Reducing Catheter-related Bloodstream Infections: Does it Stop At the Hospital’s Front Door?

Boise APIC
Meridian, Idaho
October 25, 2013

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Hierarchy of Medical Evidence

- Systematic Reviews and Meta-analyses
- Randomized Controlled Trials
- Cohort Studies
- Case Control Studies
- Case Series
- Case Reports
- Ideas, Editorials, Opinions
- Animal Research
- In Vitro ("Test Tube") Research

http://library.downstate.edu/ebm/2500.htm
Value Based Purchasing – Definition

As part of the Affordable Care Act, congress has authorized the inpatient Value Based Purchasing Program, which provides a data reporting infrastructure for hospitals to help ensure quality patient outcomes

- Value Based Purchasing program is part of the Centers for Medicare & Medicaid Services (CMS)
- CMS efforts have been linked to the Medicare payment system to improve healthcare quality, which includes quality of care provided in the inpatient setting

Value Based Purchasing – How It Works

- CMS will implement Value Based Purchasing to the Inpatient Prospective Payment System which affects 3,500 hospitals, representing largest share of Medicare spending.

- Hospitals will pay a percent withholding on the front end and will either earn money back, lose percent paid in, or earn additional dollars.

- Funding of Value Based Purchasing program will be through the reduction of hospitals DRG payments for each discharged (Inpatient Protective Payment System).

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>MS-DRG Operating Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2013</td>
<td>1%</td>
</tr>
<tr>
<td>FY 2014</td>
<td>1.25%</td>
</tr>
<tr>
<td>FY 2015</td>
<td>1.50%</td>
</tr>
<tr>
<td>FY 2016</td>
<td>1.75%</td>
</tr>
<tr>
<td>FY 2017 and Beyond</td>
<td>2%</td>
</tr>
</tbody>
</table>

[Accessed on April 26, 2013]

CMS redistributes the percent withheld across hospitals with highest achievement

- Redistribution is based on performance
- Best performers win; others break even or lose

So what does that mean?

Your hospital’s 1–2% could be redistributed to other hospitals with better performance, or you could receive other underperforming hospital’s 1–2%

Hospitals will be assessed on how much their current performance changes from their own baseline period performance.

Points will be awarded based on how much distance they cover between that baseline and the benchmark.

Hospitals measured based on how much their current performance differs from all other hospitals’ baseline period performance.

Points will be awarded based on hospital’s performance compared to threshold and benchmark scores for all hospitals.

TPS calculated by combining the greater of the hospital’s achievement or improvement points on each measure to determine a score for each domain, multiplying each domain score by the proposed domain weight and adding the weighted scores together.

### Value Based Purchasing Domains

#### Tracking VBP Measures Across Time

<table>
<thead>
<tr>
<th>Domain</th>
<th>Description</th>
<th>FY 2013</th>
<th>FY 2014</th>
<th>FY 2015</th>
<th>FY 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Process</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AMI-7a</td>
<td>Fibrinolytic therapy received within 30 minutes of hospital arrival</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>AMI-8a</td>
<td>Primary PCI received within 90 minutes of hospital arrival</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>-</td>
</tr>
<tr>
<td>HF-1</td>
<td>Discharge instructions</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>-</td>
</tr>
<tr>
<td>IMM-2</td>
<td>Influenza Immunization</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>PN-3b</td>
<td>Blood cultures performed in the ED prior to initial antibiotic received in hospital</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>-</td>
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<tr>
<td>PN-6</td>
<td>Initial antibiotic selection for CAP in immunocompetent patient</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>SCIP-Inf-1</td>
<td>Prophylactic antibiotic received within one hour prior to surgical incision</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>SCIP-Inf-2</td>
<td>Prophylactic antibiotic selection for surgical patients</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>SCIP-Inf-3</td>
<td>Prophylactic antibiotics discontinued within 24 hours after surgery end time</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>SCIP-Inf-4</td>
<td>Cardiac surgery patients with controlled 6am postoperative serum glucose</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>SCIP-Inf-9</td>
<td>Urinary catheter removed on postoperative day 1 or postoperative day 2</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>SCIP-Card-2</td>
<td>Surgery patients on prior S-blocker receive S-blocker during perioperative period</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>SCIP-VTE-1</td>
<td>Surgery patients with recommended venous thromboembolism prophylaxis ordered</td>
<td>X</td>
<td>X</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>SCIP-VTE-2</td>
<td>Patients receiving appropriate VTE prophylaxis 24 hours prior to and after surgery</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Patient Experience</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCAHPS¹</td>
<td>Patient Satisfaction Measures</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>MORT-30-AMI</td>
<td>Acute myocardial infarction 30-day mortality rate</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>MORT-30-HF</td>
<td>Heart failure 30-day mortality rate</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>MORT-30-PN</td>
<td>Pneumonia 30-day mortality rate</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>PSI-90</td>
<td>Complication/patient safety for selected indicators (composite)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>X</td>
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<tr>
<td>CAUTI</td>
<td>Catheter-Associated Urinary Tract Infection</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td>CLABSI</td>
<td>Central line associated blood stream infection</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td>SSI</td>
<td>Surgical Site Infection, Colon, Abdominal Hysterectomy</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td><strong>Efficiency</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MSPB_1</td>
<td>Medicare spending per beneficiary</td>
<td>-</td>
<td>-</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

1. Comprised of: Communication with nurses, Communication with doctors, Responsiveness of hospital staff, Pain management, Communication about medicines, Cleanliness and quietness of hospital environment, Discharge information, Overall rating of hospital

Source: CMS, Advisory Board Analysis

Monday, October 28, 2013
## Value Based Purchasing Domains

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</tr>
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</table>

| **Patient Experience**  |                                                                             |         |         |         |         |
| HCAHPS                  | Patient Satisfaction Measures                                              | X       | X       | X       | X       |
| **Outcomes**            |                                                                             |         |         |         |         |
| MORT-30-AM              | Acute myocardial infarction 30-day mortality rate                           | -       |         | X       | X       |
| MORT-30-HF              | Heart failure 30-day mortality rate                                         | -       |         | X       | X       |
| MORT-30-SN              | Pneumonia 30-day mortality rate                                             | -       |         | X       | X       |
| **Complication/patient safety** | Complication/patient safety for selected indicators (composite) | -       | -       | -       | X       |
| CAUTI                   | Catheter-Associated Urinary Tract Infection                               |      |         |         |         |
| **Central line associated blood stream infection** | Central line associated blood stream infection | -       | -       | -       | X       |
| **Surgical Site Infection** | Surgical Site Infection, Colon, Abdominal Hysterectomy | -       | -       | -       | -       |
| **Medicare spending per beneficiary** | Medicare spending per beneficiary | -       | -       | -       | X       |

Source: CMS, Advisory Board Analysis

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Eric Fontana, "The Future of Value Based Purchasing" Advisory Board Webinar May 23, 2013

Monday, October 28, 2013
Hospital–acquired Infections (HAIs): A Big Problem

According to the Centers for Disease Control and Prevention (CDC), HAIs accounted for an estimated 1.7 million infections and 99,000 deaths annually.

Top 4 Hospital Acquired Infections by Type

- Urinary Tract Infections: 42%
- Pneumonia VAP: 18%
- Bloodstream Infections: 18%
- SSI: 22%

Top 4 Hospital Acquired Infections by Annual Occurrence & Cost

<table>
<thead>
<tr>
<th>Infection Type</th>
<th>Annual Number of Infections</th>
<th>Total Annual Cost to Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bloodstream Infections</td>
<td>248,678</td>
<td>$5,779,774,076</td>
</tr>
<tr>
<td>SSI</td>
<td>290,485</td>
<td>$3,033,534,855</td>
</tr>
<tr>
<td>Urinary Tract Infections</td>
<td>561,667</td>
<td>$425,743,586</td>
</tr>
<tr>
<td>Pneumonia VAP</td>
<td>250,205</td>
<td>$6,273,139,760</td>
</tr>
</tbody>
</table>

Department of Health and Human Services, Action Plan to Prevent Healthcare–Associated Infections 06222009, Section 3 Introduction, pg 7, 8.
Center for Medicare and Medicaid Services (CMS): 10 Preventable Conditions

As of Fiscal Year 2009, CMS is tracking the incidence of selected infections, including CRBSI

- Foreign object retained after surgery
- Air embolism
- Blood incompatibility
- Stage III and IV pressure ulcers
- Falls and trauma
- Manifestations of poor glycemic control
- Catheter-associated urinary tract infections
- **Vascular catheter–associated infection**
- Surgical site infection
- Deep vein thrombosis (DVT) / pulmonary embolism (PE)

http://www.cms.hhs.gov/HospitalAcqCond/06_Hospital-Aquired_Conditions.asp Accessed on April 17, 2009
**Microbial Source of Catheter–related Bloodstream Infections**

**Extraluminal biofilm:**
- Major source of CRBSI within first week of catheterization in short-term catheters
- Major source of tunnel infections in long-term catheters

**Intraluminal biofilm:**
- Major source of CRBSI after 1 week in both short- and long-term catheters

---

**Microbiology of the Skin**

- 80% of the resident bacteria exist within first 5 layers of stratum corneum
- 20% are found in biofilms within hair follicles and sebaceous glands
- Complete recolonization of epidermis can occur within 18 hours of antiseptic application

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Monday, October 28, 2013
Pathogenesis: Does it Change Inside vs. Outside the Hospital?

Pathogenesis: Does it Change Inside vs. Outside the Hospital?

Contaminated Catheter Hub 12%

Pathogenesis: Does it Change Inside vs. Outside the Hospital?

1. Contaminated Catheter Hub: 12%
2. Contaminated Infusate: <1%

Pathogenesis: Does it Change Inside vs. Outside the Hospital?

1. Contaminated Catheter Hub 12%
2. Contaminated Infusate <1%
3. Skin Organisms 60%


Monday, October 28, 2013
Pathogenesis: Does it Change Inside vs. Outside the Hospital?

1. Contaminated Catheter Hub 12%
2. Contaminated Infusate <1%
3. Skin Organisms 60%
Unknown = 28%


Monday, October 28, 2013

Major areas of emphasis include:

1. Education and training healthcare personnel who insert and maintain catheters;

2. Using maximal sterile barrier precautions during central venous catheter insertion (CVC);

3. Using a $\geq 0.5\%$ chlorhexidine (CHG) preparation with alcohol for skin antisepsis;

4. Avoiding routine replacement of CVCs as a strategy to prevent infection;

5. Using antiseptic/antibiotic impregnated short-term CVCs 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 $\geq 0.5\%$ CHG preparations with alcohol for skin antisepsis); and

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.

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**

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% CHG 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 > 2 months of age, if the CR-BSI rate is decreasing despite adherence to basic prevention measures, including education and training, appropriate use of chlorhexidine for skin antisepsis, and MSB. **Category 1B** (changed from unresolved issue to Category 1B)

2. Use a CHG/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 CLA-BSI, the CLA-BSI 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 2% CHG preparation with alcohol 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 (CHG, 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 in patients with chronic renal failure 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., catheters inserted during a medical emergency), replace the catheter as soon as possible, i.e., within 48 hours. **Category 1B** (changed from a II to 1B)
7. 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)

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

9. Use prophylactic antimicrobial lock solution in patients with long-term catheters who have a history of multiple CR-BSI despite optimal maximal adherence to aseptic technique. **Category II** (changed from “do not use” to “use”; both Category II)
Are Peripheral Intravenous Catheters (PIVs) an Overlooked Source of Infection?
Why Should You Care About Complications Associated With Non-central Lines?

1. In 2008, the Center for Medicare and Medicaid Services (CMS) began its program of disallowing reimbursement for vascular catheter-associated infections (note there is no modification for type or location of the catheter or the type—local or bloodstream [BSI]—of infection).

2. Vascular catheter–related infections would encompass all devices used to access the vasculature without regard to the specific tip location or limiting only to BSIs.
Why Doesn’t Anyone Talk About This?

General belief is that the risk is minimal or non-existent

• But almost no one is looking!
• Body of research is starting to grow and dispel this myth.
TABLE 4. Subgroup Analyses of Studies of Short-term Intravascular Devices*

<table>
<thead>
<tr>
<th>Device</th>
<th>All studies</th>
<th>Studies requiring microbial concordance between catheter and blood cultures</th>
<th>Studies requiring microbial concordance and all devices cultured</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of</td>
<td>IVD-related BSIs per 1000 IVD-days (95% CI)</td>
<td>No. of studies</td>
</tr>
<tr>
<td></td>
<td>studies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral IV catheters</td>
<td>10</td>
<td>0.5 (0.2-0.7)</td>
<td>9</td>
</tr>
<tr>
<td>Midline catheters</td>
<td>3</td>
<td>0.2 (0.0-0.5)</td>
<td>2</td>
</tr>
<tr>
<td>Arterial catheters for hemodynamic monitoring</td>
<td>14</td>
<td>1.7 (1.2-2.3)</td>
<td>11</td>
</tr>
<tr>
<td>Peripherally inserted central catheters</td>
<td>15</td>
<td>1.0 (0.8-1.2)</td>
<td>5</td>
</tr>
<tr>
<td>Noncuffed central venous catheters</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonmedicated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nontunneled</td>
<td>79</td>
<td>2.7 (2.6-2.9)</td>
<td>63</td>
</tr>
<tr>
<td>Tunneled</td>
<td>9</td>
<td>1.7 (1.2-2.3)</td>
<td>7</td>
</tr>
<tr>
<td>Medicated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chlorhexidine-silver-sulfadiazine</td>
<td>18</td>
<td>1.6 (1.3-2.0)</td>
<td>16</td>
</tr>
<tr>
<td>Minocycline-rifampin</td>
<td>3</td>
<td>1.2 (0.3-2.1)</td>
<td>3</td>
</tr>
<tr>
<td>Pulmonary artery catheters</td>
<td>13</td>
<td>3.7 (2.4-5.0)</td>
<td>11</td>
</tr>
<tr>
<td>Noncuffed, nontunneled hemodialysis catheters</td>
<td>16</td>
<td>4.8 (4.2-5.3)</td>
<td>11</td>
</tr>
</tbody>
</table>

*BSI = bloodstream infection; CI = confidence interval; IV = intravenous; IVD = intravascular device.

Peripheral Venous Catheters (PVCs)

- PVCs are most frequently used invasive device in hospitals.
- Up to 70% of patients require a PVC during their hospital stay.
- Estimated that PVCs are in place for 15%–20% of total patient-days.
- No consensus on optimal time point for PVC change, or whether PVC replacement is required at all.
- Current estimates are that PVC-associated bloodstream infection incidence density rates are 0.2–0.7 per 1,000 device-days.

Peripheral Venous Catheter–Related Staphylococcus aureus Bacteremia

- 24 *S. aureus* bacteremias.
- A rate of 0.07/1000 line days.
- 12% of all device–related *S. aureus* bacteremias were caused by PVCs.
- Average treatment in this study was 19 days.
- Some serious complications including two patient deaths and one transfer to hospice.

Risk Factors

1. Antecubital fossa (46%)
2. Placement outside of the hospital (16%)
3. Placement in Emergency Room (67%)
4. Longer duration of catheterization
   - 46% had duration >3 days
   - A national survey showed that >90% of PIV-associated infections take place with catheters left in >3 days.

A Comparison of Bloodstream Infections in Central and Peripheral Venous Catheters

**Study Design:**
Prospective study of bloodstream infections (BSIs) in short and mid-line peripheral venous catheters (PVCs) vs. central venous catheters (CVCs) among a group of non-intensive care unit patients from October 2001 to March 2003 in a hospital in Spain.

**Results:**
- 150 vascular catheter-related BSIs in 147 patients:
  - 77 were PVC-BSIs (0.19 per 1,000 patient-days) vs. 73 CVC-BSIs (0.18 per 1,000 patient-days).
  - Patients with PVC-BSIs more often had the catheter placed in the emergency department (42% vs. 0%), had a shorter duration from catheter insertion to BSI (4.9 vs 15.4 days) and *S. aureus* as the pathogen (53% vs 33%).

Pujol M et al., J Hosp Infect 2007;67:22-9
A Comparison of Bloodstream Infections in Central and Peripheral Venous Catheters

• Rates of infection very similar between peripheral and central venous catheters.

• Difference in onset between lines placed in ER vs. inpatient units
  – Emergency Room: 3.7 days
  – Nursing units: 5.7 days

• S. aureus was more prevalent in peripheral lines, but MRSA was about the same
  – Patients with S. aureus had more complications than from other organisms.
  – This is significant not only for the patients, but for mandatory reporting that began in January 2013 in the United States (all MRSA-BSIs).

Pujol M et al., J Hosp Infect 2007;67:22-9
Prevalence of Bloodstream Infections (BSIs) in Central and Peripheral Vascular Catheters

Study Design:
Prevalence survey at 72 hospitals in Germany.

Results:
A total of 14,966 patients were surveyed. Of these 23.9% patients had a non-central catheter and 5.1% had a central catheter. Device utilization was 27.3% for peripheral and 6.1% for central. BSI prevalence was 0.3% for non-central catheters and 0.8% for central catheters.

Conclusion:
Peripheral catheters are very prevalent and associated with moderate BSI risk.

PIVs Not Without Risk

**Ritchie 2007 (New Zealand)**
- Looked at 345 PIVs.
  - 22/345 had signs of infections.
  - 6/44 in >72 hours.
  - 16/301 in <72 hours.

**Hong 2008 (Korea)**
- Purulent thrombophlebitis from IV.
- Positive for *C. albicans*.
- Developed fungal spondylitis in vertebrae.
- Patient died.

PIVs Not Without Risk

Easterlow 2010 (England)\(^1\)

- Pre-intervention: 30 MRSA bacteremias – 9 catheter-related.
- Post-intervention: 14 bacteremias – 4 definite, 2 possibly catheter-related.

Lee 2010 (Taiwan)\(^2\)

- 46 cases of soft tissue infections from peripheral lines (over 3-year period)
  - 6 with bacteremia (also with local inflammation)
  - 6 needing surgical debridement for abscess
  - 8 with purulent drainage or cellulitis at insertion site
    - 1 with bacteremia with same pathogen
  - 26 with inflammation (persisting >3 days after catheter removal).

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Monday, October 28, 2013
One More Hospital’s Experience

Period of 6 Years All LCBIs Counted

Line types associated with each infection were recorded
Over that time period, between 11% and 21% of LCBIs had only peripheral access (total of 74 patients).
  30% to 47% of patients had multiple lines in place.
  – Majority of those had peripheral as well as central lines.
  – Classified (based on NHSN definition) as CLABSI
    (But no proof of which line was truly responsible)

With These Infections, Can’t Reach Zero

House–wide in reduction of CLABSI.

PIV–only infections: did not observe the same reduction.

Cochrane Peripheral Vascular Diseases Group

• Assessed impact of removing peripheral catheters when clinically indicated vs. removing and re-siting routinely.

• Found no conclusive benefit in changing PIV every 72 hours to 96 hours.

• Looked at phlebitis as well as bacteremia.

• Also looked at costs associated with routine changes.

Results:

• Changing for clinical need rather than on routine schedule reduced the rate of bacteremia 44%
  
  • Odds Ratio (OR) = 0.57  P= 0.37

• 24% increase in phlebitis in the clinical change group
  
  • OR= 1.24 P=0.09.


Monday, October 28, 2013
CDC Recommendation

• “There is no need to replace peripheral catheters more frequently than every 72–96 hours to reduce risk of infection and phlebitis in adults. Category 1B”

• “No recommendation is made regarding replacement of peripheral catheters in adults only when clinically indicated. Unresolved issue”

• “Replace peripheral catheters in children only when clinically indicated. Category 1B”

• “Some studies have suggested that planned removal at 72 hours vs. removing as needed resulted in similar rates of phlebitis and catheter failure. However, these studies did not address the issue of CRBSI, and the risk of CRBSIs with this strategy is not well studied.”

INS Standards

• “Routine site care and dressing changes are not performed on short peripheral catheters unless the dressing is soiled or not longer intact.”

• “The nurse should consider replacement of the short peripheral catheter when clinically indicated and when infusion treatment does not include peripheral parenteral nutrition.”

• “The nurse should not routinely replace short peripheral catheter in pediatric patients.”

• “If a catheter related bloodstream is suspected, consideration should be given to culturing the catheter after removal.”
What Could Be Causing These Infections?

Back To Basics

Pre-Prep
Bacteria colonies exist not only on the surface, but below the surface as well, particularly within the hair follicles and sebaceous glands.

15:00 Mins

Post-Prep
(immediately following antiseptic application)
Prepping the skin reduces colony counts of bacteria from the surface only—it never completely disinfects the skin.

Post-Prep
(within 1-2 days following antiseptic application)
Resident bacteria begin to re-colonize the skin surface.
Technology’s Role

• What are you doing for the PIVs that are staying in >72 hours to reduce skin colonization?

• There are products out there that can help reduce the skin flora, if you are leaving your catheters in for long periods of time, i.e.
  – Biopatch® Protective Disk with CHG is the only product indicated to reduce CRBSI.
  – Indicated to use on IV catheters.

• It's up to you to decided what fits best in your hospital’s protocol
  – Look at the evidence
  – Look at product indications

![Image of Biopatch® Protective Disk with CHG](image-url)
Reporting...

- NHSN/CMS/TJC/Health departments, etc only require reporting central line-associated bloodstream infections
  - Just need to meet the definition PLUS have a central line in place.
  - No requirement for “proof” that the central line was the source or for any evidence of local site infection.

- You can still meet the definition for a LCBI and not have a central line in place, but it is not reported and no benchmarks are available within CDC’s NHSN
  - These are what can be referred to as “non-central line associated, laboratory confirmed bloodstream infections”
CDC Recommendation

Periodically assess knowledge of and adherence to guidelines for all personnel involved in the insertion and maintenance of intravascular catheters.

Category IA

• Ideally, this involves auditing actual care
  – Morris, et al. describe using audit results as educational material and making them widely available.
  – Some institutions periodically conduct audits of peripheral maintenance bundle as well as the more standard central line maintenance bundle.

• This data can have large impact on identifying areas needing further review or education
CMS and Peripheral Lines

• Starting January 1, 2013 all MRSA blood isolates were reportable via NHSN to CMS.
  – Both community onset and healthcare–associated must be reported.
  – House–wide (not just ICU) isolates must be reported from all inpatient locations.
  – Not just CLABSIs are counted, so any infections associated with peripheral vascular access also will be reported.

• Starting back in 2008, non-payment also includes vascular catheter–related infections; CLABSIs reported through NHSN are only part of this data set
  – Any coded vascular access–related infections also are included in this category.
  – Not limited to only central lines.

Review

• According to some studies, the longer a Peripheral Venous Catheter stays in place, the higher the chance there is for an infection and possible mortality.

• There have been recent changes to guidelines to allow a longer dwell time for these catheters.

• The main bacteria causing these infection is Staphylococcus spp. coming from skin flora via intra- or extra-luminal colonization.

• Beginning in January 2013, any positive blood cultures from Methicillin-resistant Staphylococcus aureus must be reported to CMS via CDC’s NHSN.

• Surveillance, training, and technology are areas to look to help get an understanding of how to reduce these infections.
Home Infusion:  
Do the Same Standards Apply?

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This promotional educational activity is brought to you by Ethicon, Inc. and is not certified for continuing medical education.
Objectives

- To discuss risk of infections in home infusion patients
- To differentiate current measures to reduce catheter-related infection in home infusion patients
- To understand the changing healthcare environment in reimbursement/readmission for home infusion
Evolution of Home Care

Prospective pricing and diagnosis-related groups, and resulting pressures to reduce inpatient length of stay, prompted additional growth of the industry.

1980

1995

1996

29% of acute care hospitals provided or were developing a home care program.

Home care represented only 3% of total national expenditures.

- Annual growth rate of home infusion industry dropped from 64% in 1982–86 to 24% in 1986–93.

- Home infusion market is being integrated into alternative sites, such as ambulatory infusion centers (AICs).

- AICs provide infusion therapy and nursing to non-institutionalized, non-home bound patients.

- Despite slowed growth in recent years, home care has a strong market in U.S.

Diseases Commonly Treated with Home Infusion Therapy

- Infections that are unresponsive to oral antibiotics
- Cancer and cancer-related pain
- Dehydration
- Gastrointestinal diseases or disorders which prevent normal functioning of the gastrointestinal system
- Crohn's Disease
- Hemophilia
- Immune deficiencies
- Multiple sclerosis
- Rheumatoid arthritis
- Congestive heart failure
Epidemiology of Bloodstream Infections in Patients Receiving Long-term Total Parenteral Nutrition (TPN)

- **STUDY DESIGN:** Descriptive, observational, epidemiologic study of patients receiving long-term TPN from Jan 1981 – July 2005 in Brazil.

- **RESULTS:** 47 patients were evaluated. Mean duration of follow-up was 4.5 years. 38 (80.9%) patients developed 248 BSIs while receiving TPN. More than one BSI episode occurred in 78.9% of these patients.

- **CONCLUSIONS:** Incidence of BSI is high, a high percentage of BSIs are polymicrobial to due to multidrug-resistant pathogens.

Central Venous Catheters (CVCs) in Home Infusion Care

**STUDY DESIGN:** To document the natural history of CVCs used in home infusion care. Data from the Strategic HealthCare Programs National Database from April 1999 to September 2000 were analyzed. Objectives to identify: 1) types of CVCs, 2) type and rate of catheter complications, and 3) outcomes in managing thrombotic catheter complications.

**RESULTS:**
- Most common complications (per 1,000 days) were: catheter dysfunction (0.83 total: 0.6 nonthrombotic, 0.23 thrombotic); catheter site infections (0.26); and bloodstream infections (0.19).
- Total of 4,138 complications were identified (1.5 per 1,000 days.)
- BSIs were reported in 541 patients, generally >30 days after catheter insertion.

## Central Venous Catheters (CVCs) in Home Infusion Care

<table>
<thead>
<tr>
<th>Catheter Type</th>
<th>Complication Rate (per 1,000 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midline</td>
<td>4.5</td>
</tr>
<tr>
<td>Peripherally inserted central catheter (PICC)</td>
<td>2.0</td>
</tr>
<tr>
<td>Non-tunneled central catheter</td>
<td>1.1</td>
</tr>
<tr>
<td>Tunneled catheter</td>
<td>1.0</td>
</tr>
<tr>
<td>Chest ports</td>
<td>0.52</td>
</tr>
</tbody>
</table>


Monday, October 28, 2013
Central Venous Catheters (CVCs) in Home Infusion Care

• **RESULTS:**
  – Catheter dysfunction with loss of patency was most common group of complications.
  – Thrombotic occlusion occurred in 28% of the patients, typically within 7 days of catheter insertion.
  – Catheter thrombosis outcomes resulted in therapy interruptions (43%), catheter replacement (29%), premature catheter removal (14%), unscheduled emergency room visits (9%) and/or hospitalizations (6%).

• **CONCLUSIONS:** Catheter dysfunction and bloodstream infections are the most common complications of outpatient home infusion catheter complications.

Surveillance of Infectious Complications Associated with Central Venous Access Devices (CVAD) in Children with Hemophilia

• **STUDY DESIGN:** Retrospective chart review of risk factors for CVAD infection among patients with congenital hemophilia who had had a CVAD implanted at a single institution from January 1993–October 2000.

• **RESULTS:**
  - 59 patients had a total of 97,936 (median 1768) CVAD days.
  - 26 (44%) patients reported CVAD infections. 24/26 had their CVAD replaced; 71% reported having infections. Among the 26 patients reporting infections, 42% had more than one CVAD–related infection.
  - Mean rate of infection was 0.45 per 1000 catheter days. For the group as a whole, median time to first infection was 1977 days from CVAD placement.

• **CONCLUSIONS:** While considerable numbers of patients develop CVAD–related infection, the interval between catheter placement and infection can be quite long.

Tarantino MD. et al., Haemophilia. 2003;9:588–92
Characterization of Post–hospital Bloodstream Infections in Children Requiring Home Parenteral Nutrition (HPN)

• **STUDY DESIGN:** Retrospective chart review of 44 children receiving HPN during a 3–year period. End points were CLA–BSI during the initial 6 months after discharge.

• **RESULTS:**
  – Primary indication for HPN was short bowel syndrome (46%).
  – 59 BSIs were documented during initial 6 months of HPN in 29 (66%) children.
  – Polymicrobial infections accounted for 52%; gram–positive: 29%; gram–negative: 17%; and fungal: 2%.
  – CA–BSI incidence per 1000 catheter–days was highest during first month post–hospital discharge (72 episodes).
  – CA–BSI incidence density ratio for children receiving HPN for >90 days compared with those receiving HPN for <30 days was 2.2 (P < .05).

• **CONCLUSIONS:** Incidence of CA–BSI in children receiving HPN is highest during the first month post–hospital discharge. Strategies to address care in the immediate post–hospital discharge period may reduce burden of infectious complications of HPN.

Review

• Catheter-associated Bloodstream Infection is one of the most common complications in Home Infusion patients.

• To differentiate current measures to reduce catheter-related infection in home infusion patients, you need to look at the evidence, the guidelines and the products labels.

• The changing healthcare environment in reimbursement/readmission rates is going to affect home infusion.

*Section 3025 of the Affordable Care Act added section 1886(q) to the Social Security Act establishing the Hospital Readmissions Reduction Program, which requires CMS to reduce payments to IPPS hospitals with excess readmissions, effective for discharges beginning on October 1, 2012. The regulations that implement this provision are in subpart I of 42 CFR part 412 (§412.150 through §412.154).
Prevention of CLA-BSIs in Patients Receiving Maintenance Hemodialysis
<table>
<thead>
<tr>
<th>Device</th>
<th>No. of studies</th>
<th>No. of catheters</th>
<th>No. of IVD (d)</th>
<th>No. of BSIs</th>
<th>Rates of IVD-related bloodstream infection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Per 100 devices</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pooled mean</td>
</tr>
<tr>
<td>Peripheral IV catheters</td>
<td>110</td>
<td>10,910</td>
<td>28,720</td>
<td>13</td>
<td>0.1</td>
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<tr>
<td>Plastic catheters</td>
<td>1</td>
<td>148</td>
<td>350</td>
<td>3</td>
<td>2.0</td>
</tr>
<tr>
<td>Steel needles</td>
<td>1</td>
<td>27</td>
<td>111</td>
<td>1</td>
<td>3.7</td>
</tr>
<tr>
<td>Venous cutdown</td>
<td>3</td>
<td>514</td>
<td>9251</td>
<td>2</td>
<td>0.4</td>
</tr>
<tr>
<td>Arterial catheters for hemodynamic monitoring</td>
<td>14</td>
<td>4366</td>
<td>21,397</td>
<td>37</td>
<td>0.8</td>
</tr>
<tr>
<td>Peripherally inserted central catheters</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inpatient and outpatient</td>
<td>15</td>
<td>3566</td>
<td>105,839</td>
<td>112</td>
<td>3.1</td>
</tr>
<tr>
<td>Inpatient</td>
<td>6</td>
<td>625</td>
<td>7137</td>
<td>15</td>
<td>2.4</td>
</tr>
<tr>
<td>Outpatient</td>
<td>9</td>
<td>2813</td>
<td>98,702</td>
<td>97</td>
<td>3.5</td>
</tr>
<tr>
<td>Short-term noncuffed central venous catheters</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonmedicated</td>
<td>79</td>
<td>20,226</td>
<td>322,283</td>
<td>883</td>
<td>4.4</td>
</tr>
<tr>
<td>Nontunneled</td>
<td>9</td>
<td>741</td>
<td>20,065</td>
<td>35</td>
<td>4.7</td>
</tr>
<tr>
<td>Tunneled</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chlorhexidine-silver-sulfadiazine</td>
<td>18</td>
<td>3367</td>
<td>54,054</td>
<td>89</td>
<td>2.6</td>
</tr>
<tr>
<td>Minocycline-rifampin</td>
<td>3</td>
<td>690</td>
<td>5797</td>
<td>7</td>
<td>1.0</td>
</tr>
<tr>
<td>Silver impregnated</td>
<td>2</td>
<td>154</td>
<td>1689</td>
<td>8</td>
<td>5.2</td>
</tr>
<tr>
<td>Silver iontophoretic</td>
<td>2</td>
<td>396</td>
<td>4796</td>
<td>16</td>
<td>4.0</td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>1</td>
<td>277</td>
<td>2493</td>
<td>12</td>
<td>4.3</td>
</tr>
<tr>
<td>Pulmonary artery catheters</td>
<td>13</td>
<td>2057</td>
<td>8143</td>
<td>30</td>
<td>1.5</td>
</tr>
<tr>
<td>Hemodialysis catheters</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temporary, noncuffed</td>
<td>16</td>
<td>3066</td>
<td>51,840</td>
<td>246</td>
<td>8.0</td>
</tr>
<tr>
<td>Long-term, cuffed and tunneled</td>
<td>16</td>
<td>2806</td>
<td>373,563</td>
<td>596</td>
<td>21.2</td>
</tr>
<tr>
<td>Cuffed and tunneled central venous catheters</td>
<td>29</td>
<td>4512</td>
<td>622,535</td>
<td>1013</td>
<td>22.5</td>
</tr>
<tr>
<td>Subcutaneous venous ports</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central</td>
<td>14</td>
<td>3007</td>
<td>983,480</td>
<td>81</td>
<td>3.6</td>
</tr>
<tr>
<td>Peripheral</td>
<td>3</td>
<td>579</td>
<td>162,203</td>
<td>23</td>
<td>4.0</td>
</tr>
<tr>
<td>Intra-aortic balloon pumps</td>
<td>1</td>
<td>101</td>
<td>414</td>
<td>3</td>
<td>3.0</td>
</tr>
<tr>
<td>Left ventricular assist devices</td>
<td>3</td>
<td>157</td>
<td>19,653</td>
<td>41</td>
<td>26.1</td>
</tr>
</tbody>
</table>


- **Study Design**: Centers for Disease Control and Prevention (CDC) estimate of CLA-BSI rates from their National Healthcare Safety Network (NHSN) surveillance system.

<table>
<thead>
<tr>
<th>Population</th>
<th>Year</th>
<th>Estimated number of CLA-BSIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intensive care unit (ICU)</td>
<td>2001</td>
<td>43,000</td>
</tr>
<tr>
<td>ICU</td>
<td>2009</td>
<td>25,000</td>
</tr>
<tr>
<td>Inpatient wards</td>
<td>2009</td>
<td>23,000</td>
</tr>
<tr>
<td><strong>Outpatient hemodialysis</strong></td>
<td>2008</td>
<td><strong>37,000</strong></td>
</tr>
</tbody>
</table>

**Conclusion**: Currently, outpatient hemodialysis patients have the highest rate of CLA-BSIs. More aggressive CLA-BSI prevention interventions (proven in ICU patients) need to be applied to these patients.

*MMWR Morb Mortal Wkly Rep 2011;60:243-8*
Surveillance of Hemodialysis-associated Primary Bloodstream Infections, Connecticut

- **Study design**: Prospective, descriptive analysis of primary BSIs over 12 months at 10 hospital-based hemodialysis centers, Connecticut.

- **Results**: A total of 158 BSIs during 142,525 dialysis sessions; 15.2% in those with fistula or graft and 84.8% in those with central venous catheters (CVCs) (P<0.001). Rates per 100 patient-years in centers ranged from 0-30.8 (mean 16.6). Rates per 1,000 dialysis sessions ranged from 0-2.1 (mean 1.1).

- **Conclusions**: Primary BSI rates ranged widely among participating centers, although all were strongly associated with CVCs.

Surveillance of Hemodialysis-associated Primary Bloodstream Infections in Canadian Hemodialysis Units

- **Study design:** Prospective, descriptive analysis of hemodialysis-related bloodstream infections (BSIs) over 6 months at 11 hemodialysis centers participating in the Canadian Nosocomial Infection Surveillance Program.

- **Results:** A total of 184 BSIs during 133,158 dialysis procedures; rates: 1.4 per 1,000 procedures or 0.6 per 1,000 patient-days. Hemodialysis access through an arteriovenous (AV) fistula was associated with the lowest risk of BSI (0.2 per 1,000 procedures). The relative risk of BSI was 2.5 with AV access, 15.5 with cuffed and tunneled CVCs, and 22.5 with uncuffed CVC access ($P<0.001$). There was marked variation in type of access and BSI rates by centers.

- **Conclusions:** Primary BSI rates ranged widely among participating centers, although all were strongly associated with CVCs.

Surveillance of Hemodialysis-associated Vascular Access Infections

- **Study design:** To develop a standardized surveillance system for monitoring vascular access infections to compare rates between centers. Prospective, descriptive analysis of incidence of infection rates at chronic outpatient hemodialysis centers in Idaho and Oregon over 18 months.

- **Results:** There were 38,096 hemodialysis sessions (31,603 via permanent fistulae or grafts, 5,060 via permanent tunneled central venous catheters (CVCs), and 1,433 via temporary CVCs). A total of 176 infections, for a rate of 4.62 per 1,000 dialysis sessions (DS); 80 (2.53/1,000 DS) involved permanent fistulae or grafts, 69 (13.64/1,000 DS) involved permanent tunneled CVCs, and 27 (18.84/1,000 DS) involved temporary CVCs. 131 vascular access site infections (without BSI) were identified (3.44/1,000 DS), including 65 (2.06/1,000DS) permanent fistulae/grafts (8.3/1,000DS) permanent tunneled CVCS, and 24 (16.75/1,000DS) temporary CVCs.

- **Conclusions:** Infection rates were highest among temporary catheters and lowest among permanent native AV or synthetic grafts.


Monday, October 28, 2013
Bloodstream Infection (BSI) Incidence in Hemodialysis Patients

- **Study design:** Two cohorts of hemodialysis patients (new or continuing patients--with new vascular access device) were enrolled from 9 Canadian hemodialysis centers and followed for 6 months for BSIs.

- **Results:** 527 patients (258 new, 269 continuing) underwent 31,268 procedures. There were 96 BSIs in 93 patients (11.97/10,000 days or 28.8/10,000 hemodialysis procedures), yielding a relative risk (RR) of infection of 3.33 for patients with a previous BSI and 1.56 for continuing patients with a new access. Compared to AV fistulae, the RR of BSI was 1.47 for AV grafts, 8.49 for cuffed CVCs, and 9.87 for uncuffed CVCs. Regression model identified earlier BSI (OR, 6.58), poor patient hygiene (OR, 3.48), or superficial access site infection (OR, 4.36) as additional risk factors.

- **Conclusions:** BSI are frequent complications in hemodialysis patients.

Adverse Events in Hemodialysis Patients, United States, 2006

- **Study design**: Surveillance for adverse events at 32 outpatient hemodialysis centers reporting to the CDC National Healthcare Safety Network (NHSN) in 2006.

- **Results**:

<table>
<thead>
<tr>
<th>Access</th>
<th>Hospitalization Rate*</th>
<th>BSI Rate*</th>
<th>Isolates N=599^</th>
</tr>
</thead>
<tbody>
<tr>
<td>AV fistulas</td>
<td>7.7</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>Grafts</td>
<td>9.2</td>
<td>0.9</td>
<td>23%</td>
</tr>
<tr>
<td>Permanent CVC</td>
<td>15.7</td>
<td>4.2</td>
<td></td>
</tr>
<tr>
<td>Temporary CVC</td>
<td>34.7</td>
<td>27.1</td>
<td>77%</td>
</tr>
</tbody>
</table>

*Mean rate per 100 Patient-months.
^ AV fistulae + grafts vs Perm + Temp CVC.

**Conclusions**: Adverse events are common among hemodialysis patients.

Cost-Benefit of Preventing Bloodstream Infections In Hemodialysis Patients, Canada, 2004

• **Study design**: Data from the Canadian Nosocomial Infection Surveillance Program were used to estimate the incidence rate of nosocomial BSI. Canadian Institute of Health data were used to estimate the extra costs of BSIs per stay across Canada in 2004.

• **Results**: A total of 2,524 hemodialysis-associated BSIs were projected among 15,278 patients in Canada in 2004. The total annual cost to treat the BSIs were estimated at CDN$49.01 million. The total costs in prevention and human resources was CDN$8.15. The savings of avoidable medical costs after establishing an infection control program was CDN$14.52. The benefit/cost was 1.0 to 1.8:1.

• **Conclusion**: The expected benefit from implementing infection control programs could be expected to be well in excess of additional costs post-infection if the reduction of BSI can be reduced by 20-30%.

Antibiotic/Antiseptic Lock Solution (ALS) Studies

Be careful reading the literature. ALS studies assess: prophylaxis, CLA-BSI therapy, or prophylaxis after CLA-BSI. Populations differ. ALS agents and heparin doses differ. Method of administration differs (dwell—minutes to days; flush, etc.). Catheter type, site of insertion and preventive measures differ or are not described. Follow-up periods differ. Outcomes measured differ.
<table>
<thead>
<tr>
<th>Author</th>
<th>Ref</th>
<th>Study Design</th>
<th>ALS</th>
<th># Pts</th>
<th>Cath type</th>
<th>CRI Rate*</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sun</td>
<td>AJKD 2012;59:102</td>
<td>RCT</td>
<td>Gentamicin-sodium citrate</td>
<td>303</td>
<td>TC/NTC</td>
<td>0.28 vs 0.91</td>
<td>0.003</td>
</tr>
<tr>
<td>Mortazavi</td>
<td>J Res Med Sci 2011;16:303</td>
<td>DB-RCT</td>
<td>Cefotaxime-heparin</td>
<td>30</td>
<td>TC</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Campos</td>
<td>J Am Soc Neph 2011;22:1939</td>
<td>RCT</td>
<td>Minocycline-EDTA</td>
<td>204 Caths</td>
<td>TC/NTC</td>
<td>1.1 vs 4.3</td>
<td>0.005</td>
</tr>
<tr>
<td>Chow</td>
<td>Hong Kong Med J 2010;16:269</td>
<td>Retrospective study</td>
<td>Gentamicin</td>
<td>149</td>
<td>95% NTC</td>
<td>1.0 vs 4.6</td>
<td>0.002</td>
</tr>
<tr>
<td>Zhang</td>
<td>Blood Purif 2009;27:206</td>
<td>RCT</td>
<td>Gentamicin-heparin</td>
<td>140</td>
<td>TC</td>
<td>0.06 vs 0.67</td>
<td>0.014</td>
</tr>
<tr>
<td>Abbas</td>
<td>Am J Kid Dis 2009;53:492</td>
<td>Observational</td>
<td>Gentamicin-heparin</td>
<td>320</td>
<td>TC</td>
<td>BSI ↓ 52% f/up 18 months</td>
<td></td>
</tr>
<tr>
<td>Pervez</td>
<td>J Vasc Access 2002;3:108</td>
<td>RCT</td>
<td>Gentamicin-citrate</td>
<td>55</td>
<td>TC</td>
<td>0.62 vs 2.11</td>
<td></td>
</tr>
</tbody>
</table>

DB-RCT=double blind randomized controlled trial; TC=tunneled catheter; NTC=non-tunneled catheter; comparison always with heparin; rate per 1,000 catheter days.
# Antibiotic/Antiseptic Lock Solution Studies in Chronic Hemodialysis Patients

<table>
<thead>
<tr>
<th>Author</th>
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<th>CRI Rate*</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Al-Hwiesh</td>
<td>Saudi J Kid Dis 2007;18:239</td>
<td>Prospective study</td>
<td>Vancomycin-gentamicin</td>
<td>63</td>
<td>TC</td>
<td>4.54 vs. 13.11</td>
<td>0.05 (RR=0.32)</td>
</tr>
<tr>
<td>Saxena</td>
<td>Kid Intern 2006;70:1629</td>
<td>Prospective study</td>
<td>Cefotaxime-heparin</td>
<td>96</td>
<td>TCC</td>
<td>1.56 vs. 3.68</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Saxena</td>
<td>Nephrology 2006;11:299</td>
<td>DB-RCT</td>
<td>Cefotaxime-heparin</td>
<td>113</td>
<td>TCC</td>
<td>F-up 1 yr; infection free survival: 68.7% vs. 31.3%;</td>
<td>0.001</td>
</tr>
<tr>
<td>Saxena</td>
<td>J Nephrology 2005;18:755</td>
<td>Prospective study</td>
<td>Cefotaxime-heparin</td>
<td>208</td>
<td>NTC</td>
<td>1.65 vs. 3.13 (RRR=50.5%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Allon</td>
<td>Clin Infect Dis 2003;36:1539</td>
<td>Prospective study</td>
<td>Tauerolidine citrate</td>
<td>50</td>
<td></td>
<td>BSI free survival: 94% vs. 47%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Dogra</td>
<td>J Am Soc Neph 2002;13:2133</td>
<td>DB-RCT</td>
<td>Gentamicin-sodium citrate</td>
<td>83</td>
<td>TC</td>
<td>0.3 vs. 4.2</td>
<td>0.003</td>
</tr>
<tr>
<td>Blayer</td>
<td>ICHE 2005;26:520</td>
<td>RCT</td>
<td>Minocycline-EDTA</td>
<td>60</td>
<td></td>
<td>Coloniz: 9/14 vs. ¼. 90d surv: 83% vs. 60%</td>
<td>0.005 0.07</td>
</tr>
</tbody>
</table>

**DB-RCT=double blind randomized controlled trial; TC=tunneled catheter; TCC= tunneled cuffed catheter; NTC=non-tunneled catheter; comparison always with heparin; rate per 1,000 catheter days**

Monday, October 28, 2013
<table>
<thead>
<tr>
<th>Author</th>
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<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maki</td>
<td>Crit Care Med 2011;34:613</td>
<td>RCT 25 centers</td>
<td>0.24M Sodium Citrate 0.15% Methylene blue 0.15% Methylparaben 0.15% Propylparaben</td>
<td>407</td>
<td>TCC-IJ</td>
<td>0.24 vs. 0.82</td>
<td>0.005</td>
</tr>
<tr>
<td>Solomon</td>
<td>Am J Kid Dis 2010;55:136</td>
<td>DB-RCT 3 centers</td>
<td>1.33% Tauloridine 4% Citrate</td>
<td>110</td>
<td>TCC</td>
<td>1.4 vs. 2.4</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Gram-negs: 0.2 vs. 1.1</td>
<td>0.02</td>
</tr>
</tbody>
</table>

DB-RCT=double blind randomized controlled trial; TCC=tunneled cuffed catheter; comparison always with heparin; IJ=internal jugular; *rate per 1,000 catheter days
# Antibiotic/Antiseptic Lock Solution Studies in Pediatric Patients

<table>
<thead>
<tr>
<th>Author</th>
<th>Ref</th>
<th>Study Design</th>
<th>ALS</th>
<th># Pts</th>
<th>Cath type</th>
<th>CRI Rate*</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouw</td>
<td>J Ped Surg 2011;12:e292</td>
<td>Retrospective study; short bowel syndrome with TPN</td>
<td>70% ethanol</td>
<td>15</td>
<td>2.06 vs. 11.15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Filippi</td>
<td>Ped Crit Care Med 2007;8:556</td>
<td>RCT; NICU</td>
<td>Fusidic acid-heparin</td>
<td>103</td>
<td>6.6 vs. 24.9</td>
<td>&lt;0.01</td>
<td></td>
</tr>
<tr>
<td>Garland</td>
<td>Peds 2005;116:e198</td>
<td>DB-RCT; NICU</td>
<td>Vancomycin-heparin</td>
<td>95</td>
<td>2.3 vs. 17.8</td>
<td>RR=0.13</td>
<td></td>
</tr>
<tr>
<td>Chatzinikola ou</td>
<td>Clin Infect Dis 2003;36:116</td>
<td>Prospective study; oncology pts.</td>
<td>Minocycline-EDTA</td>
<td>62</td>
<td>0 vs. 10 infections</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hendrickson</td>
<td>J Clin Onc 2000;18:1269</td>
<td>DB-Prospective; Oncology</td>
<td>Vancomycin-cipro-heparin vs. vancomycin-heparin vs heparin</td>
<td>153</td>
<td>VH vs. H VCH vs. H</td>
<td>0.004 0.005</td>
<td></td>
</tr>
</tbody>
</table>

DB-RCT=double blind randomized controlled trial; TC=tunneled catheter; PICC=peripherally inserted central catheter; comparison always with heparin; *rate per 1,000 catheter days.
SHEA Recommended Basic and Special Approaches for the Prevention of CLA-BSIs

- **Catheter Insertion Bundle**
- **Catheter Maintenance Bundle**

_Marschall J, et al. ICHE 2008;29:S22-30._
# Basic Practices

<table>
<thead>
<tr>
<th>Practice</th>
<th>Grade</th>
</tr>
</thead>
<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</td>
<td></td>
</tr>
<tr>
<td>Precautions</td>
<td>A− I</td>
</tr>
<tr>
<td>Chlorhexidine (CHG) Skin Prep</td>
<td>A− I</td>
</tr>
</tbody>
</table>

---

**Catheter Insertion Bundle**

**Catheter Maintenance Bundle**

---

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

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</tr>
<tr>
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</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>
</tr>
</tbody>
</table>

#### Special Approaches

<table>
<thead>
<tr>
<th>Approach</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHG Baths (ICU patients)</td>
<td>B– II</td>
</tr>
<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>
</tr>
</tbody>
</table>

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_Marschall J, et al. ICHE 2008;29:S22-30._

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*Monday, October 28, 2013*
2011 CDC Guidelines

- Intended to provide evidence-based recommendations for preventing intravascular catheter-related infections

- 5 major areas of emphasis:
  1. Education of healthcare professionals
  2. Use maximal sterile precautions (MSP)
  3. Use of > 0.5% CHG skin prep
  4. Avoiding routine replacement of CV catheters as a strategy to prevent infections
  5. Use antiseptic/antibiotic impregnated catheters and CHG impregnated sponge dressing
     (If rate of infection not decreasing despite adherence to above 4 strategies)

- Targets elimination of CRBSI from all patient-care areas

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CHG impregnated sponge dressings received a Category 1B recommendation for reducing the risk of CLABSI:

- “strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale”

- CHG impregnated sponge dressings are the only form of CHG dressing recommended in new CDC guidelines
  - “No recommendation is made for other types of chlorhexidine dressings (Unresolved Issue)”

BIOPATCH® Protective Disk with CHG
Hierarchy of Medical Evidence

LEVEL I
- Systematic Reviews and Meta-analyses
- Randomized Clinical Trials
15

LEVEL II
- Cohort Studies
- Case Control Studies
- Case Series
- Case Reports
13

LEVEL III
- Ideas, Editorials, Opinions
- Animal Research
- In Vitro (Test Tube) Research
4

No. of Studies
2
CDC Debate: CHG Dressing vs. CHG sponge dressing

1. WHAT TYPE OF CHG DRESSING (i.e., SPONGE, NON-SPONGE) SHOULD BE USED FOR TEMPORARY SHORT-TERM CATHETERS IN PATIENTS >2 MONTHS TO REDUCE THE RISK OF INFECTION?

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

3. There is evidence that CHG sponge dressing results in significantly decreased rates of infection compared to standard or no dressing.
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 Disk 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>
<thead>
<tr>
<th>Variable</th>
<th>Incidence, No./1000 Catheter-Days</th>
<th>Dressing ITT Analysis</th>
<th>Dressing Per-Protocol Analysis</th>
<th>Dressing Change Interval Incidence, No./1000 Catheter-Days</th>
<th>ITT Analysis</th>
<th>Per-Protocol Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control (n = 1825)</td>
<td>CHGIS (n = 1953)</td>
<td>HR (95% CI) P Value</td>
<td>HR (95% CI) P Value</td>
<td>HR (95% CI)</td>
<td>P Value</td>
</tr>
<tr>
<td>Catheter colonization &gt;10 CFUs/plate</td>
<td>15.8</td>
<td>6.3</td>
<td>0.36 (.28-0.46) &lt;.001</td>
<td>0.35 (.27-0.45) &lt;.001</td>
<td>10.4</td>
<td>11.0</td>
</tr>
<tr>
<td>Catheter-related bloodstream infection</td>
<td>1.3</td>
<td>0.4</td>
<td>0.24 (.09-0.65) .005</td>
<td>0.24 (.09-0.63) .004</td>
<td>0.7</td>
<td>0.9</td>
</tr>
<tr>
<td>Major catheter-related infection</td>
<td>1.4</td>
<td>0.6</td>
<td>0.39 (.16-0.93) .03</td>
<td>0.38 (.16-0.92) .03</td>
<td>0.9</td>
<td>1.1</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).
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® 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.

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® group (300 patients) vs. 34 cases in the control group (301 patients). This difference was statistically significant ($P=0.0271$).
BIOPATCH*
ANTIMICROBIAL DRESSING with Chlorhexidine Gluconate

INSTRUCTIONS FOR USE
(Please Read Carefully Before Using)

PRODUCT DESCRIPTION
BIOPATCH* Antimicrobial Dressing is a hydrophilic polyurethane absorptive foam with chlorhexidine gluconate (CHG). The foam material absorbs up to eight times its own weight in fluid, while the CHG incorporated into the dressing inhibits bacterial growth under the dressing.

Chlorhexidine Gluconate is a well-known antiseptic agent with broad-spectrum antimicrobial and antifungal activity.

INDICATION FOR USE
BIOPATCH* Antimicrobial Dressing containing Chlorhexidine gluconate is intended for use as a hydrophilic wound dressing that is used to absorb exudate and to cover a wound caused by the use of vascular and non-vascular percutaneous medical devices such as: IV catheters, central venous lines, arterial catheters, dialysis catheters, peripherally inserted coronary catheters, mid-line catheter, drains, chest tubes, externally placed orthopedic pins, and epidural catheters. It is also intended to reduce local infections, catheter-related blood stream infections (CRBSI), and skin colonization of microorganisms commonly related to CRBSI, in patients with central venous or arterial catheters.
1. **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 Central Catheters
- Midline Catheters
- Drains
- Chest Tubes
- Externally Placed Orthopedic Pins
- Epidural Catheters
Product Requirements

1. FDA Cleared Indication

2. Highest Level Evidence-based Support

3. Meets National Guidelines
Class Effect

Does a “Class Effect” Exist for Antimicrobial Catheter Site Dressings?

- Not all antimicrobials are the same
- Not all dressing materials are the same
- Not all designs are the same

CHG transfer from BIOPATCH® Protective Disk with CHG and Tegaderm™ CHG to porcine skin designed to maximize contact of the dressing with the skin and CHG migration. BIOPATCH® provides more complete, continuous protection of the skin around the insertion site.²

2. CHG Transfer Onto Porcine Skin: 2x2” pieces of porcine skin were cleaned, dried and placed on top of PBS saturated c-fold towels. Catheters were inserted through a 10 mm biopsy punch and dressed according to either product’s directions for use. Samples were incubated at 30°C for 24 hours. The skin was removed, stained with Sodium Hypobromite solution and photographed. Data on file. Ethicon, Inc.
In Vitro Comparative Analysis of a Chlorhexidine Gluconate (CHG) Sponge Dressing and a CHG-containing Hydrogel Dressing

FLUID MANAGEMENT

1. BIOPATCH® Protective Disk with CHG absorbs fluids rapidly, which helps avoid the potential for skin maceration. In vitro studies demonstrate that BIOPATCH® fully absorbs blood within 0.5 seconds (Figure 2; A, B). In contrast, Tegaderm™ CHG gel pad did not fully absorb blood even after 2 hours. This may be due to the high water content of the gel itself (70% to 90%), which limits its absorption of fluids. Tegaderm™ CHG only partially absorbs blood after 2 hours (Figure 3; C).

2. Given the fact that under normal conditions blood clots within 4 to 8 minutes, this slow absorption may lead to blood clots and proteinaceous materials remaining on the skin beneath the Tegaderm™ CHG dressing.

3. Incomplete absorption of blood or bodily fluids can create an environment conducive to bacterial growth (Figure 4).

References:
3. BIOPATCH® vs. Tegaderm™ CHG Absorption pictures: Drops of citrated porcine blood were dropped onto the foam side of Biopatch® or the gel side of Tegaderm™ CHG using an 18 gauge needle. The time for blood absorption was recorded. Data on file. Ethicon, Inc.
1. The BIOPATCH® Protective Disk with CHG design allows for superior fluid management versus the Tegaderm CHG gel pad.

2. BIOPATCH® absorbs fluids rapidly, which helps avoid the potential for skin maceration. _In vitro_ studies demonstrate that BIOPATCH® fully absorbs blood within 0.5 seconds (Figure 2; A, B).\(^1\) In contrast, Tegaderm™ CHG gel pad did not fully absorb blood even after 2 hours. This may be due to the high water content of the gel itself (70% to 90%),\(^1\) which limits its absorption of fluids. Tegaderm™ CHG only partially absorbs blood after 2 hours (Figure 3; C).\(^1\)

3. Given the fact that under normal conditions blood clots within 4 to 8 minutes,\(^1\) this slow absorption may lead to blood clots and proteinaceous materials remaining on the skin beneath the Tegaderm™ CHG dressing.

4. Incomplete absorption of blood or bodily fluids can create an environment conducive to bacterial growth (Figure 4).\(^2\)

5. An ex vivo comparative analysis demonstrated when 6 drops of citrated porcine blood were injected through the back of the skin at the insertion site, there was impaired visibility of the skin surrounding the Tegaderm™ CHG insertion site (Figures 4, 5 and 6).\(^3\)

References:
3. Ex vivo Comparative Analysis Demonstrated with injection of 6 Drops of Blood Through Back of Skin at Insertion Site: Catheters were inserted through a 1 mm puncture on 2x2” pieces of clean porcine skin. The catheter site was dressed using BIOPATCH® or Tegaderm™ CHG according to either product’s IFU’s. Six drops of citrated porcine blood were injected through the back of the insertion site by the back of the skin (Time=0). Samples were incubated at 37°C for 24 hours. The dressings were removed and the insertion sites were photographed at time=0 and time=24 hours. Data on file. Ethicon, Inc.
Labeling Comparison: Two Chlorhexidine Gluconate Sponge Dressings

- BIOPATCH® is the only CHG sponge clinically-proven carrying an FDA-cleared indication for the prevention of CRBSIs.

- GuardIVa’s packaging states: This dressing is not clinically tested for its activity to reduce local infections, CRBSI and skin colonization of microorganisms commonly related to CRBSI.
The outside appearance of GuardIVa™ is very similar to that of BIOPATCH® Protective Disk with CHG. However, on closer inspection, they are clearly different.¹

References:
DIFFERENT INDICATIONS

1. Unlike the BIOPATCH® Protective Disk with CHG, the GuardIVa™ is indicated only as an absorbent, hemostatic protective dressing and is not indicated to prevent infection.

2. According to the GuardIVa™ package insert, the CHG is added to the dressing as a preservative to prevent bacterial growth within the dressing itself\(^1\) rather than on the skin beneath it.

References:
DIFFERENT INDICATIONS

1. Unlike the BIOPATCH® Protective Disk with CHG, the GuardIVa™ is indicated only as an absorbent, hemostatic protective dressing and is not indicated to prevent infection.

2. According to the GuardIVa™ package insert, the CHG is added to the dressing as a preservative to prevent bacterial growth within the dressing itself\(^1\) rather than on the skin beneath it.

References:
GUARDIVA™ COMPARISON

In Vitro Comparative Analysis of 2 Chlorhexidine Gluconate Sponge Dressings

BIOPATCH™ CLINICALLY PROVEN THROUGH RCTS*7

GUARDIVA™ Allows Bacterial Growth

P. aeruginosa

A. baumannii

BIOPATCH™ Prevents Bacterial Growth

ZONE OF INHIBITION LARGER

1. In vitro zone-of-inhibition testing indicates that BIOPATCH™ is more effective than GuardiVa™ against several microorganisms.

2. GuardiVa™ was evaluated against 7 microorganisms that had previously been tested with BIOPATCH™. GuardiVa™ showed efficacy against 5 of the 7 challenge organisms, but showed no efficacy against P. aeruginosa and A. baumannii, and had limited efficacy against K. pneumoniae and C. albicans.2

Zone of Inhibition 7-day Efficacy

References:
3. Zone of Inhibition: Each individual test article was placed onto inoculated Mueller Hinton Agar plate where 0.1 ml inoculum (10⁶-10⁷ CFU/ml) was spread uniformly. The plates were incubated at 350-370°C for 24 hours, and the ZOI was measured from the edge of the test article to the outermost edge of the ZOI. Data on file. Ethicon, Inc.
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**

CDC Unresolved Issues. Represents an Unresolved Issue for Which Evidence is Insufficient or no Consensus Regarding Efficacy Exists

- No recommendation is made for other types of chlorhexidine dressings
- No recommendation is made regarding replacement of peripheral catheters in adults only when clinically indicated
- No recommendation can be made regarding attempts to salvage an umbilical catheter by administering antibiotic treatment through the catheter
- No recommendation can be made regarding the frequency for replacing intermittently used administration sets
- No recommendation can be made regarding the frequency for replacing needles to access implantable ports
- No recommendation can be made regarding the length of time a needle used to access implanted ports can remain in place

Joint Commission
National Patient Safety Goal #7

Hospitals implement policies and practices aimed at reducing the risk of central line-associated bloodstream infections that meet regulatory requirements and are aligned with evidence-based standards.

Elimination of CRBSIs From All Patient-care Areas:

- Extended Use Peripheral IV Lines
- CVC Lines & PICC Lines
- Arterial Lines
- Surgical Drains
- Home Infusion
- Readmission Rates
- Staff Compliance = Kits

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1 - Medicare Program: Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Payments for Graduate Medical Education in Certain Emergency Situations; Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Updates to the Long-Term Care Prospective Payment System; Updates to Prospective Payment System; Updates to Certain IPPS-Excluded Hospitals; and Collection of Information Regarding Financial Relationship Between Hospitals; Final Rule, Federal Register, Volume 73, Volume 161, Tuesday, August, 19, 2008.

2 - Medicare Program: Hospital Inpatient Value-Based Purchasing Program, Federal Register, Volume 76, Number 88, Friday, May 6, 2011.

3 - Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY2012 Rates; Hospitals’ FTE Resident Caps for Graduate Medical Education Payment, Federal Register, Volume 76, Number 160, Thursday, August 18, 2011.

4 - Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, Federal Register, Volume 76, Number 212, Wednesday, November 2, 2011.

Monday, October 28, 2013
Conclusion

- We are moving into an era of zero tolerance and reduced reimbursement for healthcare-associated infections.

- Both mandatory reporting and decreased CMS and insurance reimbursement for selected HAIs, including CLA-BSIs, has increased administrative attention on prevention of these infections.

- Economic data show that preventing CLA-BSIs is much less expensive than treating CLA-BSIs.

- Given the evidence, the economics, and the impact on patient safety, it makes sense to implement all evidence-based measures, including use of the BIOPATCH®, to prevent CLA-BSIs.
Conclusions

• Catheter-related infections are common in patients receiving hemodialysis.

• Prevention of these infections requires a multi-factorial approach, including:
  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 and CVC-related BSI rates (outcomes).

• A comprehensive catheter-related infection prevention program can dramatically reduce infection rates and improve patient safety.

• A rate of ZERO catheter-related infections in hemodialysis patients should be our goal. If “Prevention is Primary”, then action is essential!