2011 CDC Guidelines for the Prevention of Intravascular Catheter-Associated Infections

Strategies to Reduce Intravascular Catheter-Associated Infections

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Objectives

Review the epidemiology of catheter associated bloodstream infections

Review the 2011 CDC HIPAC Guidelines for the Prevention of Intravascular Catheter-Related Infections

List 6 areas that should be emphasized to prevent intravascular catheter related infections
Epidemiology

An estimated 248,000 bloodstream infections occur in U.S hospitals each year (Klevens RM, Edwards JR, et al. Pub Health Reports 2007)

Bloodstream infections are usually serious infections typically causing a prolongation of hospital stay (mean of 7 days) and increased cost (estimated attributable cost - $36,441 Stone et al AJIC 2005) and risk of mortality

CDC NHSN defines a central line as a catheter whose tip terminates in a great vessel – the aorta, PA, SVC, Inferior VC, brachiocephalic veins, IJV, subclavian veins, external iliac veins, and common femoral veins.
### Epidemiology - NHSN CLABSI Rates 2009

<table>
<thead>
<tr>
<th>Critical Care Unit</th>
<th># Locations</th>
<th># CLABSI</th>
<th>Central Line Days</th>
<th>Pooled Mean</th>
<th>10th – 90th Percentile</th>
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</thead>
<tbody>
<tr>
<td>Burn</td>
<td>33</td>
<td>193</td>
<td>36,355</td>
<td>5.3</td>
<td>0.2-12.4</td>
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<tr>
<td>Medical major/teach</td>
<td>135</td>
<td>740</td>
<td>335,840</td>
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<td>0.2-4.7</td>
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<tr>
<td>Med/Surg major/teach</td>
<td>192</td>
<td>760</td>
<td>446,751</td>
<td>1.7</td>
<td>0.0-3.8</td>
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<tr>
<td>Medical Cardiac</td>
<td>252</td>
<td>556</td>
<td>330,123</td>
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<td>0.0-4.2</td>
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<tr>
<td>Ped Med/Surg</td>
<td>142</td>
<td>504</td>
<td>228,206</td>
<td>2.2</td>
<td>0.0-4.5</td>
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<tr>
<td>Ped Med</td>
<td>15</td>
<td>36</td>
<td>13,823</td>
<td>2.6</td>
<td></td>
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<tr>
<td>Surgical</td>
<td>223</td>
<td>817</td>
<td>466,224</td>
<td>1.8</td>
<td>0.0-4.2</td>
</tr>
<tr>
<td>Surgical/CT</td>
<td>219</td>
<td>540</td>
<td>460,406</td>
<td>1.2</td>
<td>0.0-2.5</td>
</tr>
</tbody>
</table>
Epidemiology - Pathogenesis

1. Colonization from the skin/hands of healthcare workers
2. Intraluminal or hub contamination
3. Secondary seeding from a bloodstream infection
4. Rarely – Contamination of the infusate or additives such as heparin flush
5. Risk – Repeated catheterization; presence of septic focus elsewhere; catheter insertion using submaximal barrier precautions; nontunneled has a higher risk than tunneled; tunneled has a higher risk than totally implantable; femoral high risk; internal jugular has a higher risk than subclavian; and lower extremities has a higher risk than upper extremities.
A review of the 2011 CDC Guidelines for the Prevention of Intravascular Catheter-Associated Infections

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1National Institutes of Health, Bethesda, Maryland
2Infusion Nurses Society, Norwood, Massachusetts
3Barnes Hospital, St. Louis, Missouri
4University of Washington, Seattle, Washington
5Weston Franciscan Healthcare-St. Joseph, Milwaukee, Wisconsin
6University of Massachusetts Medical School, Worcester, Massachusetts
7Johns Hopkins University School of Medicine, Baltimore, Maryland
8Warren Alpert Medical School of Brown University and Rhode Island Hospital, Providence, Rhode Island
9Office of Infectious Diseases, CDC, Atlanta, Georgia
10H. E. Anderson Cancer Center, Houston, Texas
11The Children's Hospital, Boston, Massachusetts
12University of Nebraska Medical Center, Omaha, Nebraska
13Ann Arbor VA Medical Center and University of Michigan, Ann Arbor, Michigan

Major areas of emphasis include:

1. Educating and training healthcare personnel who insert and maintain catheters;
2. Using maximal sterile barrier precautions during central venous catheter insertion;
3. Using a > 0.5% chlorhexidine (CHG) preparation with alcohol for skin antisepsis;
4. Avoiding routine replacement of central venous catheters as a strategy to prevent infection
5. Using antiseptic/antibiotic impregnated short-term central venous catheters and chlorhexidine impregnated sponge dressings if the rate of infection is not decreasing despite adherence to other strategies (i.e., education and training, maximum barrier precautions, and > 0.5% chlorhexidine preparations with alcohol for skin antisepsis);
6. Performance improvement by implementing bundled strategies, and documenting and reporting rates of compliance with all components of the bundle as benchmarks for quality assurance and performance improvement.
CDC Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011

Guideline Categorization Scheme:

1. Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.

2. 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.

3. Category IC. Required by state or federal regulations, rules, or standards.

4. Category II. Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale.

5. Unresolved issue. Represents an unresolved issue for which evidence is insufficient or no consensus regarding efficacy exists.

CDC IV Guideline: What’s Added

1. Use hospital-specific or collaborative-based performance improvement initiatives in which multifaceted strategies are "bundled" together to improve compliance with evidence-based recommended practices. **Category 1B**

2. Use ultrasound guidance to place central venous catheters to reduce the number of cannulation attempts and mechanical complications [if this technology is available]. **Category 1B**

3. When needleless systems are used, the split septum valve is preferred over the mechanical valve due to increased risk of infection. **Category II**

CDC IV Guideline: What’s Added

4. Do not routinely use anticoagulant therapy to reduce the risk of catheter-related infection in general patient populations. **Category II**

5. Use a 2% chlorhexidine wash daily to reduce CRBSI. **Category II**

6. During axillary or femoral artery catheter insertion, maximal sterile barriers precautions should be used. **Category II**

7. Replace arterial catheters only when there is a clinical indication. **Category II**

8. Remove the arterial catheter as soon as it is no longer needed. **Category II**

1. Use a chlorhexidine-impregnated sponge dressing for temporary short-term catheters in patients older than 2 months of age, if the CRBSI rate is higher than the institutional goal, despite adherence to basic CRBSI prevention measures, including education and training, use of chlorhexidine for skin antisepsis, and MSB. **Category 1B (changed from unresolved issue to Category 1B)**

2. Use a chlorhexidine/silver sulfadiazine or minocycline/rifampin - impregnated CVC in adults whose catheter is expected to remain in place >5 days if, after successful implementation of a comprehensive strategy to reduce rates of CRBSI, the CRBSI rate remains above the goal set by the individual institution based on benchmark rates and local factors. The comprehensive strategy should include at least the following three components: educating persons who insert and maintain catheters, use of maximal sterile barrier precautions, and a 2% chlorhexidine preparation for skin antisepsis during CVC insertion. **Category 1A (changed from a Category 1B to a 1A)**
3. 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. **Category IA** *(upgraded from a Category 1B to a 1A)*

4. Replace dressings used on short-term CVC sites every 2 days for transparent dressings, except in those pediatric patients in which the risk for dislodging the catheter may outweigh the benefit of changing the dressing. **Category IB** *(changed from 11 to 1B)*

5. Use a fistula or graft instead of a CVC for permanent access for dialysis. **Category IA** *(changed from a 1B to a 1A)*

6. When adherence to aseptic technique cannot be ensured (i.e., when catheters are inserted during a medical emergency), replace all catheters as soon as possible and after no longer than 48 hours. **Category 1B** *(changed from a II to 1B)*

CDC IV Guideline: What’s Been Upgraded

7. Replace dressings used on tunneled or implanted CVC sites no more than once per week, until the insertion site has healed. **Category IB (changed from Category II to 1B)**

8. Use povidone iodine antiseptic ointment or bacitracin/gramicidin/polymyxin B ointment at the hemodialysis catheter exit site after catheter insertion and at the end of each dialysis session only if this ointment does not interact with the material of the hemodialysis catheter per manufacturer's recommendation. **Category IB (changed from a Category II to 1B)**

9. Use a sutureless securement device to reduce the risk of infection for intravascular catheter. **Category II (changed from unresolved issue to Category II)**

10. Use prophylactic antimicrobial lock solution in patients with long-term catheters who have a history of multiple CRBSI despite optimal maximal adherence to aseptic technique. **Category II (changed from “do not use” to “use”; both Category II)**

CDC IV Guideline: What’s Been Downgraded

1. Use maximal sterile barrier precautions, including the use of a cap, mask, sterile gown, sterile gloves, and a large sterile full body drape, for the insertion of CVCs, PICCs, or guidewire exchange. *(Changed from a Category 1A to a 1B)*

2. Do not use topical antibiotic ointment or creams on insertion sites, except for dialysis catheters, because of their potential to promote fungal infections and antimicrobial resistance. *(Changed from Category 1A to 1B)*

3. Replace catheter site dressing if the dressing becomes damp, loosened, or visibly soiled. *(Changed from a 1A to a 1B)*

4. No recommendation can be made regarding the necessity for any dressing on well-healed exit sites of long-term cuffed and tunneled CVCs. *(Changed from a Category II to unresolved issue)*
Category 1A Recommendations: Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies

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 infections.

2. Periodically assess knowledge of and adherence to guidelines for all persons who are involved in the insertion and maintenance of intravascular catheters.

3. Designate only trained personnel who demonstrate competence for the insertion and maintenance of peripheral and central intravascular catheters.

**Category 1A Recommendations:** Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies

1. Avoid the use of steel needles for the administration of fluids and medication that might cause tissue necrosis, if extravasation occurs.

2. Weigh the risk and benefits of placing a central venous device at a recommended site to reduce infectious complications against the risk for mechanical complications.

3. Avoid using the femoral vein for central venous access in adult patients.

4. Avoid the subclavian site in hemodialysis patients and patients with advanced kidney disease, to avoid subclavian vein stenosis.

5. Use a fistula or graft in patients with chronic renal failure instead of a CVC for permanent access for dialysis.

6. Promptly remove any intravascular catheter that is no longer essential.

Category 1A Recommendations: Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies

1. Sterile gloves should be worn for the insertion of arterial, central, and midline catheters

2. Prepare clean skin site with > 0.5% chlorhexidine preparation with alcohol before central venous catheter and peripheral artery catheter insertion and during dressing changes. If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives.

**Category 1A Recommendations:** Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies

1. Use either sterile gauze or sterile, transparent, semipermeable dressing to cover the catheter site.

2. Use a chlorhexidine/silver sulfadiazine or minocycline/rifampin-impregnated CVC in patients whose catheter is expected to remain in place > 5 days if, after successful implementation of a comprehensive strategy to reduce rates of CLABSI, the CLABSI rate is not decreasing. The comprehensive strategy should include at least the following three components: educating persons who insert and maintain catheters, use of maximal sterile barrier precautions, and a > 0.5% chlorhexidine preparation with alcohol for skin antisepsis during CVC insertion.

3. Do not use topical antibiotic ointment or creams on umbilical catheter insertion sites because of the potential to promote fungal infections and antimicrobial resistance.

Category 1A Recommendations: Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies

1. Keep all components of the pressure monitoring system (including calibration devices and flush solution) sterile.

2. When the pressure monitoring system is accessed through a diaphragm, rather than a stopcock, scrub the diaphragm with an appropriate antiseptic before accessing the system.

3. Do not administer dextrose-containing solutions or parenteral nutrition fluids through the pressure monitoring circuit.

4. Sterilize reusable transducers according to the manufacturers' instructions if the use of disposable transducers is not feasible.

Category 1A Recommendations: Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies

1. In patients not receiving blood, blood products or fat emulsions, replace administration sets, including secondary sets and add-on devices, no more frequently than at 96-hour intervals, but at least every 7 days.

2. Replace tubing used to administer propofol infusions every 6 or 12 hours, when the vial is changed, per the manufacturer's recommendation.

3. 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.

4. Do not use topical antibiotic ointment or creams on umbilical catheter insertion sites because of the potential to promote fungal infections and antimicrobial resistance.

Category 1B Recommendations: Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies, and a strong theoretical rationale

1. Perform hand hygiene procedures, either by washing hands with conventional soap and water or with alcohol-based hand rubs (ABHR). Hand hygiene should be performed before and after palpating catheter insertion sites as well as before and after inserting, replacing, accessing, repairing, or dressing an intravascular catheter. Palpation of the insertion site should not be performed after the application of antiseptic, unless aseptic technique is maintained.

2. Maintain aseptic technique for the insertion and care of intravascular catheters.

3. Select catheters on the basis of the intended purpose and duration of use, known infectious and non-infectious complications (e.g., phlebitis and infiltration), and experience of individual catheter operators.

Category 1B Recommendations: Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies, and a strong theoretical rationale

4. Use ultrasound guidance to place central venous catheters to reduce the number of cannulation attempts and mechanical complications if this technology is available.

5. Use a sterile sleeve for pulmonary artery catheters during insertion.

6. In adults, use of the radial, brachial or dorsalis pedis sites is preferred over the femoral or axillary sites of insertion to reduce the risk of infection.

7. Ensure that catheter site care is compatible with the catheter material.

8. Do not administer systemic antimicrobial prophylaxis routinely before insertion or during use of an intravascular catheter to prevent catheter colonization or CRBSI.

Category 1B Recommendations: Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies, and a strong theoretical rationale

1. Antiseptics should be allowed to dry according to the manufacturer’s recommendation prior to placing the catheter.

2. Use maximal sterile barrier precautions, including the use of a cap, mask, sterile gown, sterile gloves, and a sterile full body drape, for the insertion of CVCs, PICCs, or guidewire exchange.

3. Replace catheter site dressing if the dressing becomes damp, loosened, or visibly soiled.

4. Do not use topical antibiotic ointment or creams on insertion sites, except for dialysis catheters, because of their potential to promote fungal infections and antimicrobial resistance.

5. Use povidone iodine antiseptic ointment or bacitracin/neomycin/polymyxin B ointment at the hemodialysis catheter exit site after catheter insertion and at the end of each dialysis session only if this ointment does not interact with the material of the hemodialysis catheter per manufacturer’s recommendation

Category 1B Recommendations: Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies, and a strong theoretical rationale

1. Do not submerge the catheter or catheter site in water. Showering should be permitted if precautions can be taken to reduce the likelihood of introducing organisms into the catheter (e.g., if the catheter and connecting device are protected with an impermeable cover during the shower).

2. Replace dressings used on short-term CVC sites at least every 7 days for transparent dressings, except in those pediatric patients in which the risk for dislodging the catheter may outweigh the benefit of changing the dressing.

3. Ensure that the catheter site care is compatible with the catheter material.

Category 1B Recommendations: Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies, and a strong theoretical rationale.

**SKIN PREP AND CATHETER DRESSINGS**

1. Use a chlorhexidine-impregnated sponge dressing for temporary short-term catheters in patients older than 2 months of age, if the CLABSI rate is not decreasing despite adherence to basic prevention measures, including education and training, use of chlorhexidine skin antisepsis, and MSB.

2. Monitor the catheter sites visually when changing the dressing or by palpation through an intact dressing on a regular basis, depending on the clinical situation of the individual patient. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or bloodstream infection, the dressing should be removed to allow thorough examination of the site.

Category 1B Recommendations: Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies, and a strong theoretical rationale

1. There is no need to replace peripheral catheters more frequently than every 72-96 hours to reduce risk of infection and phlebitis in adults.
2. Replace peripheral catheters in children only when clinically indicated.
3. Do not routinely replace CVCs, PICCs, hemodialysis catheters, or pulmonary artery catheters to prevent catheter-related infections.
4. Do not use guidewire exchanges routinely for non-tunneled catheters to prevent infection.
5. Do not use guidewire exchanges to replace a non-tunneled catheter suspected of infection.
6. Use a guidewire exchange to replace a malfunctioning non-tunneled catheter if no evidence of infection is present.

Category 1B Recommendations: Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies, and a strong theoretical rationale

1. Cleanse the umbilical insertion site with an antiseptic before catheter insertion. Avoid tincture of iodine because of the potential effect on the neonatal thyroid. Other iodine-containing products (e.g., povidone iodine) can be used.

2. Add low-doses of heparin (0.25-1.0 U/mL) to the fluid infused through umbilical arterial catheters.

Category 1B Recommendations: Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies, and a strong theoretical rationale

1. Use disposable, rather than reusable, transducer assemblies when possible.
2. Replace disposable or reusable transducers at 96-hour intervals. Replace other components of the system (including the tubing, continuous-flush device, and flush solution) at the time the transducer is replaced.
3. Replace tubing used to administer blood, blood products, or fat emulsions (those combined with amino acids and glucose in a 3-in-1 admixture or infused separately) within 24 hours of initiating the infusion.

Category 1B Recommendations: Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies, and a strong theoretical rationale

1. In adults, use of the radial, brachial or dorsalis pedis sites is preferred over the femoral or axillary sites of insertion to reduce the risk of infection.

2. A minimum of a cap, mask, sterile gloves and a small sterile fenestrated drape should be used during peripheral artery catheter insertion.

Category 1B Recommendations: Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies, and a strong theoretical rationale

1. Use hospital-specific or collaborative-based performance improvement initiatives in which multifaceted strategies are "bundled" together to improve compliance with evidence-based recommended practices.

2. Ensure appropriate nursing staff levels in ICUs. Observational studies suggest that a higher proportion of "pool nurses" or an elevated patient–to-nurse ratio is associated with CRBSI in ICUs where nurses are managing patients with CVCs.

Category II Recommendations: Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale

**ARTERIAL CATHETER TRANSDUCER ISSUES**

1. In children, the brachial site should not be used.
2. During axillary or femoral artery catheter insertion, maximum barrier precautions should be used.
3. Replace arterial catheters only when there is a clinical indication.
4. Remove the arterial catheter as soon as it is no longer needed.
5. Do not routinely replace arterial catheters to prevent catheter-related infections.
6. Minimize the number of manipulations of and entries into the pressure monitoring system. Use a closed flush system (i.e., continuous flush), rather than an open system (i.e., one that requires a syringe and stopcock), to maintain the patency of the pressure monitoring catheters.

Category II Recommendations: Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale

1. Change the needleless components at least as frequently as the administration set. There is no benefit to changing these more frequently than every 72 hours.

2. Change needleless connectors no more frequently than every 72 hours or according to manufacturers' recommendations for the purpose of reducing infection rates.

3. Ensure that all components of the system are compatible to minimize leaks and breaks in the system.

4. When needleless systems are used, a split septum valve may be preferred over some mechanical valves due to increased risk of infection with the mechanical valves.

Category II Recommendations: Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale

1. In pediatric patients, the upper or lower extremities or the scalp (in neonates and young children) can be used as the catheter insertion site.

2. Remove and do not replace umbilical artery catheters if any signs of CRBSI, vascular insufficiency in the lower extremities, or thrombosis are present.

3. Remove and do not replace umbilical venous catheters if any signs of CRBSI or thrombosis are present.

4. An umbilical catheter may be replaced if it is malfunctioning, and there is no other indication for catheter removal, and the total duration of catheterization has not exceeded 5 days for an umbilical artery catheter or 14 days for an umbilical vein catheter.

5. Remove umbilical catheters as soon as possible when no longer needed or when any sign of vascular insufficiency to the lower extremities is observed. Optimally, umbilical artery catheters should not be left in place > 5 days.

6. Umbilical venous catheters should be removed as soon as possible when no longer needed, but can be used up to 14 days if managed aseptically.

7. In children, the brachial site should not be used. The radial, dorsalis pedis, and posterior tibial sites are preferred over the femoral or axillary sites of insertion.

**Category II Recommendations:** Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale

- If the patient is diaphoretic or if the site is bleeding or oozing, use gauze dressing until this is resolved.
- Use a 2% chlorhexidine wash for daily skin cleansing to reduce CRBSI.
- In adults, use an upper-extremity site for catheter insertion. Replace a catheter inserted in a lower extremity site to an upper extremity site as soon as possible.
- Encourage patients to report any changes in their catheter site or any new discomfort to their provider.
Category II Recommendations: Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale

- Use a sutureless securement device to reduce the risk of infection for “intravascular catheters”.
- Use prophylactic antimicrobial lock solution in patients with long term catheters who have a history of multiple CRBSI despite optimal maximal adherence to aseptic technique.
- Do not routinely use anticoagulant therapy to reduce the risk of catheter-related infection in general patient populations.
- Replace midline catheters only when there is a specific indication.
- Use a midline catheter or peripherally inserted central catheter (PICC), instead of a short peripheral catheter, when the duration of IV therapy will likely exceed six days.

Category II Recommendations: Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale

• Do not remove CVCs or PICCs on the basis of fever alone. Use clinical judgment regarding the appropriateness of removing the catheter if infection is evidenced elsewhere or if a noninfectious cause of fever is suspected.

• Use new sterile gloves before handling the new catheter when guidewire exchanges are performed.

• Use single dose vials for parenteral additives or medications when possible.

• Replace transparent dressings used on tunneled or implanted CVC sites no more than once per week (unless the dressing is soiled or loose), until the insertion site has healed.

Unresolved issues. Represents an unresolved issue for which evidence is insufficient or no consensus regarding efficacy exists.

1. No recommendation can be made for a preferred site of insertion to minimize infection risk for a tunneled CVC.

2. No recommendation can be made regarding the use of a designated lumen for parenteral nutrition.

3. No comparison has been made between using chlorhexidine preparations with alcohol and povidone-iodine in alcohol to prepare clean skin.

4. No recommendation can be made for the safety or efficacy of chlorhexidine in infants aged <2 months.

5. No recommendation can be made regarding the necessity for any dressing on well-healed exit sites of long-term cuffed and tunneled CVCs.

Unresolved issues. Represents an unresolved issue for which evidence is insufficient or no consensus regarding efficacy exists.

1. No recommendation is made for other types of chlorhexidine dressings.

2. No recommendation is made regarding replacement of peripheral catheters in adults only when clinically indicated.

3. No recommendation can be made regarding attempts to salvage an umbilical catheter by administering antibiotic treatment through the catheter.

4. No recommendation can be made regarding the frequency for replacing intermittently used administration sets.

5. No recommendation can be made regarding the frequency for replacing needles to access implantable ports.

6. No recommendation can be made regarding the length of time a needle used to access implanted ports can remain in place.
Recommendations Regarding the Use of Chlorhexidine-Impregnated Dressings

1. Use a chlorhexidine-impregnated sponge dressing for temporary short-term catheters in patients older than 2 months of age if the CLABSI rate is not decreasing despite adherence to basic prevention measures, including education and training, appropriate use of chlorhexidine for skin antisepsis, and MS. Category 1B

2. Chlorhexidine impregnated dressings have been used to reduce the risk of CRBSI. In the largest multicenter randomized controlled trial published to date comparing chlorhexidine impregnated sponge dressings vs standard dressings in ICU patients, rates of CRBSIs were reduced even when background rates of infection were low. (References: Timsit, Garland, Ho, Levy)

3. No recommendation is made for other types of chlorhexidine dressings. Unresolved issue

Recommendations Regarding Catheter Insertion Site Visualization

Monitor the catheter sites visually when changing the dressing or by palpation through an intact dressing on a regular basis, depending on the clinical situation of the individual patient. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or bloodstream infection, the dressing should be removed to allow thorough examination of the site. Category IB

# SHEA Recommended Basic and Special Approaches for the Prevention of CLA-BSIs

## Basic Practices

<table>
<thead>
<tr>
<th>Practice</th>
<th>Grade</th>
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<tbody>
<tr>
<td>Catheter Checklist</td>
<td>B- II</td>
</tr>
<tr>
<td>Hand Hygiene</td>
<td>B- II</td>
</tr>
<tr>
<td>Insertion site-Femoral</td>
<td>A- I</td>
</tr>
<tr>
<td>Cart Kit</td>
<td>B- II</td>
</tr>
<tr>
<td>Maximal Barrier Precautions</td>
<td>A- I</td>
</tr>
<tr>
<td>Chlorhexidine (CHG) Skin Prep</td>
<td>A- I</td>
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## Special Approaches

<table>
<thead>
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<tr>
<td>CHG Baths (ICU patients)</td>
<td>B- II</td>
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<tr>
<td>Impregnated Catheters</td>
<td>A- I</td>
</tr>
<tr>
<td>BioPatch Disk</td>
<td>B- I</td>
</tr>
<tr>
<td>Antimicrobial Locks</td>
<td>A- I</td>
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Conclusions

• CVC-Related BSIs are a major cause of patient morbidity and mortality.

• Prevention of CVC-Related BSIs requires a multi-factorial approach, including:
  • Implementation of CDC CVC-BSI Prevention Guideline Recommendations (2011) and SHEA 2008 Compendium Recommendations.
  • Implementing new prevention evidence.
  • Implementation of insertion and maintenance bundles.
  • Educating staff; Insuring adequate and properly trained staff
  • Insuring that policy = practice (clinician accountability)
  • Monitoring CVC insertion and maintenance processes (checklists) and CVC-related BSI rates (outcomes).

• A comprehensive CVC-related BSI prevention program can dramatically reduce infection rates and improve patient safety.
SUMMARY AND CONCLUSIONS FOR Q2: WHAT TYPE OF CG DRESSING (I.E., SPONGE, NON-SPONGE) SHOULD BE USED FOR TEMPORARY SHORT TERM CATHETERS IN PATIENTS OLDER THAN 2 MONTHS TO REDUCE THE RISK OF INFECTION?

There are no studies directly comparing different types of CG dressing (sponge vs. non-sponge). There is 1 SR/MA which compared CG dressing vs. placebo or PVP-I dressing but likely included different types of CG dressings and included patients with epidural catheters.\textsuperscript{10}

There is evidence that CG sponge dressing results in significantly decreased rates of infection compared to standard or no dressing.
1. CDC Category 1B Recommendation is based on the review of 4 clinical studies exclusive to BIOPATCH® Protective Disk with CHG:
   - Timsit et al.
   - Ho et al.
   - Levy et al.
   - Garland et al.

2. These studies are based on the clinical use of BIOPATCH® and demonstrate statistically significant reduction of CLABSI rates.

3. All references cited by the CDC in support of the Category 1B recommendation were BIOPATCH® clinical studies.
Chlorhexidine-Impregnated Sponges and Less Frequent Dressing Changes for Prevention of Catheter-Related Infections in Critically Ill Adults: A Randomized Controlled Trial

This randomized clinical trial assessed the superiority of BIOPATCH® Protective Disk with CHG regarding the rate of major CRIs (clinical sepsis with or without bloodstream infection) and noninferiority (less than 3% colonization-rate increase) of 7-day vs. 3-day dressing changes.

- 1,636 patients from 7 intensive care units in 3 university and 2 general hospitals.

- Patients required an arterial catheter, CVC, or both for ≥48 hours.
  - 1,727 of the total 3,778 lines enrolled in this study were arterial catheters

- The median duration of catheter insertion was 6 days.

- A chlorhexidine gluconate-impregnated sponge or standard dressing (control) was used for the patients.

- The scheduled change of unsoiled adherent dressings was every 3 or 7 days, with immediate change of any soiled or leaking dressings.

### Table 3. Hazard Ratios in the Intention-To-Treat and Per-Protocol Analyses

<table>
<thead>
<tr>
<th>Variable</th>
<th>Incidence, No./1000 Catheter-Days</th>
<th>ITT Analysis</th>
<th>Per-Protocol Analysis(^a)</th>
<th>Dressing Change Interval</th>
<th>Incidence, No./1000 Catheter-Days</th>
<th>ITT Analysis</th>
<th>Per-Protocol Analysis(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control (n = 1825)</td>
<td>CHGIS (n = 1953)</td>
<td>HR (95% CI)</td>
<td>P Value</td>
<td>HR (95% CI)</td>
<td>P Value</td>
<td>HR (95% CI)</td>
</tr>
<tr>
<td>Catheter colonization &gt;10 CFUs/plate</td>
<td>15.8</td>
<td>6.3</td>
<td>0.36 (0.28-0.46)</td>
<td>&lt;.001</td>
<td>0.35 (0.27-0.45)</td>
<td>&lt;.001</td>
<td>10.4</td>
</tr>
<tr>
<td>Catheter-related bloodstream infection</td>
<td>1.3</td>
<td>0.4</td>
<td>0.24 (0.09-0.65)</td>
<td>.005</td>
<td>0.24 (0.09-0.63)</td>
<td>.004</td>
<td>0.7</td>
</tr>
<tr>
<td>Major catheter-related infection</td>
<td>1.4</td>
<td>0.6</td>
<td>0.39 (0.16-0.93)</td>
<td>.03</td>
<td>0.38 (0.16-0.92)</td>
<td>.03</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Abbreviations: CFU, colony-forming unit; CHGIS, chlorhexidine gluconate–impregnated sponge; CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat.

\(^a\)Analysis adjusted on imbalanced parameters (ie, presence of ≥1 chronic disease for comparison of control and CHGIS groups).
Conclusions:

In this study, use of the BIOPATCH® Protective Disk with CHG decreased the rates of catheter-related bloodstream infection by 76 percent.

A randomized trial comparing povidone-iodine to a chlorhexidine gluconate-impregnated dressing for prevention of central venous catheter infections in neonates.\textsuperscript{22}

**Purpose.** A multicenter randomized clinical trial was undertaken to ascertain the efficacy of a novel chlorhexidine-impregnated dressing (BIOPATCH\textsuperscript{®} Protective Disk with CHG Antimicrobial Dressing) on the CVC sites of neonates for the prevention of catheter tip colonization, CRBSI, and bloodstream infection (BSI) without a source.

**Conclusion.** The novel chlorhexidine-impregnated dressing, replaced weekly, was as effective as cutaneous disinfection with 10\% PI and redressing the site every 3 to 7 days for preventing CRBSI and BSI without a source in critically ill neonates requiring prolonged central venous access. The risk of local contact dermatitis under the chlorhexidine dressing limits its use in low birth weight (<1000 grams) infants who require prolonged central access during the first 2 weeks of life.

WARNING: DO NOT USE BIOPATCH\textsuperscript{®} ON PREMATURE INFANTS. USE OF THIS PRODUCT ON PREMATURE INFANTS HAS RESULTED IN HYPERSENSITIVITY REACTIONS AND NECROSIS OF THE SKIN. THE SAFETY AND EFFECTIVENESS OF BIOPATCH\textsuperscript{®} HAS NOT BEEN ESTABLISHED IN CHILDREN UNDER 16 YEARS OF AGE.
Use of chlorhexidine-impregnated dressing to prevent vascular and epidural catheter colonization and infection: a meta-analysis

Kwok M Ho, Edward Litton

• Vascular and epidural catheters, commonly used in patients requiring anesthesia, cause significant morbidity and mortality in hospitalized patients

Results
BIOPATCH® Protective Disk with CHG reduced the risk of catheter colonization and exit site infections
• For epidural catheters – 3.6% versus 35% with control (P= 0.0005)
• For intravascular catheters – 14.8% versus 26.9% with control (P< 0.0001)
• Overall risk for combined catheter types – 14.3% versus 27.2% (P<0.0001)

The authors concluded that chlorhexidine – impregnated sponge dressing effectively reduces vascular and epidural catheter bacterial colonization and is also associated with a trend towards reducing catheter – related bloodstream or coagulase –negative staphylococci (CNS) infections

Journal of Antimicrobial Chemotherapy 2006;58:281-287
Prevention of central venous catheter-related infections with chlorhexidine gluconate impregnated wound dressing: A randomized controlled trial.

Nineteen cases of CR-BSI occurred in the BIOPATCH® Protective Disk with CHG group (300 patients) vs. 34 cases in the control group (301 patients). This difference was statistically significant ($P=0.0271$).

<table>
<thead>
<tr>
<th>Rates of CRBSI and microbiology results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
</tr>
<tr>
<td>CRBSI</td>
</tr>
<tr>
<td>34</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Germs causing CRBSI</th>
<th>Control</th>
<th>Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus epidermidis</td>
<td>22</td>
<td>11</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Staphylococcus hominis</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>E. coli</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Lactobacillus spp.</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Candida albicans</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Candida tropicalis</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Staphylococcus haemolytic</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Enterococcus faecalis</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Prevention of central venous catheter-related infections with chlorhexidine gluconate impregnated wound dressing: A randomized controlled trial.

- 601 patients receiving catheters were randomized to receive either BIOPATCH® Protective Disk with CHG over the catheter insertion site or a standard sterile control dressing.

- All patients received triple-lumen CVCs (Arroguard® Blu, Arrow, Erding, Germany) impregnated with chlorhexidine-silversulphadiazine under standardized sterile conditions.

- Catheters were removed when no longer needed or CR-BSI was suspected.

- Daily routine included clinical assessment of insertion site, body temperature, white blood count, and C-reactive protein.

- The groups were comparable in demographic and clinical data.
BIOPATCH® Protective Disk with CHG is the *ONLY device of its kind with an FDA-cleared indication to reduce local infections, catheter-related blood stream infections (CRBSI), and skin colonization of microorganisms commonly related to CRBSI.* BIOPATCH® Disk is indicated for use with vascular and non-vascular percutaneous devices such as:

- Central Venous Lines
- **Arterial Catheters**
- Dialysis Catheters
- Peripherally Inserted Coronary Catheters
- Midline Catheters
- **Drains**
- Chest Tubes
- Externally Placed Orthopedic Pins
- Epidural Catheters
**BIOPATCH® Protective Disk with CHG Randomized Controlled Trial Results**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>% local infections (N=1,401 lines)</th>
<th>% CRBSIs (N=589 subjects)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIOPATCH®</td>
<td>16.4</td>
<td>2.4</td>
</tr>
<tr>
<td>Control</td>
<td>29.3</td>
<td>6.1</td>
</tr>
</tbody>
</table>

- **613 of the total 1,401 lines enrolled in this study were arterial catheters**

Comparative efficacy findings:

- **44% reduction in the incidence of local infection (catheter colonization)**
- **60% reduction in the incidence of CRBSI**
- Statistically significant reduction in skin colonization

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**Economic Impact of Use of BIOPATCH® Protective Disk with CHG**

1. Treating a single episode of catheter-related bloodstream infections costs hospitals as high as $56,000, which are considered as “NEVER” events no longer receiving reimbursement from payers.

2. A cost-effectiveness evaluation of the use of BIOPATCH® compared with standard care from a hospital perspective was conducted based a peer-reviewed economic model using the existing clinical and economic data.

3. A 400-bed hospital inserting 3078 central venous catheters (CVCs) per year is expected to avoid an average of 35 CRBSIs, 145 local infections, and 281 intensive care unit days annually.

4. It is estimated an average of 400-bed hospitals can save approximately $900,000 with the systematic implantation of BIOPATCH®.

5. Extensive sensitivity analyses confirmed BIOPATCH® can reduce overall hospital costs even for hospitals with low infection rates AND low cost to treat CRBSIs.

6. HHS national Patient Safety initiative has the goal of improving patient safety and reducing costs; results of this economic model are in line with these goals, i.e., reduction in preventable infections (thus improved patient safety) and reduction in costs of care.

7. BIOPATCH® is a cost-effective and cost saving treatment for prevention of CRBSI.

1. **Objectives**: To compare the daily risk and risk factors for colonization and catheter-related infection between arterial catheters and central venous catheters.

2. **Methods**: We used data from a trial of seven intensive care units evaluating different dressing change intervals and use of the BIOPATCH® Protective Disk with CHG. Determined the daily hazard rate and identified risk factors for colonization using a marginal Cox model for clustered data.
Risk of Colonization or Infection in Arterial or Central Venous Catheters

1. 2095 patients with >1 intravascular catheter, 1636 were enrolled

2. Of these, 1525 had >1 assessable catheter (1212 patients had >1 AC, 1403 had >1 CVC, and 1090 patients had >1 AC plus >1 CVC)

3. A total of 3532 catheters (1617 ACs and 1915 CVCs) with 27,541 catheter-days were cultured and analyzed

Lucet JC et al., Crit Care Med 2010; 38:1-6.
1. Colonization rates did not differ between arterial catheters (ACs) and central venous catheters (CVCs) (7.9% [11.4/1000 catheter-days] and 9.6% [11.1/1000 catheter-days], respectively)

2. AC- and CVC-related infection rates were 0.68% (1.0/1000 catheter-days) and 0.94% (1.09/1000 catheter-days)
Conclusions

1. Risks of colonization and catheter-related infection did not differ between ACs and CVCs, indicating that AC use should receive the same precautions as CVC use.

2. Daily risk was constant over time for CVCs after the fifth catheter day but increased significantly over time after the seventh day for ACs.

3. Randomized studies are needed to investigate the impact of scheduled AC replacement.

Lucet JC et al., Crit Care Med 2010; 38:1-6.
IVD-BSI Risk Associated with Central Venous and Arterial Catheters

1. If 6 million ACs inserted annually and risk of CR-BSI ranges from 0.7%-3.7%, then there are ~42,000-222,000 AC-BSIs annually

2. Despite this, ACs are ignored in many guidelines (SHEA, UK, CDC) and prevention bundles have not been applied to ACs