Using Evidence Based Medicine to Decrease CRBSI and Improve Outcomes

Utilizing a Chlorhexidine Gluconate Impregnated Sponge Dressing

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The Problem

50 PATIENTS DIE EACH DAY in US hospitals due to Bloodstream Infections (BSIs) [1]

The Affordable Care Act's Value Based Purchasing (VBP) and Hospital Acquired Conditions (HAC) Programs impact hospitals' reimbursement and look specifically at CRBSIs [3]

1. http://www.cdc.gov/hai/surveillance/. Accessed 11-7-14
2. http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/NHSN_eNewsletter_June2014.pdf. Accessed 11-7-14
3. http://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2013-fact-sheets-items/2013-08-02-3.html. Accessed 11-7-14
4. Bicudo D, Batista R, et at; Risk factors for catheter-related bloodstream infection: a prospective multicenter study in Brazilian intensive care units. Brazil Journal of Infectious Disease. 2011;15(4):328-331.

Current CRBSI Cost Estimates[1]

- Associated with longer length of stay (+7 days)
- As much as $129,000 in additional billed costs
- 3-fold increase in the risk of death

Systematic efforts to prevent CRBSI can have a significant impact on a hospital's financial viability

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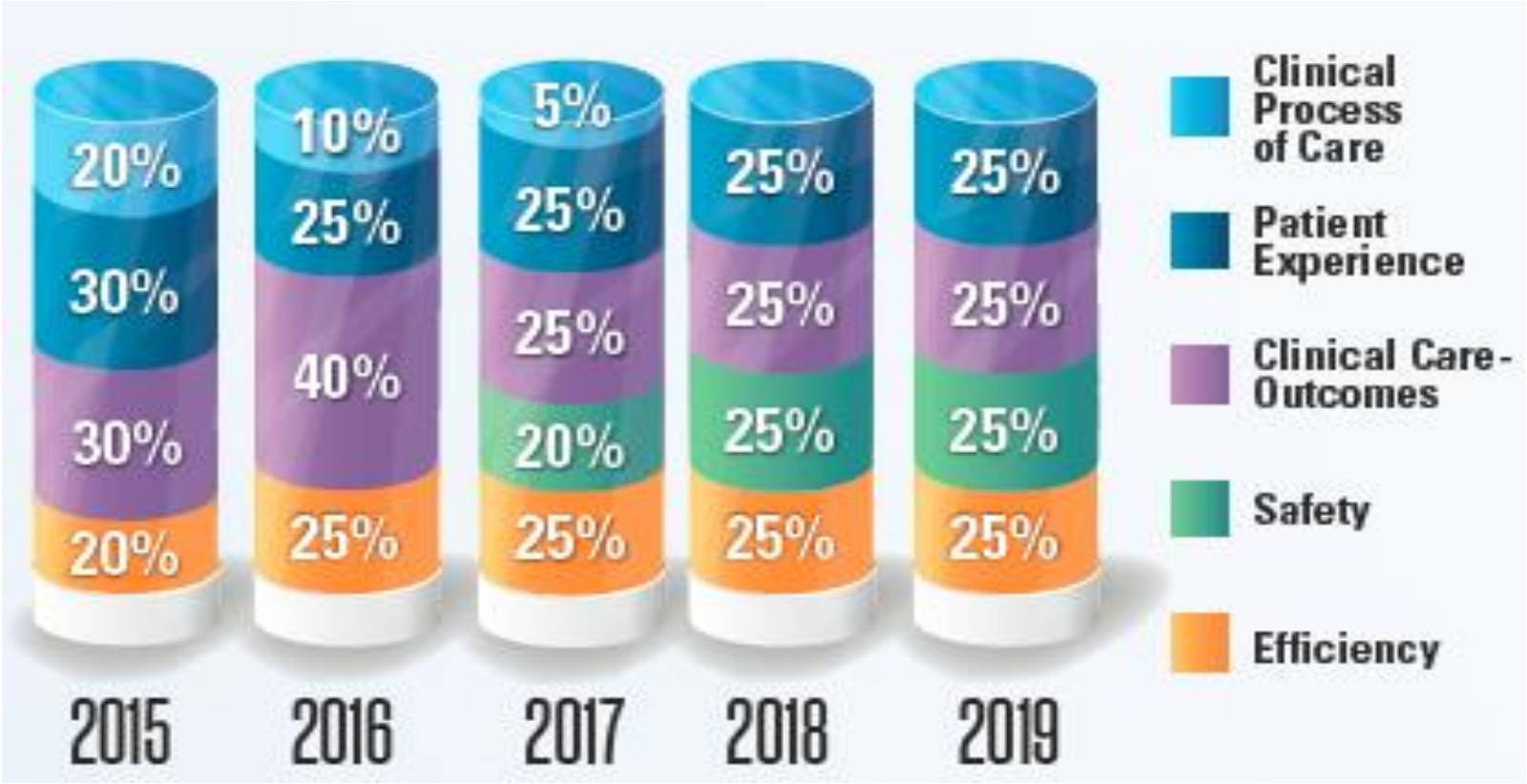
1. Brunelli, S. Clinical and economic burden of bloodstream infections in critical care patients with central venous catheters. Journal of Critical Care 35 (2016) 69–74.

The Affordable Care Act
Value Based Purchasing Timeline



Clinical process gives way to outcomes and efficiency over time as the model becomes more Pay for Performance

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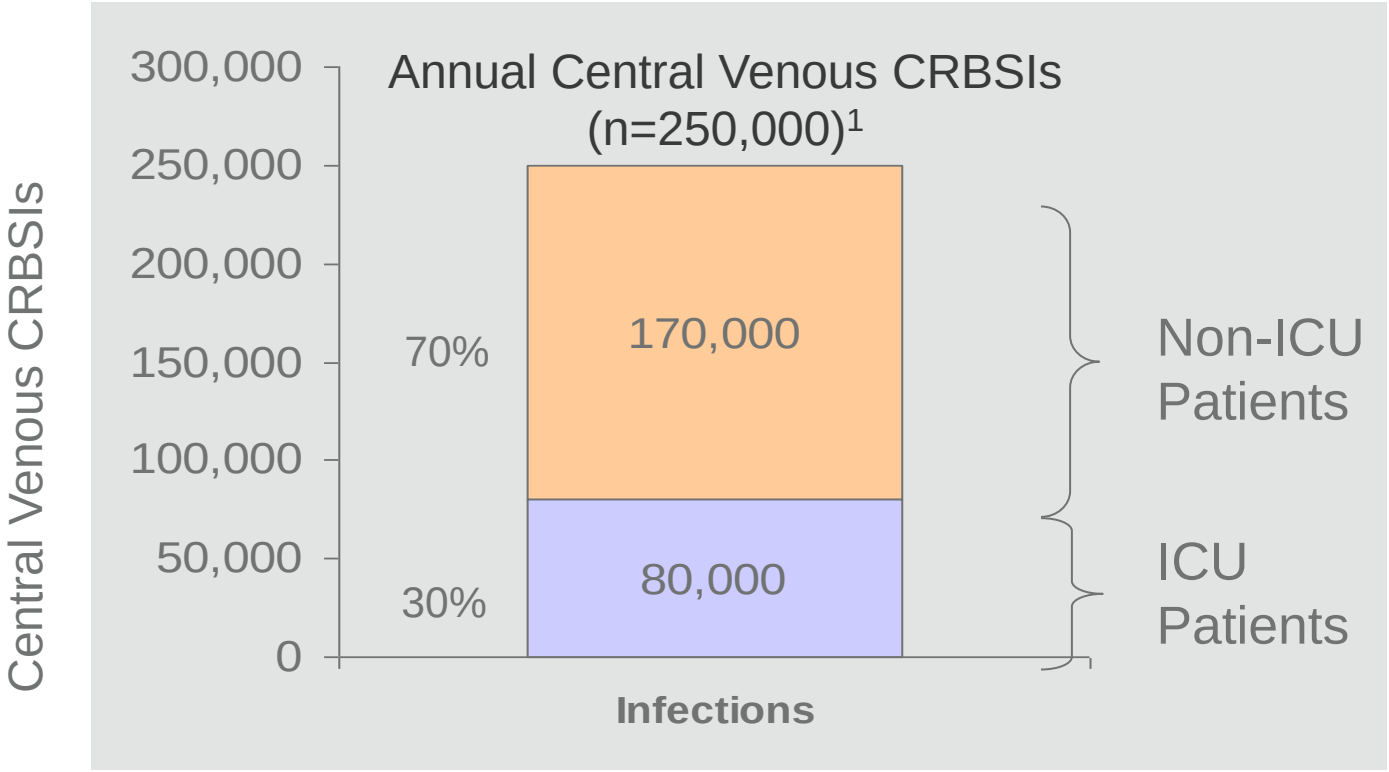
The Advisory Board Company, Healthcare Industry Committee. Hospital Value-Based Purchasing. C-Suite Cheat Sheet Series. August 2013.
http://www.stratishealth.org/documents/FY2017-VBP-fact-sheet.pdf Accessed October 7, 2014
https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-10-26.html Accessed 11/5/15

The Majority of CRBSIs Occur Outside of the ICU



A significant opportunity exists to reduce CRBSI incidence in non-ICU settings. [1,2]

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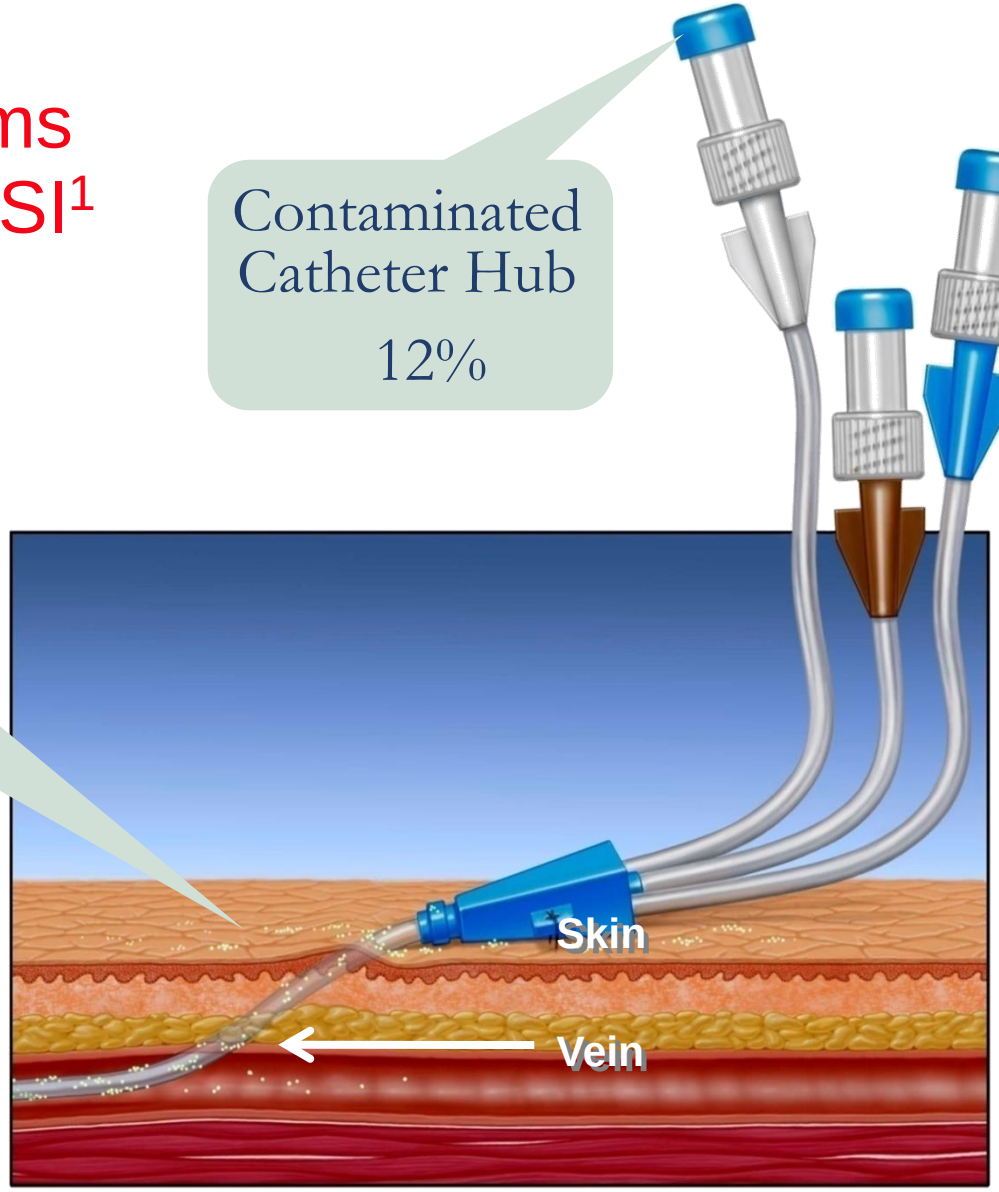
1. Mermel L, Farr B, Sheretz R. Guidelines for the management of intravascular catheter-related infections. *Clinical Infectious Diseases*. 2001;32:1249-1272.
2. Strategies to Prevent Central Line–Associated Bloodstream Infections in Acute Care Hospitals: 2014 Update. Infection Control and Hospital Epidemiology. electronically published June 9, 2014. http://www.jstor.org/stable/10.1086/676533

The Origin of Microorganisms Causing CRBSI[1]

Contaminated Catheter Hub 12%

Contaminated Infusate <1%

Skin Organisms 60%



Undetermined 28%

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1. Safdar N, Maki DG. The pathogenesis of catheter-related bloodstream infection with nuncuffed short-term central venous catheters. Int Care Med. 2004; 30:62-67.

Isn't Good Skin Prep Enough?

Regardless of the type of vascular access device used within hours of thorough antiseptic application, resident bacteria quickly re-colonize the skin surface.[8]
[1]

Patients need to be protected from their own skin's microflora.[8]
[1]

Patient Risk of Infection: Low Medium High

With BIOPATCH® Disk, post-prep environment extends for up to 7 days.[14]
[2]

Patient Risk of Infection: Low High

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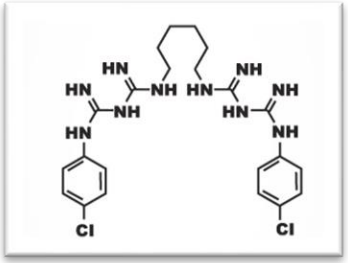
1. Hendley JO, Ashe KM. Effect of topical antimicrobial treatment on aerobic bacteria in the stratum corneum of human skin. Antimicrobial Agents and Chemotherapy. April 1991; 35(4):627-631
2. BIOPATCH Instructions for Use

Chlorhexidine Gluconate (CHG)
Mechanism of Action



- Broad-spectrum biocide effective against Gram-positive bacteria, Gram-negative bacteria and fungi
  - upon application *in vitro*, chlorhexidine can kill nearly 100% of Gram-positive and Gram-negative bacteria within 30 seconds.
- Inactivates microorganisms with a broader spectrum than other antimicrobials (e.g. antibiotics) and has a quicker kill rate than other antimicrobials (e.g. povidone-iodine)
- It has both bacteriostatic and bactericidal mechanisms of action, depending on its concentration
- Since chlorhexidine formulations can destroy the majority of categories of microbes, there is limited risk for the development of an opportunistic infections.

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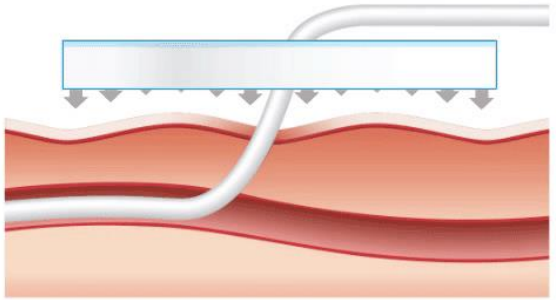
www.Chlorhexidinefacts.com accessed 6/10/16

Chlorhexidine Gluconate (CHG)

Clinical Application

- Unique ability to bind to the proteins present in human tissues such as skin and mucous membranes with limited systemic or bodily absorption



- Protein bound chlorhexidine releases slowly leading to prolonged activity and longer duration of antimicrobial action against a broad spectrum of bacteria and fungi

- Is not affected by the presence of body fluids such as blood

www.Chlorhexidinefacts.com accessed 6/10/16

2011 HICPAC Guidelines
Highlights

Guidelines for the Prevention of Intravascular Catheter Related Infections, 2011

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

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O'Grady, N.P., et al. Guidelines for the Prevention of Intravascular Catheter-Related Infections. *American Journal of Infection Control.* 2011; 39 (4 Suppl 1):S1-34.

2011 HICPAC Guidelines
Highlights

Skin Prep and Site Care

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. (1B)

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O'Grady, N.P., et al. Guidelines for the Prevention of Intravascular Catheter-Related Infections. *American Journal of Infection Control.* 2011; 39 (4 Suppl 1):S1-34.

~~2011~~ HICPAC Guidelines
Highlights

Recommendation Update [July 2017] For patients aged 18 years and older: Chlorhexidine-impregnated dressings with an FDA-cleared label that specifies a clinical indication for reducing catheter-related bloodstream infection (CRBSI) or catheter-associated bloodstream infection (CABSI) are recommended to protect the insertion site of short-term, non-tunneled central venous catheters. **(1A)**

These recommendations supersede only the two statements about C-I dressings in the section on *Catheter Site Dressing Regimens (Recommendations 12 and 13)* in the *2011 Guidelines*.

2017 Updated Recommendations on the Use of Chlorhexidine-Impregnated Dressings for Prevention of Intravascular Catheter-Related Infections Published Nov 1, 2017. (https://www.cdc.gov/infectioncontrol/guidelines/bsi/c-i-dressings/index.html)

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SHEA Compendium 2014 Update

Highlights


CHICAGO JOURNALS

SHEA

Strategies to Prevent Central Line–Associated Bloodstream Infections in Acute Care Hospitals: 2014 Update

Author(s): Jonas Marschall, MD; Leonard A. Mermel, DO, ScM; Mohamad Fakih, MD, MPH; Lynn Hadaway, MSA, RN, BC, CNNI; Alexander Kallen, MD, MPH; Naomi P. O'Grady, MD; Ann Marie Pettis, RN, BSN, CIC; Mark E. Rupp, MD; Thomas Sandora, MD, MPH; Lisa L. Maragakis, MD, MPH; Deborah S. Yokoe, MD, MPH

Source: *Infection Control and Hospital Epidemiology*, Vol. 35, No. 7 (July 2014), pp. 753-771

Published by: The University of Chicago Press on behalf of The Society For Healthcare Epidemiology of America

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Strategies to Prevent Central Line-Associated Bloodstream Infections in Acute Care Hospitals: 2014 Update

Intent:

Highlight practical recommendations in a concise format designed to assist acute care hospitals in implementing and prioritizing their (CLABSI) prevention efforts.

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Strategies to Prevent Central Line–Associated Bloodstream Infections in Acute Care Hospitals: 2014 Update. Infection Control and Hospital Epidemiology. electronically published June 9, 2014.
http://www.jstor.org/stable/10.1086/676533

SHEA Compendium 2014 Update

Highlights

Rationale and Statements of Concern

Besides central venous catheters (CVCs), peripheral arterial catheters also carry a risk of infection.

Factors associated with increased risk of CLABSI includes heavy microbial colonization at the insertion site.

Patients at risk: non-ICU population: ... Majority of CLABSIs occur in hospital units outside the ICU or in outpatient units.

Infection prevention and control efforts should include... patient receiving hemodialysis through catheters.

Strategies to Prevent Central Line–Associated Bloodstream Infections in Acute Care Hospitals: 2014 Update. Infection Control and Hospital Epidemiology. electronically published June 9, 2014.
http://www.jstor.org/stable/10.1086/676533

SHEA Compendium 2014 Update

Highlights

Basic Strategies for preventing and monitoring CLABSI

Recommended for all acute care hospitals

The optimal choice of antiseptic agents is unresolved for children under 2 months of age.

- However, chlorhexidine is widely used in children under 2 months of age.
- A U.S. survey found that in the majority of neonatal ICUs (NICUs) chlorhexidine products are used for catheter insertion in this age group
- Some institutions have used chlorhexidine-containing sponge dressings for CVCs and chlorhexidine for cleaning CVC insertion sites in children in this age group with minimal risk of such reactions.
- Providers must carefully weigh the potential benefit in preventing CLABSI in children under 2 months.

Do not use BIOPATCH on premature infants. The safety and effectiveness of BIOPATCH has not been established in children under the age of 16 years of age. Refer to the BIOPATCH instructions for use for complete indications, warnings, and adverse reactions.

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Strategies to Prevent Central Line–Associated Bloodstream Infections in Acute Care Hospitals: 2014 Update. Infection Control and Hospital Epidemiology. electronically published June 9, 2014. http://www.jstor.org/stable/10.1086/676533

SHEA Compendium 2014 Update
Highlights

“Special approaches for preventing CLABSI”

- Use antiseptic- or antimicrobial-impregnated CVCs in adult patients. (quality of evidence: I)
- Use chlorhexidine-containing dressings for CVCs in patients over 2 months of age. (quality of evidence I)
- Use an antiseptic-containing hub/connector cap/port protector to cover connectors. (quality of evidence I)

Do not use BIOPATCH on premature infants. The safety and effectiveness of BIOPATCH has not been established in children under the age of 16 years of age. Refer to the BIOPATCH instructions for use for complete indications, warnings, and adverse reactions.

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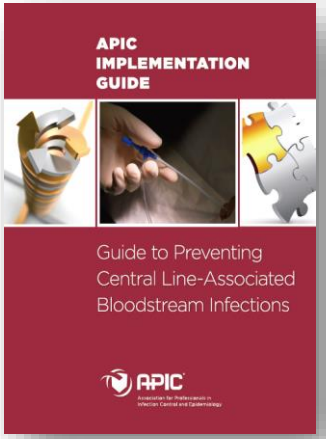
Strategies to Prevent Central Line–Associated Bloodstream Infections in Acute Care Hospitals: 2014 Update. Infection Control and Hospital Epidemiology. electronically published June 9, 2014. http://www.jstor.org/stable/10.1086/676533

APIC Implementation Guide
Highlights



Guide to Preventing Central Line-Associated Bloodstream Infections

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

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APIC Implementation Guide to Preventing Central Line-Associated Bloodstream Infections; Association for Professionals in Infection Control and Epidemiology, 2015.

APIC Implementation Guide

Highlights

"The use of a post-insertion care bundle was associated with a significant reduction in CLABSI. The clinical team at the Department of Veterans Affairs (VA) Eastern Colorado Health System added to the basic bundle daily inspection of the insertion site, site care as needed, application of a CHG sponge dressing at the insertion site and application of an alcohol scrub to the infusion hub for 15 seconds before each entry. The incidence density of CLABSI dropped from 5.7 per 1,000 catheter days to 1.1"

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APIC Implementation Guide to Preventing Central Line-Associated Bloodstream Infections; Association for Professionals in Infection Control and Epidemiology, 2015.

APIC Implementation Guide

Highlights

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

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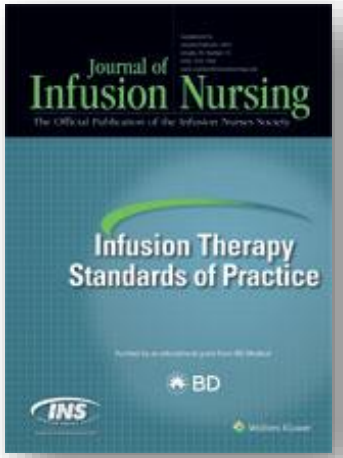
APIC Implementation Guide to Preventing Central Line-Associated Bloodstream Infections; Association for Professionals in Infection Control and Epidemiology, 2015.

INS 2016 Standards
Highlights



Infusion Nurses Society (INS) 2016 Infusion Therapy Standards of Practice

"The Infusion Nurses Society (INS) is recognized as the global authority in infusion nursing… The Infusion Nursing Standards of Practice will be invaluable to guide decision making and for developing patient-centered plans of care."

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Infusion Therapy Standards of Practice, Journal of Infusion Nursing. 2016, V39 (1S)

INS 2016 Standards
Highlights

SECTION SIX: VASCULAR ACCESS DEVICE (VAD) MANAGEMENT

Standard 41. Vascular Access Devices (VAD) Assessment, Care, and Dressing Change

J. "Use chlorhexidine-impregnated dressings over CVADs to reduce infection risk when the extraluminal route is the primary source of infection. Even when organizations show a low baseline central line-associated bloodstream infection (CLABSI) rate, further reduction in CLABSI rate has been demonstrated with use of chlorhexidine impregnated dressings…"

M. "Consider the use of chlorhexidine-impregnated dressings with peripheral arterial catheters as an infection reduction intervention. (III)"

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INS 2016 Standards
Highlights

SECTION SIX: VASCULAR ACCESS DEVICE (VAD) MANAGEMENT

Standard 41. Vascular Access Devices (VAD) Assessment, Care, and Dressing Change

F4. "Use chlorhexidine with care in premature infants and infants under 2 months of age due to risks of skin irritation and chemical burns. (IV)"

J2. "Use chlorhexidine-impregnated dressing with caution in premature neonates and among patients with fragile skin and/or complicated skin pathologies; contact dermatitis and pressure necrosis have occurred. (V)"

Do not use BIOPATCH on premature infants. The safety and effectiveness of BIOPATCH has not been established in children under the age of 16 years of age. Refer to the BIOPATCH instructions for use for complete indications, warnings, and adverse reactions.

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Infusion Therapy Standards of Practice, Journal of Infusion Nursing. 2016, V39 (1S)

INS 2016 Standards
Highlights

SECTION SIX: VASCULAR ACCESS DEVICE (VAD) MANAGEMENT

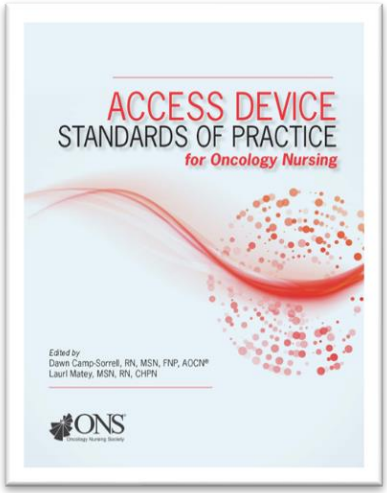
Standard 44. Vascular Access Device Removal

44.1 "The clinical need for each peripheral and non-tunneled central vascular access device CVAD is assessed on a daily basis."

44.2 "Vascular access devices VADs are removed upon unresolved complication discontinuation of infusion therapy or when deemed no longer necessary for the plan of care."

44.3 "VADs are not removed based solely on the length of dwell time because there is no known optimal dwell time."

ONS Access Device Standards
Highlights



Oncology Nurses Society Access Device Standards of Practice for Oncology Nursing 2017

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ONS Access Device Standards
Highlights

Short Term PIV Catheters

"Emerging data suggests that the rate of catheter-related bloodstream infections from peripheral catheters may be higher than once thought"

Implanted Venous Ports

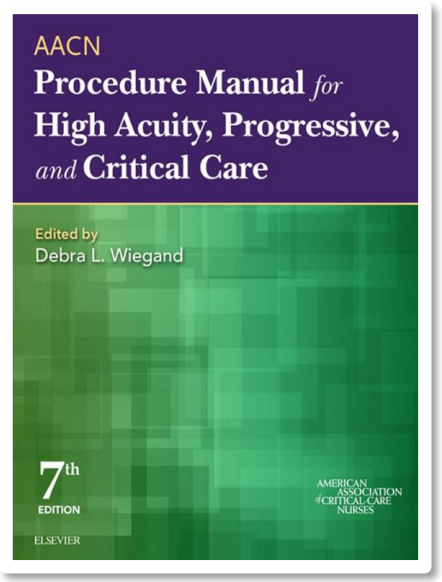
"Following chlorhexidine (CHG) skin preparation, use a CHG –impregnated sponge dressing for any long-term infusion exceeding 4-6 hours or if the port remains accessed for intermittent infusion for greater than 4-6 hours"

Long-Term Venous Access

"Infection – Use a CHG sponge dressing for all catheters, including specialty catheters in patients older than 2 months of age"

"Monitor all device exit sites visually or by palpation through an intact dressing on a regular basis, depending on the clinical situation of the patient"

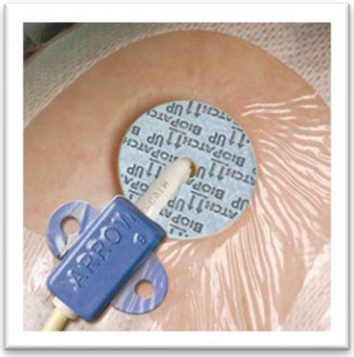
AACN
Procedure Manual
Highlights



American Academy of Critical Care Nurses

Procedure Manual for High Acuity, Progressive, and Critical Care

AACN Procedure Manual *Highlights*



Procedure 82 & 83, Central Venous Catheter insertion

Consider use of a chlorhexidine impregnated sponge dressing

Procedure 66, Central Venous Catheter Site Care

Apply a chlorhexidine-impregnated sponge to the site

Patient Monitoring and Care

Assess the catheter site daily and as needed by palpation through an intact dressing

Procedures 58 & 59 Arterial Catheters

Arterial catheter sites are a source of bloodstream infections, with the femoral site being more heavily associated with colonization compared with other sites.

The infective potential of the arterial catheter is equivalent to the short term central venous device regarding colonization and bloodstream infections, and should be assessed together for signs and symptoms of infection.

Additional equipment, to have available as needed includes a chlorhexidine-impregnated sponge

AACN Procedure Manual *Highlights*

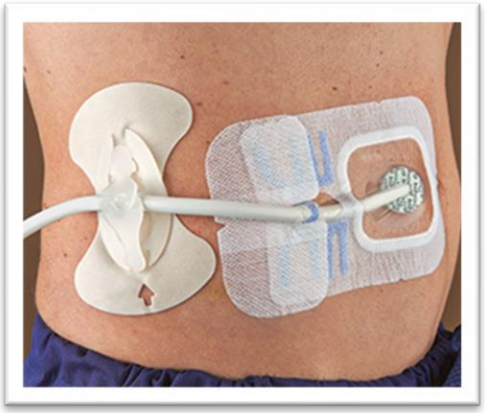
Procedure 86 (Midlines) and 87 (PICCs)

Apply a dressing: A. If bleeding is noted, cover the insertion site with a sterile, 2 × 2 gauze pad and then cover the site with a sterile, transparent, semipermeable dressing

If there is no bleeding, omit the gauze and apply a chlorhexidine impregnated gel dressing or sponge to the site and then cover it with a sterile transparent semipermeable membrane dressing

A 2 × 2 gauze pad can be folded and placed immediately below the insertion site to act as a "wick" for any drainage in the first 24 hours. If a chlorhexidine impregnated sponge or gel dressing is applied at the insertion site, the dressing can remain for 7 days before changing.

AACN Procedure Manual *Highlights*



Procedure 120 Hemodialysis

Dressing supplies (sterile barrier , 4 × 4 gauze pads, transparent dressing, tape, triple-antibiotic ointment **or** chlorhexidine-impregnated sponge)

Procedure 53, Ventricular Assist Devices

Equipment includes: Sterile dressing supplies for chronic dressing change: "Prepackaged driveline management system consisting of… BIOPATCH"

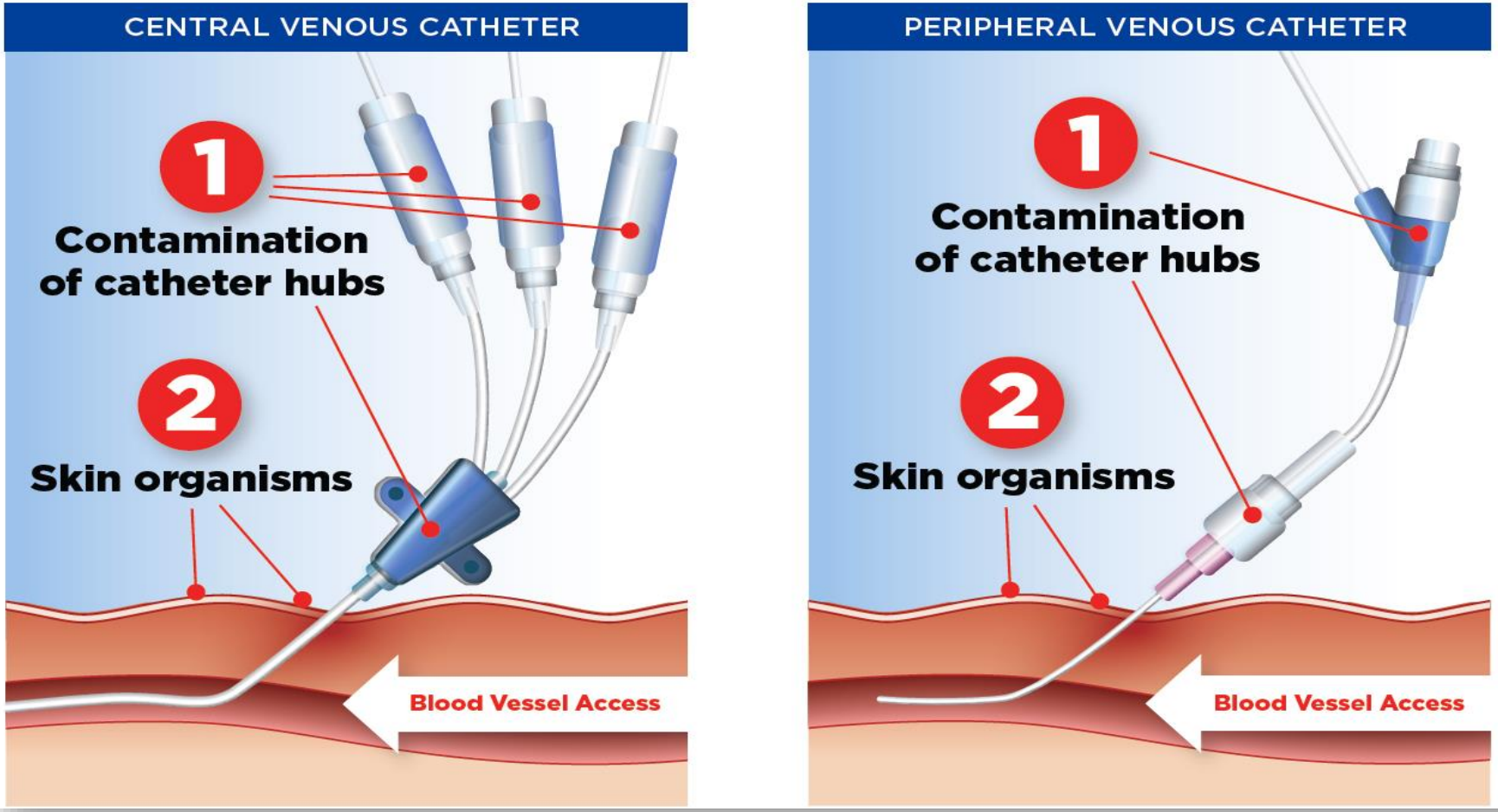
"Place a BIOPATCH around driveline"

Procedure 100 Thermoregulation: External and Intravascular Warming/ Cooling Devices

Equipment includes: Occlusive dressing, Antimicrobial (e.g., chlorhexidine gluconate)–impregnated disc/dressing

AACN *Procedure Manual for High Acuity, Progressive, and Critical Care*. 7th Ed, AACN 2017.

Entry Points of Exogenous Contamination of Vascular Devices



What is BIOPATCH?

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For full prescribing information, please visit www.biopatch.com

What Makes BIOPATCH® Protective Disk with CHG Unique?

Proprietary Urethane composite material designed to continuously release CHG over 7 days to maintain skin antisepsis[1,2]

Cleared Indication to reduce local infections, catheter-related blood stream infections (CRBSI), and skin colonization of microorganisms commonly related to CRBSI in patients with central venous and arterial catheters

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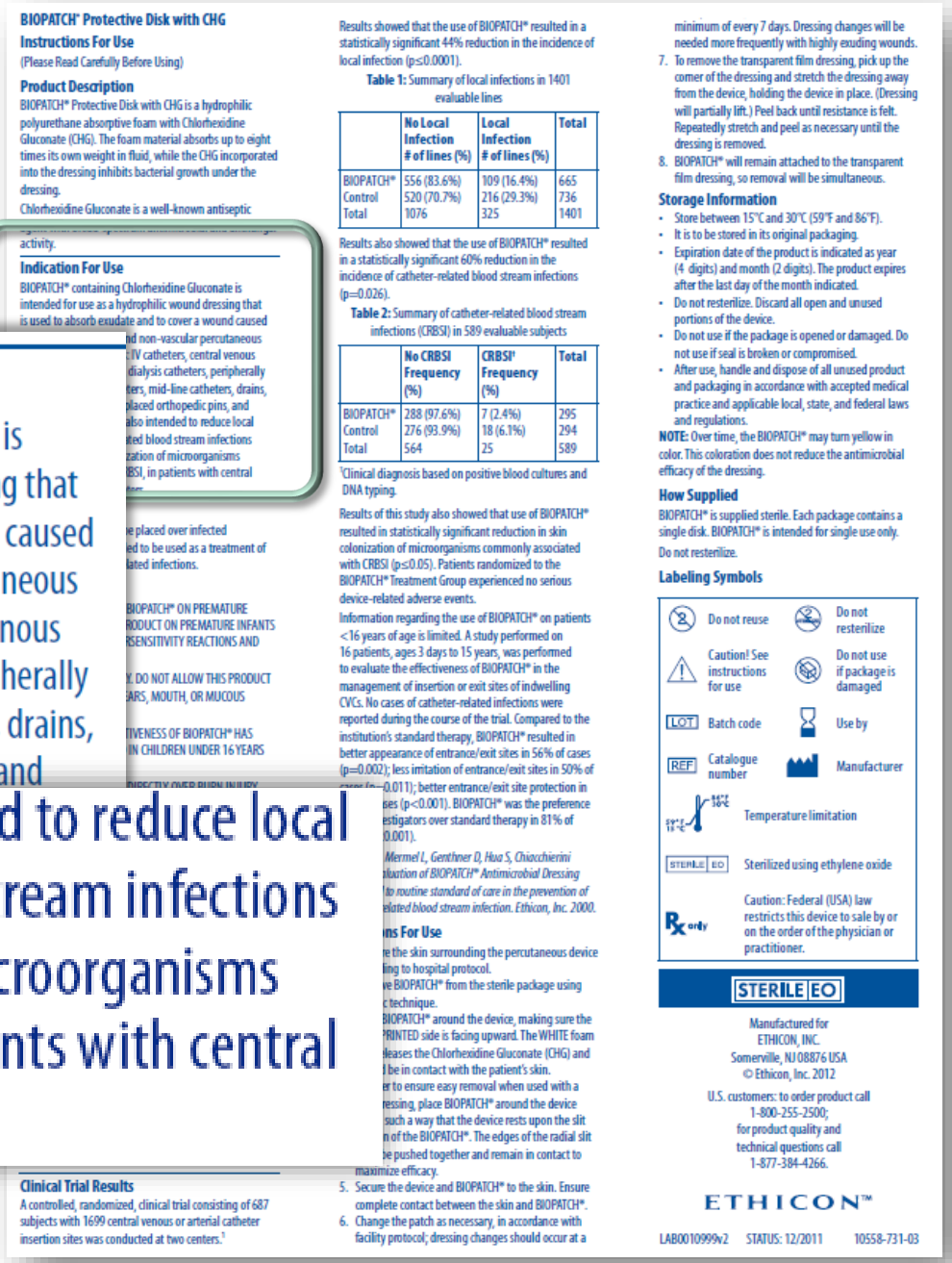
1. Shapiro JM, Bond EL, Garman JK. Use of a chlorhexidine dressing to reduce microbial colonization of epidural catheters. *Anesthesiology*. 1990 Oct;73(4):625-31.
2. Bootman, Yamamoto. Bootman United States Patent. Polyurethane-biopolymer composite. Integra LifeSciences I, Ltd. (Plainsboro, NJ). 1998.

Package Insert[1]



BIOPATCH® Protective Disk with CHG

Instructions For Use

(Please Read Carefully Before Using)

Product Description

BIOPATCH® Protective Disk with CHG 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

activity.

Indication For Use

BIOPATCH® containing Chlorhexidine Gluconate is intended for use as a hydrophilic wound dressing that is used to absorb exudate and to cover a wound caused

id non-vascular percutaneous

IV catheters, central venous

dialysis catheters, peripherally

ters, mid-line catheters, drains,

placed orthopedic pins, and

also intended to reduce local

ted blood stream infections

zation of microorganisms

BSI, in patients with central

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e placed over infected

ed to be used as a treatment of

ated infections.

BIOPATCH® ON PREMATURE

RODUCT ON PREMATURE INFANTS

RSENSITIVITY REACTIONS AND

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TIVENESS OF BIOPATCH® HAS

N CHILDREN UNDER 16 YEARS

DIRECTLY OVER BURN INJURY

Clinical Trial Results

A controlled, randomized, clinical trial consisting of 687 subjects with 1699 central venous or arterial catheter insertion sites was conducted at two centers.[1]

Results showed that the use of BIOPATCH® resulted in a statistically significant 44% reduction in the incidence of local infection ($p \leq 0.0001$).

Table 1: Summary of local infections in 1401 evaluable lines

	No Local Infection # of lines (%)	Local Infection # of lines (%)	Total
BIOPATCH®	556 (83.6%)	109 (16.4%)	665
Control	520 (70.7%)	216 (29.3%)	736
Total	1076	325	1401

Results also showed that the use of BIOPATCH® resulted in a statistically significant 60% reduction in the incidence of catheter-related blood stream infections ($p=0.026$).

Table 2: Summary of catheter-related blood stream infections (CRBSI) in 589 evaluable subjects

	No CRBSI Frequency (%)	CRBSI[1] Frequency (%)	Total
BIOPATCH®	288 (97.6%)	7 (2.4%)	295
Control	276 (93.9%)	18 (6.1%)	294
Total	564	25	589

[1]Clinical diagnosis based on positive blood cultures and DNA typing.

Results of this study also showed that use of BIOPATCH® resulted in statistically significant reduction in skin colonization of microorganisms commonly associated with CRBSI ($p \leq 0.05$). Patients randomized to the BIOPATCH® Treatment Group experienced no serious device-related adverse events.

Information regarding the use of BIOPATCH® on patients <16 years of age is limited. A study performed on 16 patients, ages 3 days to 15 years, was performed to evaluate the effectiveness of BIOPATCH® in the management of insertion or exit sites of indwelling CVCs. No cases of catheter-related infections were reported during the course of the trial. Compared to the institution's standard therapy, BIOPATCH® resulted in better appearance of entrance/exit sites in 56% of cases ($p=0.002$); less irritation of entrance/exit sites in 50% of

0.011); better entrance/exit site protection in

es ($p<0.001$). BIOPATCH® was the preference

estigators over standard therapy in 81% of

0.001).

Mermel L, Genthner D, Hsu S, Chiacchierini

olution of BIOPATCH® Antimicrobial Dressing

to routine standard of care in the prevention of

elated blood stream infection. Ethicon, Inc. 2000.

ns For Use

e the skin surrounding the percutaneous device

ing to hospital protocol.

e BIOPATCH® from the sterile package using

c technique.

BIOPATCH® around the device, making sure the

PRINTED side is facing upward. The WHITE foam

eases the Chlorhexidine Gluconate (CHG) and

be in contact with the patient's skin.

er to ensure easy removal when used with a

ssing, place BIOPATCH® around the device

such a way that the device rests upon the slit

n of the BIOPATCH®. The edges of the radial slit

e pushed together and remain in contact to

maximize efficacy.

5. Secure the device and BIOPATCH® to the skin. Ensure complete contact between the skin and BIOPATCH®.
6. Change the patch as necessary, in accordance with facility protocol; dressing changes should occur at a minimum of every 7 days. Dressing changes will be needed more frequently with highly exuding wounds.
7. To remove the transparent film dressing, pick up the corner of the dressing and stretch the dressing away from the device, holding the device in place. (Dressing will partially lift.) Peel back until resistance is felt. Repeatedly stretch and peel as necessary until the dressing is removed.
8. BIOPATCH® will remain attached to the transparent film dressing, so removal will be simultaneous.

Storage Information

- Store between 15°C and 30°C (59°F and 86°F).
- It is to be stored in its original packaging.
- Expiration date of the product is indicated as year (4 digits) and month (2 digits). The product expires after the last day of the month indicated.
- Do not resterilize. Discard all open and unused portions of the device.
- Do not use if the package is opened or damaged. Do not use if seal is broken or compromised.
- After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

NOTE: Over time, the BIOPATCH® may turn yellow in color. This coloration does not reduce the antimicrobial efficacy of the dressing.

How Supplied

BIOPATCH® is supplied sterile. Each package contains a single disk. BIOPATCH® is intended for single use only.

Do not resterilize.

Labeling Symbols

Do not reuse

Do not resterilize

Caution! See instructions for use

Do not use if package is damaged

LOT Batch code

Use by

REF Catalogue number

Manufacturer

Temperature limitation

STERILE EO Sterilized using ethylene oxide

Rx only Caution: Federal (USA) law restricts this device to sale by or on the order of the physician or practitioner.

STERILE EO

Manufactured for
ETHICON, INC.
Somerville, NJ 08876 USA
© Ethicon, Inc. 2012

U.S. customers: to order product call 1-800-255-2500;
for product quality and technical questions call 1-877-384-4266.

ETHICON™

LAB0010999v2 STATUS: 12/2011 10558-731-03

Indication For Use

BIOPATCH® 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 catheters, 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.

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1. Biopatch, Instructions for Use

For full prescribing information, please visit www.biopatch.com

What Makes BIOPATCH® Protective Disk with CHG Unique?

Proprietary Urethane composite material designed to continuously release CHG over 7 days to maintain skin antisepsis[1,2]

Cleared Indication to reduce local infections, catheter-related blood stream infections (CRBSI), and skin colonization of microorganisms commonly related to CRBSI in patients with central venous and arterial catheters

Evidence-based support materials (over a dozen randomized control trials to date)

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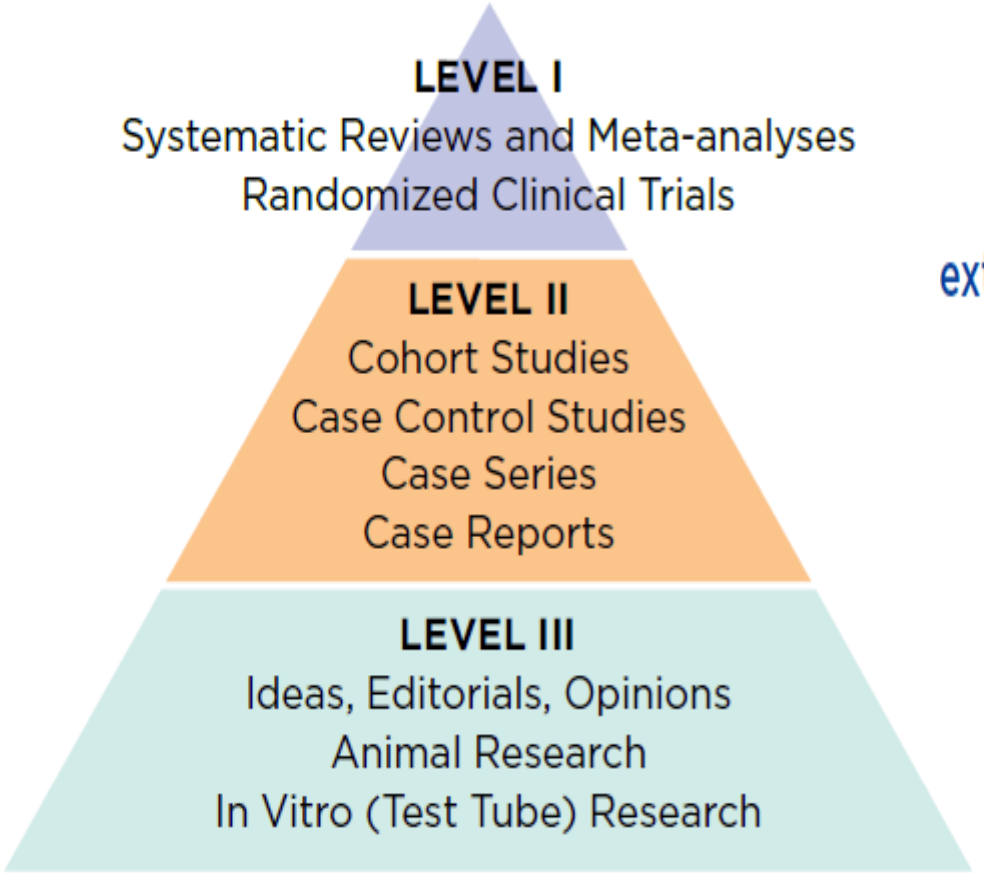
1. Shapiro JM, Bond EL, Garman JK. Use of a chlorhexidine dressing to reduce microbial colonization of epidural catheters. *Anesthesiology*. 1990 Oct;73(4):625-31.
2. Bootman, Yamamoto. Bootman United States Patent. Polyurethane-biopolymer composite. Integra LifeSciences I, Ltd. (Plainsboro, NJ). 1998.

The Evidence

Clinical evidence hierarchy for BIOPATCH® Protective Disk with CHG



Only BIOPATCH® has over 15 years of extensive clinical experience with more than:

- 14 Randomized Controlled Trials
- 12 Level II forms of evidence
- 5 Level III forms of evidence.

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www.biopatch.com, accessed June 6, 2016

BIOPATCH® Protective Disk with CHG- Timsit Study

Chlorhexidine-Impregnated Sponges and Less Frequent Dressing Changes for Prevention of Catheter-Related Infections in Critically Ill Adults: A Randomized Controlled Trial

29 months * 5 hospitals * 7 ICUs * 1636 patients evaluated * CVC and Arterial Lines

Major CRI were reduced by 57% in the CHGIS group vs the standard dressing (0.6 vs 1.4 per 1000 catheter days; P = .03)

CRBSI were reduced by 69% in the CHGIS group versus the standard dressing (0.4 vs 1.3 per 1000 catheter days; P = .006)

CONCLUSION: "Use of CHGIS dressings with intravascular catheters in the ICU reduced risk of infection even when background infection rates were low"

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Timsit, J, Schwebel C, Bouadma L, et al. Chlorhexidine-Impregnated Sponges and Less Frequent Dressing Changes for Prevention of Catheter-Related Infections in Critically Ill Adults: A Randomized Controlled Trial. JAMA. 2009; 301(12):1231-1241 (doi: 10.1001/jama.2009.376

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Evidence-based support materials (over a dozen randomized control trials to date)

Nearly all evidence used in National Guidelines is BIOPATCH® Data: CDC, SHEA/IDSA, INS, AACN, Joint Commission Resources

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1. Shapiro JM, Bond EL, Garman JK. Use of a chlorhexidine dressing to reduce microbial colonization of epidural catheters. *Anesthesiology*. 1990 Oct;73(4):625-31.
2. Bootman, Yamamoto. Bootman United States Patent. Polyurethane-biopolymer composite. Integra LifeSciences I, Ltd. (Plainsboro, NJ). 1998.

What are your goals?

- ❑ NOT ALL ANTIMICROBIALS ARE THE SAME
- ❑ NOT ALL DRESSING MATERIALS ARE THE SAME
- ❑ NOT ALL DESIGNS ARE THE SAME

Evidence you should ask for

- ☑ **Cleared Indication for Reduction of CRBSI**
- ☑ **Highest Level of Evidence/ Studies**
- ☑ **National Guideline Recommendations**

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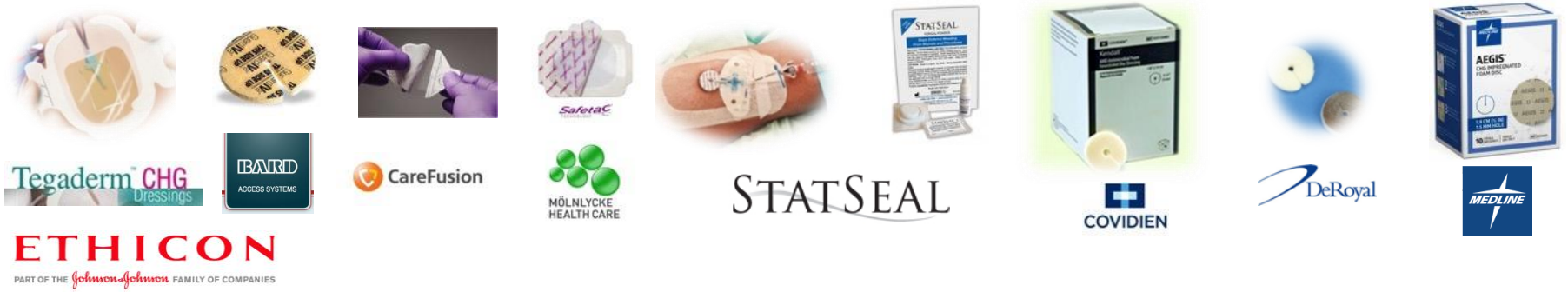
Many Options But Only One Choice

- BIOPATCH® Protective Disk with CHG is the only polyurethane foam protective disk with a cleared indication and proven to reduce the incidence of catheter-related bloodstream infections (CRBSIs), local infections and skin colonization in patients with central venous and arterial catheters
- BIOPATCH® Protective Disk with CHG is the only dressing that meets all the following criteria:
  - ✓ Has a cleared indication to reduce local infections, catheter related bloodstream infections (CRBSI), and skin colonization of microorganisms commonly related to CRBSI, in patients with central venous or arterial catheters.
  - ✓ Is constructed from polyurethane foam allowing quick absorption of fluid decreasing the likelihood of skin maceration.
  - ✓ Is designed to deliver chlorhexidine gluconate a full 360° around the catheter insertion site providing optimal coverage and protection.



1. BIOPATCH® Protective Disk with CHG Instructions for Use

Thank you for your time!

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