Evidence Based Strategies for Effective Skin Antisepsis: An HAI Prevention Approach

FRAN CANTY, M.A., B.S.N., R.N., VA-BC
Medical Science Liaison
PDI Healthcare

Disclosures
PDI Healthcare Employee

Objectives
• Discuss the impact of contamination of the skin on the risk for HAI
• Review the FDA’s Tentative Final Monograph for skin antiseptics
• Review the evidence-based methods to reducing CLABSI
• Discuss the standard evaluation questions to consider when evaluating skin antiseptics
What do these have in common?

Self Check

“So with all of the evidence based practices that exist for the prevention of HAIs, why do most healthcare facilities fail to utilize these recommendations approximately 60% of the time?”

Consumers Union
The Importance of a Checklist

WHO Checklist for Safer Surgical Care

Healthcare-Associated Infections (HAIs)

- 1 out of 25 hospitalized patients affected
- Associated with increased mortality
- Attributed costs: $26-33 billion annually
- HAIs occur in all types of facilities, including:
  - Long-term care facilities
  - Dialysis facilities
  - Ambulatory surgical centers
  - Hospitals

- Year of stay in the hospital increased by 17.6 days
- 98,987
- 334,837
How do you view life?

How do you view mortality?

How Does Transmission Occur?
- Contaminated Skin of the Patient
- Environmental Surfaces
- Contaminated Hands of HCP & the Patient
- Patient Care Equipment
Sources of Evidence

Outbreaks vs. Endemic Problems
- Endemic problems represent the majority of HAIs
- Device-associated infections
  - Catheter-associated urinary tract infections (CAUTI)
  - Central line-associated Blood stream infections (CLABSI)
  - Ventilator-associated Pneumonia (VAP)
- Procedure-associated infections
  - Surgical site infections (SSI)
- Adherence problems
  - Antimicrobial stewardship
  - Hand hygiene
  - Isolation precautions

Healthcare has moved beyond hospitals

Hospitals
Dialysis Facilities
Ambulatory Facilities
Urgent Care
Challenges of Tomorrow

- Decreasing Reimbursement
- Evolving Technological Needs
- Resistant Microbes
- Antimicrobial Resistance
- Higher Acuity
- Staffing
- Transparency
- Public Reporting

Physiology of the Skin

Illustration of Cross-section of Human Skin

- Skin is composed of two layers: epidermis & dermis
- Bacterial flora are on and within the epidermis, hair follicles, sweat & sebaceous glands
- Dermis and subcutaneous tissue are free of microbial flora


Patient Preoperative Skin Preparation

Label Indication:
- Helps reduce bacteria that potentially cause skin infection.
- For the preparation of the skin prior to surgery.
- For the preparation of the skin prior to injection.

Testing Process:

TFM Endpoints:

<table>
<thead>
<tr>
<th>Bacterial Reduction (log CFU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-log CFU / pre-injection</td>
</tr>
<tr>
<td>2-log CFU / abdomen (dry site)</td>
</tr>
<tr>
<td>3-log CFU / groin (moist site)</td>
</tr>
</tbody>
</table>
Patient Preoperative Skin Preparation

Methodology

- Inclusion / Exclusion
- Washout period for 14 days
- No bathing 24 hrs prior to baselines
- Baseline screening counts
  - Pre-injections $\geq 1.0 \times 10^3$
  - Large enough to show $\geq 2$ log for Abdomen (dry site)
  - $\geq 3$ log for Groin (moist site)

Patient Preoperative Skin Preparation

(Abdominal Site)

- Application of prep formulation
- Cover area with a sterile gauze pad

Pre-injection

<table>
<thead>
<tr>
<th>Surgical Scrub</th>
<th>Industry Coalition's Proposal Reduction ($\log_{10}$)</th>
<th>FDA TFM Proposal Reduction ($\log_{10}$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-injection</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Abdomen</td>
<td>1 (No persistence criteria)</td>
<td>2 (persistence*)</td>
</tr>
<tr>
<td>Groin</td>
<td>2 (No persistence criteria)</td>
<td>3 (persistence*)</td>
</tr>
</tbody>
</table>

*Persistence: prolonged or extended antimicrobial activity that prevents or inhibits the proliferation or survival of microorganisms after product application.
Industry Coalition’s Comments

TFM Criteria
- "overly stringent"
- inappropriate in antiseptic products with proven clinical benefit because they cannot meet the current criteria.
  - Monograph: alcohol & iodine
  - NDA: chlorhexidine gluconate
- all antiseptic products only need to be effective after a single use.

Current utilization

- Pre-Operative Skin Antiseptics:
  - Vascular Access
    - PICC Line Insertion
  - Traditional Operating Room
    - Hips, CABG, etc.
  - Cardiac Catheterization
    - Femoral Catheter Insertion
  - Special Procedures
    - Primary Care and Ambulatory Surgery
      - Minor Knee Repairs, Excisions and Biopsies, etc.
    - Site Maintenance
      - Orthopedic Pin Care
      - Dressing Changes

Back to the Basics

- Aseptic Technique is a set of specific practices and procedures performed under carefully controlled conditions with the goal of minimizing contamination by pathogens
- Goals of skin antisepsis:
  - Designed to minimize exposure to pathogenic organisms (both intrinsic and extrinsic)
  - Reduce the likelihood of infection
  - Prevent spread of pathogen
Properties of an Ideal Antiseptic

• Broad Spectrum
• Quick
• Ease of Use for Clinician
• Persistence
• Maintain activity in the presence of organic matter
• Non-irritating

2013 AORN Guideline

• Nonscrubbed personnel should apply the skin antiseptic. The risk of contamination to sterile gown and gloves is high, in most circumstances, when scrubbed personnel perform the prep.
• Sterile gloves should be worn unless the antiseptic prep applicator is of sufficient length to prevent the antiseptic and patient’s skin from contact with the non-sterile glove

Purpose of Skin Antisepsis
Potential Risk Factors:
What are the concerns of IPs and Vascular Access Professionals?

<table>
<thead>
<tr>
<th>Intrinsic Risk Factors</th>
<th>Extrinsic Risk Factors (potentially modifiable factors associated with CVC insertion or maintenance)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient’s age</td>
</tr>
<tr>
<td></td>
<td>Prolonged hospitalization before CVC insertion</td>
</tr>
<tr>
<td></td>
<td>Underlying diseases or conditions</td>
</tr>
<tr>
<td></td>
<td>Multiple CVCs</td>
</tr>
<tr>
<td></td>
<td>Patient’s gender</td>
</tr>
<tr>
<td></td>
<td>Parenteral nutrition</td>
</tr>
<tr>
<td></td>
<td>Formal or internal jugular access site</td>
</tr>
<tr>
<td></td>
<td>Heavy microbial colonization at insertion site</td>
</tr>
<tr>
<td></td>
<td>Multilumen CVC</td>
</tr>
<tr>
<td></td>
<td>Lack of neutral sterile barriers for CVC insertion</td>
</tr>
<tr>
<td></td>
<td>CVC insertion in an ICU or emergency department</td>
</tr>
</tbody>
</table>

Sample Core Questions to Ask

- Is your product FDA registered/approved? If so, what is the FDA registration number?
- Are there any independent studies available supporting the efficacy of your product?
- Is it broad spectrum?
- Is it non-irritating?
- Is it compliant with the CDC EBP?
- What value-adds are available to enhance compliance, improve outcomes, and decrease cost?
- Is it aligned with the healthcare reform outcome measures?

Transient vs. Resident Skin Flora

- Transient flora is found on and within the epidermal layer of the skin:
  - Almost all disease-producing microorganisms belong to this category
  - Is easily removed with proper skin prep and hand hygiene
- Resident flora is found in the dermis of the skin
  - Removal is more difficult
Antimicrobial Log Reduction Explained

• Log reduction in easy terms:
  ✓ 1 log_{10} = reduced by 90%
    (90% of 100,000 organisms = 90,000 killed, leaves 10,000 on skin)
  ✓ 2 log_{10} = reduced by 99%
  ✓ 3 log_{10} = reduced by 99.9%
  ✓ 4 log_{10} = reduced by 99.99%

Antimicrobial Log Reduction Explained

• Log reduction is the number of organisms reduced by the effect of an antiseptic
  • 1 log_{10} = 10^1
  • 2 log_{10} = 10^2
  • 3 log_{10} = 10^3
  • Ex. 100,000 S. epidermidis on skin
    ✓ After 1 log_{10} reduction = 10,000 bacteria left
    ✓ After 2 log_{10} reduction = 1,000 bacteria left
    ✓ After 3 log_{10} reduction = 100 bacteria left

FDA regulated antiseptics

• Isopropyl Alcohol
• PVP/Iodine
• PCMX
• Chlorhexidine gluconate
**Antiseptic Agents for Skin Preps**

<table>
<thead>
<tr>
<th>Agent</th>
<th>Action</th>
<th>Gram Pos</th>
<th>Gram Neg</th>
<th>MTCs</th>
<th>Fungi</th>
<th>Virus</th>
<th>Rapid Action</th>
<th>Resid. Action</th>
<th>Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol</td>
<td>Denaturant</td>
<td>Excellent</td>
<td>Excellent</td>
<td>Good</td>
<td>Good</td>
<td>Good</td>
<td>Most Rapid</td>
<td>None</td>
<td>Drying, Volatile</td>
</tr>
<tr>
<td>CHG</td>
<td>Gentle Cell Membrane</td>
<td>Excellent</td>
<td>Poor</td>
<td>Fair</td>
<td>Good</td>
<td>Intermed</td>
<td>Excellent</td>
<td>Ototoxic, Keratitis</td>
<td></td>
</tr>
<tr>
<td>Iodine/PVP</td>
<td>Oxidation Sub. Free Prot.</td>
<td>Excellent</td>
<td>Good</td>
<td>Good</td>
<td>Good</td>
<td>Intermed</td>
<td>Minimal</td>
<td>Absorb from skin, possible toxic skin reaction</td>
<td></td>
</tr>
</tbody>
</table>

**Is it?**

- Safe for the Patient
- Safe for the User
- Safe for the Skin
- Safe for the Environment

**FDA Questions for Skin Antiseptics**

- Is the product FDA approved as a skin antiseptic?
- What approvals does the product have? Preinjection or Preoperative?
- What is the wet prep time vs. dry prep time?
- What efficacy claims does the product have?
- Is the product compliant with the CDC Guidelines for Prevention of Intravascular Catheter Related Infections?
Impact of Neonatal CLABSI

- Inherent risk with CVCs
- Difficult to identify and treat
- Prolonged & often frequent exposure to antibiotics
- Major contributor of morbidity and mortality
- Increased length of stay and hospital costs
- Infants are especially vulnerable
- Standardization of Procedures

Holistic Bundled Approach

The Debate of CHG in Neonates
### Summary of US Clinical Guidelines for Skin Antisepsis

<table>
<thead>
<tr>
<th>Organization and Guideline</th>
<th>Skin Antisepsis Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centers for Disease Control and Prevention (CDC)</td>
<td>Protocols that involve a 5% chlorhexidine preparation with either alcohol-based or alcohol-free skin antiseptics are recommended. Chlorhexidine is preferred to alcohol-based antiseptics (category IA). Category IB: Protocols that involve alcohol-based or alcohol-free skin antiseptics are recommended. Chlorhexidine is preferred to alcohol-based antiseptics. Category II: Protocols that involve alcohol-based antiseptics are recommended. Chlorhexidine is preferred to alcohol-based antiseptics.</td>
</tr>
<tr>
<td>Society for Healthcare Epidemiology of America (SHEA)</td>
<td>Use chlorhexidine gluconate or alcohol-based antiseptics for skin preparation in patients older than 3 months of age. Chlorhexidine is preferred to chlorhexidine gluconate. Category IA: Use chlorhexidine gluconate or alcohol-based antiseptics for skin preparation in patients older than 3 months of age. Chlorhexidine is preferred to chlorhexidine gluconate. Category IB: Use chlorhexidine gluconate or alcohol-based antiseptics for skin preparation in patients older than 3 months of age. Chlorhexidine is preferred to chlorhexidine gluconate.</td>
</tr>
<tr>
<td>American Society for Microbiology (ASM)</td>
<td>Use chlorhexidine gluconate or alcohol-based antiseptics for skin preparation in patients older than 3 months of age. Chlorhexidine is preferred to chlorhexidine gluconate. Category IA: Use chlorhexidine gluconate or alcohol-based antiseptics for skin preparation in patients older than 3 months of age. Chlorhexidine is preferred to chlorhexidine gluconate. Category IB: Use chlorhexidine gluconate or alcohol-based antiseptics for skin preparation in patients older than 3 months of age. Chlorhexidine is preferred to chlorhexidine gluconate.</td>
</tr>
</tbody>
</table>

### Summary of US Clinical Guidelines for Port/Hub Cleansing

<table>
<thead>
<tr>
<th>Organization and Guideline</th>
<th>Port/Hub Cleansing Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centers for Disease Control and Prevention (CDC)</td>
<td>Minimize contamination risk by enabling the access port with an appropriate antiseptic (chlorhexidine, povidone-iodine, alcohol, or tincture of iodine) before accessing the port with the sterile device. Category IA: Use chlorhexidine alcohol for skin preparation during central venous catheter insertion. Category IB: Use an antiseptic for skin preparation during central venous catheter insertion that is based on scientific literature or endorsed by professional organizations.</td>
</tr>
<tr>
<td>Infection Nursing Standards of Practice (INS)</td>
<td>The needleless connector should be consistently and thoroughly disinfected using alcohol, tincture of iodine, or iodophor prior to accessing the port (category IA). Category IB: Use a standardized protocol to disinfect catheter hubs and injection ports before accessing the ports.</td>
</tr>
<tr>
<td>Society for Healthcare Epidemiology of America (SHEA)</td>
<td>Use a standardized protocol to disinfect catheter hubs and injection ports before accessing the ports. Category IA: Use a standardized protocol to disinfect catheter hubs and injection ports before accessing the ports. Category IB: Use a standardized protocol to disinfect catheter hubs and injection ports before accessing the ports.</td>
</tr>
<tr>
<td>American Society for Microbiology (ASM)</td>
<td>The needleless connector should be consistently and thoroughly disinfected using alcohol, tincture of iodine, or iodophor prior to accessing the port (category IA). Category IB: Use a standardized protocol to disinfect catheter hubs and injection ports before accessing the ports.</td>
</tr>
</tbody>
</table>

### Survey of Neonatal CHG Use

- **Survey of Neonatology Fellowship Directors in the United States**
  - **61% reported use of CHG for skin antisepsis for neonates**
    - 51% limited use on basis of birth weight, gestational age or chronological age.
    - Skin reactions (erythema, erosions, burns) occurring primarily in those weighing <1500 grams were reported by 51%.
  - No difference in adverse events between the alcoholic or aqueous CHG preparations
  
**Tama, K. & others, 2003**
FDA Releases New Labeling

“Directions” section of the Drug Facts label

Add the following direction (if there is no language currently on the label regarding use in infants) or replace current directions related to use in infants to read:

- Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

What about me?

Can I be offered Hand Hygiene too?

One Needle, One Syringe, Only One Time.

The One Needle, One Syringe Campaign is a public health campaign aimed at increasing awareness among the general public and healthcare providers about single injection practices.
State of prevention knowledge and science

- Guidelines developed for each type of infection and based on systematic reviews of medical literature
  - Prevention of central line-associated blood stream infections
  - Prevention of catheter-associated urinary tract infections
  - Prevention of surgical site infections
  - Prevention of healthcare-associated pneumonia
  - Management of multidrug-resistant organisms
- Recommendations graded according to evidence
- Guidelines contain many recommendations
- Current efforts to help prioritize interventions that are most effective

Adherence to infection control guidelines is incomplete

- Many HAIs are preventable with current recommendations
- Failure to use proven interventions is unacceptable
- Only 30%-38% of U.S. hospitals are in full compliance
- Just 40% of healthcare personnel adhere to hand hygiene
- Insufficient infection control infrastructure in non-acute care settings has allowed major lapses in safe care

Local success fuels national prevention
The need for HAI prevention research

- Need for complete implementation of practices known to prevent HAIs
- Need for ongoing research to identify new strategies to prevent the remaining HAIs

Formula for Success

GOAL: ZERO HEALTHCARE ASSOCIATED INFECTIONS

Healthcare Professionals + Evidence-Based Practices Implementation = Infection Prevention
Hypothetical?

• If you knew.........................

• That you could do something simple, easy, cost effective, and that was

• Evidence-Based, but took a little extra time.....

• Would you do it???? If it saved a life.....
Questions

• How will you approach Infection Prevention differently within your own practice setting?

• Contact Information:
  – Email: Fran.Canty@pdihc.com
  – Phone: (845) 323 - 0375