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Device Swab

CLINICAL COMPENDIUM

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Background and Overview

Central Line Associated Bloodstream Infections (CLABSI's) are a leading cause of death and Healthcare Associated Infections. CLABSI's result in thousands of death each year and billions of dollars in added costs to the U.S. Healthcare System. These infections are widely preventable through the implementation and adherence to evidence-based practices. The US Centers for Disease Control and Prevention (CDC) has estimated that there are approximately 72,000 Primary Bloodstream Infections in hospitalized patients in the US annually.

INTRODUCTION

According to the US Centers for Disease Control and Prevention (CDC), hand hygiene remains the single most important intervention in the quest for "Targeting Zero Healthcare Infections" (HAIs); however experts recognize the growing role that the patient's own skin plays in the potential development of a Healthcare Associated Infections[1].

In healthcare settings, the majority of HAIs occur as a result of 1) the contaminated hands of the healthcare provider or patient, 2) the contaminated environmental surfaces that are common in a variety of healthcare settings (both inpatient and outpatient), or 3) the contaminated skin of the patient themselves.

Bloodstream Infections (BSIs) are a major cause of healthcare-associated mortality and morbidity. Recent statistics from the US CDC have demonstrated an up to 35% attributable mortality, and an excess length of stay of 24 days. Annually, there are more than 250,000 CLABSIs reported in the United States[2].

Likewise the terms used to describe intravascular catheter-related infections can also be confusing because catheter-related bloodstream infection (CRBSI) and central line–associated bloodstream infection (CLABSI) are often used interchangeably even though the meanings differ.

CRBSI is a clinical definition, used when diagnosing and treating patients, that requires specific laboratory testing that more thoroughly identifies the catheter as the source of the BSI. It is not typically used for surveillance purposes. It is often problematic to precisely establish if a BSI is a CRBSI due to the clinical needs of the patient (the catheter is not always pulled), limited availability of microbiologic methods (many labs do not use quantitative blood cultures or differential time to positivity), and procedural compliance by direct care personnel (labeling must be accurate). Simpler definitions are often used for surveillance purposes. For example, CLABSI is a term used by CDC's National Healthcare Safety Network (NHSN). 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, since some BSIs are secondary to sources other than the central line (e.g., pancreatitis, mucositis) that may not be easily recognized, the CLABSI surveillance definition may overestimate the true incidence of CRBSI.

EPIDEMIOLOGY AND MICROBIOLOGY OF CENTRAL LINE-ASSOCIATED BLOODSTREAM INFECTIONS

National estimates of CLABSI rates are available through CDC's NHSN, a surveillance system for healthcare-associated infections, and are available on the CDC website. A recent report highlights data from 1,545 hospitals in 48 States and the District of Columbia that monitor infections in one or more ICUs and/or non-ICUs (e.g., patient care areas, wards)[3]. Because BSI rates are influenced by patient-related factors, such as severity of illness and type of illness (e.g., third-degree burns versus post-cardiac surgery), by catheter-related factors, (such as the condition under which the catheter was placed and catheter type), and by institutional factors (e.g., bed-size, academic affiliation), these aggregate, risk-adjusted rates can be used as benchmarks against which hospitals can make intra-and inter-facility comparisons.

REFERENCES:

1. Centers for Disease Control and Prevention, www.cdc.gov/hai, 2012.
2. National Healthcare Safety Network, Centers for Disease Control and Prevention, 2012.
3. Edwards, JR, Peterson KD, Mu Y, et al. National Healthcare Safety Network report: data summary for 2006 through 2008, issued December 2009. Am J Infection Control 2009; 37: 783-805.

The most commonly reported causative pathogens remain coagulase-negative staphylococci, *Staphylococcus aureus*, enterococci, and *Candida* spp. Gram negative bacilli accounted for 19% and 21% of CLABSIs reported to CDC and the Surveillance and Control of Pathogens of Epidemiological Importance (SCOPE) database, respectively[4].

For all common pathogens causing CLABSIs, antimicrobial resistance is a problem, particularly in ICUs. Although Methicillin-resistant *Staphylococcus aureus* (MRSA) now accounts for more than 50% of all *Staphylococcus aureus* isolates obtained in ICUs, the incidence of MRSA CLABSIs has decreased in recent years, perhaps as a result of prevention efforts. For gram negative rods, antimicrobial resistance to third generation cephalosporins among *Klebsiella pneumoniae* and *Escherichia coli* has increased significantly as has imipenem and ceftazidine resistance among *Pseudomonas aeruginosa*. *Candida* spp. are increasingly noted to be fluconazole resistant. As you can see from the latest estimates from the CDC, many of these organisms have the potential to develop resistance mechanisms, which can dramatically increase the patient mortality and morbidity.

PATHOGENESIS OF CENTRAL LINE-ASSOCIATED BLOODSTREAM INFECTIONS

Central Line-Associated Bloodstream Infections can result from a variety of sources, both intrinsic and extrinsic. Potential sources of transmission include[5].

1) Contaminated Hands of the Healthcare Provider and/or Patient

2) Contamination at the Insertion Site (Lack of Proper Skin Antisepsis)

3) Extraluminal Contamination

4) Intraluminal Contamination

5) Hub Contamination

6) Contaminated Infusate

7) Hematogenous Spread

EVIDENCE-BASED PRACTICES TO PREVENTION OF CLABSI

The CDC guidelines were developed to provide evidence-based practices for preventing CLABSI, and have five major areas of emphasis. First, those with responsibility for inserting and/or maintaining catheters must receive ongoing formal education and training on proper technique. Next, clinicians should utilize maximal sterile barrier precautions during the insertion process of the central venous catheter. Third, prior to inserting the device, clinicians should perform thorough skin antisepsis using a greater than 0.5% Chlorhexidine preparation with alcohol. Fourth, clinicians should avoid the routine replacement of central venous catheters as a strategy to prevent infection. Lastly, healthcare providers should consider the use of a Chlorhexidine impregnated sponge if the rate of infection is not decreasing despite strict adherence to basic infection prevention techniques as identified in the evidence-based guidelines[6].

REFERENCES:

4. Gaynes R, Edwards JR. Overview of Nosocomial Infections caused by gram-negative bacilli. Clin Infec Dis 2005: 41: 848-54.

5. Raad I, Hanna HA, Awad A, et al. Optimal frequency of changing intravenous administration sets: it is safe to prolong use beyond 72 hours. Infect Control Hosp Epidemiol 2001; 22: 136-9.

6. Guidelines for the Prevention of Intravascular Catheter-Related Infections, Centers for Disease Control and Prevention, 2011.

CHECKLIST FOR THE PREVENTION OF CENTRAL LINE ASSOCIATED BLOODSTREAM INFECTIONS

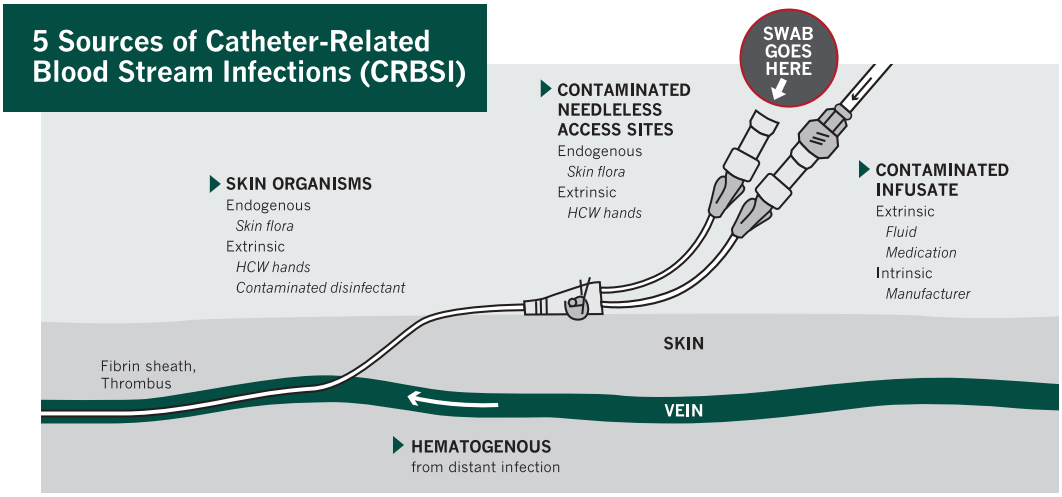
The following checklist is based on the 2011 CDC Guideline for the Prevention of Intravascular Catheter-Associated Bloodstream Infections:

- Promptly remove unnecessary central lines. Perform daily audits to assess whether each central line is still needed
- Follow proper insertion practices:
    - o Perform hand hygiene before insertion of the line
    - o Adhere to aseptic technique
    - o Use maximal sterile barrier precautions (i.e. mask, cap, gown, sterile gloves, and sterile full-body drape)
    - o Perform skin antisepsis with >0.5 Chlorhexidine with isopropyl alcohol
    - o Choose the best site to minimize infections and mechanical complications (Avoid the femoral site in adult patients)
    - o Cover the site with sterile gauze or sterile, transparent, semipermeable dressings
- Handle and maintain central lines appropriately:
    - o Comply with hand hygiene requirements
    - o Scrub the access port or hub immediately prior to use with an appropriate antiseptic (e.g. Chlorhexidine, povidone iodine, an iodophor, or 70% alcohol)
    - o Access catheters only with sterile devices
    - o Replace dressings that are wet, soiled, or dislodged
    - o Perform dressing changes under aseptic technique using clean or sterile gloves
- Empower staff to stop non-emergent insertion if proper procedures are not followed
- Bundle supplies to ensure items are readily available for us
- Provide the checklist above to clinicians to ensure all insertion practices are followed
- Ensure efficient access to hand hygiene

PATHOGENESIS OF CATHETER-RELATED BLOODSTREAM INFECTIONS (CRBSI'S):

There are several potential routes of infection that can contribute to the development of a Catheter-Related Bloodstream Infection:

- Contamination of the device prior to insertion, which is usually extrinsic and rarely results of manufacturing.
- Contamination from the patient's endogenous flora (own skin organisms), extrinsic sources (i.e. healthcare worker's hands or contaminated antiseptic), or from an invading wound.
- Contamination of the Catheter Hub from extrinsic sources (e.g. healthcare worker) or endogenous flora (from the skin of the patient).
- Contaminated Infusate from a fluid or medication, extrinsic sources such as a healthcare worker's hands, or manufacturing process lapses
- Hematogenous from a distant infection within the patient



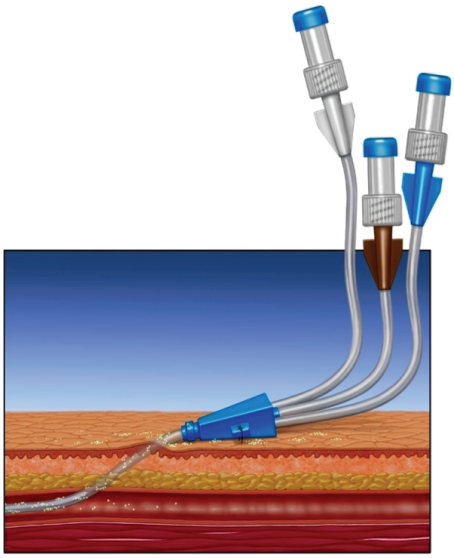
Source: Medscape, 2008.

INTRALUMINAL AND EXTRALUMINAL CONTAMINATION SOURCES:

Vascular access is the extension of the vascular system outside the body by means of a catheter. The catheter must have a closed proximal end. The intraluminal pathway includes the connector, the internal catheter wall and lumen. The extraluminal pathway includes the insertion site, outside wall of the catheter and the track the catheter follows through the skin into the vein. In order to achieve zero CR-BSI rates the bundle must focus on not only assiduously followed aseptic insertion, but also extraluminal and intraluminal care and maintenance actions that prevent active and passive bacterial migration and minimize fibrin adhesion.

According to D. Maki, it was estimated that there were three common routes to CR-BSI[7]:

- Intraluminal:
  - o Needleless Access Site Contamination (12%)
  - o Infusate Contamination (<1%)
- Extraluminal:
  - o Skin Contamination (60%) and Unknown (28%)



REFERENCES:

7. Maki D. , et al (2004). Intensive Care Med, 30:62 Garland JS et al. (2008). ICHE, 29:243

In-Vitro Studies

SIMULATED USE STUDY[8]

Materials and Methods: Sterile needleless injection ports (e.g., MaxPlus® Clear) were artificially contaminated with suspensions of six bacterial and yeast species: *Candida albicans* (ATCC #10231), *Candida parapsilosis* (ATCC #7330), *Escherichia coli* (ATCC #25922), *Pseudomonas aeruginosa* (ATCC #27853), *Staphylococcus aureus* MRSA (ATCC #33591), and *Staphylococcus epidermidis* MRSE (ATCC #51625). Each suspension of each species was prepared and evaluated with a 5% v/v soil load (sterile human serum), as well as without added soil. Droplets of each suspension were inoculated onto the luer surface of separate injection ports and dried at 25 ± 2 °C for 90 minutes. Three injection ports per challenge suspension were cleaned using each of three (3) lots of Prevantics® Device Swab (nearing end of shelf life) [test product] as well as the control/vehicle product. In addition, one (1) lot of Curos® Port Protector was similarly prepared and used in this study as the predicate device.

Following the cleaning procedure, the number of viable microorganisms remaining on each injection port was determined by neutralizing, diluting, and plating aliquots, in duplicate. The number of microorganisms recovered was compared to the approximated number inoculated onto each injection port; the Log_{10} reduction from the microbial population recovered from contaminated and untreated injection ports (untreated controls) was calculated.

MICROORGANISM	SOIL	OVERALL MEAN PREVANTICS® LOG REDUCTION (CFU/ML) OF NEEDLELESS ACCESS SITE AFTER 5 SECOND APPLICATION
Candida albicans (ATCC #10231)	No	6.0
	Yes	6.2
Candida parapsilosis (ATCC #7330)	No	6.5
	Yes	4.6
Escherichia coli (ATCC #25922)	No	5.0
	Yes	4.7
Pseudomonas aeruginosa (ATCC #27853)	No	4.1
	Yes	4.2
Staphylococcus aureus MRSA (ATCC #33591)	No	4.1
	Yes	5.5
Staphylococcus aureus (ATCC #6538)	No	5.8
	Yes	5.4
Staphylococcus epidermidis (ATCC #12228)	No	5.4
	Yes	5.9

The results demonstrate that Prevantics® Device Swab produces a >4.0 Log_{10} reduction in microbial CFU/mL for the above tested microorganisms.

REFERENCES:

8. Data on File, PDI, Study No 14E0372G-M01G.

CLOSED PATCH TEST FOR DELAYED-TYPE HYPERSENSITIVITY (ISO 10993-10:2010)[9]

Materials and Methods: Twenty-eight guinea pigs were used in this study. Animals were assigned to the following groups; eleven animals were assigned to the Test group, six animals to the Negative Control group, and six animals to the Positive Control group. Additional five Naïve negative control animals were added for the re-challenge.

The study was divided into two major phases: the induction phase and the challenge phase. In the induction phase, animals were exposed to the test or control article in nine six-hour exposures given on three consecutive days a week, for three weeks. For each exposure, the Test group animals were exposed to approximately 1 sq. in. of the test article. The Negative control animals were exposed to approximately 1 sq. in. of gauze. The test or control articles were placed on surgical tape to create a patch. Animals were wrapped with gauze and the dental dam was used to provide occlusion. Animals from the Positive control group were exposed to 1-chloro-2, 4-dinitrobenzene (DNCB). During the inductions phase, 0.050% DNCB was placed on Hill Top Chambers® patches and was applied directly to the animal's skin.

Conclusions: The study was performed according to ISO 10993-10 guidelines. All animals were healthy during the course of the study. Based on ISO interpretation criteria for this test, the test article is rated a potential sensitizer. However, it is notable that although the test article elicited slight reactions during the challenge and re-challenge phase, the reactions were slight and did not appear to follow a typical skin sensitization pattern as observed in animals challenged with positive control (e.g., DNCB).

IN VITRO CYTOTOXICITY PER ISO 10993-5[10]

Materials and Methods: Cytotoxicity testing (direct contact testing) was performed according to ISO 10993-5:2009. Based on ISO 10993-5 guidelines, cell morphology graded greater than 2 was considered to have a cytotoxic effect. Prevantics® Device Swab has four (4) components: a rayon non-woven 2.0" x 2.0" pad, and a solution composed of 3.15% chlorhexidine gluconate w/v, 70% isopropyl alcohol v/v and water. In an effort to understand the outcome, the BD Alcohol Swab (composed of a nonwoven pad and 70% isopropyl alcohol v/v) was tested separately.

The cytotoxicity direct contact (ISO 10993 5:2009) test was performed on both the predicate and test device. Mammalian fibroblast cells were incubated with a representative portion of the test article (either BD Alcohol Swab or Prevantics® Device Swab) and examined after 24 hours. Cells treated with the predicate device exhibited a response of grade 2 (mild reactivity) and the report concluded that the predicate device was not considered to have a cytotoxic effect.

The entire contents of the Prevantics® Device Swab is 1 mL (16.7 mg/mL) which would result in a dose of 16.7 mg per single use for the same 70 kg individual (0.24 mg/kg) [a 3500 fold reduction in dose] if the entire contents of the swab were to somehow be administered intravenously. There is a low likelihood of product solution coming into contact with patient blood, due to the indirect contact path through the needleless access site and would likely be in microliter quantities, further reducing the likelihood of any biological reactivity. It is clear from the non-clinical study and clinical case reports that chlorhexidine can cause severe system toxicity when high concentrations of the drug (15 mg/kg or greater) are either absorbed

REFERENCES:

9. Data on File, PDI, Study No 14E0115H-X02G
10. Data on File, PDI, Study No 14E0115H-M01G

or administered into the bloodstream. However, these concentrations are several orders of magnitude higher than the indented use case. Based on the dose there is little risk that the Prevantics® Device Swab could cause any systemic adverse event even if administered parenterally. The intended use for the device is for external use only and if used as labeled, only under rare circumstances would miniscule amounts of product solution would come in contact with subepidermal layers of skin.

Conclusions: For these reasons, based on the Cytotoxicity: Direct Contact testing, Prevantics® Device Swab appears to be substantially equivalent to the predicate device.

INTRACUTANEOUS REACTIVITY AND DERMAL HYPERSENSITIVITY PER ISO 10993-10[11]

Materials and Methods: Prevantics® Device Swab was tested according to the procedures outlined in ISO 10993-10:2010. All animals appeared healthy during the course of the study. No erythema or edema was noted on test sites on any of the test animals. The Primary Irritation index for the test article was 0. The positive control reacted as expected and the results substantiate the susceptibility of the rabbit to react to a known irritant.

Conclusions: The irritation response category for this test article was classified as negligible. No irritation responses were observed on any of the tested animals. Prevantics® Device Swab demonstrated neither intracutaneous reactivity nor dermal hypersensitivity.

CYTOTOXICITY: DIRECT CONTACT PER ISO 10993-5:2009[12]

Materials and Methods: The cytotoxicity direct contact (ISO 10993-5:2009) test was performed on both the predicate and test device. Mammalian fibroblast cells were incubated with a representative portion of the test article (either BD Alcohol Swab or Prevantics® Device Swab) and examined after 24 hours.

Conclusions: The results from the Cytotoxicity: Direct Contact are unsurprising given the antimicrobial action of the product solution which includes both chlorhexidine gluconate and isopropyl alcohol. Individually, each antimicrobial is capable of causing demonstrable internal cellular changes to eukaryotic cells. The intended use for the device is for external use only and if used as labeled, only under rare circumstances would miniscule amounts of product solution would come in contact with subepidermal layers of skin. For these reasons, based on the Cytotoxicity: Direct Contact testing, Prevantics® Device Swab is substantially equivalent to the predicate device.

Additional Clinical and Toxicological Data is available upon request from the PDI Clinical Affairs Department.

REFERENCES:

11. Data on File, PDI, Study No 14E0115H-X03G

12. Data on File, PDI, Study No 14E0372G-M01G

A RANDOMIZED CROSS-OVER CLINICAL TRIAL TO COMPARE 3.15% CHLORHEXIDINE/70% ISOPROPYL ALCOHOL (CHG) VS 70% ISOPROPYL ALCOHOL ALONE (ALCOHOL) AND 5S VS 15S SCRUB FOR ROUTINE DISINFECTION OF NEEDLELESS CONNECTORS (NCS) ON CENTRAL VENOUS CATHETERS (CVCS) IN AN ADULT MEDICAL INTENSIVE CARE UNIT (ICU)[13]

Background: Disinfecting NCs before access prevents introduction of microbes and reduces the risk of CVC-associated bloodstream infection. The best disinfection method is unknown.

Methods: We conducted a prospective, randomized, crossover clinical trial in a 24-bed ICU to compare 2 disinfectants (CHG vs alcohol) and 2 scrub times (5s vs 15s) for routine disinfection of CVC NCs (negative displacement). Interventions were assigned randomly to each of 2 clinically identical, geographically separate ICU regions. Disinfectant was crossed over twice; scrub times remained the same. Blank stickers were affixed to fronts of prep pads to blind providers to disinfectant. Fidelity to the interventions was monitored by surreptitious observation.

NCs from centrally or peripherally inserted CVCs that had been in place ≥24 hours were eligible for study. Tunneled, antibiotic-impregnated, and dialysis CVCs and CVC introducers were excluded. NCs were changed routinely every 4 days. Biofilm contamination of NC interiors was assessed by sonication and culture. The primary outcome measure was proportion of contaminated NCs.

Results: From March 26, 2012 – June 14, 2013, 1323 NCs were evaluated for eligibility. 509 NCs from 159 catheters (141 patients) were collected and processed. No deviation from assigned disinfectant was observed (101 observations). Mean scrub time was 7s (95% CI, 6-9s) in 5s arms and 9s (95% CI 8-11s) in 15s arms (p=0.071). Proportion of NC contamination was lower in CHG vs alcohol arms, but the difference was significant only for 5s scrub time *(Table)*.

STUDY ARM	NO. NCs STUDIED	NO. (%) CONTAMINATED NCs	RISK RATIO	95% CI	P-value
CHG 5s	112	14 (12)	0.32	0.19, 0.56	<0.001
Alcohol 5s	101	39 (39)			
CHG 15s	102	18 (18)	0.82	0.50, 1.34	0.45
Alcohol 15s	194	42 (22)			

In exploratory analysis, subclavian vein CVC site vs other anatomic sites was associated with lower risk of NC contamination (RR=0.28, 95% CI 0.07-1.07, p=0.042.) In a multilevel mixed effects model in which NCs were nested within lines, the scrub-time + disinfectant interaction term was significant (p<0.001) in predicting NC contamination. Distributions of

REFERENCES:

13. Hayden, M. K., et al. A Randomized Cross-Over Clinical Trial to Compare 3.15% Chlorhexidine/70% Isopropyl Alcohol (CHG) vs 70% Isopropyl Alcohol Alone (Alcohol) and 5s vs 15s Scrub for Routine Disinfection of Needleless Connectors (NCs) on Central Venous Catheters (CVCs) in an Adult Medical Intensive Care Unit (ICU), Oral Abstract Presented at 2014 ID Week Conference, October 11, 2014, Philadelphia, PA.

contaminating microbes were similar across arms (51% coagulase-negative staphylococci, 3% *Staphylococcus aureus*, 26% other Gram positive spp., 9% Gram negative rods, 10% *Candida* spp.)

Conclusion: CHG scrub resulted in less NC contamination than alcohol scrub but the difference was significant only for the shorter scrub time.

CHANGING PORT/HUB DISINFECTION PRODUCT DECREASES CATHETER RELATED BLOODSTREAM INFECTIONS IN A PEDIATRIC INTENSIVE CARE UNIT[14]

Issue: Pediatric intensive care unit (PICU) was not able to maintain a zero CRBSI rate.

Practice guidelines for central line access were not consistent within similar units. Some units were noted using a 3.15% chlorhexidine/70% isopropyl alcohol swab to scrub the hub/port for 15 seconds prior to line access, while the PICU was using a 70% alcohol swab to scrub the hub/port prior to line access.

PICO Question: For hospitalized pediatric patients with a central venous catheter, does the use of chlorhexidine gluconate with isopropyl alcohol for hub disinfection reduce the rate of catheter-related bloodstream infection (CRBSI), compared to the use of isopropyl alcohol alone?

Literature Synthesis:

- CHG/alcohol products provide more effective and persistent antimicrobial effect than alcohol alone, lasting up to 24 hours after application (as indicated by two Level I studies).
- Using CHG/alcohol to scrub hubs results in fewer BSIs, compared to alcohol alone (as indicated by three Level I studies and one Level II study)
- Scrubbing hubs with alcohol alone is not effective in preventing BSIs (as indicated by one level I and one level II study).

Implementation:

- The results of the literature search were reviewed by a team of stakeholders including the infectious disease team, staff nurses, the unit medical director, and nursing management.
- The decision was made to implement a practice change from 70% IPA alone to a 3.15% CHG/ 70% IPA combination product for the disinfection of central venous catheter hubs in the pediatric intensive care unit (PICU) for a trial period of six months.
- Group education and one-on-one education was provided to nurses prior to initiating the practice change and at 4 months following implementation.

REFERENCES:

14. Duffy, S. Changing Port/Hub Disinfection Product Decreases Catheter Related Bloodstream Infections in a Pediatric Intensive Care Unit, Abstract Presented at 2014 APIC Conference, Anaheim CA.

• Outcomes measured by monitoring the rate of blood stream infections, nursing satisfaction with the product, and compliance with recommended scrub time.

Results:

	AVERAGE 12 MONTHS PRIOR TO CHANGE	AVERAGE 5 MONTHS FOLLOWING CHANGE	NOV	DEC	JAN	FEB	MAR	APRIL
BSI rate per 1000 line days	2.8	**0.42**	0	0	2.1	0	0	0
Total BSIs	12	**1**	0	0	1	0	0	0
Compliance with 15-second scrub	60.1%	79.3%	100%	100%	100%	0%*	85%	90.9%

**Based on 3 observations for the month*

REDUCTION IN CENTRAL LINE ASSOCIATED BLOODSTREAM INFECTION IN THE NEONATAL INTENSIVE CARE UNIT FOLLOWING INTRODUCTION OF CHLORHEXIDINE GLUCONATE FOR DISINFECTION OF NEEDLELESS CONNECTORS[15]

Background: Neonates are at greater risk of central line associated bloodstream infection (CLABSI) due to dysfunction of their immune system and prolonged need for vascular access devices to support use of nutritional solutions and medications. Historically, these infections were considered an entitlement to receiving care in the neonatal intensive care unit (NICU) rather than the current and emerging view of them as a preventable complication of care.

Objective: Following implementation of several identified best practices for insertion and maintenance of central lines during 2007, including the use of alcoholic chlorhexidine gluconate (CHG) for skin antisepsis, the rate of CLABSI markedly declined. However, the CLABSI rate reached a plateau and remained higher than desired and higher than the national benchmark for the NICU.

Methods: A practice change was implemented changing cleaning of the needleless connectors used to enter all peripheral and central vascular access devices from an alcohol wipe to an alcoholic CHG (3.15%) wipe. Although CHG is FDA approved for skin antisepsis prior to surgery and injection and cleansing/disinfecting of medical devices is considered off label use, this product is widely described in the literature for this described purpose with positive results. The process for cleaning the needleless connector was unchanged and included scrubbing with friction ten times and allowing complete drying prior to entry.

REFERENCES:

15. Pettit, P., Sharpe, E. Reduction in Central Line Associated Bloodstream Infection in the Neonatal Intensive Care Unit Following Introduction of Chlorhexidine Gluconate for Disinfection of Needleless Connectors, Abstract Presented at 2010 APIC Conference, Washington, DC.

Needleless connectors were not routinely changed and no other process change related to use of vascular access devices or infection prevention was implemented during this time.

Results: CLABSI rates dropped from 7.1/1000 catheter days in 2008 to 0.56/1000 catheter days in 2009 following use of alcoholic 3.15% CHG with only one CLABSI occurring during the entire year. Monthly monitoring of practice demonstrates at least a 90% sustained compliance with this protocol.

ARMED AND READY FOR CHANGE: VALIDATION OF USING ALCOHOLIC CHLORHEXIDINE GLUCONATE FOR BLOOD DONOR SERVICES[16]

Background: A hemodialysis catheter is the major risk factor for bacteremia for dialysis patients. Relative risk for bacteremia for patients with permanent (cuffed) hemodialysis catheters is about sevenfold the risk for patients with arteriovenous fistulas. By 2008, 72% of 103 hemodialysis patients at our facility had a catheter, exceeding regional and national percentages. In 2007, 11 BSIs were noted at a rate of 1.7 per 100 patient months; this increased to a rate of 2.4 per 100 patient months during the first 4 months of 2008. Of concern is MDRO colonization, which had risen from 8% in 2005 to over 35% in 2007, increasing risk of exposure and infection. Noncompliance with CDC recommendations for prevention of infection in hemodialysis was observed. For example, hand hygiene was omitted between touching machines or when performing non-invasive procedures. Supplies were stored adjacent to the patients' chairs, and a few surfaces were not cleaned between patients. Catheter manipulations were performed without hub disinfection, and patients were not required to wash their hands prior to a procedure.

Methods:

Practice modifications

- Catheter hub disinfection prior to each accession with chlorhexidine gluconate 3.15% (w/v) and 70% isopropyl alcohol (v/v)
- Hand hygiene between patients and machines
- Patient hand hygiene before procedures
- Environmental cleaning practices strengthened
- Chlorhexidine gluconate impregnated dressing on catheters at high risk for infection
- Comprehensive fistula placement program

Results:

- MDRO colonization remained stable
- BSI rate dropped from 2.4 per 100 patient months to 0, sustained for 15 months
- 24 bloodstream infections saved an estimated $480,000
- Fistula utilization reached 41% by 2009

REFERENCES:

16. Bren, V. R., Greek, C. I. Driscoll, C. J.. et. al. Getting to Zero: Outpatient Hemodialysis Catheter-Associated Bloodstream Infections, Abstract Presented at 2010 Fifth Decennial Conference, Atlanta, GA .

Conclusions: A bundle of best practices is effective in reducing and sustaining infection rates but did not affect the prevalence of MDROs. Targeting chlorhexidine impregnated dressings preserved resources. Optimal hand hygiene and gloving in a busy dialysis unit is extremely challenging. Interpreting best practices for dialysis catheter care is challenging because guidelines are somewhat inconsistent. Sustaining zero healthcare associated infections is directly related to reduction of utilization of catheter accesses.

TARGETING ZERO: A SYSTEMATIC APPROACH TO ELIMINATION OF CATHETER RELATED BLOODSTREAM INFECTIONS (CR-BSI) IN A PEDIATRIC HEALTHCARE SYSTEM[17]

Issue: Catheter Related Bloodstream Infections plague healthcare systems worldwide, resulting in significant morbidity, mortality, and healthcare cost. Repeated accession of both peripheral and central lines was identified as a key risk of infection, therefore a standardized and safer approach to cleaning these entry ports prior to accessing them was necessary to reduce introduction of microorganisms.

Method: A six month controlled observational study was conducted in the Cardiac Intensive Care Unit of one campus location to evaluate the effectiveness of utilization of a 3.15% Chlorhexidine gluconate (CHG) /70% Isopropyl Alcohol antiseptic for cleaning all intravascular ports and hubs prior to accessing the device. Following successful outcomes in the six month study, the use of the CHG Swab was implemented system wide at both hospital campuses prior to accessing any intravascular device. The use of isopropyl alcohol prep pads for accessing devices was discontinued, and replaced with the use of CHG. An extensive educational outreach program was conducted throughout the system to engage all stakeholders in the prevention of Catheter Related Bloodstream Infections. Earlier infection prevention efforts contributed to an ongoing reduction of BSI rates·conversion to split septum access hubs and environmental cleaning and a renewed focus on hand hygiene furthered the overall reduction of BSI's.

Results: System wide CR·BSI rates decreased by over 44% since 2005 as a result of system implementation of CHG swabs. In addition, over 298 CR·BSI infections were avoided, resulting in a cost avoidance of 13.5 million dollars (based on a per CR·BSI cost of $46,133) throughout the system, and the prevention of 58 patient deaths based on the facility calculated mortality of twenty·five percent for CR·BSI.

Lessons Learned: Due to the overwhelming complexity of a system wide roll·out of this magnitude, the choice to study the potential results in a smaller unit setting proved valuable at building the business case for a systematic, full system implementation. With any massive new technology implementation comes significant objection from the fear of change, as well as the requirement for additional training. To overcome this obstacle, education regarding the issue was critical to the success of new clinical improvement initiatives.

REFERENCES:

17. Peace, D., Watson, R., Cocks, A. Targeting Zero: A Systematic Approach to Elimination of Catheter Related Bloodstream Infections (CR·BSI) in a Pediatric Healthcare System, Abstract Presented at 2010 APIC Conference, New Orleans, LA.

CHG swabs for cleaning line access point proved to be best clinical practice for eliminating CR-BSIs. Split septum technology, a renewed focus on hand hygiene and environmental cleaning, and cleaning of the line access points resulted in progressive decline of BSI rates system wide.

OUR NICU JOURNEY TO ZERO CENTRAL LINE-ASSOCIATED BLOODSTREAM INFECTIONS: SPECIAL PATIENTS REQUIRE SPECIAL INTERVENTIONS[18]

Background: Central Line-Associated Bloodstream Infection (CLABSI) is a constant threat to any patient with an indwelling central venous catheter, but particularly to fragile patients such as neonates and infants. The most significant challenge in the neonatal environment is the significant lack of well –documented, evidence-based practice specific to the care of a neonatal patient. The use of chlorhexidine gluconate (CHG) solutions has been widely documented as best practice for skin antisepsis for central line insertion and maintenance in the adult population, but no CHG containing solutions have Food and Drug Administration (FDA) approval for use with patients under two months of age. We estimate that the cost per CLABSI in our NICU was approximately $40K.

Project: Based on an assessment of our internal practices in the prevention of CLABSI, we implemented a robust clinical algorithm to address the potential sources of introduction of infection into the central line. We specifically addressed the risk for contamination at the time of insertion, but also placed greater importance on the maintenance of the line and insertion site. During 2006, staff led work teams were assembled to evaluate possible practice change, including: new needleless connector, closed medication & arterial systems, and IV tubing assembly process.

In 2007, CHG /70% isopropyl alcohol was implemented for skin antisepsis prior to line insertion in infants > 1000 grams.

During 2008, 3.15% CHG/alcohol was implemented for cleaning the needleless connectors.

Results: CLABSI rates dropped from 7.1/1000 catheter days in 2008 to 0.56/1000 catheter days in 2009. We have sustained zero CLABSI for more than 24 months consecutively as a result of our interventions. In addition, we had zero incidence of skin breakdown or erythema associated with the use of the CHG solution, further demonstrating the safety of CHG solutions for the neonatal population. Monthly monitoring of practice demonstrates at least a 90% sustained compliance with this protocol.

Lessons Learned: HAIs, which were always assumed an entitlement in the neonatal population, are truly preventable, and we have demonstrated this is not only achievable, but sustainable. The untraditional use of the CHG swab for cleaning hubs and needless connectors was the crucial intervention that allowed us to achieve zero. Evolving clinical evidence suggests the use of CHG as best practice for cleaning needless connectors, as well as for skin antisepsis for insertion and maintenance of central venous catheters. Staff buy-in along with clinical best practices make zero possible.

REFERENCES:

18. Pettit, P., Sharpe, E. Our NICU Journey to Zero Central Line-Associated Bloodstream Infections: Special Patients Require Special Interventions, Abstract Presented at 2011 APIC Conference, Baltimore, MD.

COMPARATIVE EFFECTIVENESS OF CHLORHEXIDINE VERSUS ISOPROPYL ALCOHOL ON CONTAMINATED NEEDLESS CONNECTORS[19]

Purpose: Blood stream infections account for greater than 250,000 healthcare associated infections in the United States annually. While advances have been made in instrumentation and culture techniques, there is a lack of best practice guidelines regarding disinfection of lumens prior to access. The purpose of this study is to evaluate a 3.15% Chlorhexidine gluconate/70% Isopropyl alcohol product and a 70% Isopropyl Alcohol product for their ability to eliminate organisms from seeded lumens. This study evaluates the variables of scrub and dry time intervals to determine the most effective disinfection method and scrub time.

Methods: Three separate groups of lumens were seeded with 106 organisms of: Escherichia *coli*, Pseudomonas *aeruginosa*, or *Staphylococcus aureus*. The scrub and dry time intervals were: single swipe, zero dry; scrub 10 seconds, dry 10 seconds; scrub 15 seconds, dry 15 seconds; and, scrub 30 seconds, dry 30 seconds. The lumens were cultured using a sterile cotton swab plated onto a 5% sheep's blood agar plate. All plates were incubated overnight and visually inspected for pathogen growth.

Results: All isopropyl alcohol cultures showed growth at every time interval. The Chlorhexidine gluconate product showed no growth when scrub and dry interval was 15 seconds or greater.

Limitations: This study, though done in triplicate, was performed in a lab controlled environment at a single center.

Conclusions: Chlorhexidine gluconate is effective in eliminating pathogens on needless connectors with a 15 second swab and 15 second dry time. However, isopropyl alcohol alone is not effective after a 30 second scrub and 30 second dry time. The results of this study confirm our current practice of utilizing Chlorhexidine swabs for disinfection of needless connectors.

REFERENCES:

19. Karez, A. N., Kendrick, L., et al. Comparative Effectiveness of Chlorhexidine Preparation versus Isopropyl Alcohol on Needleless Connectors, Abstract Presented at 2012 AVA Conference, Nashville, TN.

BREAKING THE BLOODSTREAM INFECTION CONNECTION: CENTRAL VENOUS CATHETER (CVC) HUB DISINFECTION UTILIZING A SWAB CONTAINING CHLORHEXIDINE GLUCONATE (3.15%) AND ISOPROPYL ALCOHOL (70%)[20]

Objective: To reduce the incidence of blood stream infections (BSI) in patients on a bone marrow transplant (BMT)/hematology unit.

Significance and Background: The St. Francis BMT unit is a 17 bed unit caring for hematology patients in all aspects of care from routine to critical care. Bone marrow transplant/hematology patients with central venous catheters (CVC) have an increased risk of developing BSI. Minimizing this risk improves outcomes. Developing an evidence-based intervention was needed to decrease BSI rates.

Purpose: To decrease the incidence of BSI in our bone marrow transplant/hematology patient population using a swab with 3.15% Chlorhexidine Gluconate and 70% alcohol for central line hub and lumen care.

Interventions: Chlorhexidine-impregnated sponge dressing was added to our CVC site care in 2009. A literature review identified that current guidelines recommend cleaning hubs prior to each access. All nursing staff members were educated regarding the use of the swab. A data collection sheet was completed by each nurse after any access of the CVC. Nurses on the in-patient bone marrow transplant/hematology unit apply pressure and friction for 10 seconds in a 360 degree circular motion with the swab. The CVC hub/lumen is dried completely before being accessed. All Isopropyl alcohol swabs were taken out of the room to ensure compliance.

Evaluation: Preliminary data indicates a current decrease in BSI rate with prolonged periods of no BSIs occurring.

Discussion: Although previous intervention using chlorhexidine-impregnated sponge dressing lowered the BSI rates by 50 percent, the reduction could not be consistently sustained. Adding the 3.15% Chlorhexidine Gluconate and 70% alcohol swab for central line hub and lumen care has further reduced BSI rates with periods where no BSIs have occurred. Evaluating practice of staff and minimizing practice variations decreases the patient's risk of developing BSI.

REFERENCES:

20. Hillman, D. Breaking the Bloodstream Infection Connection: Central Venous Catheter (CVC) Hub Disinfection Utilizing a Swab containing Chlorhexidine Gluconate (3.15%) and Isopropyl Alcohol (70%), Abstract Presented at 2012 APIC Conference, San Antonio, TX.

Summary:

SUMMARY OF EVIDENCE-BASED CLINICAL GUIDELINES

Prevantics® Device Swab is fully compliant with the evidence-based recommendations from the following clinical organizations:

- US Centers for Disease Control and Prevention (CDC)
- Infusion Nurses Society (INS)
- Association for Vascular Access (AVA)
- The Society for Healthcare Epidemiology of America (SHEA)
- The Infectious Disease Society of America (IDSA)
- The Association for Professionals in Infection Control and Epidemiology (APIC)

The specific recommendations are as follows:

SUMMARY OF US CLINICAL GUIDELINES FOR DISINFECTION OF NEEDLELESS ACCESS DEVICES

ORGANIZATION AND GUIDELINE	PORT/HUB CLEANSING RECOMMENDATIONS
Centers for Disease Control and Prevention: Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011 **www.cdc.gov**	Minimize contamination risk by scrubbing the access port with an appropriate antiseptic (chlorhexidine, povidone iodine, an iodophor, or 70% alcohol) and accessing the port only with sterile devices. Appropriate disinfectants must be used to prevent transmission of microbes through connectors. Some studies have shown that disinfection of the devices with chlorhexidine/alcohol solutions appears to be msot effective in reducing colonization.
Infusion Nurses Society (INS): Infusion Nursing Standards of Practice, 2011 **www.ins1.org**	The needleless connector should be consistently and thoroughly disinfected using alcohol, tincture of iodine, or chlorhexidine gluconate/alcohol combination prior to each access. The optimal technique or disinfection time frame has not been identified.
Society for Healthcare Epidemiology of America (SHEA): Strategies to Prevent Central-Line Associated Bloodstream Infections in Acute Care Hospitals, 2014 **www.shea-online.org**	Before accessing catheter hubs, needleless connectors, or injection ports, vigorously apply mechancial friction with an alcohol chlorhexidine preparation, 70% alcohol, or povidone-iodine. Alcoholic chlorhexidine may have additional residual activity compared with alcohol for this purpose. Apply mechanical friction for no less than 5 seconds to reduce contamination.
The Joint Commission: 2014 National Patient Safety Goals for Hospitals **www.jointcommission.org**	Use a standardized protocol to disinfect catheter hubs and injection prots before accessing the ports.
Infectious Diseases Society of America (IDSA): Clinical Practice Guidelines for the Diagnosis and Management of Intravascular Catheter-Related Infection: 2009 Update by the Infectious Deiseadses Society of America. **www.idsociety.org**	If a blood sample is obtained through a catheter, clean the catheter hub with either alcohol or tincture of iodine or alcoholic chlorhexidine (>0.5%), allowing adequate drying to mitigate blood culture contamination (A-1).
APIC Guide to the Elimination of Infections in Hemodialysis, 2010 **www.apic.org**	Disinfect IV ports prior to accessing, using friction and 70% alcohol, iodophor, or chlorhexidine/alcohol agent. Allow to dry prior to accessing.

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