervene and advocate for line removal, replacement, or if appropriate, proper justification for retention of the line. Feedback and education was provided directly to noncompliant providers with specific attention to developing concepts in primary prevention of device associated infections.

Specific units and types of patients posed additional challenges, such as acute intravascular needs of oncologic patients who often had limited access and were prone to venous thrombosis or high risk for bleeding or required acute chemotherapy that did not allow for easy replacement of central lines. For such scenarios, infection prevention worked closely with nursing and PICC teams to optimize dressing and insertion site care, stressing the importance of additional preventive measures such as daily chlorhexidine gluconate bathing.

Results

Decrease in Localized Inflammation/Infection and CLABSI.

We evaluated oncology and intensive care unit patients with central lines using periodic photo surveys of insertion sites at baseline (4/1/14-3/31/15) and post-intervention (4/1/15-3/31/16), after hospital-wide implementation of (1) electronic nursing documentation of CLISA cascaded into physician electronic progress notes (2) automated alerts prompting documentation and removal of lines with local inflammation/infection (CLISA >2). Hospital CLABSI rates were compared pre- and post-intervention using 2014 NHSN criteria for both time periods (chi-square test). We evaluated 402 lines at baseline, including 271 peripherally inserted central catheters (PICCs) and 131 centrally inserted venous catheters (CVCs) and 322 lines post-intervention (178 PICCs, 140 CVCs). A total of 724 lines with 1763 insertion site assessments were assessed. No significant differences were found in line type, site, or unit distribution between baseline and intervention (Table 1). The number of lines with no/minimal inflammation (CLISA 0-1) and moderate inflammation CLISA 2 did not change significantly (p=0.21 and p=0.6, respectively). Device utilization rates were unchanged. On multivariate logistic regression analysis adjusting for unit and line type, there was a statistically significant decrease in lines with CLISA 3 (severe erythema/purulence) from 40 (10%) pre-intervention to 14 (4%) post-intervention (p<0.01). CLABSIs decreased from 19 (0.52/1000 line-days) to 13 (0.37/1000 line-days) post-intervention (p=0.42).

Improvements in Documentation and Communication.

Since implementing the CLISA Score, central line documentation by nursing has fundamentally changed. Prior to the intervention, nursing flowsheets had variable documentation of central line site appearance. Now, the CLISA Score replaces the prior documentation options and provides more detailed assessment of line site

inflammation/infection. Furthermore, while documentation on line site appearance by physicians was rarely, if ever, present before the intervention, now all physician daily progress notes contain information on how long a central line has been in place, how the skin around the line site appears, and why the line is medically necessary. If a high risk line is identified, physician progress notes now contain information on the plan for removal.

Over 7 inpatient units (including Oncology) reported easy adoptability, improved nurse-to-nurse and nurse-to-physician communication, and increased attention to and recognition of early signs of infection. We have received reports in which patients identified as high risk for central line infection based on the CLISA score have had timely line removals, with improved communication and agreement between nurses and physicians on necessity of line removal.

Significance of Results

The CLISA score enabled a programmable primary prevention strategy to standardize insertion site assessment across providers and to decrease localized infections that can progress to CLABSI. The significant decrease in the frequency of lines with localized infection suggests that our intervention can be used to successfully identify patients with lines at high risk for infection. CLABSI rates decreased after our intervention as well but did not reach statistical significance, likely due to the low numbers of CLABSIs overall. Since our intervention, we have had 6 units reaching sustained zero CLABSIs for $\geq$ 1.5 years. Our results demonstrate an outstanding achievement in the setting of already low CLABSI rates and a strong commitment to patient safety, with a goal towards reaching zero CLABSIs housewide.

Our intervention provides a novel framework for primary prevention strategies within healthcare settings. Through the development of a much-needed standardized tool for assessing localized inflammation and infection at CVC insertion sites, this intervention provided a unified language and expectation for action between providers. By centering this common language around a scoring system, we were able to program customized alerts to physicians about recommended actions and devise a strategy to monitor compliance and provide real-time feedback.

Table 1: Multivariate Logistic Regression Model: Localized Insertion Site Infection Before and After Intervention, Adjusted for Age, Line Site, and Unit

Variable	OR	CI	p-value
Age	1.0	0.9-1.0	0.09
Line Site			0.2
Brachial	--	--	
Internal Jugular	0.3	0.1-0.9	
Subclavian	0.7	0.2-2.1	
Femoral	0.8	0.2-3.7	
Unit			0.08
Neurosurgical Intensive Care Unit (ICU)	--	--	
Surgical ICU	1.9	0.6-6.0	
Medical ICU/Cardiac Care Unit	2.4	0.8-7.2	
Burn ICU	4.8	1.4-16.3	
Oncology	3.3	1.2-9.0	
CLISA 3 (Severe Erythema or Purulence)	2.3	1.2-4.4	0.01

Sustainability and Scalability

Since its introduction in our inpatient units, the CLISA score has become ingrained in central line care parlance at our facility; it has been championed by nurses and physicians who are considering other areas of applicability, such as the monitoring and evaluation of peripheral intravenous catheters and wound evaluation. The value of the CLISA score has been recognized by our nursing educators, who have noted enhanced awareness, documentation, and assessment of central lines. Nurses who have used the CLISA score on the inpatient units are introducing it to outpatient clinics within our system. We have also received requests from other hospitals who are exploring the adoption of the CLISA score at their facilities.

The strategic approach of our intervention is translatable across disciplines, workflows, and healthcare settings. Importantly, early identification and alerting for patients at high risk for infection is critically important to meet the challenges of outpatient settings, where care coordination occurs between healthcare workers who are often separated from each other in space and time. The CLISA scoring system offers a means of engaging patients and healthcare providers in early prevention efforts and provides a platform for standardizing assessment and actions between a diverse body of healthcare providers. The elements of the strategic approach employed by our intervention can be translated to address other problems that warrant early and uniform recognition of and response to high risk events.

Lessons Learned

A critical lessons learned through the implementation of our intervention was the importance of obtaining physician and nursing input and concordance prior to implementation. These stakeholders helped lay the groundwork for culture change and promoted the successful adoption of the CLISA Score within their groups. In addition, multi-disciplinary input served a key role in shaping the success of the CLISA Score implementation.

Perhaps one of the most important factors that led to the success of our intervention was the strong executive leadership support we received in moving this initiative forward. The impact of leadership to shape and mold an institution cannot be overstated; in our experience, support from our highest leadership helped engender enthusiasm and active participation at a system-wide level across multiple types of providers and disciplines.