Home Infusion: Do the Same Standards Apply?

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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

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

home care represented only 3% of total national expenditures.

1996

- Annual growth rate of home infusion industry dropped from 64% in 1982-86 to 24% in 1986-93\(^1\)
- 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

• **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 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>

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.

Central Venous Access Devices (CVADs) for Pediatric Patients with Hemophilia

- **STUDY DESIGN**: Retrospective review of pediatric patients with bleeding disorders at the Mayo Clinic Comprehensive Hemophilia Center who were receiving home infusions of factor.

- **RESULTS**:
  - 37 CVADs were placed in 18 patients for a total of 45,952 CVAD days; median time the CVAD remained in place was 1361 days)
  - 10 CVAD-related infections occurred (median: 672 days; range: 72-1941 days), of which six were in one patient with FVIII inhibitors
  - Overall infection rate was 0.22 (95% confidence interval [CI], 0.10-0.40) per 1000 CVAD days, with 0.11 infections in patients without FVIII inhibitors compared with a pooled incidence of 0.66 (95% CI, 0.44-0.97) reported in the literature

- **RESULTS**: Infection is the most common complication associated with CVAD use and is increased in patients who have inhibitors.

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.
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.

Microbial Source of Catheter Related Blood Stream 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
Pathogenesis: Does it Change Inside vs. Outside the Hospital?

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

4. BIOPATCH® Protective Disk with CHG (Full Prescribing Information). Somerville, NJ. Ethicon, Inc.
Product Requirements

1. FDA Cleared Indication

2. Highest Level Evidence-based Support

3. Meets National Guidelines
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.
Clinical Evidence For Reducing Catheter Related Blood Stream Infections

**Not Containing CHG Products**

- Algidex® Ag
- Kendall™ AMD Foam

**CHG Products**

- Tegaderm™ CHG
- BIOPATCH® Protective Disk with CHG
- GuardIVa™

**No Clinical Evidence For Reducing Catheter Related Blood Stream Infections**

>0 RCTs

>5 RCTs

>10 RCTs
## Kendall™ AMD Foam vs BIOPATCH®

### A Review of the Facts

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>BioPatch® Protective Disk with CHG</th>
<th>PHMB Foam Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHG - chlorhexidine gluconate</td>
<td>PHMB - polyhexamethylene biguanide</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mode of Action</th>
<th>Suppress bacteria regrowth on skin</th>
<th>Kills bacteria within/on dressing</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Release Profile</th>
<th>Continuous release of CHG for 7 days</th>
<th>No Release</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Randomized control trials demonstrating reduction of CRBSI, local infection and skin colonization</th>
<th>YES</th>
<th>NO</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>FDA cleared indication to reduce CRBSIs</th>
<th>YES</th>
<th>NO</th>
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</table>

<table>
<thead>
<tr>
<th>CDC recommended antimicrobial for reduction of CRBSIs</th>
<th>CHG - YES</th>
<th>PHMB - NO</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Product included in SHEA/IDSA practice recommendations</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Meets JCAHO National Patient Safety Goal #7 requirement to use Evidence Based Guidelines</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>

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### BioPatch®

Bacteria can recolonize the skins surface from within hair follicles and sebaceous glands within 18 hours after antiseptic application.1

BioPatch®’s 360° contact around the insertion site and 7 day continuous release of CHG provides ongoing antimicrobial protection.

### PHMB Foam Dressing

PHMB attacks bacteria on and within the dressing.2 Does not release onto the skin.

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Ryder, Marcia A. PhD, MS, RN. Catheter-Related Infections: It’s All About Biofilm. *Topics in Advanced Practice Nursing eJournal*. 2005;5(3)

**GUARDIVa™ COMPARISON**

**In Vitro Comparative Analysis of 2 Chlorhexidine Gluconate Sponge Dressings**

**BIOPATCH™ CLINICALLY PROVEN THROUGH RCTs²⁻⁷**

- **GUARDIVa™** Allows Bacterial Growth
  - Bacteria (lack of inhibition) seen in central opening and around disk perimeter
  - Visual bacterial growth seen beneath the GUARDIVa™ disk

- **A. baumannii**

**BIOPATCH™** Prevents Bacterial Growth

- Inhibition of bacterial growth in the central opening (catheter insertion point)

**DIFFERENT TEST RESULTS BIOPATCH™**

**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.

**Zone of Inhibition 7-day Efficacy**

<table>
<thead>
<tr>
<th>Challenge Organism</th>
<th>BIOPATCH™</th>
<th>GUARDIVa™</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Staphylococcus</strong></td>
<td><img src="image" alt="Graph showing Zone of Inhibition for Staphylococcus" /></td>
<td><img src="image" alt="Graph showing Zone of Inhibition for GUARDIVa™" /></td>
</tr>
<tr>
<td><strong>Klebsiella</strong></td>
<td><img src="image" alt="Graph showing Zone of Inhibition for Klebsiella" /></td>
<td><img src="image" alt="Graph showing Zone of Inhibition for GUARDIVa™" /></td>
</tr>
<tr>
<td><strong>Pseudomonas</strong></td>
<td><img src="image" alt="Graph showing Zone of Inhibition for Pseudomonas" /></td>
<td><img src="image" alt="Graph showing Zone of Inhibition for GUARDIVa™" /></td>
</tr>
<tr>
<td><strong>Acinetobacter</strong></td>
<td><img src="image" alt="Graph showing Zone of Inhibition for Acinetobacter" /></td>
<td><img src="image" alt="Graph showing Zone of Inhibition for GUARDIVa™" /></td>
</tr>
<tr>
<td><strong>Klebsiella</strong></td>
<td><img src="image" alt="Graph showing Zone of Inhibition for K. pneumoniae" /></td>
<td><img src="image" alt="Graph showing Zone of Inhibition for GUARDIVa™" /></td>
</tr>
</tbody>
</table>

References:

3. Zone of Inhibition: Each individual test article was placed onto inoculated Mueller Hinton Agar plate where 0.1 ml inoculum (10⁵-10⁷ 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.
Silver Products vs. BIOPATCH® Protective Disk with CHG
Average Zone of Inhibition\(^1\)

Class Effect

Does a “Class Effect” Exist for Anti-Microbial Catheter Site Dressings?

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

Figure 2. BIOPATCH® provides 360° CHG coverage

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.
Class Effect

Does a “Class Effect” Exist for Anti-Microbial Catheter Site Dressings?

There is no “class effect” for antimicrobial dressings. Drugs with similar chemical structures or mechanisms of action are often thought to produce similar clinical outcomes – a concept known as the “class effect”.¹

• BIOPATCH® is the only dressing with an FDA-cleared indication for the reduction of CRBIs, and the only product with proven clinical efficacy.²⁻⁵

• Medical devices contain many components and the effect of all the components working together must be considered when evaluating the effectiveness of a device.

¹ Soares I, Carneiro AV. Drug class effects: definitions and practical applications. Rev Port Cardiol. 2002;21(9):1031-1042.
Recommendations Regarding Use of Chlorhexidine-Impregnated Dressings

Use a chlorhexidine-impregnated sponge dressing for temporary short-term catheters in patients older than 2 months of age if the CLABSIs 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*

Chlorhexidine impregnated dressings have been used to reduce the risk of CRBSIs. 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)

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

Changing Healthcare Landscape

**Reimbursement Landscape**
- Non payment of Healthcare Acquired Infections (HAIs) ¹
- Value-based purchasing ²
- CMS readmission penalties ³
- “Accountable Care” ⁴

**Regulatory Requirements**
- Reportable quality metrics ²,³,⁴
- Measured patient outcomes ²,⁴
- Evidence-based medicine practices/protocols
- Patient satisfaction reporting ²,⁴

**Provider Opportunities in Changing Landscape**
- Increase patient outcomes
- Lower/eliminate readmissions
- Eliminate healthcare acquired infections
- Increase patient satisfaction

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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.
What is coming down the line for reimbursement for Home Infusion?
Review

• Catheter-Related Blood Stream I 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).