The Regulatory Aspects of Infection Prevention and Control

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Objectives

- Discuss the role of the Food and Drug Administration and the Environmental Protection Agency in the usage of infection control products
- Review the current regulatory classification of healthcare disinfectants, skin antiseptics, and hand hygiene products
- Discuss the appropriate steps to evaluate infection prevention and control products
Just in the last 6 Months...
- Measles
- Ebola Virus Disease
- Enterovirus
- Influenza
- CRE
- Shigella
- Zika Virus

Safe Injection Practices

Safe Injection Practices

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### CDC Estimates of HAI’s

- 722,000 estimates HAI’s in the US healthcare system in the acute care population
- 75,000 deaths from HAI’s in hospitalized patients
- 1/3 of HAI’s are now occurring outside of the traditional ICU setting
- 1 in 25 hospitalized patients contract an HAI

#### Table 2. Distribution of 504 Health Care–Associated Infections

<table>
<thead>
<tr>
<th>Type of Infection</th>
<th>Rank</th>
<th>No. of Infections</th>
<th>Percentage of All Health Care–Associated Infections (% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumonia</td>
<td>1</td>
<td>110</td>
<td>21.8 (18.4–25.4)</td>
</tr>
<tr>
<td>Surgical-site infection</td>
<td>2</td>
<td>86</td>
<td>21.8 (18.4–25.4)</td>
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<tr>
<td>Gastrointestinal infection</td>
<td>3</td>
<td>130</td>
<td>17.1 (14.0–20.5)</td>
</tr>
<tr>
<td>Urinary tract infections</td>
<td>4</td>
<td>110</td>
<td>12.9 (10.2–16.0)</td>
</tr>
<tr>
<td>Primary bloodstream infections</td>
<td>5</td>
<td>50</td>
<td>9.9 (7.3–12.8)</td>
</tr>
<tr>
<td>Eye, ear, nose, throat, or mouth</td>
<td>6</td>
<td>28</td>
<td>7.5 (3.8–11.3)</td>
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<tr>
<td>Lower respiratory tract infection</td>
<td>7</td>
<td>70</td>
<td>4.0 (2.5–5.6)</td>
</tr>
<tr>
<td>Skin and soft-tissue infection</td>
<td>8</td>
<td>16</td>
<td>3.2 (1.8–4.6)</td>
</tr>
<tr>
<td>Cardiovascular system infection</td>
<td>9</td>
<td>6</td>
<td>1.2 (0.3–2.3)</td>
</tr>
<tr>
<td>Bone and joint infection</td>
<td>10</td>
<td>5</td>
<td>1.0 (0.4–2.2)</td>
</tr>
<tr>
<td>Central nervous system infection</td>
<td>11</td>
<td>4</td>
<td>0.8 (0.3–1.9)</td>
</tr>
<tr>
<td>Reproductive tract infection</td>
<td>12</td>
<td>3</td>
<td>0.6 (0.2–1.6)</td>
</tr>
<tr>
<td>Systemic infection</td>
<td>13</td>
<td>1</td>
<td>0.2 (0.01–1.0)</td>
</tr>
</tbody>
</table>

*Infected were defined with the use of National Healthcare Safety Network (NHSN) criteria. CI denotes confidence interval.

A total of 48 pneumonia events (19.1%), were associated with a mechanical ventilator,

A total of 44 urinary tract infections (22.7%) were associated with a catheter,

A total of 42 primary bloodstream infections (8.4%) were associated with a central catheter.

#### Table 3. Reported Hospital Acquired Pathogens, According to Type of Infection

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>All-cause</th>
<th>Acquired</th>
<th>Pneumonia</th>
<th>Sepsis</th>
<th>GI</th>
<th>CRUTIA</th>
<th>Skin</th>
<th>UTI</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acinetobacter baumannii</td>
<td>0.04%</td>
<td>0.06%</td>
<td>0.06%</td>
<td>0.07%</td>
<td>0</td>
<td>0.01%</td>
<td>0.04%</td>
<td>0.05%</td>
<td>0</td>
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<tr>
<td>Anaerobic bacteria</td>
<td>0.01%</td>
<td>0.02%</td>
<td></td>
<td>0.02%</td>
<td>0</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0</td>
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<tr>
<td>Anaerobic cocci</td>
<td>0.01%</td>
<td>0.01%</td>
<td></td>
<td>0.01%</td>
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<td>0.01%</td>
<td>0.01%</td>
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<tr>
<td>Enterococcus faecalis</td>
<td>0.01%</td>
<td>0.01%</td>
<td></td>
<td>0.01%</td>
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<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
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<tr>
<td>Enterococcus faecium</td>
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<td>0.01%</td>
<td></td>
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<td>0.01%</td>
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<td>0.01%</td>
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<tr>
<td>Enterococcus gasseri</td>
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<td>0.01%</td>
<td></td>
<td>0.01%</td>
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<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0</td>
</tr>
<tr>
<td>Enterococcus gallinarum</td>
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<td>0.01%</td>
<td></td>
<td>0.01%</td>
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<td>0.01%</td>
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<tr>
<td>Escherichia coli</td>
<td>0.01%</td>
<td>0.01%</td>
<td></td>
<td>0.01%</td>
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<td>0.01%</td>
<td>0.01%</td>
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<tr>
<td>Klebsiella pneumonia</td>
<td>0.01%</td>
<td>0.01%</td>
<td></td>
<td>0.01%</td>
<td>0</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
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<tr>
<td>K. oxytoca</td>
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<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
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<tr>
<td>Pseudomonas aeruginosa</td>
<td>0.01%</td>
<td>0.01%</td>
<td></td>
<td>0.01%</td>
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<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
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<tr>
<td>Serratia marcescens</td>
<td>0.01%</td>
<td>0.01%</td>
<td></td>
<td>0.01%</td>
<td>0</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0</td>
</tr>
<tr>
<td>Stenotrophomonas maltophilia</td>
<td>0.01%</td>
<td>0.01%</td>
<td></td>
<td>0.01%</td>
<td>0</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0</td>
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<tr>
<td>Staphylococcus aureus</td>
<td>0.01%</td>
<td>0.01%</td>
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<td>0.01%</td>
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<td>0</td>
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<tr>
<td>Staphylococcus lugdunensis</td>
<td>0.01%</td>
<td>0.01%</td>
<td></td>
<td>0.01%</td>
<td>0</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0</td>
</tr>
<tr>
<td>Streptococcus pneumoniae</td>
<td>0.01%</td>
<td>0.01%</td>
<td></td>
<td>0.01%</td>
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<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0</td>
</tr>
<tr>
<td>Streptococcus pyogenes</td>
<td>0.01%</td>
<td>0.01%</td>
<td></td>
<td>0.01%</td>
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<td>0.01%</td>
<td>0.01%</td>
<td>0.01%</td>
<td>0</td>
</tr>
<tr>
<td>Viridans streptococci</td>
<td>0.01%</td>
<td>0.01%</td>
<td></td>
<td>0.01%</td>
<td>0</td>
<td>0.01%</td>
<td>0.01%</td>
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<td>0</td>
</tr>
</tbody>
</table>

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The Future of Healthcare Delivery

Health of a Population
Experience of Care
Per Capita Cost

The Triple Aim

How Does Transmission Occur?

Contaminated Hands
Contaminated Skin
Contaminated Environmental Surfaces

The Science of Safety

Unsafe road conditions
Safe road conditions
Driver awareness
Accident
Raising
Low tone
High tone
Hands free phone conversation

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Image Courtesy: National Patient Safety Foundation

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What do these have in common?

The Importance of a Checklist
Checklists for Safer Care

Emerging Outbreak: CRE

Pathogens of Particular Concern

NADONA Infection Prevention and Control
Webinar Series
Learn From The Past Prepare for the Future

Prevention of Transmission

Prevention of the Pathogen

What is the Ideal?

NO GERM ZONE

How do you view mortality?

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FDA vs. EPA

**FDA:**
- OTC Drugs
- Skin Antiseptics
- NDA or TFM
- Rx Drug
- High Level Disinfectants/Sterilants

**EPA:**
- Pesticides
- Healthcare Grade Disinfectants:
  - Low Level Disinfectants
  - Intermediate Level Disinfectants

Off Label Guidance by Federal Agencies

**FDA:**
- Off Label Use allowed at the discretion of the prescriber
- Manufacturer Regulations in place to share evidence-based clinical practice

**EPA:**
- User and Facility Liable for Off-Label use
- No protection under federal law
- FIFRA

Pathogens of Significance

- Yeasts
- ESBL
- K. pneumoniae
- NDM-1
- CRE
- GNR
- E. Coli
- MERS
Sample Core Questions to Ask

• Is the disinfectant EPA or FDA registered/approved? If so, what is the EPA/FDA registration number?
• Does the team receive advanced training on the proper use of this product?
• Are there any independent studies available supporting the efficacy of the disinfectant?
• Is there a clinical support team if I have a medical question?
• What value-adds are available to enhance compliance, improve outcomes, and decrease cost?

Healthcare Grade Disinfectants

• All disinfectants used in the US MUST be EPA-registered
• In healthcare settings, use a healthcare grade disinfectant
• Do not use sanitizers in healthcare settings

Levels of Sterilization/Disinfection Product Approval

- Sterilization
- High Level Disinfectants
- Intermediate Level Disinfectants
- Low Level Disinfectants
- Sanitizers
All about Terminology

Critical items (e.g., surgical instruments) are objects that enter sterile tissue or the vascular system and must be sterile prior to use.

Semi-critical items (e.g., endoscopes used for upper endoscopy and colonoscopy) contact mucous membranes or non-intact skin and require, at a minimum, high-level disinfection prior to reuse.

Non-critical items (e.g., blood pressure cuffs) are those that may come in contact with intact skin but not mucous membranes and should undergo low- or intermediate-level disinfection depending on the nature and degree of contamination.

Environmental surfaces (e.g., floors, walls) are those that generally do not come into contact with the patient during delivery of care. Cleaning may be all that is needed for the management of these surfaces but if disinfection is indicated, low-level disinfection is appropriate.
Key Disinfection Recommendations for Environmental Surfaces

- Establish policies and procedures for routine cleaning and disinfection of environmental surfaces
  - Focus on those surfaces in proximity to the patient and those that are frequently touched
- Select EPA-registered disinfectants or detergents/disinfectants with label claims for use in healthcare
- Follow manufacturer’s recommendations for use of cleaners and EPA-registered disinfectants (e.g., amount, dilution, contact time, safe use, and disposal)
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

Key Components for Evaluation of Environment of Care Disinfectants

- Efficacy
- Compatibility
- Safety

Key Recommendations for Disinfection and Sterilization of Medical Equipment

- Facilities should ensure that reusable medical equipment (e.g., blood glucose meters and other point-of-care devices, surgical instruments, endoscopes) is cleaned and reprocessed appropriately prior to use on another patient
- Reusable medical equipment must be cleaned and reprocessed (disinfection or sterilization) and maintained according to the manufacturer’s instructions. If the manufacturer does not provide such instructions, the device may not be suitable for multi-patient use
- Assign responsibilities for reprocessing of medical equipment to HCP with appropriate training
- Ensure HCP have access to and wear appropriate PPE when handling and reprocessing contaminated patient equipment
- Maintain copies of the manufacturer’s instructions for reprocessing of equipment in use at the facility; post instructions at locations where reprocessing is performed
- Establish procedures to document competency of HCP responsible for equipment reprocessing upon assignment of those duties, whenever new equipment is introduced, and on an ongoing basis (e.g., quarterly)
Total Contact Time

Contact Times:
- Bacteria
- Viruses
- TB
- Fungi
- Spores

Clinicians should follow the US EPA FIFRA standards, and all applicable user instructions.

Total Contact Time is the longest contact time required.

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.


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.
FDA regulated antiseptics

- Isopropyl Alcohol
- PVP/Iodine
- PCMX
- Chlorhexidine gluconate

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 (log10)</th>
<th>1-log CFU / pre-injection</th>
<th>2-log CFU / abdomen (dry site)</th>
<th>3-log CFU / groin (moist site)</th>
</tr>
</thead>
</table>

Properties of an *Ideal* Antiseptic

- Broad Spectrum
- Quick
- Non-irritating
- Maintain activity in the presence of organic matter
- Persistence
FDA Questions for Skin Antiseptics

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

Evidence-Based Medicine

- 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
  - Management of multidrug-resistant organisms
- Recommendations graded according to evidence
- Guidelines contain many recommendations
- Current efforts to help prioritize interventions that are most effective

Opportunities for Improvement and Reform

- 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
Resolve the Process, Not Bring in Another Product

• Most lapses in Infection Prevention and Control Practices are not related to products, but rather related to systems and practice violations
• These practice lapses are opportunities for improvement and the system must be designed to be high reliability and sustainable
• It is important to address underlying practice related issues prior to implementation of any products
• Most infection prevention and control challenges do not require a “new product” but rather integration of the infection prevention and control practices to address the problems of today, tomorrow, and the future

Moving From the Past to the Future

Questions and Answers

• Whose Infection will you prevent when you return to your institution?
• How will you approach HAI prevention differently in LTCF’s?

• Contact Information:
  – Email: Hudson.garrett@nadona.org
  – Visit: www.nadona.org for more information