APIC IMPLEMENTATION GUIDE



Guide to Preventing Central Line-Associated Bloodstream Infections



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Only individuals who have made declarations of potential conflicts have been listed here.

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Introduction

Prevention of device-associated infection represents a complex challenge for the infection prevention team as well as the many stakeholders involved in those prevention activities. Furthermore, as the characteristics of the host patient become increasingly compromised, it is vital that there be an attention to basic practice coupled with knowledge of process improvement opportunities. This implementation guide is designed to provide basic information regarding the prevention of central line-associated bloodstream infection that is applicable for use by all infection preventionists (IPs), regardless of their practice setting or their level of experience. The information provided will facilitate the learning of basic concepts and provide both the novice and the experienced IP with an opportunity to objectively evaluate current practice within the framework of continuous improvement.

The goal of this implementation guide is to outline practices that are core to prevention efforts, demonstrate application through associated tools and resources, and provide information that augments existing evidence-based guidelines—including the Healthcare Infection Control Practices Advisory Committee (HICPAC) 2011 Guidelines for the Prevention of Intravascular Catheter-Related Infection.

A strength of this implementation guide is demonstrated by the collaborative efforts of the many contributors and reviewers who have worked together to compose a document that has been peer-reviewed and is immediately useful in practice. The true measure will be a reduction in infection experienced by patients.

Chapter 1: Success in CLABSI Reduction through Major Initiatives

Central venous catheters (CVCs) or central venous access devices (CVADs), often described by healthcare professionals as "central lines," refer to a broad category of invasive devices used to administer fluids, medications, blood and blood products, and parenteral nutrition. Unlike the short, temporary catheters inserted into the peripheral vasculature, these central devices access major vessels that are most often located in the neck or adjacent to the heart. CVADs are threaded through a vein in the arm (basilic, brachial, and cephalic), chest (axillary, subclavian), neck (internal jugular), or groin (femoral) and advanced into the lower one-third of the superior vena cava or the inferior vena cava above the diaphragm.¹ There are four general categories of CVADs: nontunneled (e.g., access via subclavian or internal jugular veins); peripherally inserted central catheters (PICCs) inserted via peripheral veins (such as the cephalic or basilic veins); subcutaneously tunneled; and implanted vascular access ports.

The use of central lines, particularly nontunneled central lines and PICCs, is a mainstay of treatment in intensive care units (ICUs) and infection risks and rates have therefore been most extensively studied in critical care patients. However, central lines are also used in other areas of the hospital and across the continuum of care, as patients' transition to outpatient, home care, and long-term care settings for continued infusion therapy needs. Most often these patients will have PICCs, implanted ports, or subcutaneously tunneled catheters for longer-term use. PICCs and implanted ports are discussed in greater detail in Chapter 10.

The risks of central line use are significant. Central lines are a major risk factor for bloodstream infection, are associated with a 2.27-fold increased risk for mortality, and drive up health costs.² Reports of central line-associated bloodstream infection (CLABSI) costs vary. Umscheid and colleagues performed a systematic review and reported that costs from studies in general U.S. populations ranged

The Scope of Vascular Access in the United States

Analysis of the vascular access device market indicates that it will continue to grow in the years ahead, with a total value that may surpass \$2 billion by 2022.* Although short peripheral catheters will remain the least expensive and most frequently used devices, technological enhancements will drive an increased utilization of central venous products. For example, the increasing use of PICC tip positioning systems that facilitate easier placement, new synthetic surgical grafts that can be cannulated for hemodialysis much sooner than older grafts, and improved antithrombogenicity of PICC and implanted ports will support even wider use of long-term central access devices.

*News Release from Decision Resources Group: "US Vascular Access Device Market Will Surpass \$2 Billion by 2022."

from \$21,400 to \$110,800 (2009 dollars).³ It is apparent that CLABSI represents not only a serious and ongoing patient safety threat but also a major economic burden for healthcare providers.

Research indicates that the majority of CLABSIs are preventable. Umscheid and colleagues also suggest that 65-70 percent of CLABSIs are preventable by implementing evidence-based strategies currently available to healthcare professionals. In comparison to other healthcare-associated infections, CLABSIs were associated with the highest number of preventable deaths. It was estimated that 5,520 to 20,239 lives would be saved annually with best practice implementation.³

During 2001-2002, the Institute for Healthcare Improvement (IHI) became a pioneer in the field of CLABSI reduction when it introduced its first bundle of prevention practices. The IHI defines a bundle as a small set of evidence-based interventions for a defined patient population and care.⁴ The CLABSI bundle

identified a group of interventions supported by the highest level of research, which when used together would ideally produce better outcomes than if one or more had been used separately.

The practices described in the IHI CLABSI bundle include:

- Hand hygiene
- Maximal sterile barrier precautions upon insertion
- Chlorhexidine skin antisepsis
- Optimal site selection (avoidance of femoral vein in adults)
- Daily review of central line necessity and prompt removal of unnecessary lines

These five evidence-based interventions remain the cornerstone of CLABSI prevention, especially at the time of catheter insertion. For detailed information regarding the CLABSI bundle, see www.ihi.org. Additional information is presented in Chapters 5 and 6.

In addition to IHI, many other state, regional, and national initiatives have been launched to address CLABSI. This chapter summarizes major initiatives; it is not a complete list. As a result of funding that was made available under the American Recovery and Reinvestment Act of 2009, many states received grants through the Centers for Disease Control and Prevention (CDC) for projects and infection prevention collaboratives. Infection preventionists (IPs) seeking examples of state-sponsored CLABSI projects should check with the state health department and the CDC.

In reviewing these examples, it is important to remember that early project goals that sought to eliminate CLABSI, often referred to as "targeting zero," have gradually shifted to a more incremental improvement approach. The feasibility of preventing CLABSI in all situations is not likely and may be viewed as a more aspirational rather than practical goal.⁵ Meanwhile, and as these examples clearly demonstrate, significant improvement is possible when clinical prevention practices are based in evidence, used consistently, and linked to an organizational culture of safety.

Pittsburgh Regional Health Initiative

This project used the best practices described in the IHI bundle, adding education, numerous tools for tracking adherence, and emphasizing the engagement of hospital leadership as well as clinicians. The project reported a 68-percent reduction in CLABSI in the 32 participating hospitals and 66 ICUs in southwestern Pennsylvania. In some hospitals, CLABSI was reduced by more than 95 percent and CLABSI-related deaths eliminated.⁶ The consistent use of lean thinking and its model of Perfecting Patient Care[™] in the Pittsburgh Initiative were, and continue to be, foundational components of sustainable culture change and programmatic success. For more information, see www.prhi.org.

Michigan Keystone Project

This project also built upon the IHI bundle foundational elements. The use of checklists and the promotion of safety culture were integral to the success achieved here as well. A research team from The Johns Hopkins University School of Medicine partnered with the Michigan Health and Hospital Association to launch what became known as the Comprehensive Unit-based Safety Program (CUSP). This project demonstrated not only significant improvements but also sustainability. There was a 66-percent CLABSI reduction reported in 103 ICUs in Michigan during the initial 18-month period. In addition, improvements continued for another 18 months. After almost 3 years, the mean CLABSI rate in participating ICUs was 1.1, and the median remained 0.⁷

On the CUSP: Stop BSI

Funded by the Agency for Healthcare Research and Quality (AHRQ), *On the CUSP: Stop BSI* was a national initiative to implement CUSP, a proven culture change model, and interventions to prevent CLABSI (see Figure 1.1). The initiative ultimately reduced mean rates of CLABSI in participating units by an average of 40 percent, preventing more than 2,000 CLABSIs, saving more than 500 lives, and avoiding more than \$34 million in excess healthcare costs.

On the CUSP: Stop BSI was led by the Health Research and Education Trust (HRET) of the American Hospital Association. HRET's National Project Team consisted of the Michigan Health and Hospital Association's Keystone Center for Patient Safety and Quality (MHA Keystone Center) and The Johns Hopkins Medicine Armstrong Institute for Patient Safety and Quality (formerly The Johns Hopkins University Quality and Safety Research Group). Forty-four states, the District of Columbia, and Puerto Rico enrolled hospital units in the program. Collectively, more than 1,000 hospitals and 1,800 hospital unit teams participated in the initiative.

Figure 1.1. On the CUSP: Stop BSI

Central Line-Associated Bloodstream Infections Fact Sheet (Excerpt)

Bottom Line

CLABSIs result annually in:

- 84,551 to 203,916 preventable infections
- 10,426 to 25,145 preventable deaths
- \$1.7 billion to \$21.4 billion avoidable costs
- The following interventions decrease the risk for CLABSI:
- Use appropriate hand hygiene
- Use chlorhexidine for skin preparation
- Use full-barrier precautions during CVC insertion
- Avoid using the femoral vein for CVCs in adult patients
- Remove unnecessary CVCs

Source: Umscheid CA, Mitchell MD, et al. Estimating the proportion of healthcare-associated infections that are reasonably preventable and the related mortality and costs. Infect Control Hosp Epidemiol 2011 Feb;32(2):101-114.

Our Current Performance

Based on our current performance, our opportunity to improve the care that we provide to patients if we eliminated CLABSI in our unit:*

- Current CLABSI rate
- Deaths/year
- Excess intensive care unit days/year
- Excess dollars/year

*These data may be calculated using the CLABSI Opportunity Estimator at www.hopkinsmedicine.org/armstrong_institute/improvement_projects/ stop_bsilclabsi_estimator.html. The opportunity estimator uses current evidence from multiple studies, and the list of references can be found on the opportunity estimator website.

Source: Onthe CUSPS top HAI.org. For complete document, see The CLABSI Elimination Toolkit: www.onthecuspstophai.org/on-the-cuspstop-bsi/ toolkits-and-resources/#clabsi.

Institute for Healthcare Improvement

The IHI Trigger Tool

While efforts to detect adverse events (AEs) have historically focused on voluntary reporting and tracking of errors, public health researchers have established that only 10 to 20 percent of errors are ever reported and, of those, 90 to 95 percent cause no harm to patients.⁸ Hospitals must develop a better and more effective method to identify events that cause harm to patients in order to select and test changes to reduce harm. The first IHI Trigger Tool was developed in 2000 and aimed to detect a greater number of AEs. Many topic and location-specific Trigger Tools have been developed since then, and the IHI Global Trigger Tool combines several of these into one tool that can be used to measure AEs at the hospital level.

Use of the IHI Global Trigger Tool has spread from collaborative projects to large-scale improvement efforts used by hundreds of hospitals in multiple countries to monitor AE rates while working to improve patient safety. The U.S. Department of Health and Human Services (HHS) completed a pilot study in 2008 to measure AEs in Medicare beneficiaries, using the IHI Global Trigger Tool as one method of detection. This has allowed the opportunity to collect feedback from tool users and identify opportunities to clarify definitions and update material.

The Trigger Tool can be used in addition to National Healthcare Safety Network (NSHN) CLABSI surveillance and reporting. It is a measurement (not outcomes reporting) system and can be integrated into an existing quality/performance improvement program. It is also helpful in understanding CLABSI risks within the larger institutional context of all AEs and in helping foster safety culture within an organization. For additional information, including a toolkit, web-based training, and other resources, visit www.ihi.org/resources/Pages/IHIWhitePapers/IHIGlobalTriggerToolWhitePaper.aspx.

5 Million Lives Campaign

The 5 Million Lives Campaign was based on IHI's earlier success with its 100,000 Lives Campaign. The aim of the 5 Million Lives Campaign was to support the improvement of medical care in the United States, significantly reducing levels of morbidity (illness or medical harm, such as adverse drug events or surgical complications) and mortality. IHI quantified this aim and set a numeric goal: IHI challenged hospitals participating in the campaign to prevent 5 million incidents of medical harm over a period of 2 years (December 12, 2006, to December 9, 2008). More than 2,600 participating hospitals committed to reduce CLABSI as part of this ambitious program. Results proved difficult to measure, although IHI reported significant improvements at participating hospitals. Since the end of the campaign, IHI has not renewed it and has focused on other approaches to facilitating widespread change.

Partnership for Patients

Physicians, nurses, hospitals, employers, patients and their advocates, and the federal and state governments have joined together to form the Partnership for Patients (PfP). The initiative is part of CMS and includes more than 3,700 hospitals. One of the most important goals of the project was to make healthcare safer. By the end of 2013, preventable hospital-associated conditions, including CLABSI, would decrease by 40 percent compared to 2010. Rather than creating new tools and resources, the PfP focused on wide dissemination of current proven and readily accessible materials from authoritative sources, such as the CDC, SHEA, Association for Professionals in Infection Control and Epidemiology (APIC), and others. Learn more about PfP at http://partnershipforpatients.cms.gov. A reference list of resources, based on those recommended by PfP, is located in the appendix..

The Joint Commission National Patient Safety Goals

In 2002, The Joint Commission (TJC) established its National Patient Safety Goals (NPSGs) program; the first set of NPSGs was effective January 1, 2003. The NPSGs were established to help accredited organizations address specific areas of concern in regard to patient safety. TJC determines the highest priority patient safety issues and how best to address them. It also determines whether an NPSG is applicable to a specific accreditation program and, if so, tailors the goal to be program-specific. CLABSI prevention is addressed in the NPSGs for both the acute care and long-term care settings. For more information regarding the NPSG Program, see www.jointcommission.org/standards_information/npsgs.aspx.

CDC HICPAC Guidelines

The Healthcare Infection Control Practices Advisory Committee (HICPAC) is a federal advisory committee of 14 external infection control experts assembled to provide advice and guidance to the CDC and the HHS Secretary regarding the practice of and strategies for surveillance, prevention, and control of HAIs, antimicrobial resistance, and related events in United States healthcare settings. The committee's primary activity is to provide advice on periodic updating of existing CDC guidelines and development of new CDC guidelines. These guidance documents can be found online at www.cdc.gov/hicpac. Recommended or best practices included in all HICPAC guidelines are ranked according to the level of supporting scientific evidence. The rating system is explained in each guideline.

In 2011, HICPAC updated the *Guidelines for the Prevention of Intravascular Catheter-Related Infections*. The document is available from the CDC at www.cdc.gov/hicpac/bsi/bsi-guidelines-2011.html. The HICPAC guideline is referenced extensively throughout this guide.

HHS HAI National Action Plan

In 2009, HHS introduced the *National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination.* This 5-year plan (2009-2013) identified the reduction of HAIs as an "Agency Priority Goal for the Department." The first phase targeted acute care facilities. In the second phase, high-risk post-acute areas were added, specifically, ambulatory surgery centers and hemodialysis centers. Influenza vaccination participation target for healthcare personnel was also included. The third phase expanded the action plan to include long-term care facilities. Ongoing meetings and engagement from a wide variety of stakeholders have been used not only to establish appropriate targets and metrics, but also to improve surveillance and monitor results.

CLABSI was among the first HAIs identified in the Action Plan to be reduced, and it was monitored throughout the first 5 years of the project. HHS committed to reducing the national CLABSI rate by 50 percent in ICU and ward-located patients or a .50 standardized infection rate (SIR). The data source

for this project is the CDC's NHSN database. Table 1.1 provides a summary of the national results in achieving the Action Plan target.

HHS is currently analyzing the impact of the first five years of outcome data collected under the Action Plan framework and considering continuation of these efforts according to updated targets and metrics. *Table 1.1.* CLABSI: Assessment of Progress in Achieving HHS Reduction Target, 2010-2013

Year	% Reduction	SIR
2013	46%	0.54
2012	44%	0.56
2011	41%	0.59
2010	32%	0.68

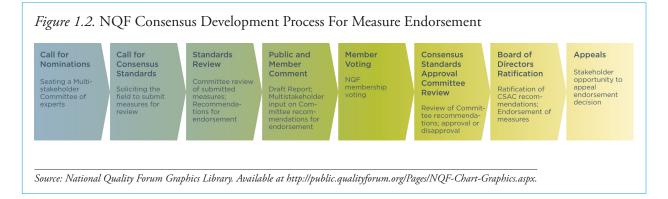
Sources: www.cdc.gov/hai/progress-report/index.html and www.health.gov/hai/prevent_hai.asp.

Role of the National Quality Forum

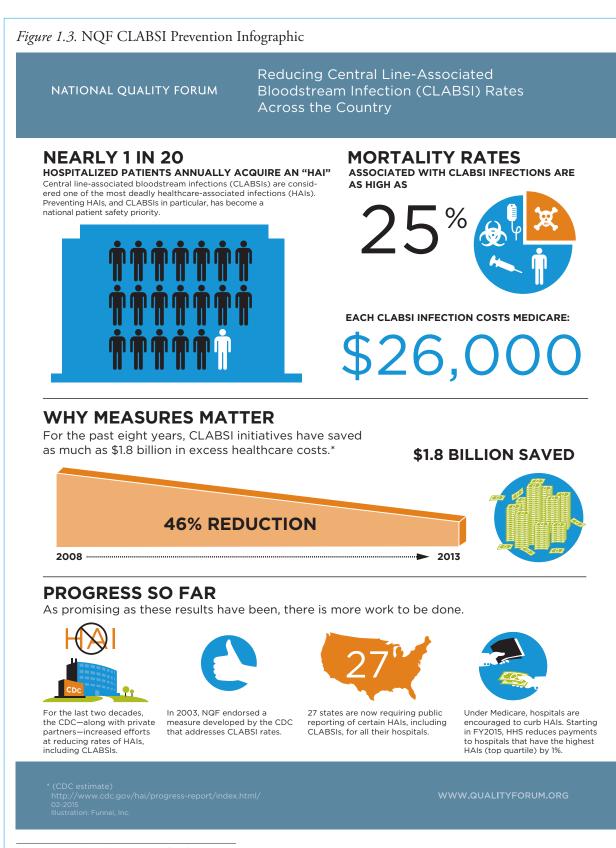
The National Quality Forum (NQF) engages in a wide variety of activities, foremost of which is the development of standard measures used to assess healthcare performance. NQF-endorsed measures are considered the gold standard for healthcare measurement in the United States. Expert committees made up of varied stakeholders, including patients, participate in the standard development process. The federal government and many private sector entities use NQF-endorsed measures. One use is in public reporting and payment programs. By 2017, nine percent of all Medicare payments will be performance-based. Under legislated authority, NQF advises the federal government and private sector payers on the optimal measures for use in specific payment and accountability programs.

The NQF patient safety measure that specifically addresses CLABSI is identified in 0139: The NHSN CLABSI outcome measure.

The development of NQF measures is a complex process (Figure 1.2).



The intended use of the CLABSI outcome measure is to support hospital quality and payment programs, public health/disease surveillance, public reporting, and organizational (internal) quality improvement programs, as well as external benchmarking to multiple organizations. An example of an NQF infographic on CLABSI is shown in Figure 1.3.



CLABSI and Nurse Sensitive Measures of Care

Nursing-sensitive indicators or measures reflect the structure, process, and outcomes of nursing care. Nursing care structure is affected by the supply of nursing staff, the skill level of the nursing staff, and the education of nursing staff. Process indicators measure aspects of nursing care, such as assessment, intervention, and registered nurse job satisfaction. Patient outcomes that are determined to be nursing sensitive are those that improve if there is a greater quantity or quality of nursing care (e.g., pressure ulcers, falls, and intravenous infiltrations).⁹

In recent years, the American Nurses Association (ANA) and the Joint Commission collaborated via a grant from the Robert Wood Johnson Foundation to identify specific nursing-sensitive measures. Launched in 1998, these measures were outlined and established in the ANA's National Database of Nursing Quality Indicators (NDNQI[®]); this is the only national nursing quality measurement program designed to compare measures of organization-specific quality against national, regional, and state levels. Over the past 3–5 years, NDNQI[®] has submitted nursing-sensitive quality indicator definitions to the NQF in response to requests for indicators. Several NDNQI[®] indicators have been endorsed through NQF's consensus measure process, including measures for HAIs. The CLABSI measure was among the first 10 measures proposed among the initial 10 nursing-sensitive measures identified by the ANA and later endorsed by NQF.⁹

Of note, Press Ganey acquired NDNQI and is committed to carrying on the efforts initiated by ANA.¹⁰ For more information about NDNQI, see www.nursingquality.org.

CLABSI and the U.S. Federal Regulatory and Reimbursement Programs

After the 1999 Institute of Medicine report "To Err Is Human," consumers and governments began looking more closely at improving patient safety, including reducing HAIs. In 2003, states began enacting laws requiring HAI reporting, and often making this information available to the public. CLABSI was included in many of these laws. With the Deficit Reduction Act of 2005, the federal government began looking to improve healthcare quality and reduce healthcare spending by limiting Medicare payments for certain adverse impacts. This led to the Centers for Medicare and Medicaid Services (CMS) Hospital-Acquired Condition (HAC) policy, which laid the groundwork for expansion of federal efforts to promote patient safety via payment incentives and penalties.

CMS Hospital-Acquired Condition Non-Reimbursement Policy

Beginning in FY 2009 (October 2008), hospitals were not reimbursed for additional treatment of defined HACs when not present on admission and were not permitted to transfer treatment costs to the patient.

- HACs are determined through claims data.
- HACs included "vascular catheter-associated infection."
- July 1, 2012 The CMS extended the policy to Medicaid, prohibiting federal payments to states for treatments of healthcare-acquired conditions (HCACs) and other provider-preventable conditions (PPCs). HCACs included vascular catheter-associated infections.

CMS Quality Reporting Programs

The Quality Reporting Programs (QRPs) for various care settings grew out of quality improvement requirements in the Patient Protection and Affordable Care Act of 2010 (ACA), which included reduction of HAIs. The following QRPs include CLABSI.

- Hospital Inpatient Quality Reporting Program
 - Reporting CLABSI in ICUs in acute-care hospitals through the CDC/NHSN
 - Reporting began in January 2011 for FY 2013 Medicare payment determination
 - January 2015 CMS expanded CLABSI reporting to medical, surgical, and medical/surgical wards for FY 2017 Medicare payment determination
- Long-Term Care Quality Reporting Program (long-term acute care hospitals)
 - Reporting CLABSI through NHSN
 - Reporting began in October 2012 for FY 2014 payment determination
- Prospective Payment System-exempt Cancer Hospital Quality Reporting Program
 - Reporting CLABSI through NHSN
 - Reporting began in October 2012 for CY 2014 payment determination

Hospital Value-based Purchasing Program

Also required by the ACA, value-based purchasing (VBP) is a "voluntary" incentive program that is self-funded. Funding for incentive payments comes from across-the-board reductions of base-operating diagnosis-related group payments for all hospitals. The amount of the reduction goes into a funding pool, which is then divided up among participating hospitals based on each facility's Total Performance Score (TPS). All participating hospitals "contribute" the same percentage, and the total amount available for incentive payments is determined by the amount CMS has in the funding pool. Depending on the TPS, a hospital's adjustment may be positive (the hospital gets money back from CMS as an incentive payment), negative (the hospital doesn't qualify for an incentive payment, so it loses the amount of its "contribution"), or unchanged (the hospital gets an incentive payment equal to its contribution, so it breaks even).

- TPS is determined by the hospital's achievement and improvement compared to a 9-month baseline period.
- Outcome measures were added for FY 2014.
- In order to be included in VBP, measures must be in use in the Hospital Inpatient Quality Reporting (IQR) program for at least two years.
- CLABSI and Patient Safety Indicator (PSI-90) composite will be added for FY 2015.
 - PSI-90 includes PSI #07-CVC-related bloodstream infections.

Hospital-Acquired Condition Reduction Program

The HAC Reduction Program, also mandated by the ACA, requires that hospitals that rank in the lowest-performing quartile for HACs receive a 1-percent payment penalty.

- Medicare payment adjustment began with October 1, 2014 (i.e., FY 2015) discharges.
- Hospital HAC rankings will be determined by total HAC score, based on measures in two domains: Domain 1 includes certain AHRQ Patient Safety Indicators (which are determined by claims data), and Domain 2 consists of certain HAI measures reported through NHSN. CLABSI is included in the Domain 2 measures. The total HAC score will equal Domain 1 + Domain 2, with the two domains weighted equally. Higher scores indicate worse performance and the 25 percent of hospitals with the highest score will be subject to the 1-percent reduction in Medicare reimbursement.

- The HAI measures in Domain 2 are the same measures used in the Hospital IQR program and also in (or being considered for) Hospital VBP. This means the measures reported into NHSN are or would be used to calculate scores that determine payment adjustments in three programs: Hospital IQR (incentive payment for reporting), VBP (incentive payment based on better quality of care), and HAC Reduction Program (penalty for poor performance).
- HACs used for this program are different measures than those used for the HAC nonreimbursement policy.

For additional information and updates, IPs should check the APIC website as well as consult with APIC chapter legislative representatives.

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Chapter 2: Epidemiology and Pathogenesis

Epidemiologic analysis of central line-associated bloodstream infection (CLABSI) first focused on intensive care unit (ICU) patients; it has now expanded to include acute inpatients and hemodialysis patients. In the past 10 years, improvement initiatives to reduce CLABSI have yielded encouraging and often dramatic results, including a more in-depth understanding of the pathogenesis of these infections. In 2011 the Centers for Disease Control and Prevention (CDC) released a report that described the changing epidemiology of CLABSI. It provided national estimates of the number of CLABSIs among patients in three locations (ICU, inpatient wards, and hemodialysis) in 2008 and 2009 and compared ICU estimates with 2001 data. Key findings from this study included:

- In 2001 an estimated 43,000 CLABSIs occurred among patients hospitalized in ICUs in the United States. In 2009 the estimated number of ICU CLABSIs had decreased to 18,000.
- Reductions in CLABSI caused by methicillin-resistant *Staphylococcus aureus* (MRSA) were more marked than reductions in infections caused by Gram-negative rods, Candida spp., and Enterococcus spp.
- In 2009 an estimated 23,000 CLABSIs occurred among patients in inpatient wards, and in 2008 an estimated 37,000 CLABSIs occurred among patients receiving outpatient hemodialysis.

In 2009 alone, an estimated 25,000 fewer CLABSIs occurred in U.S. ICUs than in 2001, a 58-percent reduction. This represents up to 6,000 lives saved and \$414 million in potential excess healthcare costs in 2009, and approximately \$1.8 billion in cumulative excess healthcare costs saved since 2001.

A substantial number of CLABSIs continue to occur, however, especially in outpatient hemodialysis centers and inpatient wards.¹

CDC Vital Signs: CLABSI–United States, 2001, 2008, and 2009

The goal of eliminating CLABSI or "targeting zero" for many institutions remains difficult to both achieve and sustain. Recent research suggests that elimination of CLABSI may be most likely in ICU patients with a central catheter dwell time of less than nine days following aseptic insertion.²

Infections associated with the use of vascular access devices, especially central lines, are most often caused by bacteria or fungi. *Staphylococcus epidermidis* and other coagulase-negative staphylococci have been increasingly linked to CLABSI, including those that lead to infective endocarditis. MRSA is another significant and commonly identified pathogen in CLABSI. Other clinical conditions associated with catheter use include mycotic aneurysms and suppurative thromboembolism. In both cases the catheter causes inflammation or damage to the vessel wall that eventually leads to infection.³

The most common pathogens associated with intravenous catheters³ are:

• Staphylococcus epidermidis

- Candida spp.
- Other coagulase-negative staphylococci
- MRSA

- Corynebacterium spp.
- Other Gram-negative rods

• Enterobacteriaceae

Bacterial Biofilm

Donlan defines a biofilm as a sessile microbial community in which the organisms produce an extracellular polymeric substance matrix.⁴ In simple terms, it is a group of microorganisms that stick to each other on a surface. Shortly after insertion, intravascular catheters are coated with the polymeric matrix which consists of fibrin, plasma proteins, and cellular elements, such as platelets and red blood cells. Microbes interact with the conditioning film, resulting in colonization of the catheter. Formation of these sessile communities and their inherent resistance to antimicrobial agents are at the root of many persistent and chronic bacterial infections and often prompt the removal of central lines when organisms are cultured.

Although biofilms occur naturally, the current increased association between biofilms and disease reflects changes in medical practices. Biofilms are the preferred method used by microorganisms for survival, especially when environmental selective pressures are present. For example, naturally occurring biofilms are found in drinking water lines, urban water systems, oil recovery equipment, food processing areas, ship hulls, and at any interface between a solid and nonsolid surface. The increased impact of biofilms in medicine is a result of the explosive growth in the past decade or so in the use of both simple and complex indwelling medical devices. In the United States, millions of catheters of all types are used annually. The occurrence of CLABSI is associated with biofilm; biofilm organisms result in infection by detachment of individual cells from the surface of the catheter, by production of endotoxins or other pyrogenic substances, and provide a setting for the development of antimicrobial resistant organisms.⁴

Rigorous skin antisepsis upon insertion and subsequent aseptic management of the catheter, especially during intermittent access, can help reduce the growth of the biofilm. However, there is no absolute method for mitigating the risk; all indwelling medical devices are associated with biofilm formation. Various experiments have been conducted to eliminate intraluminal biofilms through the use of antibiotics, ethanol, and thrombolytics, but no best practice for "catheter salvage" has yet been identified. For a more detailed discussion of biofilms, see Chapter 70 in *APIC Text*, 4th edition.

Venous Thrombosis

Increasing attention is being paid to the risk of deep vein thrombosis associated with central venous access. The risk is greater with peripherally inserted central catheters compared to other types of CVADs, especially in critically ill patients or those with malignancy.⁵ Growing evidence has shown an inter-relationship between central line-related thrombosis and infection.⁶

Dissemination of Microbes Due to Central Line Use

The dissemination of potential pathogens throughout the bloodstream is thought to occur via four potential routes. Infection prevention practices seek to minimize the risk for the routes of spread.

Hematogenous Spread

Organisms can be carried hematogenously to the indwelling catheter from remote sources of local infection, such as pneumonia. Hematogenously spread flora from a distant site, such as the urinary tract, are thought of in theory rather than in fact when looking for a source of catheter infection. Due to the rare occurrence of hematogenous seeding of catheters, a catheter is usually not removed in the presence of a bloodstream infection from a well-documented secondary source.⁷

Intraluminal and Extraluminal Spread

Microorganisms can contaminate the catheter hub (and lumen) when the catheter is inserted over a percutaneous guide wire or later manipulated in a variety of ways. Incomplete or missed disinfection of access sites (i.e., needleless connectors), incorrect use of stop cocks and other types of connectors,

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and inadvertent contamination of intravenous administration sets and tubing all provide opportunities for microorganisms to be introduced into an otherwise sterile system. Potential pathogens, such as *Pseudomonas aeruginosa*, enterococci, and Candida, as well as staphylococci, are commonly identified in these cases. Intraluminal colonization becomes an even more significant clinical risk in the pathogenesis of CLABSI with increasing time of placement (often referred to as dwell time). This risk is one reason for the emergence of CLABSI maintenance bundles (see Chapter 6). Antiseptic or antimicrobialimpregnated catheters may be used to reduce the risk of CLABSI in patients with an increased risk of severe complications from a CLABSI.⁸ Minocycline/rifampin and chlorhexidine/silver catheters impregnated on both the inner lumen and outside surface of the catheter reduce the risk of intraluminal microbial growth.

Careful hand hygiene, attention to aseptic technique with all infusion-related procedures, minimal manipulation of the central catheter and adjunct administration components, and rigorous disinfection practices when the system must be manipulated represent the core measures for reducing the risk of intraluminal contamination. Extraluminal spread occurs when skin organisms, most commonly coagulase-negative staphylococci and *Staphylococcus aureus*, incite an infection through portals of entry, including skin and catheter hubs. This is the mostly likely source of an incubating infection for catheters in place for < 14 days.⁹

Contaminated Infusates

Infusates, such as parenteral fluid, blood products, or intravenous medications are sterile products administered through a vascular access catheter. Infusates can potentially become contaminated and lead to device-associated bloodstream infection (BSI). Most healthcare-associated epidemics of infusionassociated BSI have been traced to contamination of infusate by Gram-negative bacilli, introduced during manufacturing (intrinsic contamination) or during preparation and administration in the healthcare setting (extrinsic contamination). Contamination is, fortunately, an uncommon cause of endemic infusionassociated infection during short-term catheter use.

Modifiable Risks

As this guide shows, many CLABSI risk factors can be reduced by careful and consistent use of targeted prevention practices. However, these practices can vary according to a wide variety of characteristics. For example, although several large veins may support the use of a central catheter, infection risks have been shown to vary according to insertion site.¹⁰ Similarly, central catheters placed quickly in less than aseptic conditions during an emergency situation have higher risks than those placed by expert inserters under controlled circumstances.¹¹ Table 2.1 summarizes the most common modifiable CLABSI risk factors.

Characteristic	Higher Risk	Lower Risk
Insertion circumstances	Emergency	Elective
Skill of inserter	General	Specialized
Insertion site	Femoral vein	Subclavian vein
Skin antisepsis	70% alcohol, 10% povidone-iodine	2% chlorhexidine
Catheter lumens	Multilumen	Single lumen
Duration of catheter use	Longer duration	Shorter duration
Barrier precautions	Submaximal	Maximal

Table 2.1. Modifiable Risk Factors for CLABSI Prevention

Source: Adapted from the TJC monograph Preventing Central Line-Associated Infections—A Global Challenge, A Global Perspective, May 16, 2012, and O'Grady NP, Alexander M, Burns LA et al. (2011). Guidelines for the prevention of intravascular catheter-related infections. Am J Infect Control 2011;39:S1-34.

Emerging Risks

Recent and ongoing CLABSI research indicates that the full spectrum of associated risks has not yet been fully identified or studied. One clinical area of increasing concern focuses on the potential for translocation of gut microbiota in patients with chemotherapy-induced neutropenia, with or without febrile episodes. In one study, exclusion of BSI associated with *Escherichia coli* (*E. Coli*), enterococcus, and streptococcus reduced the CLABSI rate in one hospital's large transplant and oncology populations from 2.12 to 1.79 cases per 1,000 line-days.¹² In another hospital-based study of patients with hematologic malignancies, modification of the current National Healthcare Safety Network (NHSN) CLABSI definition had a significant impact on the causative agents. When using the standard NHSN criteria, the major pathogens were *Enterococcus* species, *Klebsiella* species, and *E. coli*. However, using a modified definition to exclude gut bacteria, the major pathogens were coagulase-negative staphylococci, *Pseudomonas aeruginosa*, and *Staphylococcus aureus*.¹³ These studies point to the need for further research to better understand if translocation of gut bacteria skew or even overstate the true number of CLABSI in immunosuppressed cancer patients.

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Chapter 3: Surveillance

Surveillance for Central Line-Associated Bloodstream Infection

Data on healthcare-associated infections (HAIs) collected by infection preventionists (IPs) is one of the most effective and powerful tools for advancing patient safety and elimination of HAIs. This is the "coin of the realm" of infection prevention and control programs, as the data provided to healthcare providers can be very effective in improving performance. Surveillance is defined as the "the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health."¹ Essential elements of surveillance include (1) assessing the population served and at risk of an HAI; (2) selection of the process/outcome metrics for surveillance; (3) use of standardized definitions/criteria for surveillance; (4) collection of surveillance data; (5) calculation/analysis of data; (6) application of risk stratification to these data; and (7) reporting and use of surveillance data for those who need this information—e.g., to direct care providers and others.² The last is one of the most important elements, as sharing of the data advances performance improvement.

Central line-associated bloodstream infection (CLABSI) is a laboratory-confirmed primary bloodstream infection (LCBI) where the central line (CL) or umbilical catheter (UC) was in place for > 2 calendar days on the date of the event. The day of the device placement is considered day 1. A patient who is admitted or transferred into a facility with an implanted central line (port) already in place, and it is their only central line, and it is first accessed in an inpatient location, is considered day 1. The CL or UC had to be in place on the date of the event or the day before. If the CL or UC was in place for > 2 calendar days and then removed, the LCBI criteria must be fully met on the day of discontinuation or the next day. These cannot be secondary to a community-acquired infection or an HAI meeting the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) criteria at another body site. One critical epidemiologic element is attribution of CLABSI to the patient care unit, most likely where the infection began. As such, if CLABSI develops in a patient within 48 hours of transfer from one inpatient location to another, in the same or a new facility, the IP needs to capture the *transferring* location on the infection report. The timeframe for defining the CLABSI is included in the general infection window or the 7-day period. The date of the event is the date that the first element used to meet the CLABSI definition occurred for the first time during the infection window period. The repeat infection timeframe (RIT) is a 14-day period during which repeat infections of the same type will not be reported to NHSN. Surveillance of CLABSI includes active process, prospective and focused on patients at risk. Key criteria for identification of CLABSI based on the CDC's NHSN definitions are as follows.

Numerator

Criterion 1: Patient has a recognized pathogen cultured from one or more blood cultures and organism cultured from blood is not related to an infection at another site.

Criterion 2: Patient has at least one of the following signs or symptoms:

- fever (> 38° C), chills, or hypotension; and
- signs and symptoms and positive laboratory results not related to an infection at another site, and common commensal (i.e., diphtheroids [*Corynebacterium* spp. not *C. diphtheriae*], *Bacillus* spp. [not *B. anthracis*], *Propionibacterium* spp., coagulase-negative staphylococci [including *S. epidermidis*], viridans group streptococci, *Aerococcus* spp., *and Micrococcus* spp.) cultured from two or more blood cultures drawn on separate occasions. The final elements must occur within the infection window period. This is a 7-day time period which includes the date the positive blood culture was collected, the three calendar

days before, and the three calendar days after. The matching common commensals represent a single element and the collection date of the *first* common commensal is the date of the element used to determine the date of the event.

Criterion 3: Patient < 1 year of age has at least one of the following signs or symptoms:

- fever (> 38° C) hypothermia (< 36° C), apnea, or bradycardia;
- symptoms and positive laboratory results are not related to an infection at another site; and
- common skin commensal (i.e., diphtheroids [*Corynebacterium* spp. not *C. diphtheriae*], *Bacillus* spp. [not *B. anthracis*], *Propionibacterium* spp., coagulase-negative staphylococci [including *S. epidermidis*], viridans group streptococci, *Aerococcus* spp., *Micrococcus* spp.) cultured from two or more blood cultures drawn on separate occasions. The final elements must occur within the infection window period. The matching common commensals represent a single element and the collection date of the *first* common commensal is the date of the element used to determine the date of the event.

Criterion Mucosal Barrier Injury Laboratory-Confirmed Bloodstream Infection (MBI-LCBI):

- The criterion applies to a patient of any age that meets criteria 1 for LCBI with at least one culture growing any of the following intestinal organisms with no other organism isolated: *Bacteroides* spp., *Candida* spp., *Clostridium* spp., *Enterococcus* spp., *Fusobacterium* spp., *Peptostreptococcus* spp., *Prevotella* spp., *Veillonella* spp., or Enterobacteriaceae. Enterocaberiaceae must be of eligible genera. The patient must also meet one of the following: (1) The patient must have received an allogeneic stem cell transplant within the past year with a documentation of Grade III or IV gastrointestinal graft vs. host disease [GI GVHD] or > or equal to 1 liter diarrhea in a 24-hour period (or > or equal to 20 mL/kg in a 24-hour period for patients < 18 years of age) with onset on or within seven calendar days before the date the positive blood culture was collected; or (2) the patient is neutropenic, defined as at least two separate days with values of absolute neutrophil count (ANC) or total white blood cell count (WBC) < 500 cells/mm³ within a 7-day time period.
- Reporting of this event must include underlying conditions if any were met. MBI-LCBI criteria include LCBI 1, LCBI 2, and LCBI 3. These criteria were added to help distinguish true primary CLABSI from bloodstream infections caused by other health problems and/or procedures that are unrelated to vascular catheter use.

Note: The NHSN surveillance definitions are periodically revised. It is essential that IPs responsible for NHSN surveillance and reporting have the most current information to assure accuracy in the data submitted. The surveillance information in this section has been updated to reflect the 2015 changes. Additional information can be found in the device-associated module of the NHSN Patient Safety Component Manual, January 2015 edition, available at http://www.cdc.gov/nhsn/acute-care-hospital/ clabsi/index.html.

Denominator

Accurate assessment of denominator data is essential for tracking and reporting purposes. With the focus on public reporting, rates of infection can be negatively impacted if the denominator data aren't correct. When validating data from electronic databases, the counts must be (+ /- 5%) from manually collected counts and for a minimum of three months prior to use.

For ICU and locations that are not specialty care areas/oncology (SCA/ONC) or neonatal ICU (NICU), count at the same time each day:

- Number of patients on the unit
- Number of patients on the unit with one or more central lines

For SCA/ONC and NICU, count at the same time each day:

• Number of patients on the unit

For SCA/ONC:

- Number of patients on the unit with one or more permanent central line(s)
- Number of patients on the unit with one or more temporary central line(s)

NOTE: If the patient has both a temporary and permanent central line, count the day only as a temporary central line day.

For NICU locations, count at the same time each day:

- Number of patients in each birth weight category on the unit
- Number of patients in each birth weight category on the unit with one or more central line(s)

Areas other than SCA/ONC and NICUs may use an alternative method and sample denominator data weekly in lieu of daily collection. The data should be collected on a specific day each week at the same time during the month. Saturdays and Sundays should not be selected as the designated denominator collection day. Eligible locations are those ICU and ward locations with an average of 75 or more central line-days per month.

Electronic sources for denominator data may be used as long as the counts have been validated and are not significantly different (+/-5%) from manually collected counts. Validation of electronic counts should be done for each separate location.

Outcome Metrics

CLABSI rate To calculate the device-associated infection rate (per 1,000 device-days) use the following formula:

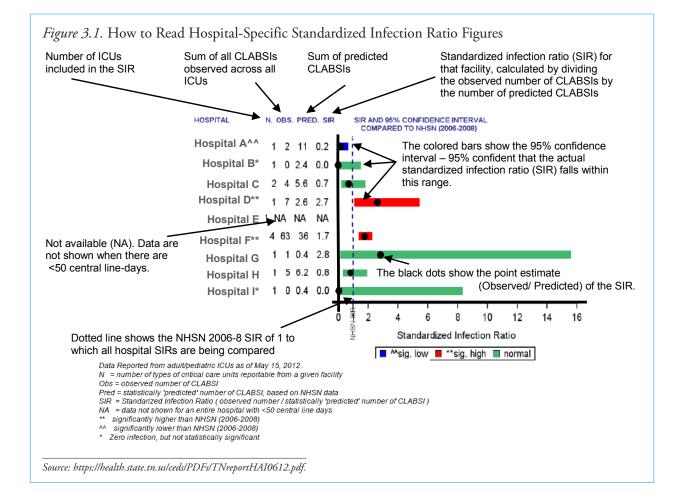
Number of central line-associated bloodstream infections (BSIs) identified for the patient care unit(s) under surveillance x 1,000

Number of central line-days for the patient care units under surveillance

Standardized Infection Ratio

The standardized infection ratio (SIR) is calculated by dividing the number of observed infections by the number of expected infections. The number of expected infections, in the context of statistical prediction, is calculated using CLABSI rates from a standard population during a baseline time period as reported in the NHSN Report.

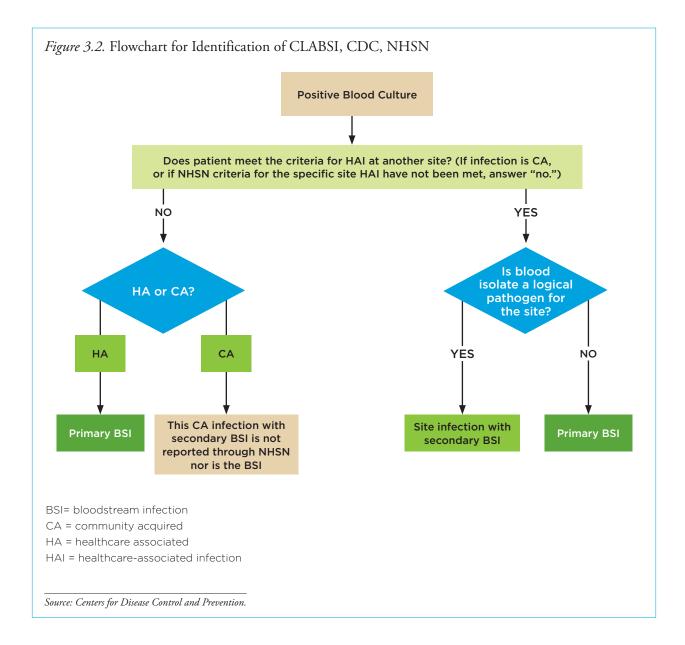
SIR is increasingly being used to assess performance compared to a national, comparative benchmark. A caterpillar plot is useful for display of SIRs. The State of Tennessee publishes reports on frequency of HAIs for various sites, and Figure 3.1 provides a good illustration of the use of this method for displaying SIR outcome data.



Stepwise Approach to Surveillance of CLABSI

A flowchart for collection of CLABSI cases is provided in Figure 3.2. As illustrated, surveillance begins with review of detection of microorganisms from blood cultures obtained from patients. From this, the next steps involve investigation of whether a central line was or is in place within 48 hours of detection of microbes in blood and then application of criteria listed previously.

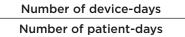




Process and Related Metrics

Device Utilization Ratio

The number of patient-days is used as the denominator of the device utilization ratio (DUR). Patient-days are the total number of days that patients are in the location during the selected time period. The numerator is the total of central line-days for the location(s) under surveillance for the specified time period.



The DUR provides an indication of the level of intensity of use of an invasive device, such as a central line. It is a helpful indicator of the prevalence of use of various devices.

As discussed in the previous chapters, the risk for CLABSI is reduced through proper placement and management of the central line. The CDC's Healthcare Infection Control Practices Advisory Committee *Guidelines for the Prevention of Intravascular Catheter-Related Infections*, 2011² recommends evidence-based central line insertion practices known to reduce the risk of subsequent CLABSI. These include proper hand hygiene practices by inserters, use of maximal sterile barriers during insertion, proper use of a skin antiseptic prior to insertion, and allowing skin antiseptic to dry before catheter insertion. The NHSN has a central line insertion practices (CLIP) module that can be used to capture frequency of adherence to insertion technique. This is discussed further in Chapter 5.

Additional Aspects Related to Surveillance of CLABSI

Terminology: CLABSI or CRBSI

The terms used to describe intravascular catheter-related infections can be confusing. Catheter-related (e.g., central venous) bloodstream infection (CRBSI) is often used interchangeably with CLABSI. However, they are not identical. CRBSI is a clinical definition of BSI used for diagnosis and treatment of infection that requires definitive laboratory evidence that the central venous catheter is the source of an individual patient's BSI. CLABSI, by contrast, refers to surveillance definition applied to populations at risk. Therefore, the CDC's NHSN definition is "a CLABSI is a primary BSI in a patient that had a central line within the 48-hour period before the development of the BSI and is not related to an infection at another site. However, because some BSIs are secondary to other sources other than the central line (e.g., pancreatitis, mucositis) that may not be easily recognized, the surveillance definition may overestimate the true incidence of CRBSI..."³ The criteria differentiating CLABSI from CRBSI are summarized in Table 3.1.

Criteria	CLABSI	CRBSI
Purpose of definition	Surveillance	Clinical diagnosis
Device removal required	Usually no	Usually yes
Cultures	Qualitative blood cultures	Blood cultures with differential time to positivity
Catheter tip culture recommended	No	Yes
Major advantage	Convenience, lower cost, readily available in most laboratories	High sensitivity; better positive predictive value
Major disadvantage	Often unable to distinguish a primary and secondary BSI; may overstate the true incidence of primary CLABSI	More complex, less convenient, expensive

Table 3.1. Differentiating CLABSI and CRBSI

Source: APIC 2014.

Microbiologic Aspects Involved in Identification of CLABSI vs. CRBSI

Aseptic collection of blood cultures is critical to ensure that the results obtained truly represent detection of bacteria from the patient's bloodstream because the blood culture media is designed to be extremely sensitive and the primary route of collection, percutaneous phlebotomy, is very susceptible to recovery of skin microflora. This is particularly true for coagulase-negative staphylococci (CoNS), and a recent investigation found that in only 10 percent of the instances were CoNS clinically significant.⁴

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Contaminated, or false positive blood cultures, often lead to unnecessary antibiotic therapy and other complications. Therefore, when indicated, cultures should be collected with effective skin antisepsis, disinfection of transfer devices/septum of the blood culture bottle, and use of aseptic technique. Detailed guidance on collection of blood culture is available elsewhere.⁵

The Infectious Diseases Society of America (IDSA) published the following select recommendations regarding collection of blood cultures and other specimens related to the central line in patients in whom BSI is suspected:⁶

- Catheter cultures should be performed when a catheter is removed for suspected catheter-related bloodstream infection (CRBSI); catheter cultures should not be obtained routinely (A-II).
- For central venous catheters (CVCs), the catheter tip should be cultured, rather than the subcutaneous segment (B-III).
- Growth of > 15 colony-forming units (CFU) from a 5 cm segment of the catheter tip by semiquantitative (roll-plate) culture or growth of > 10^2 CFU from a catheter by quantitative (sonication) broth culture reflects catheter colonization (A-I).
- When catheter infection is suspected and there is a catheter exit-site exudate, swab the drainage to collect specimens for culture and Gram staining (B-III).
- Skin preparation for obtaining percutaneously drawn blood samples should be performed carefully, with use of either alcohol or tincture of iodine or alcoholic chlorhexidine (> 0.5 percent) rather than povidone-iodine, allowing adequate skin contact and drying times to mitigate blood culture contamination (A-I).
- If a blood sample is obtained through a catheter, clean the catheter hub with alcohol or a tincture of iodine or alcoholic chlorhexidine (> 0.5 percent), allowing adequate drying time to mitigate blood culture contamination (A-I).
- For suspected CRBSI, paired blood samples, drawn from the catheter and a peripheral vein, should be cultured before initiation of antimicrobial therapy, and the bottles should be appropriately marked to reflect the site from which the samples were obtained (A-II).
- If a blood sample cannot be drawn from a peripheral vein, it is recommended that two blood samples should be drawn through different catheter lumens (B-III). It is unclear whether blood cultures should be drawn through all catheter lumens in such circumstances (C-III)."⁶

Readers are encouraged to investigate techniques for collection and capabilities/methods in use in the clinical laboratories at their facility. The IDSA guideline provides a wealth of additional detail on various laboratory methods that can improve the identification of CRBSI. While collection of blood cultures from indwelling central lines is the least desirable, when there are circumstances that limit two sets of peripherally collected specimens the negative predictive value of a set drawn from the central line that does not detect growth versus the set from peripheral phlebotomy that does is strong evidence the central line is not the source of the patient's infection. The Infusion Nurses Society has also published guidelines on use of intravascular therapy and recommends removal of needleless connectors attached to the central line/catheter hub prior to collection of blood cultures to mitigate contamination.⁷

With the increased attention and incentives for providers to provide data on CLABSI to the general public, the issue of precision of identification of this site of HAI has been studied. Lin and colleagues recently reported weak correlation between CLABSI identified by IPs as compared to a computerized detection algorithm; notably, the facility with the lowest incidence of CLABSI reported by the IP had the highest incidence using the algorithm.⁸ This finding highlights the challenges of applying surveillance criteria and also leads to questions on the ideal method for surveillance of CLABSI. Other investigators have confirmed findings from Lin's investigation, finding weak agreement among IPs who reviewed a standard series of possible cases of CLABSI.⁹ This highlights the need to minimize variability in the surveillance process to

ensure that case finding are reliable and reproducible so that valid comparison between institutions can be made. Some subjectivity in application of CLABSI surveillance criteria exists, and this may explain some of this weak inter-rater reliability.¹⁰ This reality places the IP at the center of a desire for providers to be transparent yet ensure that instances of CLABSI are as accurate as possible.

Automating Detection of CLABSI

The NHSN is actively working with IPs, researchers, vendors of surveillance technology, and providers to explore use of electronic data elements to aid the detection and reporting of CLABSI; this approach has the potential to both minimize variability (increase reliability) and decrease the data collection burden.¹¹ A lot of progress has been made in use of algorithmic detection of CLABSI using electronic databases, and this trend will likely continue.

New Horizons for Classifying BSIs

Initiatives to prevent CLABSI have been extremely successful; most recently, a 44-state collaborative was able to reduce the incidence of CLABSI by 40 percent.¹² With this success, however, providers are recognizing that the incidence of CLABSI is being driven down as new understanding of the source of bloodstream infections is being discovered. In particular, certain populations, such as those with underlying hematologic and oncologic malignancies, will have microbes recovered from blood culture, but the source likely is not an indwelling central line. Rather, these microbes are from mucositis or translocation of microbes from the gastrointestinal tract.¹³ However, correct application of current CLABSI surveillance criteria would classify these as associated with the central line. The NHSN is working with clinicians to call out those instances that are especially important when public reporting of rates of HAI is susceptible to misinterpretation.

Improving Surveillance Skills

The *American Journal of Infection Control* has published a series of case scenarios involving possible HAIs with a link to an online website to answer a series of questions related to the cases. Several of these include possible CLABSI; this method of independent study offers a mechanism for IPs to enhance their skill in detection of these infections.¹⁴

The Association for Professionals in Infection Control and Epidemiology (APIC) offers sessions and workshops annually at its national conference. In addition, APIC webinars, including those available in the archive, provide numerous opportunities for additional learning, including basic statistics, use of data and their interpretation, surveillance skills, and understanding and applying the SIR.

Validation of CLABSI Reporting

The U.S. Centers for Medicare and Medicaid Services (CMS) has begun a mechanism to validate CLABSI findings reported into the CDC NHSN with the intent of publishing the data on its website, Hospital Compare. Validation is important, and many states have used federal funding to establish HAI data coordination and validation programs within public health agencies. Validation is based on the following principles: (1) Review of cases must match the criteria used to initially identify and report results; (2) the individual performing validation cannot be the same person who collected or processed the original data; and (3) validation systems must be conducted as performance improvement rather than punitive activities.

Validation may be manual, electronic, or hybrid. The manual approach is time intensive and costly. The challenges of inter-rater reliability may confound the best efforts to achieve objectivity. No matter how

complex the current challenges, the demand for validated data will only escalate going forward. It will be increasingly important for IPs to understand and utilize data-validation skills in order to provide the most accurate CLABSI data possible to regulators, payers, and other external stakeholders.

To facilitate this process, the CDC introduced the *NHSN Validation Guidance and Toolkit; Validation for 2012 Central Line-associated Bloodstream Infection (CLABSI) in ICUs.* This resource introduces the process of CLABSI validation and offers numerous tools and references. The toolkit can be downloaded at www.cdc.gov/nhsn/toolkit/validation-clabsi/index.html. Toolkits for subsequent years will be available at http://www.cdc.gov/nhsn/validation/index.html.

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Chapter 4: Beyond the ICU: Expanding Target Populations

Traditionally, research on central line-associated bloodstream infection (CLABSI) has focused on patients in intensive care units (ICU); however, recent research is highlighting numerous variations to this approach. While the rate of ICU patients with central venous access devices (CVADs) is higher, the total number of patients with CVADs in non-ICU settings is greater. CVAD use outside of the ICU must be examined for two diverse groups: (1) hospitalized patients in general medical-surgical nursing units; and (2) patients in alternative care settings, such as home care, long-term care, and ambulatory care. Additionally, infection rates from other settings, such as CVADs inserted in the emergency department (ED) and those used for outpatient hemodialysis, require separate assessments.

A single-day point prevalence survey of six large academic medical centers reported that 506 of 2,076 patients outside the ICU had CVADs, for a device utilization ratio of 0.244. In ICU patients, there were 212 out of 383 with CVADs for a utilization ratio of 0.554.¹ Marschall et al. reported a similar device utilization rate for CVADs of 0.22 in four general medical units at a single large academic medical center and emphasized that most patients with a CVAD will be outside the ICU. This study found the incidence of CLABSI in general medical patients and ICU patients to be similar. The majority of studies on CLABSI prevention have been performed on ICU patients, thus warranting the need for more studies in the non-ICU patient population.²

A systematic literature review of CLABSI from CVADs inserted in the ED included 11 studies suggesting that these devices are a significant source of infection. Numerous issues and problems were identified, such as use of a standard definition for CVAD infection and identification of CVADs actually inserted in the ED during the study process. These CVADs may be inserted in true emergent conditions, and the CDC guidelines call for their replacement within at least 48 hours. This literature review found that ED-inserted CVADs were allowed to remain indwelling for nearly one week on average. Other factors identified included poor compliance with infection prevention measures, such as use of maximal barriers during insertion, reliance on self-reported rates of compliance, and inadequate statistical power in many studies. The authors called for quality improvements in both clinical practice and data collection on ED-inserted CVADs.³

CVADs have long been used in outpatient settings; however, there are many differences in catheter types and patient comorbidities.

Assessing for Vascular Access Needs in All Populations

The goal of choosing the most appropriate vascular access device should focus on the patient's peripheral vasculature; the number of available venipuncture sites; the prescribed therapy, including the final pH and osmolarity of all fluids and medications; the anticipated length of therapy; the ability and resources to care for the device in the specific healthcare setting; and the patient's preferences, especially when the patient must learn to manage and live with the CVAD. The least invasive device with the smallest lumen size and the fewest number of lumens capable of accommodating the prescribed therapy should be chosen.⁴

Optimum device selection requires a proactive assessment of the vascular access needs for each patient. This assessment should begin upon admission to any healthcare facility and, to the extent possible, consider the probability that the patient will require extended infusions after discharge. Early assessment for appropriate device placement helps prevent the need to change catheter types as the patient transitions to another level of care or back to home. This early assessment, however, is often challenging to achieve, especially

when catheters are inserted in urgent or emergent situations. During the periods of acute inpatient care, the device assessment is performed on a daily basis with the CVAD being removed as quickly as possible. Current controversy exists about CVAD removal when all infusion therapy is completed or when therapy requiring central venous infusion is completed. Concern over extended CVAD-dwell time and the risk of CLABSI must be weighed against the risk of other serious complications.

According to the 2011 Infusion Nurses Society Standards, infusions not appropriate for administration through a short peripheral catheter include continuous vesicants, parenteral nutrition, infusates with a pH < 5 or > 9, and infusates with an osmolality > 600 mOsm/L.⁴ These characteristics indicate the need for infusion through a CVAD and should prohibit the early removal of the CVAD and/or complete reliance on peripheral veins for infusion. Consideration of the type and chemical properties of infusates is also important when therapy will occur in an ambulatory, long-term care, or home setting.

Early and appropriate catheter selection can have an impact on both inpatient and outpatient costs. When central lines are not used, repeated peripheral venipuncture sites may be required for lengthy courses of fluids and medications, thus increasing operational costs. Superficial phlebitis results in pain and lack of peripheral venipuncture sites can delay treatment and prolong hospitalization. Venipuncture has been documented to produce nerve damage, such as complex regional pain syndrome, a life-long condition requiring aggressive pain management.⁵⁻⁷ Additionally, the vesicant nature of medications can result in necrotic ulcers requiring surgical debridement. It is possible for these conditions to result in costs that equal or exceed the cost of treating CLABSI. The risks of these complications must be balanced with assessment of the needs and relative risks of using a central catheter much earlier in the course of treatment, even when the patient is not admitted to the ICU.

Maintaining CVADs in the Presence of Systemic Infection in All Populations

Treatment of systemic infections usually requires the intravenous administration of anti-infective medications. This treatment is no longer restricted to the ICU; ongoing infusions often continue post discharge from acute care.

Insertion of a new CVAD or removal and insertion of a second CVAD in the presence of CLABSI is a controversial issue. The answer lies in assessment of numerous factors, including the type of CVAD, the hemodynamic stability of the patient, and the organism cultured from the CVAD. The Infectious Diseases Society of America (IDSA) has produced a detailed plan for diagnosis and management of patients with a catheter-related infection. This set of recommendations addresses all types of patients and CVADs, both peripheral and central.⁸

The question still remains about the risk of relapse of infection after treatment of the infected CVAD. Often the type of infusion therapy requires access of a central vein (e.g., parenteral nutrition). Moreover, the patient may have very limited or no peripheral venous access sites, and therefore removal of the current CVAD is not possible. A systematic literature review assessed the rate of CLABSI relapse when CVAD salvage was attempted with anti-infective lock therapy (ALT), systemic antibiotics, and exchange over a guide wire. Eight studies with a total of 396 patients met the inclusion criteria. ALT plus systemic antibiotics were superior to systemic antibiotic alone. Ten percent of the patients treated with both methods required CVAD removal, whereas 33 percent of those were treated without the ALT. Patients with ALT experienced a 20-percent relapse rate while the control group experienced 30-percent relapse of CLABSI. Data on catheter exchange were not sufficient to draw conclusions, and catheter use, especially outside the ICU, remains under investigation.⁹

Insertion of a new CVAD in the presence of positive blood cultures is another challenge. Daneman et al. reported retrospectively on a cohort of patients with positive blood culture results and the timing of peripherally inserted central catheter (PICC) insertion. They used the blood culture most closely preceding the PICC insertion and reported the risk of relapsing bacteremia with the same pathogen within 30 days after PICC insertion. In a 4-year period, 3,636 positive blood cultures were reported in 1,988 patients. During this same period, 3,951 PICCs were placed. Within 30 days following PICC insertion, 33 (9.5 percent) patients had developed a recurrent bacteremia; however, only eight patients were cultured with the same organism as before PICC insertion. Assessment by two infectious disease specialists determined that only three of these eight patients were true relapses of the original bacteremia, for a relapse rate of 0.9 percent. Intra-abdominal infection and pneumonia were judged to be the cause of the other recurrent bacteremia.¹⁰

In neonates, a Cochrane Database analysis found no studies meeting the eligibility criteria for comparison of CVAD removal versus treatment of the infection with CVAD retention. Management of CLABSI in neonates is currently guided by only observational studies, and randomized controlled trials are needed.¹¹ Additional information on CLABSI prevention in pediatrics, including the neonatal intensive care unit, is presented in Chapter 8.

Patients with long-term CVADs, such as tunneled catheter and implanted ports, are dependent upon these catheters for critical infusion therapies. These CVADs require surgical insertion and removal; therefore, careful consideration is required if infection is suspected or confirmed. An infection in the subcutaneous tunnel or port pocket requires removal. The presence of septic thrombophlebitis, endocarditis, and osteomyelitis also requires removal. In patients without these additional complications, removal depends upon the infecting organism. Allowing the CVAD to remain in place may be possible if the organism is enterococcus or coagulase negative *Staphylococcus aureus*; however, infections with *Staphylococcus aureus*, Gram-negative bacilli, and candida species require removal. The IDSA guidelines recommend that blood cultures that show no growth are necessary for insertion of a new CVAD following *Staphylococcus aureus* bloodstream infection.¹² See Chapter 10 for additional information on long-term device use.

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Chapter 5: Ensuring Adherence to the Central Line Bundle—Prevention during Insertion

Use of an evidence-based bundle of interventions can improve patient outcomes only if the interventions are consistently completed. Ongoing monitoring is needed to ensure adherence to elements of the bundle. Furthermore, outcome improvement must be documented in a clear, consistent manner and reported according to specific criteria. As previously described, the initial set of bundled CLABSI prevention practices has been widely adopted and often used in combination with an insertion checklist. However, the terms "bundle" and "checklist" are not interchangeable. A checklist can be used to supplement a bundle and is most effective when used as part of a broader, more comprehensive approach to patient safety. ^{1,2} The checklist usually includes additional practices, some of which may not be based on level I evidence and may, in certain instances, be optional. Checklist content may also be developed to include specific regulatory or accreditation requirements. The checklist format allows the broad bundled strategies to be carefully aligned with detailed institutional policies, procedures, and specific resources. Of note, in 2013, the Agency for Healthcare Research and Quality named bundles that include checklists to prevent central line-associated bloodstream infection (CLABSI) one of the top 10 "strongly encouraged patient safety practices."³

Checklists are both effective and popular, as well as championed by international experts, such as Atul Gawande, MD, author of the bestselling *The Checklist Manifesto* (2009), and Peter Pronovost, MD, co-author of *Safe Patients, Smart Hospitals: How One Doctor's Checklist Can Help Us Change Health Care from the Inside Out* (2010). Their work repeatedly demonstrates that checklists can lead to substantial improvements in patient outcomes, but only when integrated with enhanced organizational safety culture, an invigorated sense of teamwork, and regular, open communications and feedback.

A CLABSI insertion checklist can be easily adapted from those already designed and frequently shared. It can also be developed independently; there is no preferred design template. It is far more important to use a tool that is acceptable to and consistently used by the physicians and teams inserting central lines rather than a specific design (or template) as long as the recommended criteria are included. An example is shown in Figure 5.1.

CDC Central Line Insertion Practices Adherence Monitoring

The Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) provides resources to facilitate monitoring. The Central Line Insertion Practices (CLIP) bundle, part of the NHSN device-reporting system, has been developed to capture CLABSIs that originate at the time of catheter insertion.⁴ In order to standardize collecting and reporting of data, the NHSN identified central lines in the CLIP module as being located in any of a number of vessels. See the NHSN patient safety module for the complete list.

However, while the CLIP module contains many of the same elements as the original Institute for Healthcare Improvement (IHI) bundle (chlorhexidine skin antisepsis, avoidance of the femoral vein, maximal barrier precautions), it adds additional components as required for reporting. These include whether or not the catheter was changed over a guide wire and whether an antimicrobial catheter was used. Additional important features of the CLIP module include:

• An introducer is considered an intravascular catheter and, depending on the location of its tip and use, may be a central line.

□ Joh	Ins Hopkins Hospital Ins Hopkins Hospital Ins Hopkins Bayview Iner: Line Insertion Care	·				
Date	Time			Addres	sograph	
Type of line	PLACED		LOCATION OF LINE		#	of lumens
appropriate	CI The Assistant completes t column when the task is p ded. The Supervisor may	performed. If the task	is not performed, a cor	nment	Yes 🖌	Yes with Remi (If No-add comment
1. P	erform a time out usi	ng the informed o	onsent form.			
2. C	lean hands					
co pi	lear cap, mask, steril ontact with or crossin rocedure. . All others entering cap and mask.	g the sterile field	*at any time durin	g the		
4. P	rep site with chlorhex	idine and let air o	Iry. (*See instructi	ons)		
5. D	rape patient from hea	ad to toe using st	erile technique.			
	repare catheter by pr se during procedure.	-	amping all lumens	not in		
	lace patient in trende e.g., increased ICP) o					
8. M	laintain sterile field.					
	nsure grasp on guide nd removed post pro		ed throughout pro	cedure		
10. A	spirate blood from al	l lumens, flush, ar	nd apply sterile ca	ps.		
11. E	nsure venous placen	nent. (*See instru	ctions)			
	lean site with chlorhe terile caps on all hubs		ile dressing, and a	apply		
*Checklist	instructions located or	back of form				
Operator_		_ Supervisor		Assista	ant	
Comments	E					
					VAD Policy	

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- In neonates, catheters in the umbilical artery and vein are considered central lines.
- Neither the location of the insertion site nor the type of device may be used to determine if a line qualifies as a central line.
- Pacemaker wires and other nonlumen devices inserted into central blood vessels or the heart are not considered central lines because fluids are not infused, pushed, or withdrawn through such device.

Comprehensive information, including introductory online training, can be obtained at www.cdc.gov/ nhsn/acute-care-hospital/clip/index.html. The CLIP adherence monitoring tool (Figure 5.2) can also be downloaded at this website.

Participation in NHSN CLIP surveillance enables participating facilities and the CDC to:

- Monitor central line insertion practices in individual patient care units and facilities and to provide aggregate adherence data for all participating facilities. Facilities have the option of recording inserter-specific adherence data.
- Facilitate quality improvement by identifying specific gaps in adherence to recommended prevention practices, thereby helping to target intervention strategies for reducing CLABSI rates.

Settings: Surveillance may occur in any type of patient care location where central lines are inserted.

Requirements: Surveillance for central line insertion practices in at least one location in the healthcare institution for at least one month as indicated in the *Patient Safety Monthly Reporting Plan* (CDC 57.106). Participating facilities may perform surveillance for insertion practices during a month in which concomitant CLABSI surveillance is being conducted, or may collect insertion practice data during a month when no CLABSI surveillance is being conducted, or in locations where CLABSI is not monitored (e.g., emergency department, operating room, etc.). If participating facilities wish to identify associations between insertion practices and outcomes (i.e., CLABSI), surveillance for insertion practices and CLABSI must be done concomitantly.

Numerator and denominator data: The *Central Line Insertion Practices Adherence Monitoring Form* (CDC 57.125) is used to collect and report central line insertion practices for every central line insertion attempt, including unsuccessful attempts, occurring during the month in the unit(s) selected for surveillance. The table of instructions for completion of the Central Line Insertion Practices Adherence Monitoring Form contains directions for collection and entry of each data element on the January 2015 *Device-associated Module CLIP* (available at http://www.cdc.gov/nhsn/forms/instr/57_125.pdf).

Although the CLIP module states that the form can be completed at or near the time of insertion either by "the inserter or an observer present at the insertion," it is important that an individual who is observing the procedure complete the form. And though there are organizations that allow the inserter to complete a checklist, this does not ensure adherence to the procedure as the individual placing the line may not recognize breaches in his or her own procedure. The more recent 2014 SHEA/IDSA guidelines specifically state that the observer may be a nurse, physician, or other healthcare provider who has received appropriate education to ensure adherence to aseptic technique. Furthermore, the observer should be empowered to stop the central line insertion procedure if any breaches in technique are observed.⁵ Alternately, the form could be completed from documentation in the patient chart, but only if all elements of the monitoring form have been incorporated into standard central line insertion procedure notes. This is evident in the electronic health records (EHR) that are formatted to emulate the paper documents. The form includes information pertaining to demographics of the patient; information pertaining to the inserter; information on maximal sterile barriers used; the reason for central line insertion; whether the insertion was successful; skin antisepsis; hand hygiene practice before insertion; type of central line, including whether it was antimicrobial coated; insertion site; and, if placed because of suspected existing central line infection, the use of a guide wire. Elements of these data will be used to calculate adherence to recommended insertion practices.

Data analyses: Adherence rates for specific insertion practices will be calculated by dividing the number of central line insertions during which the recommended practice was followed by the total number of central line insertions and multiplying the result by 100. Such calculations can also be done for a bundle of practices that have been shown to reduce the incidence of CLABSI. In the NHSN, adherence to the bundle requires "yes" to all of the following:

- Hand hygiene performed
- Appropriate skin prep
 - Chlorhexidine gluconate (CHG) for patients > 60 days old
 - Povidone iodine, alcohol, CHG, or other specified for children < 60 days old
- Skin prep agent completely dry before insertion
- All 5 maximal sterile barriers used:
 - Sterile gloves
 - Sterile gown
 - Cap
 - Mask worn
 - Large sterile drape (a large sterile drape covers the patient's entire body)

NOTE: In 2012, the U.S. Food and Drug and Administration revised the labeling of CHG cloth use in relation to use with infants and states that CHG should be used with care in premature infants or infants under two months of age as these products may cause irritation or chemical burns.⁶

These calculations can be performed separately for different types of locations in the institution. Participants have the option of calculating inserter-specific adherence rates.

Source: CDC, NHSN Device associated module CLIP, January 2014. Available at www.cdc.gov/nhsn/PDFs/pscManual/5psc_CLIPcurrent.pdf.

What Are Maximum Sterile Barrier Precautions?

According to the CDC, maximum sterile barrier precautions are defined as wearing a sterile gown, sterile gloves, and cap and using a full-body drape (similar to the drapes used in the operating room) during the placement of a central venous catheter.⁷ This recommendation is supported by numerous studies that can be located at the CDC website (available at www.cdc.gov/hicpac/BSI/05-bsi-background-info-2011.html).

NHSN National Healthcare	Form Approved OMB No. 0920-0666 Exp. Date: 12/31/2017
National Healthcark Central Line Insertion Page 1 of 2	on Practices Adherence Monitoring
*required for saving	
Facility ID:	Event #:
*Patient ID:	Social Security #:
Secondary ID:	Medicare #: Middle:
	*Date of Birth: / (mm/dd/yyyy)
*Gender: F M Other	
*Event Type: CLIP *Location:	Race (specify): *Date of Insertion: / / (mm/dd/yyyy)
*Person recording insertion practice data:	
	e, Last: First:
*Occupation of inserter:	, <u></u>
	edical student
	ending physician Intern/resident Registered nurse
-	her (specify):
*Was inserter a member of PICC/IV Team?	
*Reason for insertion:	
□ New indication for central line (e.g	g., hemodynamic monitoring, fluid/medication administration, etc.)
□ Replace malfunctioning central lin	
□ Suspected central line-associated	
□ Other (specify):	
	ection, was the central line exchanged over a guidewire? \Box Y \Box N
-	tral line insertion: $\Box Y \Box N$ (if not observed directly, ask inserter)
	$\Box N \qquad \text{Sterile gown } \Box Y \Box N$
	e drape \Box Y \Box N Sterile gloves \Box Y \Box N Cap \Box Y \Box N
-	Chlorhexidine gluconate
	Dther (specify):
	ie, was there a contraindication to chlorhexidine? \Box Y \Box N \Box U
	of first skin puncture? \Box Y \Box N (if not observed directly, ask inserted
	Lower extremity Scalp Subclavian Umbilical Upper extrem
Antimicrobial coated catheter used:	
*Central line catheter type:	
□ Non-tunneled (other than dialysis)) 🗆 PICC
□ Tunneled (other than dialysis)	□ Umbilical
 Dialysis non-tunneled 	
	Other (specify):
Dialysis tunneled	lines can be categorized accurately by selecting from options provided.
*Did this insertion attempt result in a successf	
collected with a guarantee that it will be held in strict confidence, consent of the individual, or the institution in accordance with Sec Public reporting burden of this collection of information is estimate data sources, gathering and maintaining the data needed, and co	tion obtained in this surveillance system that would permit identification of any individual or institution will be used only for the purposes stated, and will not otherwise be disclosed or released without the ctions 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)). ted to average 5 minutes per response, including the time for reviewing instructions, searching existing completing and reviewing the collection of information. An agency may not conduct or sponsor, and a nless it displays a currently valid OMB control number. Send comments regarding this burden estimal practions for reducing this burden to CDC. Report Clearance, Officer 1600 Cliftor Pd. MS D-74

Source: http://www.cdc.gov/nhsn/forms/57.125_CLIP_BLANK.pdf.

Development of a Specialized Team

Prevention of CLABSI includes establishment of a team dedicated to all aspects of intravenous therapy. A recommendation of the Consensus Conference on Prevention of Central Line-Associated Bloodstream Infections was the establishment of dedicated intravenous therapy teams, citing studies that showed reductions in infections and complications from central and peripheral intravenous catheters.⁷ The expert panel suggested that the multidisciplinary team's responsibilities include catheter insertion, daily inspection, and maintenance, and providing education and development of policies and procedures. A dedicated team with expertise in peripherally inserted central catheter (PICC) assessment, placement, and care can serve as an invaluable resource for the organization. The team can also provide information to infection preventionists (IPs) in the form of data collection and identification of trends. Including the team members in infection prevention meetings will assist in guiding the focus of prevention during insertion of the PICC. The team member concept was expanded upon in implementation of a "better bundle" described by author and study lead Timothy Royer, as a Vascular Access Team (VAT).8 Royer described the VAT members as the dedicated PICC insertion staff, surgical and medical directors, nursing services, and members of the infection control committee. Responsibilities of the VAT included simultaneous surveillance of CLABSI with review of blood cultures and line cultures by both the VAT and infection control. With the shared responsibilities, emphasis was placed on the prevention and not limited to IP job duties. The effects were studied and Royer concluded a decrease in CLABSI was due in part to a dedicated and trained VAT.

Furthermore, published guidelines state that specialized "IV teams" have shown unequivocal effectiveness in reducing the incidence of catheter-related bloodstream infections, associated complications, and costs.⁹ Additionally, infection risk increases with nursing staff reductions below a critical level. Whether or not a facility can support a PICC team, research indicates that any inserter must be well educated and skilled at aseptic insertion procedures. The risk of both central line colonization and infection have increased when inexperienced clinicians are allowed to insert central catheters.¹⁰

Ultrasound Placement

Insertion of central lines, guided by the patient's anatomy or "landmarks," has been replaced by ultrasound guided placement. In two meta-analyses, the use of real-time two-dimensional ultrasound for the placement of central venous catheters substantially decreased mechanical complications and reduced the number of attempts at required cannulation and failed attempts at cannulation compared with the standard landmark placement. Evidence favors the use of two-dimensional ultrasound guidance over Doppler ultrasound guidance. Site selection should be guided by patient comfort, ability to secure the catheter, and maintenance of asepsis, as well as patient-specific factors (e.g., pre-existing catheters, anatomic deformity, and bleeding diathesis), relative risk of mechanical complications (e.g., bleeding and pneumothorax), the availability of bedside ultrasound, the experience of the person inserting the catheter, and the risk for infection.^{8,11,12}

The CDC recommends ultrasound use to place central venous catheters (CVCs) by those fully trained in its technique.⁹ A prospective randomized trial of ultrasound versus landmark guided CVC access in the pediatric population found decreased incidence of cannulations, which could lead to decreased complications. The evidence clearly suggests that the use of two-dimensional ultrasound is an important patient safety tool.¹³

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Chapter 6: Preventing Infections during Catheter Maintenance

It is apparent that optimal care at the time of insertion, adherence to the central line bundle (as previously discussed), and prompt removal when a central line is no longer needed are vital components in central line-associated bloodstream infection (CLABSI) prevention. However, the risk for infection is present during the entire dwell time of the catheter. Research and attention are now aimed at care beyond the central line bundle—that is, post-insertion care. As discussed in Chapter 2, intraluminal colonization becomes an even more significant clinical risk in the pathogenesis of CLABSI with increasing time of placement (often referred to as dwell time). This risk is the reason for the current focus on CLABSI maintenance bundles. Data submitted to and analyzed by the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) is useful in infection prevention programs. For example, in 2010 in the state of Pennsylvania, 71.7 percent of CLABSI occurred more than five days after insertion, suggesting the need to pay more attention to catheter maintenance.¹

Expanding the Insertion Bundle

The Institute for Healthcare Improvement (IHI) states that only practices based on level I evidence should be included in a bundle and that the number of components should ideally be restricted to no more than five.² However, to include practices routinely required for ongoing safe catheter maintenance, more than five key insertion practices are usually needed. Some experts claim that additional practices should be incorporated into checklists used to monitor bundle use rather than changing the original bundle. Others disagree, stating that expanding the bundle will extend the uniformity and reliability it offers to a more comprehensive approach to central catheter care.

The IHI has not developed a catheter maintenance or post-insertion care bundle. Others, however, have attempted to do so, claiming that infectious risks are ongoing, frequent manipulation of the catheter is common, and prompt removal is not always possible. One reason offered for this approach is the decline in Gram-positive pathogens as the primary causative agent in CLABSI. A study done July 2006 through April 2010 examined CLABSI rates in five intensive care units (ICUs). With the use of the IHI bundle, CLABSI rates decreased from 8.01/1,000 line-days in 2007 to 0.44/1,000 line-days in 2010. However, while the proportion of CLABSI due to Gram-positive organisms declined from 54 percent to 20 percent, the portion due to Gram-negative organisms and yeast increased from 30 percent to 70 percent. The investigators argue that the changing epidemiology of CLABSI now necessitates interventions that go beyond the IHI model.³

Developing a Post-Insertion Care Bundle

For infection preventionists (IPs) considering bundle modification, the CDC categorization of evidence, combined with the organization's best practices, serves as the starting point for any revision. A review of the literature, while still limited on this topic, does provide examples of effective implementation of post-insertion care bundles, which are highlighted later in this chapter. Examples of models used in other organizations, even if unpublished, can serve as templates.

An example of a potential template (Figure 6.1) shows how the original IHI practices have been included in an enhanced model that adds up to three additional practice categories. The example is based on the insertion and care of a subclavian catheter in an adult. Figure 6.2 shows a tool that can used or adapted in a variety of catheter maintenance situations.

Modified HICPAC Categorization Scheme for Recommendations							
Category IA	A strong recommendation supported by high- to moderate-quality evidence suggesting net clinical benefits or harms						
Category IB	A strong recommendation supported by low-quality evidence suggesting net clinical benefits or harms or an accepted practice (e.g., aseptic technique) supported by low- to very low-quality evidence						
Category IC	A strong recommendation required by state or federal regulation						
Category II	A weak recommendation supported by any quality evidence suggesting a tradeoff between clinical benefits and harms						
No recommendation Unresolved issue	Unresolved issue for which there is low- to very low-quality evidence with uncertain tradeoffs between benefits and harms						

Figure 6.1. Expanded Bundle Template Based on the 2011 CDC HICPAC Guideline Modified HICPAC Categorization Scheme for Recommendations

Example: Adult Subclavian Catheter (Nontunneled)

CDC Recommendation	Evidence Category
Avoid subclavian site in hemodialysis patients and patients with advanced kidney disease	IA
Hand hygiene prior to insertion and manipulation	IB
Maximum sterile barriers on insertion	IB
CHG skin antisepsis on insertion	IA
Optimum insertion site selection:Use subclavian, rather than jugular or femoral vein, in adult patients for nontunneled CVC placement	IB
 Avoid using femoral vein in adult patients 	IA
Use antimicrobial catheter for expected duration of use > 5 days.	IA
Designate only trained personnel for catheter insertion and maintenance.	IA
 Aseptic site and topical dressing management: Clean skin with > 0.5 percent CHG with alcohol or designated alternative during dressing changes 	IA
• Use a sterile dressing (gauze or transparent semipermeable) to cover the insertion site	IA
Use sutureless catheter securement device	11
Replacement of components:Replace primary and secondary administration sets and add- on devices no more than every 96 hours but at least every 7 days	IA
• Replace tubing for blood, blood products, or fat emulsions (those admixed with amino acids and glucose or infused separately) within 24 hours of initiating the infusion	IB
 Replace needleless components at least as frequently as the administration set. Do not change needleless connectors more frequently than every 72 hours 	II
Aseptic intermittent access with appropriate antiseptic	IA
Daily patient bathing with 2 percent CHG	11
Use antimicrobial lock solution for prophylaxis	11
Use CHG sponge dressing for short-term catheters in patients > 2 months.	IB
Prompt removal of catheter when no longer required	IA
For therapy > 6 days, use a midline or PICC (if not already in place)	Ш

Source: Hanchett M. The CLABSI Bundle: Looking beyond Insertion Practices. Prevention Strategist Summer 2011; Vol 4;(2):44-48.

Figure 6.2. Central Line Maintenance Bundle Checklist

Central Line Maintenance Bundle

http://www.cdc.gov/hicpac/BSI/BSI-guidelines-2011.html

Hand Hygiene

□ Wash hands with conventional soap and water or with an alcohol-based hand rub (ABHR) prior to and after accessing (Cat. IB):

 \checkmark The central line

 $\sqrt{}$ The dressing

 \checkmark The needleless access device (including hubs, connectors, and ports)

Dressing Change

Dressing is clean, dry, and intact (IB).

Transparent dressing changed at least every 7 days (IB)

or

- \Box If gauze dressing is used, gauze dressing is changed every 48 hours (II).
- □ Site is cleaned with chlorhexidine-based preparation using a back and forth motion for 30 seconds (IA).

Scrub the Hub

□ Catheter hubs, needleless connectors, and injection ports are cleaned before accessing the catheter with chlorhexidine, iodine, or 70 percent alcohol (IA) and a twisting motion used for at least 15 seconds.

Tubing and Devices

- Administration sets not used for blood products or lipids are changed no more frequently than 96 hours (IA).
- □ IV tubing and devices for total parenteral nutrition (TPN) and blood/blood products are replaced within 24 hours of starting the infusion (IB).
- □ Needleless access devices are changed using aseptic technique, no more frequently than 72 hours (II).

Removing the Line When No Longer Needed

□ The need for daily intravascular access with a central line is assessed daily to determine if the line is still indicated and documented in the medical record (IA). If not indicated, the central line is removed.

Optional

- □ If applicable, chlorhexidine-impregnated sponge dressing (IB) or chlorhexidine-impregnated dressing can be used. If a chlorhexidine-impregnated sponge dressing is used, it is oriented correctly and changed at the same time as the transparent dressing.
- □ If applicable, a sterile, suture-free securement device for catheter stabilization is used and changed it at the same time as the transparent dressing (II).

 \Box If applicable, patient bathed daily with 2 percent chlorhexidine (II).

This material was prepared by IPRO, the Medicare Quality Improvement Organization for New York State, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents do not necessarily reflect CMS policy. 10SOW-NY-AIM7.1-10

Issues to Consider

At previously stated, there is no nationally accepted post-insertion care bundle. For organizations attempting to develop a bundle, the following issues must be carefully considered:

- The challenges of ensuring adherence to a post-insertion care bundle are significant. The IHI central line bundle is focused on placement, a single point in time. Post-insertion care involves every catheter access procedure, many clinicians and potentially several healthcare settings, and it is impossible to observe and monitor all behaviors.
- In the example shown in Figure 6.1, moving downward the proportion of practices based on level I evidence decreases. This does not mean that no evidence exists to support certain measures, only that existing research is not at the highest level. (The categorization system used by the Healthcare Infection Control Practices Advisory Committee (HICPAC) for rating evidence is included with Figure 6.1.) It is very important to critically review other types of evidence and be prepared to assess the findings they report. Methods used in the studies, including sampling, statistical analysis, and potential bias, vary widely in research. These studies are useful in making associations, examining the before/after results of interventions and offering case studies, but unfortunately offer neither definitive proof nor a reliable basis for prediction.
- Expansion categories are not absolute and must reflect the organization's prior CLABSI experience and internal clinical decisions. For example, in Figure 6.1, both the use of antimicrobial catheters and chlorhexidine gluconate (CHG) daily bathing are listed as measures the institution might consider when other practices have not produced the desired results. In some cases this may be what is being done. However, in other hospitals, where either infection trends have been identified or leaders have taken a more aggressive prevention position, antimicrobial catheters may be used routinely and daily CHG bathing done for all patients with the device. In this case, those practices would be listed in a maintenance category rather than additional.
- Not all catheter maintenance issues (e.g., irrigation or "flushing" practices) are addressed in the new CDC guideline. Clinicians must be especially careful when considering adding these measures to an expanded bundle. In such situations, including these measures in policies and procedures and a maintenance checklist, rather than the bundle itself, may be a more acceptable option when both the number and quality of existing studies is very limited and likely to remain so in the near future.

Moving from Science to Practice

Bundles, whether used in the original form or an expanded design, as well as the checklists used to implement them, are primary examples of how scientific studies move from publication into practice. This process does not happen quickly or spontaneously; it requires the combined efforts of many stakeholders at many different levels acting intentionally and in different ways. Implementing best practices to prevent or minimize infectious risks is a primary, albeit challenging, goal for all IPs. Implementation science, exemplified in the use of bundles and checklists, helps IPs meet these challenges within the larger context of organizational safety culture and better patient outcomes.

If evolving clinical challenges call for bundle expansion, it is necessary to include practices that may not be supported by level I evidence. While this deviates from the IHI definition, it is reasonable, perhaps even necessary, especially when considering that randomized clinical trials are virtually impossible or at least cost-prohibitive for some infusion-related practices. When the highest level of evidence is not available and is unlikely to be, the clinician must rely on the best evidence available.

Success with Post-Insertion Care Bundles

A number of studies have identified key components of post-insertion care and developed bundles. In general, post-insertion care focuses on:

- Hand hygiene prior to all infusion-related procedures
- Aseptic technique with all catheter access procedures
- Proper changing of administration sets
- · Changing needleless connectors according to manufacturer guidelines
- Attention to disinfection of needleless connectors prior to access
- Regular site care and dressing changes

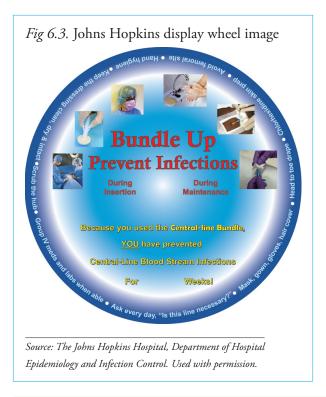
The IHI central line insertion bundle does include central venous access device (CVAD) removal when it is no longer needed. This needs to be part of post-insertion care as well. Because the very existence of the CVAD is a risk factor for catheter-associated bloodstream infection, daily review of catheter necessity, and prompt removal when it is no longer needed, are critical because the risk of bloodstream infection is increased as catheter duration is extended. Catheter removal when it is no longer needed, are equally applicable in all healthcare settings.

It is important to focus on the individual needleless connectors and be aware of the specific manufacturer recommendations to facilitate appropriate use. Failure to disinfect the needleless connector before accessing has been an important problem and area of concern. The catheter hub and needleless connector are known sources of microbial contamination and present a source for development of a bloodstream infection.⁴ Although historically, the method for disinfecting the access port involved a "scrub the hub" process whereby alcohol, iodophors, chlorhexidine, alcohol/chlorhexidine combinations could be used. More recently, the focus has shifted to use of disinfection caps that can be placed on the access port and maintain a level of disinfection. Various disinfection combinations are currently available, including alcohol and alcohol/chlorhexidine combinations. These plastic caps are placed on the access point in between intermittent infusions, thus minimizing contamination opportunities of the access point. The recent Society for Healthcare Epidemiology of America (SHEA) guidelines recommend use of disinfection caps as a special approach in locations/populations with unacceptably high CLABSI rates despite implementation of basic practice recommendations.⁵ In terms of how long to scrub the needleless connector, a 5-second scrub was found adequate with split septum type of needleless connectors.⁶ There is not a well-accepted guideline for other types of needleless connectors, but at least 15 seconds is common in some studies as cited below.

The use of a post-insertion care bundle was associated with a significant reduction in CLABSI. The clinical team at the Department of Veterans Affairs (VA) Eastern Colorado Health System added to the basic bundle daily inspection of the insertion site, site care as needed, application of a CHG sponge dressing at the insertion site and application of an alcohol scrub to the infusion hub for 15 seconds before each entry. The incidence density of CLABSI dropped from 5.7 per 1,000 catheter days to 1.1.⁷

Similarly, CLABSI rates dropped to zero when a maintenance bundle was implemented at the VA Puget Sound Health Care System. This expanded bundle included use of a dedicated vascular access team, use of a clear, swabbable, needleless connector, application of a CHG sponge dressing to the insertion site, increased utilization of peripherally inserted central catheters (PICCs), as well as the basic practices identified by IHI.⁸

In a recent study involving six hospitals over 4.5 years, the focus was on post-insertion care outside of the intensive care unit setting.⁹ The maintenance bundle included hand hygiene, a 10-15 second needleless connector scrub, attention to needleless connector, dressing and IV tubing changes, and central line need.



The CLABSI rate was reduced from 2.6 to 1.3 per 1,000 catheter-days, pre- to post-intervention. Furthermore, a nursing survey pre- and post-intervention showed reported improvement in needleless connector disinfection from less than 20 percent to 70 percent reported compliance.

Based on numerous other success stories, improvement teams have devised many creative ways to celebrate and continue their success. One popular approach focuses on sharing the number of weeks a hospital or a unit/ward has gone without a CLABSI. Figure 6.3 is an example of how you can document the number of weeks a unit has gone without a CLABSI.

The case study, One Hospital's Road to Zero CLABSI, describes the successful collaboration of a bundle approach within a collaborative model.

Case Study: One Hospital's Road to Zero CLABSI

Contributed by Vicki G. Allen MSN, RN, CIC, Infection Prevention Manager, CaroMont Health

North Carolina hospital's Vascular Access Safety Team (VAST), including team members from infection prevention and control, the facility IV team, risk management, and nurses from the medical intensive care unit (ICU) most recently completed a collaborative effort with the NC Quality Center to reduce central line-associated bloodstream infection (CLABSI) rates in its facility. Strategies were implemented and, in spite of an outbreak of vancomycin-resistant *Enterococcus* (VRE) bacteremia, the medical ICU was able to bring its rate down to zero and has sustained that rate for the past nine months.

The problem was CLABSI. Bloodstream infections represent 14 percent of hospital healthcareassociated infections (HAIs), and it is estimated that 80,000 CLABSIs occur in ICUs in the United States each year. Knowing that CLABSI is serious but preventable, the VAST proceeded with joining the collaborative in 2011. This was the second collaborative with the Quality Center focused on the prevention of CLABSI; however, even though the first collaborative resulted in a reduction of CLABSI, the results were not sustainable. The focus of the first collaboration was on housewide initiatives, including hand hygiene, scrub the hub, and multidisciplinary patient care rounds. The second collaborative was unit-based and the team determined to focus on engagement and ownership of frontline staff to drive and sustain reduction efforts. The medical ICU was the unit chosen, as this ICU had the highest incidence of CLABSI and the patients on this unit are considered most at risk for CLABSI.

The goal in joining the collaborative was not only the prevention of CLABSI but also access to state and national experts with the ability to provide education, instruction, and coaching, as well as knowledge sharing among the other participating hospitals. In reviewing the hospital and unit specific data for CLABSI, the team knew that changes were necessary and that staff ownership of the process was a key element in making the hardwired changes in the ICU essential for success. The team was formed and included medical ICU frontline staff nurses. Frontline staff had the opportunity to participate in regularly scheduled committee meetings and webinars. Arrangements were made for these nurses to attend off-site education and celebrations arranged by the Quality Center. This required a full-day offsite as well as hotel and travel. Three to five nurses were usually able to attend these off-site meetings.

Data were shared and posted on the medical ICU monthly as well as added to the agenda for discussion at unit meetings. Upon identification of CLABSI, team members participated in a defect analysis. The process of defect analysis promoted ownership of the event and encouraged problem solving and ownership among the team members. As a result of this engagement and ownership, the team was able to identify a lack of standardization as well as differences in practice. Staff created the central line maintenance bundle that was used as a teaching tool and competency check. "Super users" were trained in aseptic technique and blood culture collection. The super users then trained their peers and performed competencies. The maintenance bundle checklist was also used as an audit tool to track compliance. This tool was later reformatted and is currently used housewide as a competency check.

In the spring of 2012, a cluster of central line-associated bloodstream infections was identified. Although the defect analysis did not reveal a particular root cause, the team began re-emphasizing previous evidence-based interventions and searching for any and all prevention strategies that had not already been implemented. After attending a collaborative conference, the VAST team discovered one strategy that had not been employed—bathing with chlorhexidine gluconate (CHG). A 3-month pilot study in the surgical intensive care unit in 2011 using CHG cloths for bathing had resulted in zero CLABSI for that time period and the return on investment performed indicated a cost-per-bath increase of \$4.68 for the CHG bathing and an estimated cost savings of \$114,695 if CLABSI rates were to decrease to zero. Using this information along with a literature review and recommendations from the CDC, the team recommended CHG bathing in all critical care units. Approval was received from the Infection Prevention and Control Committee and supported by senior leadership.

Since this approval was received, CHG bathing has been implemented throughout the hospital for all patients with central lines for both critical and noncritical care units. The ICU has continued for nine consecutive months without a central line-associated infection.

Additional Information

Gastonia Memorial is a 435-bed acute-care community hospital located west of Charlotte, North Carolina. The hospital is designated as a level II trauma center and is also a certified Magnet hospital. The infection prevention department consists of four full-time registered nurses, three infection preventionists (IPs), and one IP manager. Three of the four nurses are certified in infection control. The infection prevention team is supported by two infectious disease physicians; the chief medical officer is also an infectious disease physician.

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Chapter 7: Review of Current and Additional Prevention Strategies

In guidelines issued by the Centers for Disease Control and Prevention (CDC) and the Healthcare Infection Control Practices Advisory Committee (HICPAC), each recommendation is categorized on the basis of existing scientific data, theoretical rationale, applicability, and economic impact. The system for categorizing recommendations in this guideline is as follows:

- **Category IA:** Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies
- **Category IB:** Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale; or an accepted practice (e.g., aseptic technique) supported by limited evidence
- Category IC: Required by state or federal regulations, rules, or standards
- **Category II:** Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale
- Unresolved issue: Represents an unresolved issue for which evidence is insufficient or no consensus regarding efficacy exists.

The following summarizes information from the 2011 Guidelines for the Prevention of Intravascular Catheter-Related Infections. See the guidelines for complete details and references.¹

Table 7.1. CLABSI Prevention Measures Supported by Category I Level Evidence

Insertion of Arterial and Central Venous Catheters

- Perform hand hygiene prior to any invasive procedure.
- Maintain aseptic technique during insertion of intravascular catheters.
- Use maximum barrier precautions: a cap, mask, sterile gown, sterile gloves, and a large sterile drape for the insertion of a central venous access device (CVAD) and guide wire exchange.
- Prepare clean skin with a > 0.5 percent chlorhexidine preparation or with alcohol before insertion. If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70-percent alcohol can be used as alternatives.
- Select the catheter (least number of lumens possible)
- Select the insertion site and technique, with the lowest risk for complications (infectious and noninfectious) for the anticipated type and duration of IV therapy. Avoid femoral insertion site. Weigh the risk and benefits of placing a device in subclavian site to reduce infectious complications against the risk for mechanical complications compared with jugular site (e.g., pneumothorax, subclavian artery puncture, subclavian vein laceration, subclavian vein stenosis, hemothorax, thrombosis, air embolism, and catheter misplacement/malposition).
- When adherence to aseptic technique cannot be ensured, such as during a medical emergency, replace the catheter as soon as possible or at least within 48 hours.

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Care and Maintenance of Arterial and Central Venous Catheters

- Perform hand hygiene prior to access and care of central line dressing and management of administration set or add-on devices, flushing and locking, and all fluid and medication administration.
- Maintain aseptic technique during care and maintenance of intravascular catheters.
- Use either sterile gauze or sterile, transparent, semipermeable dressings to cover the catheter site.
- Replace semipermeable dressings every 7 days, except with pediatric patients, for whom the risk of dislodgement may outweigh the benefit of changing the dressing.
- Replace gauze dressings every 2 days.
- Replace the dressing if it becomes damp, loosened, or visibly soiled or when inspection of the site is necessary.
- Replace sterile dressing on implanted ports when they are accessed with a needle, which may last for a few hours or several days at a time.
- Replace dressings used on tunneled or implanted central venous catheter sites no more than once per week until the insertion site has healed.
- Scrub the injection site of needleless connector attached to the hub (or injection site on an IV administration set) for 15 seconds with alcohol or chlorhexidine gluconate (CHG)/alcohol prior to accessing central line (e.g., withdrawing blood, administering IV medications or fluids).
- Perform daily assessment of line necessity, and promptly remove any intravascular catheter that is no longer essential.
- Replace administration sets used for continuous infusion no more than every 96 hours (including secondary piggyback sets attached to primary continuous set when remains connected). For sets used for intermittent infusion, change every 24 hours.
- Replace tubing used to administer propofol infusions every 6 or 12 hours, depending on its use, per the manufacturer's recommendation.
- Change arterial line transducers/tubing, secondary sets, and add-on devices no more frequently than 96 hours, but at least every 7 days.
- Complete the infusion of lipid-containing solutions (e.g., 3-in-1 solutions) within 24 hours of hanging the solution.
- All parenteral fluids should be compounded in the pharmacy in a laminar airflow workbench using aseptic technique. Medications compounded outside of the laminar airflow workbench are deemed to be critical in need and must be used within one hour of the preparation time. This is defined by USP 797 as immediate use.
- Cleanse the access diaphragm of all vials with 70-percent alcohol before inserting a device into the vial. Cleaning is not limited to multidose vials; it applies to all vials (even single dose vials). The plastic cap covering the top of all vials is not intended to provide a sterile injection surface.
- Do not use guide wire techniques to replace catheters in patients suspected of having catheterrelated infection.

Source: 2011 Guidelines for the Prevention of Intravascular Catheter-Related Infections, AJIC, 2011.

In addition to practices supported by level I evidence, many other prevention practices may be used, especially when those described here are insufficient to reduce CLABSI rates. Additionally, CLABSI prevention practices involve many different types of products, including emerging and novel technology, for which supporting evidence is often minimal but may be in development. Product development for CLABSI prevention is a dynamic field that seeks to offer either new, innovative solutions or refine existing products to enhance patient outcomes. The infection preventionist (IP) must be alert to product updates and the evidence supporting their use.

When considering supplemental prevention recommendations, the IP should:

- Carefully review the existing literature and fully understand any limitations the published studies may have. The sample size, exclusions, methodology, and potential bias are important considerations.
- Understand that before-after studies, commonly seen in the introduction of novel technology, are of interest but offer no predictive basis for broader use. Prediction is limited to the highest levels of scientific evidence.
- Evaluate inclusion of supplemental recommendations with the interdisciplinary team. Obtain consensus before changing institution procedures.
- Perform a cost-benefit analysis based on the institution's value analysis model. Project the cost implications associated with any new recommendation.
- Appreciate that measurement of specific recommendations is challenging; precise measurement of any single recommendation may be limited or beyond the scope of the IP and/or institution's resources. Assessment of CLABSI rate and standardized infection rate (SIR) outcomes may be more practical than measuring specific processes or products.

Source: HICPAC Guidelines, 2011.

Supplemental recommendations are summarized in Table 7.2. While most of these practices are addressed in some way in the *2011 HICPAC Guidelines*, it is important to be aware that new studies and product innovation occur more rapidly than the CDC can include them. In 2014 the Society for Healthcare Epidemiology of America and Infectious Diseases Society of America (SHEA/IDSA) published updated guidelines for CLABSI prevention in acute care hospitals.² These guidelines are highlighted in the table below. It is essential that the IP review the current state of CLABSI prevention practices to remain up to date in a rapidly evolving field.

Table 7.2. CLABSI Prevention Practices Not Supported by Level I Evidence or Currently Unrated Compared to Recent Guidelines by SHEA/IDSA

Prevention Practice	CDC Recommendation	Level of Supporting Evidence	SHEA/IDSA (Evidence Level)*	IP Considerations
CHG dressing types other than impregnated sponge	Unresolved	Unrated	Use CHG containing dressing in patients > 2 months of age (I—special approach).	Evaluate available information and supporting studies when nonsponge dressing products are being considered.
Daily CHG patient bathing	Use 2-percent CHG daily skin wash.	11	Bathe ICU patients > 2 months of age with CHG preparation daily (I).	Methods for the optimum application of CHG during bathing remain under investigation.

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		Level of	SHEA/IDSA	
Prevention	CDC Recommendation	Supporting	(Evidence	IP Considerations
Practice		Evidence	Level)*	
Antibiotic Catheter Lock	Use prophylactic antimicrobial solution in patients with long-term catheters with history of multiple CRBSI despite maximal adhere to aseptic technique.	II	Use antimicrobial locks in patients with long-term hemodialysis catheters, those with limited access and history of CLABSI, those at heightened risk (I— special approach).	Use of antimicrobial locking solutions has no standard protocol and is not approved by the FDA. Impact on antimicrobial resistance is unknown.
Removal of central line when patient is febrile.	Do not remove CVC or PICC on the basis of fever alone. Use clinical judgment regarding the appropriateness of removing the catheter if infection is advanced elsewhere or if an infectious cause of fever is suspected.	II	Not addressed	Decisions should be based on a thorough assessment of the patient rather than limited to device management.
Routine replacement of intermittently used IV administration sets	Unresolved issue	Unrated	Same	Monitor for aseptic management of administration sets that are reused. Verify compliance with institutional policy regarding time frames for use and replacement.
Routine replacement of needles used to access implanted ports; length to time the needle may remain in place	Unresolved issues	Unrated	Not addressed	Monitor for aseptic management of needles used to access implanted ports. Verify compliance with institutional policy regarding time frames for (a) duration of use and (b) replacement.
Replacement of needleless connectors	Change the needleless connector at least as frequently as the administration set. Change no more frequently than every 72 hours or according to manufacturer recommendations for the purpose of reducing infection rates.	11	Not addressed	Determine compliance with institutional policy regarding connector replacement frequency. Identify if institutional policy describes special circumstances for connector replacement (e.g., when blood is withdrawn from the catheter).
Type of needleless connector (note: the term <i>valve</i> is often used interchangeably with <i>connector</i>)	A split septum valve may be preferred over some mechanical valves due to increased risk of infection with the mechanical valves.	11	Not addressed	Analyze the type of connector/valve used by the institution; in some cases, the institution may use more than one type. Understand the infectious risk potential associated with the external and internal design features of connectors currently in use. Identify if connectors in use have a split septum access feature.

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Prevention Practice	CDC Recommendation	Level of Supporting Evidence	SHEA/IDSA (Evidence Level)*	IP Considerations
Securement devices, nonsuture	Use a sutureless securement device to reduce the risk of infection.	Π	Not addressed	Modified dressings or adhesive anchor type products replace the need for sutures but must be carefully applied for maximum benefit. Determine whether this type pf securement product is available at the time of insertion/included in kits or carts.
Antimicrobial silver/platinum coated catheters	No recommendation due to discrepancies in published studies	Unrated	Use antiseptic or antimicrobial impregnated CVCs in adult patients (I—special approach)	Determine which types of antimicrobial catheters are used by the institution and the circumstances under which they are inserted.
Silver coated needleless connectors	No randomized trials have been published.	Unrated	Not addressed	Determine whether antimicrobial connectors are used, and, if so, review supporting studies, design specifications, and outcomes in areas where these devices are used.
Disinfecting caps	No randomized trials have been published.	Unrated	Use an antiseptic containing hub/ connector cap/ port protector to cover connectors (I—special approach)	Determine whether disinfecting caps are used and, if so, whether or not they are intended to remain in place on the connector. Investigate to ensure that that disinfecting caps are used consistently and per manufacturer instructions.
Consolidation of supplies: kits and carts	Not addressed	Not applicable	Use an all-inclusive catheter cart or kit (II)	Facility-specific studies support the use of readily accessible, standard supplies to support optimum infection risk reduction.
*I – High grade				
II– Moderate grade				
III– Low grade	re indicated if institutional CLABI rates h	nigh doctite inchland	ntation of basis turnerstime	natagiac

Source: APIC 2014.

Education, Training, and Staffing

Staff education and competency are also important components of central line-associated bloodstream infection (CLABSI) prevention that are supported by level I evidence. The guidelines identify these recommendations as the following:¹

- Educate healthcare personnel regarding the indications for intravascular catheter use, proper procedures for the insertion and maintenance of intravascular catheters, and appropriate infection control measures to prevent intravascular catheter-related infection. Category IA
- Maintain intravascular catheters. Category IA
- Designate only trained personnel who demonstrate competence for the insertion and maintenance of peripheral and central intravascular catheters. Category IA
- Ensure appropriate nursing staff levels in intensive care units (ICUs). Observational studies suggest that a higher proportion of "pool nurses" or an elevated patient-to-nurse ratio is associated with catheter-related bloodstream infections in ICUs where nurses are managing patients with CVCs. Category I

When attempting to implement evidence-based practices into daily work, it has been stated that there is too much reliance on education and transmission of information as a change strategy; furthermore, lack of time and staff autonomy contribute to the challenges of implementation.^{3,4} In a survey of nurses investigating their "intention" to disinfect needleless connectors, researchers found that there was a strong relationship between *concern* for preventing bacterial migration into bloodstream and propensity to use best practice and suggest that teaching should focus not only on knowledge and skills but also address the affective domain of learning, such as caring and patient advocacy.⁵ The Society for Healthcare Epidemiology of America and Infectious Diseases Society of America (SHEA/IDSA) guidelines present a framework for implementing change. Highlights of the framework include:²

- Engage: Involving frontline and senior leadership in the process and outcome improvement plan; focusing on a safety culture and involving local champions.
- Educate: Address knowledge, critical thinking, behavior and psychomotor skills, and attitudes and beliefs; use multiple teaching methods; evaluate learning.
- Execute: Standardize care processes—implement guidelines, bundles, and protocols, and create redundancy to increase compliance.
- Evaluate: Link process and outcome data to competency assessments; perform surveillance.

Improving Competency: Does Simulation Training Help Reduce CLABSI?

The insertion of a central line poses numerous risks for the patient, especially if the physician is new to practice and/or does not perform this skill regularly. To improve performance and patient outcomes, training programs have been developed that are analogous to live situations and are required before the physician is allowed to actually insert a central venous catheter (CVC). These procedurally structured programs increase skill mastery, enhance confidence, and reduce the risk of complications at the time of insertion.

Although simulation training for central catheter insertion has not been extensively studied, the initial results are promising. Initially studies focused on the reduction of common complications, such as the need for multiple needle passes; pneumothorax; and arterial puncture. Simulation training has also been effective at increasing pre- and post-test scores.⁶ Similar findings have been reported when simulation training was used to train nephrology fellows when placing temporary hemodialysis catheters.⁷ However, a systematic

review of the literature conducted in 2011 reported that simulation-based training was not associated with a significant reduction of CLABSI.⁸

More recent studies appear to contradict the previous analysis. For example, when simulation training for 524 nurses was added to a CVC dressing-change protocol, CLABSI rates decreased from 5.3 to 2.9/1,000 catheter-days. This decrease was statistically significant.⁹ In a study of ICU residents who completed simulation training for catheter insertion, CLABSI rates declined from 3.82/1,000 catheter-days to 1.29/1,000 catheter-days in the 21 months following the training.¹⁰

Simulation training requires skills laboratories or other training centers equipped with the appropriate equipment. While technological advances and the use of computers have advanced many programs beyond the use of mannequins, the costs of adding simulators can be a challenge for academic medical centers. IPs should be aware of the types of training available to the medical staff of their facility and include simulation-based competency developments as one of numerous possible factors affecting changes in CLABSI rates.

The Role of Value Analysis

Today many healthcare institutions have incorporated a system of value analysis in their performance improvement programs. But the traditional definitions and impressions of value analysis methods that were based on a standard inventory and a limited number of vendors may no longer be appropriate to balance acquisition and inventory costs with increasingly complex patient needs and rapidly evolving technology. Fundamentally, value analysis is a process to analyze and find opportunities to improve the value of any product or service where:

Current approaches to value analysis now involve product life cycle costs and clinical benefits to drive desirable patient outcomes.¹¹

The value analysis process is no longer limited to supply chain management and frequently includes IP participation. Value analysis is evolving from a structured, coordinated effort between purchasing and clinical end-users to a much more comprehensive and integrated view of institutional supply and equipment requirements. The role of the IP is to work within the interdisciplinary team to make product decisions based on a holistic, educated understanding of how a product will impact patient care, support a facility's strategic goals, and align with the financial needs of the organization.

Unfortunately, most IPs have little or no training and often minimal experience in the value analysis process. This represents a serious challenge, as product utilization for CLABSI is a major component of the prevention plan; specific products are frequently described in policies, procedures, bundles, and checklists. To begin to build a baseline understanding or to expand upon initial experience, the IP can use the basic model for the steps of a value analysis process shown in Table 7.3.

Table 7.3. Value Analysis for a Prevention Product¹²

- **Understanding Phase** Identify and analyze products currently used and potential alternatives. Thoroughly review supporting literature and scientific studies, as available.
- Investigative Phase Interview current/past users of the proposed product(s). Obtain other empiric and anecdotal information as available.
- **Speculation Phase –** Propose how new product(s) may or may not offer enhanced patient benefits in terms of their costs. Explore justification of new or additional costs within the organization's quality model and improvement targets.
- Analytical Phase Based on the previous investigation, identify two to three alternative products and rank them, including their cost. Identify which is likely to offer the best solution. Present results of analysis to the oversight team and obtain consensus regarding pilot testing.
- **Planning Phase** Conduct a test of the proposed product in a controlled environment. In some circumstances more than one alternate product may be tested in different areas of the facility. Rarely are two or more proposed products tested in the same area simultaneously. A final decision regarding the alternate product(s) is made at the end of this process.
- **Execution Phase –** The new product is introduced in all appropriate areas of the institution, along with staff training, follow-up coaching, and competency verification.
- Follow-Up Phase Following the introduction and an initial period of use, the team checks to verify that the product is performing as expected, staff are adhering to the approved procedure/protocol, and quality measures reflect the anticipated improvement.

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Chapter 8: Preventing CLABSI in the Pediatric Population

Intravenous devices used in clinical treatment modalities are a known risk factor for central line-associated bloodstream infection (CLABSI) in both adult and pediatric populations. Some of these risks may be a result of internal or natural protective responses through which the body acknowledges an artificial device by enveloping the implant with fibrin, blood cells, and plasma beginning shortly after insertion.¹ External risks include such concerns as frequency of healthcare exposure and quality of care received. Data suggest that central lines may be accessed 30 to 50 times during the day.² This finding also correlates to another study that revealed that, during the course of a 12-hour shift, care, and maintenance of central lines comprises five to six hours of their shift.³

Children and premature infants are at risk for CLABSI due to intrinsic risks, such as gestational age, birth weight, and immune system immaturity. Extrinsic risks include invasive and frequent vascular access for infusion and blood sampling, patient positioning and handling, and variation in line technique due to prolonged healthcare exposure.^{4,5,6} Observations have suggested that certain conditions, such as congenital cardiac heart disease, have the potential to contribute to CLABSI development by limiting anatomical sites for vascular placement and altering response to infection. The critical status, length of stay, type of device, and age of these children may lead to multiple transfusions, cardiopulmonary bypass, delayed sternal closure, extracorporeal membrane oxygenation, altered tissue perfusion, and hypoxia, subsequently increasing the associative risks for infection.⁷ Children with hematologic and oncologic disease processes may be at risk for CLABSI as a result of profound neutropenia, prolonged total parenteral nutrition, relatedness of transplant, and impaired mucosal integrity.^{8,9} In response to these observations, the Centers for Disease Control and Prevention (CDC) modified the current CLABSI definitions to include categorization for mucosal barrier injury laboratory confirmed bloodstream infection in eligible patient populations.

Normal skin flora may be altered during hospitalization and awareness may guide the infection preventionist (IP) in designing and implementing prevention strategies. Normal flora is established shortly after birth as a result of feeding and handling the infant. Throughout the continuum of life, especially time spent in receiving healthcare services, normal flora may be transiently influenced.¹⁰ Though CDC guidelines do not recommend limiting catheter placement for pediatrics, in adults it has been identified that normal colonization rates of unwashed skin on neck or chest average between 1,000 to 10,000 colony-forming units per cubic centimeter (CFUs/cm²) compared to an average of 10 CFUs/cm² on the drier, less oily arm.¹¹

In addition to the aforementioned healthcare risks and inherent host factors, the following issues may also contribute to adverse outcomes in the pediatric population.¹²

- Development: Healthcare services, needs, and supplies change as a child matures.
 - In the context of CLABSI prevention, IPs should help reinforce that pediatric care is not homogenous. Securing a central line in a neonate is different than in a child or teenager. With a neonate, one might consider proximity of all medical devices (such as gastrostomy tubes) and securing the line away from opportunities for transient contamination (such as secretions from endotracheal tubes or being tucked into a diaper). Figure 8.1 identifies examples of specific criteria to consider adapting when implementing a checklist approach to catheter maintenance.
 - It is important to secure the line away from opportunities that might allow an infant to manipulate the catheter or place the line in his or her mouth. Especially when feeling better, children with central lines may interact with siblings and pets and may engage in rough play that could potentially dislodge the central line.

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- Dependency: Children are vulnerable and many of their basic and complex healthcare needs are dependent on the care provided by parents and others. They may not be able to advocate for themselves and are reliant on parents or other caregivers to communicate their needs to healthcare providers.
 - While many programs have focused on ensuring that patients are an active participant in care, depending on their age, they may not be able to advocate for themselves (i.e., remind the clinician to clean their hands prior to care). Bathing or oral care, both activities that might reduce the risk of CLABSI, may not be performed by the parents, once again leaving the child dependent upon the performance of others.
- Different epidemiology: Many pediatric episodes of care span beyond the inpatient setting, with more treatment (and often complex treatment such as chemotherapy) being provided in the ambulatory setting.
 - Limited time with the parent caregiver can impact the ability to assess parent knowledge and skill in providing appropriate care at home. In an ambulatory environment, there are limited opportunities to reinforce expected care activities. Each clinical visit may be a family's only window of medical education. The absence of repeated healthcare encounters may result in variation in line care and unclear expectations for parents related to the care of their child's line.
- Site of line insertion: A thorough assessment of the vein(s) using ultrasound is recommended for choosing the appropriate vein, predicting vessel patency, determining the correct catheter size to place, increasing insertion success rates, and decreasing complications.¹³

Considerations for Use of Needleless Connectors in Pediatrics

Connector profile – A larger profile cap may result in unintended issues such as a breakdown in skin integrity due to pressure from the connector or inadvertent dislodging of an intravenous line due to the weight and pull of the larger cap. Also, a larger profile cap may be difficult to secure on a small baby or neonate.

Surface features – Irregular, raised, or concave surfaces may affect the ability to adequately disinfect the surface. Gaps between the surface and the internal parts of the connector may pose difficulty in disinfecting

Flush volume – A smaller flush volume is best, especially for patients that are fluid restricted or are unable to manage a bolus of fluid (e.g., very low birth weight babies, small infants, and neonates). Additionally, pediatric patients may require small volume delivery of medications, thereby making a larger volume connector problematic.

Flushing performance – Connectors that maintain blood after being flushed present a risk for infection. Connectors should be able to be cleared of blood with the minimal amount of fluid.

High-pressure compatibility – On occasion, patients may require administration of fluids at a higher pressure (e.g., rapid infusers in the emergency department).

Source: Pediatrics Vascular Access Network, Best Practice Guidelines in the Care and Maintenance of Pediatric Central Venous Catheters, March 2010.

Date:	Mon		Tues	:	Wed	:	Thu	ʻs:	Fri:		Sat:		Sun:	
Was patient on enteral feeding?	□ < ` ml/k day		□ < ` ml/k day		□ < ml/k day		□ < ml/k day		□ < ` ml/k day		□ < ` ml/k day		□ < ml/k day	
Volume:	□ <u>></u> ml/k day	g/	uay □≥ ml/k day											
In multidisciplinary rounds today, did we	□ Ye		□ Ye		□ Ye		□ Ye		□ Ye		□ Ye		□ Ye	
decide the baby still		C		C		C		C		C		C		С
needs this line?	D Do Kr	on't now	D Do Kr	on't now	D Do Kr	on't now	D Do Kr	on't now	D Do Kr	on't now	D Do Kr	on't now	D Do Kr	on't now
Type of catheter:	U U/	AC E			PICC	🗆 Bi	roviac		Dther					
Shift:	Α	В	Α	В	Α	В	Α	В	Α	В	Α	В	Α	В
Was catheter accessed for any reason during your shift?	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Ye Na
If yes, did staff don gloves before access?	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Ye
If yes, did staff perform hand hygiene before and after gloving?	Yes No	Yes	Yes	Yes No	Yes	Yes No	Yes No	Yes	Yes	Yes No	Yes	Yes No	Yes No	Ye
If yes, was hub/ connector cleaned for at least 15 seconds with alcohol?	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Ye No
If yes, was solution allowed to dry?	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Ye No
Was infusion tubing changed during	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Ye
your shift?				110	1.10		110							1 1 1 1

Figure 8.1. Example of a Central Catheter Maintenance Form Used in Pediatrics

Source: Jo Ellen Harris, RN, CIC, All Children's Hospital, Johns Hopkins Medicine, Saint Petersburg, FL.

CLABSI in the NICU

Preventing and managing CLABSIs in the neonatal intensive care unit (NICU) is challenging because of the need for invasive devices and the extreme vulnerability of this population. The risk of infection due to a central line varies based on a number of factors, including birth weight, gestational age, type of line, and life of the line. A multicenter study showed evidence of increased risk of infection for neonates during the two weeks after PICC insertion with an increase in the risk as the line ages. Milstone et al. demonstrated that peripherally inserted central catheter (PICC) lines in place < 7 days had a lower risk of infection when compared with PICC lines in neonates for 8 to 13 days, 14 to 22 days, and > 23 days.¹³ Development of programs to prevent and manage CLABSI in the neonatal population should be done with consideration of gestational age of the patient. Gestational age may indicate the patient's risk of infection and the skin's ability to act as a barrier against infection.

Skin has multiple functions for a newborn. It acts as a barrier against toxins and microorganisms, is a reservoir for fat storage and insulation, and assists in thermoregulation. Full-term newborns typically have 10 to 20 layers of the stratum corneum. A premature infant may have fewer layers (as few as two to three layers depending on gestational age). As a result, the skin of a premature infant can be quite thin and prone to breakdown. Extremely premature infants are at a higher risk of skin tears, epidermal stripping, and infections due to the inability of the skin to act as a barrier. Choosing an appropriate skin disinfectant is essential both to infection prevention and preservation of the skin integrity. Depending on the gestational age of the infant, he or she may be at risk for burns and/or scalding related to use of certain disinfectants such as chlorhexidine gluconate (CHG), or systemic absorption of other disinfectants, such as providence iodine (PI).¹⁴

Additional studies are needed to determine best practices related to skin disinfectant of the premature infant. To that end, Quach et al. published findings from a study conducted at Montreal Children's Hospital, citing a decrease in CLABSI utilizing CHG on select neonates without adverse events.¹⁵ Additionally, the Association of Women's Health Obstetric and Neonatal Nurses (AWHONN) provides a comprehensive guide for care and disinfection of the skin of premature infants. AWHONN recommends use of CHG or PI based on institutional preference. CHG is to be applied for 30 seconds or with two consecutive swipes. PI should be applied and allowed to completely dry. AWHONN also recommends that CHG or PI be removed with sterile water or saline after use for invasive procedures to prevent systemic absorption of either product. Although some institutions have implemented use of CHG and PI only in certain age groups (i.e., CHG in infants < 26 weeks gestational age or greater than 2 weeks of age), there is no national guideline to clearly identify at what age the products are most efficacious and safe to use. Studies have indicated that the stratum corneum of the premature infant matures in the first 14 days of life except in extremely low birth weight infants. AWHONN suggests the following considerations for determining appropriate skin disinfection of the premature infant:¹⁶

- Product efficacy in the neonatal population
- · Potential for system toxicity via skin absorption
- Potential for skin irritation, chemical burns, or erosive contact dermatitis related to product use

Institutions should review their historical CLABSI rate compared to the National Healthcare Safety Network (NHSN) mean, skin integrity issues in the NICU population, and average age of the premature infant in their units when determining what products to use for skin disinfection. A short Plan-Do-Study-Act cycle of a few patients will enable institutions to identify early problems related to use of one product over another. An example of the inclusion of age-specific consideration within a CHG skin antisepsis policy is shown in Figure 8.2.

8	
Categories:	Infection Control
Section:	Procedures
Applicable To:	Healthcare Providers
Specialized Education Required:	No
Physician Order Required:	No

Figure 8.2. Sample Policy: Use of CHG/Isopropyl Alcohol for Skin Antisepsis

I. Policy Statements:

A. 2% chlorhexidine gluconate/70% isopropyl alcohol (CHG/IPA) skin prep products will be used on patients during:

- 1. Central line, umbilical line, arterial line and midline insertions at the bedside.
- 2. Central line, umbilical line, arterial line and midline dressing changes.
- 3. Peripheral blood culture draws.
- B. CHG/IPA must be rinsed with saline after 30 seconds on patients who are less than 28 weeks gestational/corrected age.
- C. CHG/IPA skin prep must be allowed to dry completely prior to applying sterile drapes or occlusive dressing.

II. Definitions:

- A. Corrected Age: The age expressed in weeks and is based on the gestational age the child would be if the pregnancy had actually gone to term.
- B. Gestational Age: The estimated age of a neonate expressed in weeks, calculated from the first day of the last normal menstrual period.
- C. Neonate: Patient less than 28 days old.

III. Guidelines:

- A. CHG/IPA skin prep solutions have been documented to cause skin burns in neonatal patients.
- B. It is important to allow CHG/IPA skin preps to dry completely prior to covering prepped area with towels or dressing to prevent chemical burns.
- C. CHG skin prep solutions *should not be* used for:
 - 1. Ear canal, may cause deafness
 - 2. The eyes, may cause blindness
 - 3. Lumbar puncture
 - 4. Shunt taps
 - 5. In contact with the meninges
 - 6. Urinary catheterizations
 - 7. Open skin wounds
 - 8. As a general skin cleanser
 - 9. In patients who are allergic to CHG
- IV. Procedures:
 - A. Apply CHG/IPA skin prep per manufacturer's directions, using a back and forth scrubbing motion and friction to allow the CHG/IPA to penetrate the layers of skin.
 - If there is a concern for damaging or irritating the skin with friction and scrubbing, use a softer application method.
 - B. After procedure (line insertion or dressing change) has been performed, wipe off any excessive solution CHG/IPA that is on skin around dressing.
 - C. On patients less than 28 weeks gestational/corrected age, rinse with sterile saline after 30 seconds of CHG/IPA application.

V. Safety:

- A. Ensure that solution does not pool under patient during procedures.
- B. Do not use CHG/IPA with iodine povidone: may cause chemical burns.
- C. CHG/IPA is highly flammable.
- VI. Education: None
- VII. Documentation: Document in the patient's medical record the skin condition before and after line insertion and dressing changes.

Source: Jo Ellen Harris, RN, CIC, All Children's Hospital, Johns Hopkins Medicine, Saint Petersburg, FL.

Blood Cultures

Most coagulase negative staph positive blood cultures are considered contaminants in adult populations. In pediatrics, especially the neonatal population, these organisms can represent true infection. National guidelines recommend multiple paired quantitative peripheral blood cultures to diagnoses bacteremia. The volume of blood obtained is also important with most guidelines recommending 5 to 10 mls of blood per culture. These cultures should be obtained prior to the initiation of antibiotics.¹⁷ In the pediatric population, these guidelines are not always practical or practiced. There are multiple challenges with obtaining blood cultures in pediatrics: amount of blood obtained for the culture specimen, number of blood cultures obtained, blood culture source, techniques used while obtaining cultures, and the skill level of the clinician.

Practice varies from single blood cultures, drawn either from an indwelling catheter to venous stick or multiple cultures from multiple indwelling catheters. When only a single culture is performed, it is difficult to determine contamination and real infection. Practitioners will often initiate and treat with empiric antibiotics based on a single, positive blood culture.

Cultures obtained from either arterial lines or peripheral IVs should be discouraged due to the higher contamination rates. One study demonstrated a reduction from 6.7 percent contamination rate via PIV to a 2.3 percent contamination rate when practice was changed for blood cultures to be obtained by a separate venipuncture.^{18,19,20}

Blood cultures obtained from indwelling catheters might represent false positive cultures leading to unnecessary treatment. These false positive cultures can occur due to either the injection cap being colonized or the central line being colonized.^{21,22} Every effort should be made to draw peripheral cultures. If cultures are obtained from an indwelling catheter, the injection cap should either be removed or replaced. The sample should be drawn either straight from the hub of the catheter or via the new injection cap. It is important to encourage paired cultures for the initial sepsis work up, either a single peripheral culture paired with a single blood culture obtained via the indwelling central catheter or two cultures obtained via the central catheter drawn separately.^{23,24}

Blood cultures obtained by venous punctures in the pediatric population require skill. Both phlebotomy and nursing staff should be properly trained and demonstrate competency in maintaining aseptic technique while obtain blood cultures. Multiple studies demonstrate education and hands-on skills assessment have reduced contamination rate.^{25,26,27}

Proper skin preparation has been demonstrated to reduce contamination rates. Use of a CHG-alcohol product for skin antisepsis has demonstrated lower contamination rates than aqueous povidone-iodine.^{28,29} In neonatal patients, this product can be used safely with caution.

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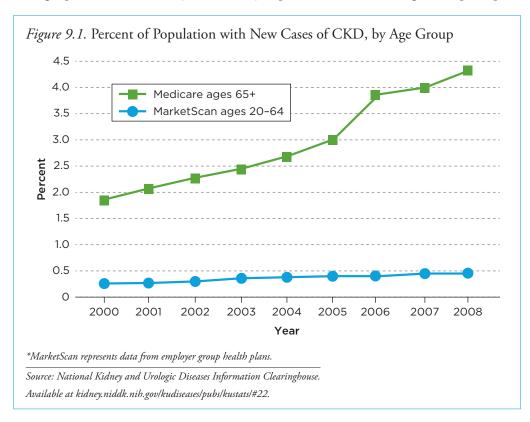
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Chapter 9: CLABSI Prevention in the Setting of Renal Disease

End-stage renal disease (ESRD) and chronic kidney disease (CKD) represent a significant health burden. At the end of 2009, more than 871,000 people in the United States were being treated for ESRD. Between 1980 and 2009, the prevalence rate for ESRD increased nearly 600 percent, from 290 to 1,738 cases per million. At the end of 2009, 398,861 ESRD patients were being treated with some form of dialysis; 172,553 ESRD patients had a working transplanted kidney. The prevalence of CKD is growing most rapidly in those age 60 and older (Figure 9.1).¹

More than 10 times as many ESRD patients receive hemodialysis (HD) treatments at a clinic as those who do peritoneal dialysis (PD) and home HD combined. Although the total number of ESRD patient deaths has continued to rise, the death *rate* has *declined* in recent years after peaking in 2001. Meanwhile ESRD annual expenditures per patient, including transplant costs, have increased slightly in recent years. Annual costs for treating a patient on hemodialysis are nearly triple the costs for treating a transplant patient.¹



Bloodstream infections are the leading cause of death among hemodialysis patients, second only to vascular disease, and have been identified as a significant safety threat among these high-risk patients. For example, in 2008 the Centers for Disease Control and Prevention (CDC) estimated that 37,000 bloodstream infections (BSIs) occurred among hemodialysis patients with central lines.² One in four of these infected patients may have died as a result of the infection. Since 1993, hospitalization rates among hemodialysis patients have increased 47 percent for bloodstream infection and 87 percent for vascular access infection.

Over the past 35 years, Centers for Medicare and Medicaid Services (CMS), the major payer for ESRD patients, has instituted a series of quality initiatives to improve dialysis care. The ESRD Quality Incentive Program (QIP) builds upon the CMS commitment to improve quality by allowing CMS for the first time to tie ESRD facility payments to their performance on measures of quality. In addition to the previous two clinical quality measures addressing anemia management and adequacy of dialysis, the type of vascular access is now included. This quality measure has been added to encourage the use of arteriovenous fistulae and discourage the use of catheters because of the high rate of vascular access infections and complications associated with catheter use.³

CMS published a final rule encouraging all ESRD facilities to track quality indicators related to bloodstream infection through the National Healthcare Safety Network (NHSN) by following the Dialysis Event Surveillance Protocol. Facilities must comply with the rule to receive full payment through the CMS Prospective Payment System ESRD QIP. Three types of dialysis events are reported by users in NHSN Module: IV—antimicrobial start; positive blood culture; and pus, redness, or increased swelling at the vascular access site. The following measures are also generated from the reported data: BSI, local access site infection, access-related bloodstream infection, and vascular access infection. For more information about the NHSN Dialysis Event Module, see http://www.cdc.gov/nhsn/dialysis/dialysis-event.html. Frequently asked questions are summarized in Table 9.1.

Table 9.1. CDC FAQS about Dialysis Event Reporting

Can my dialysis clinic/unit/facility use NHSN for dialysis event surveillance?

The surveillance population for this module is "chronic hemodialysis outpatients" (i.e., patients who receive maintenance hemodialysis). If you have a hospital-based unit that cares for inpatients in addition to outpatients, you can participate as long as you have the ability to separate out your inpatients from your outpatients for the purpose of reporting (for both events/numerator and census/ denominator data).

Does the dialysis event surveillance population include pediatric patients?

Yes, include all hemodialysis outpatients in dialysis event surveillance, including pediatric patients. Date of birth is a required event field, so age is captured for each dialysis event.

If a dialysis patient has a bloodstream infection and then is admitted to an inpatient facility for treatment, will the bloodstream infection be "double-counted?"

If a dialysis outpatient met the criteria for an NHSN Dialysis Event and then was admitted, the inpatient facility would not report the BSI because per the NHSN central line-associated bloodstream infection (CLABSI) module inpatient facilities are instructed to exclude CLABSIs that are present or incubating at the time of admission.

A patient's central venous catheter is not used for hemodialysis; do I still include it in dialysis event reporting?

Yes, all central venous catheters are included for the purposes of dialysis event reporting, regardless of whether they are currently in use for hemodialysis or any other treatment.

The vascular access site has some suspicious redness, but the patient does not receive antibiotic treatment, is the redness reportable?

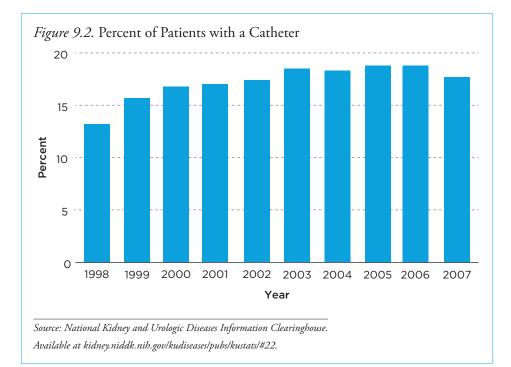
If you would describe the redness as "suspicious" for infection or if it is greater than would be expected, report it regardless of whether or not the patient receives treatment.

Source: FAQs about Dialysis Event Reporting. Available at www.cdc.gov/nhsn/dialysis/faq/FAQ-dialysis-event-reporting.html.

Types of Catheters

Central catheters may be required for immediate initiation of hemodialysis or if treatment is expected to last for less than one week. A nontunneled catheter may be used. If longer treatment is needed and before an arteriovenous fistula or graft can be surgically created, a tunneled catheter is usually preferred. Large bore, double lumen catheters are commonly used for temporary dialysis. Once placed, catheters should be manipulated as little as possible; for example, hemodialysis catheters should be used only for hemodialysis.⁴

A patient receiving dialysis may also need other vascular access. A central line may be used in addition to the dialysis catheter; these are not used interchangeably. Generally speaking, the term catheter, when applied to patients with kidney disease, refers to hemodialysis catheters rather than the more common central line. Although all treatment guidelines strongly recommend vein preservation via the use of a fistula or graft, hemodialysis catheter usage remains high, especially during the early phases of treatment. See Figure 9.2.



Subclavian vein catheterization is associated with central venous stenosis. Significant subclavian vein stenosis generally will preclude the use of the entire ipsilateral arm for vascular access. Thus, subclavian vein catheterization should be avoided for temporary access in patients with kidney disease. The incidence of central vein stenosis and occlusion after upper-extremity placement of peripherally inserted central catheters (PICCs) and venous ports was seven percent in one retrospective study of 150 patients. PICCs also are associated with a high incidence of upper-extremity thrombosis. The incidence of upper-extremity venous thrombosis varies between 11 percent and 85 percent, which leads to loss of potential upper-extremity fistulae. Because of the substantial risk for loss of useable upper-extremity veins and central venous stenosis with PICCs, the workgroup recommends strongly that PICCs not be used in patients with CKD.⁵

Figure 9.3. Sample Policy for Appropriate Vascular Access Device Selection for Renal Patients

Purpose

To provide best practice guidance for early assessment and selection of an appropriate vascular access device for renal patients in compliance with the Guidelines for Venous Access in Patients with Chronic Kidney Disease authored and/or supported by the American Society of Diagnostic and Interventional Nephrology (ASDIN) Diseases, National Kidney Foundation—Kidney Disease Outcomes Quality Initiative NKF- KDOQI, The Association for Vascular Access (AVA), Infusion Nurses Society (INS) and the American Nephrology Nurses Association (ANNA).

Policy Statements

- Renal patients, patients with end-stage renal disease (ESRD), or patients with chronic kidney disease (CKD) will be assessed upon admission or consultation with the vascular access specialist team (VAST) for selection of the best vascular access site, to provide preservation of the vasculature of the bilateral upper extremities and subclavian veins for possible future dialysis fistula needs.
- 2. Obtain approval from the nephrologists for any peripherally inserted central catheter (PICC) ordered on patients who are being followed by a nephrology physician team.
- 3. The internal jugular vein will be used for central vascular access on all renal patients, unless contraindicated or approval for other central venous catheter (CVC) insertion site is obtained from the nephrologist or primary team physician.
- 4. Peripheral intravenous vascular (PIV) access will be limited on renal patients to less than 48 hours unless central venous access is contraindicated.
- 5. Lab draws should be limited to the dorsum of the hand regardless of dominance.

Guidelines for Venous Access in Patients with CKD

- A. Identify CKD patients who may need hemodialysis treatment in the future, particularly patients with CKD Stages 3, 4 or 5. This also includes stage 5 CKD patients currently receiving hemodialysis or peritoneal dialysis and/or patients with a functional kidney transplant.
- B. Venous Access for Stages 3-5 CKD Patients
 - 1. The dorsal veins of the hand are the preferred location for phlebotomy and peripheral venous access.
 - 2. The internal jugular veins are the preferred location for central venous access.
 - 3. The external jugular veins are an acceptable alternative for venous access.
 - 4. The subclavian veins should not be used for central venous access.
 - 5. Placement of a PICC should be avoided.

Source: Alice Atcher, BSN, RN, CCRN, CRNI, Louisville, KY.

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Chapter 10: Preventing Infection during Long-Term Device Use

Peripherally Inserted Central Catheters

Peripherally inserted central catheters (PICCs) are one form of a central vascular access device (CVAD). As described in Chapter 1, all CVADs have their terminal (distal) tip positioned in the distal superior vena cava (SVC), proximal right atrium, or distal inferior vena cava. If the tip of the catheter is displaced to a position other than one of these, it is considered a peripheral venous catheter, and the potential for some complications, such as catheter-related thrombosis, is significantly increased. The Infusion Nurses Society recommends CVADs "to administer short- or long-term continuous or intermittent infusion solutions, such as antineoplastic medications, vesicants or known irritants, parenteral nutrition, a variety of antibiotics, and any medications with a pH of < 5 or > 9 and osmolarity of > 600mOsm/L."¹ To that end, vesicant drugs are agents that can cause local tissue to necrose in an extravasation while irritant drugs cause inflammatory reactions without persistent damage to the tissue.¹

A patient's history of diseases and conditions may be an influential factor for facilitating proper venous access and PICCs are an alternative access device for extended therapy for inpatient and outpatient settings. CVADs come in two categories, as defined by the Food and Drug Administration (FDA)—short-term (up to 29 days) and long-term (indefinite).² PICCs are classified by the FDA as long-term devices and can be left for an extended length of time, as long as there are no unmanageable complications. PICCs can be inserted at the bedside or outpatient setting utilizing sterile technique or in an interventional radiology suite.

Selection of the PICC or other form of vascular access should include a thorough assessment utilizing specific indications and protocols. Indications include prescribed therapy, length of treatment, duration, integrity of the patient's vasculature, and the ability to maintain the access. Short peripheral catheters are usually inserted for treatments expected to last one week or less, and when the infusate is appropriate for peripheral administration, whereby the PICC has an indefinite dwell time.

Assessment for PICC Placement

Assessment of the patient for PICC placement should include a thorough review of the clinical condition of the patient. Core competencies based on the infusion nursing core curriculum include assessment, insertion, and maintenance of a PICC and knowledge of the following:³

- Technology and clinical application
- Fluid and electrolyte balance
- Pharmacology
- Infection prevention
- Neonate and pediatric patients

- Transfusion therapy
- Antineoplastic and biologic therapy
- Parenteral nutrition
- Quality improvement

In the adult population the assessment includes impaired renal function and vein preservation. The form shown in Figure 10.1 can be used to assist the vascular access specialist in his or her assessment.

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Service							
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Current IV Medicati	ons						
*Type of Vascular A	ccess De	evice (VAD) r	eques	sted: PICC	C Midline_		
Line Necessity:	<i>t</i> .						
Physical Assessment Signs and/or sympton		rombus/NVT					
Signs and/or symptol	ns of th		•				
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EXISTING LINES				VAD			
				REMOV	AL/CULTURE		
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WBC							
PLATELETS							
PT/PTT							
INR							
CREATNINE/BUN							
GFR/STAGE							
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Source: Sample form provided by Linda Goss, MSN, APRN, NP-C, CIC, COHN-S, Louisville, KY, and Alice Archer, BSN, RN, CCRN, CRNI, Louisville, KY.

Subcutaneously Tunneled CVADs

The subcutaneously tunneled catheter is considered a long-term catheter for patients who require lifelong or long-term infusion therapy. The type of therapy may include parenteral nutrition (PN) or chemotherapy. Tunneled catheters may be used for procedures related to stem cell transplant or for hemodialysis.

The catheter is placed or "tunneled" in the subcutaneous tissue between an "entrance" and an "exit" site. The exit site is where the catheter extrudes, usually in the lower area of the chest. The entrance site is where the catheter enters the venous circulation, generally in the area of the clavicle and most often via the subclavian or internal jugular vein. Outwardly this will appear as an incision. Of note, the Centers for Disease Control and Prevention (CDC) states that there is no recommendation for a preferred site for a tunneled catheter.⁴ A synthetic "cuff" attached to the catheter lies in the subcutaneous tissue along the tunnel tract and, over time, tissue adheres to the cuff to stabilize the catheter and hold it in place. The cuff becomes embedded with fibroblasts within one week to 10 days after insertion, which reduces the chances for accidental removal and minimizes the risk of ascending bacterial infection. Scar tissue typically grows onto the cuff, assisting in prevention of migration of microorganisms. The tunneling/cuff also serves to seal the path from the exit site to the vein, which reduces the risk of bloodstream infection.⁵ After the site is well healed, the tunneled catheter is difficult to dislodge and may be managed without a dressing.⁶

Care of the tunneled CVAD includes general post-insertion care guidelines as discussed in Chapter 6, including:

- Hand hygiene prior to all infusion-related procedures
- Aseptic technique with all catheter access procedures
- Proper changing of administration sets
- · Changing needleless connectors according to manufacturer guidelines
- Attention to disinfection of needleless connectors prior to access

In relation to site management, the 2011 CDC *Guidelines for the Prevention of Intravascular Catheter-related Infections* make the following recommendations:

- Replace transparent dressings used on tunneled (or implanted) CVAD sites no more than once per week (unless the dressing is soiled or loose), until the insertion site is healed.
- No recommendations can be made regarding the necessity for any dressing on well-healed exit sites of long-term cuffed and tunneled CVADs.

Implanted Infusion Ports

The implanted port is a long-term CVAD that has been used for vascular access for many years. Implanted ports were originally targeted for use in oncology patients who required frequent intermittent vascular access for chemotherapy administration. This is still a common indication for implanted port use. Other patient populations include those with long-term infusion needs that may be intermittent. Patients with hemophilia, cystic fibrosis, and sickle cell disease, and patients who desire a completely implanted device despite daily use, are candidates for an implanted port. When a port is not accessed for use, the only external evidence is a small protrusion in the skin.

The implanted port is surgically placed, typically in an operating room or an interventional radiology suite. The center of the port is covered with a dense silicone septum which is accessed using a non-coring needle. Manufacturer directions will provide specific information about port access, particularly the number of times the septum can be punctured. The port is a CVAD with the tip location in the SVC.

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A wide variety of designs are now available, including ports used for power injection.⁷ An implanted port should be accessed at least monthly to assess and ensure catheter patency using either a heparin or saline flush. The type of flush depends on the port type and manufacturer's directions for use. Infection risk-reduction strategies include aseptic technique required during port access, including the steps of hand hygiene; use of a mask and sterile gloves; and skin antisepsis in preparation for access through the skin using a non-coring needle. Needles used that are not non-coring may damage the septum, causing leaking which could in turn provide a possible reservoir for pathogens. The non-coring needle is removed and replaced, which is commonly done every seven days if continued access is required.

General post-insertion care guidelines as discussed in Chapter 6 include:

- · Hand hygiene prior to all infusion-related procedures
- Aseptic technique with all catheter access procedures
- Proper changing of administration sets
- Changing needleless connectors according to manufacturer guidelines
- Attention to disinfection of needleless connectors prior to access
- Maintaining a sterile dressing over the needle-insertion site
- Maintenance of a port or other CVAD requires strict adherence to infection prevention practices

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Appendix: Major Interdisciplinary Resources for CLABSI Prevention

The following table identifies major interdisciplinary resources; it is not a comprehensive list. Infection preventionists may obtain additional resource information from local or regional CLABSI collaboratives, state and local health departments, discipline-specific professional societies (e.g., Infusion Nurses Society, American Association of Nurse Anesthetists, and quality improvement associations, including QIOS). Product manufacturers often serve as an additional source of CLABSI-related information and staff training materials.

Title	Developed By	Description	See Also
Guidelines for the Prevention of Intravascular Catheter- Related Infections, 2011 and many others	CDC	In addition to the <i>HICPAC Guidelines,</i> the CDC provides numerous other easily accessible resources for both patients and professionals, including toolkits and forms.	CDC also supports access to the NHSN surveillance and reporting system. Translations of some patient materials are available; check the CDC for topics and availability.
Tools for Reducing CLABSI	AHRQ	The AHRQ offers multiple web-based tools, including forms for CLABSI prevention.	AHRQ, which funded the On the CUSP Stop BSI program, provides links to CUSP information and resources.
Implementation Guide for CLABSI Prevention	APIC	Practical resources targeting novice and early proficient IPs; open-access publication from the APIC website.	APIC Text, 4th edition (2014) provides detailed discussion of vascular access devices, biofilm and related topics.
			The APIC webinar archive offers on- demand CLABSI-related topics (free to APIC members).
			Original research is published regularly in APIC's scientific journal, the American Journal of Infection Control (AJIC).

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Title	Developed By	Description	See Also
IDSA-SHEA Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals	SHEA	The Compendium, sponsored by SHEA and IDSA, includes partner associations including APIC. It can be accessed at the SHEA website. It is currently undergoing a comprehensive update.	Chapter 16 in the SHEA text <i>Practical Healthcare</i> <i>Epidemiology</i> , 3rd ed., 2010 discusses CLABSI prevention. Original research is published regularly in SHEA's scientific journal, <i>Infection Control and</i> <i>Hospital Epidemiology</i> (<i>ICHE</i>).
Clinical Practice Guidelines for the Diagnosis and Management of Intravascular Catheter- Related Infection	IDSA	Comprehensive clinical guideline includes numerous algorithms and tables. (Note: IDSA is also a major sponsor of the IDSA/SHEA Compendium described above.)	Original research is published regularly in IDSA's scientific journal <i>Clinical Infectious</i> <i>Disease</i> (CID).
On the CUSP: Stop BSI	On The Cusp: Stop HAI Project	Web-based resources are developed around the CUSP model and include toolkits, educational materials, and success stories (includes NICU).	CUSP materials, including interim progress reports, are available from AHRQ.
How-to Guide: Prevent Central Line-Associated Bloodstream Infections	IHI	The guide describes how to implement the IHI CLABSI bundle and recommends measures to gauge improvement. A pedantic supplement is available.	CLABSI bundle materials and the IHI Trigger Tool are available at separate areas of the IHI website.
CLABSI Toolkit and Monograph—Preventing Central Line-Associated Bloodstream Infections: Useful Tools, An International Perspective	The Joint Commission (TJC), Joint Commission Resources (JCR), and Joint Commission International (JCI)	The web-based toolkit addresses both U.S. domestic and international issues pertaining to CLABSI prevention.	CLABSI prevention is also addressed in TJC's National Patient Safety Goals, accessible at the TJC website.
SafePatientProject.org	Consumers Union	Consumer-focused website addresses HAIs, with emphasis on MRSA and <i>C. difficile.</i>	Topics covered are expanding and since 2012, have begun to periodically examine CLABSI rates in hospitals.

Source: APIC 2014.



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