Disinfection, Sterilization and Antisepsis: An Overview

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DISCLOSURES
2017-2018

- Consultations
  - ASP (Advanced Sterilization Products), PDI
- Honoraria
  - PDI, Kennall
- Scientific Advisory Board
  - Kinnos
- Grants
  - CDC, CMS
Disinfection, Sterilization and Antisepsis

- Provide overview of disinfection, sterilization and antisepsis
  - Indications and methods for sterilization, high-level disinfection and low-level disinfection
  - Cleaning of patient-care devices
  - Sterilization
  - Disinfection (high-level and low-level disinfection)
  - Antisepsis
www.disinfectionandsterilization.org
Sources of Healthcare-Associated Pathogens

- **Endogenous flora (SSI, UTI, CLABSI):** 40-60%
- **Exogenous:** 20-40% (e.g., cross-infection via contaminated hands [staff, visitors])
- **Other (environment):** 20%
  - Medical devices
  - Contact with environmental surfaces (direct and indirect contact)
Guideline for Disinfection and Sterilization
in Healthcare Facilities, 2008

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EH Spaulding believed that how an object will be disinfected depended on the object’s intended use (developed 1968).

**CRITICAL**—medical/surgical devices which enter normally sterile tissue or the vascular system or through which blood flows should be sterile.

**SEMICRITICAL**—medical devices that touch mucous membranes or skin that is not intact require a disinfection process (high-level disinfection [HLD]) that kills all microorganisms but high numbers of bacterial spores.

**NONCRITICAL**—medical devices that touch only intact skin require low-level disinfection.
Critical Medical/Surgical Devices

Rutala et al. ICHE 2014;35:883; Rutala et al. ICHE 2014;35:1068; Rutala et al. AJIC 2016;44:e47

- Critical
  - Transmission: direct contact
  - Control measure: sterilization
  - Surgical instruments
    - Enormous margin of safety, rare outbreaks (2 in 60 years)
    - ~85% of surgical instruments <100 microbes
    - Washer/disinfector removes or inactivates 10-100 million
    - Sterilization kills 1 trillion spores
Critical Objects

- Surgical instruments
- Cardiac catheters
- Implants
Efficacy of Disinfection/Sterilization

Influencing Factors

Cleaning of the object
Organic and inorganic load present
Type and level of microbial contamination
Concentration of and exposure time to disinfectant/sterilant
Nature of the object
Temperature and relative humidity
### Penicylinders Sterilized by Various Low-Temperature Sterilization Methods

Alfa et al. Infect Cont Hosp Epidemiol 1996;17:92-100

<table>
<thead>
<tr>
<th>Challenge:</th>
<th>12/88</th>
<th>100%ETO</th>
<th>HCFC-ETO</th>
<th>HP Plasma</th>
</tr>
</thead>
<tbody>
<tr>
<td>10% Serum, 0.65% Salt (7 organisms, N=63)</td>
<td>97%</td>
<td>60.3%</td>
<td>95.2%</td>
<td>37%</td>
</tr>
<tr>
<td>No Serum or Salt, (3 organisms, N=27)</td>
<td>100%</td>
<td>100%</td>
<td>96%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Cleaning

- Items must be cleaned using water with detergents or enzymatic cleaners before processing.
- Cleaning reduces the bioburden and removes foreign material (organic residue and inorganic salts) that interferes with the sterilization process.
- Cleaning and decontamination should be done as soon as possible after the items have been used as soiled materials become dried onto the instruments.
Cleaning

- **Mechanical** cleaning machines—automated equipment may increase productivity, improve cleaning effectiveness, and decrease worker exposure
  - Utensil washer-sanitizer
  - Ultrasonic cleaner
  - Washer sterilizer
  - Dishwasher
  - Washer disinfector
- **Manual**
## Washer/Disinfector
### Removal/Inactivation of Inoculum (Exposed) on Instruments


<table>
<thead>
<tr>
<th>WD Conditions</th>
<th>Organism</th>
<th>Inoculum</th>
<th>Log Reduction</th>
<th>Positives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine</td>
<td>MRSA</td>
<td>$2.6 \times 10^7$</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td>VRE</td>
<td>$2.6 \times 10^7$</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td><em>P. aeruginosa</em></td>
<td>$2.1 \times 10^7$</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td><em>M. terrae</em></td>
<td>$1.4 \times 10^8$</td>
<td>7.8</td>
<td>2/8</td>
</tr>
<tr>
<td>Routine</td>
<td>GS spores</td>
<td>$5.3 \times 10^6$</td>
<td>4.8</td>
<td>11/14</td>
</tr>
<tr>
<td>No Enz/Det</td>
<td>VRE</td>
<td>$2.5 \times 10^7$</td>
<td>Complete</td>
<td>0/10</td>
</tr>
<tr>
<td>No Enz/Det</td>
<td>GS spores</td>
<td>$8.3 \times 10^6$</td>
<td>5.5</td>
<td>8/10</td>
</tr>
</tbody>
</table>
DON'T YOU EVER WASH YOUR WEAPONS BEFORE YOU USE THEM?

NO, WHY?

YOU COULD GIVE SOMEONE AN INFECTION
IS THERE A STANDARD TO DEFINE WHEN A DEVICE IS CLEAN?

- There is currently no universal standard to define when a device is “clean”, cleanliness controlled by visual
- Potential methods: level of detectable bacteria; protein (6µg/cm²); endotoxin; ATP; lipid; hemoglobin; carbohydrate; bilirubin; total organic carbon; cleaning indicators for washer disinfectors; boroscope
- This is due in part to the fact that no universally accepted test soils to evaluate cleaning efficiency and no standard procedure for measuring cleaning efficiency
- At a minimum, a cleaning process should: reduce the natural bioburden; remove organic/inorganic contaminants; provide devices that when sterilized have a SAL 10⁻⁶
Methods in Sterilization
Sterilization of “Critical Objects”

Steam sterilization
Hydrogen peroxide gas plasma
Ethylene oxide
Ozone and hydrogen peroxide
Vaporized hydrogen peroxide
Sterilization

Enormous Margin of Safety!

100 quadrillion ($10^{17}$) margin of safety

Sterilization kills 1 trillion spores, washer/disinfector removes or inactivates 10-100 million; ~100 microbes on surgical instruments
Sterilization Practices
Objectives of Monitoring the Sterilization Process

- Assures probability of absence of all living organisms on medical devices being processed
- Detect failures as soon as possible
- Removes medical device involved in failures before patient use
Sterilization monitored routinely by combination of mechanical, chemical, and biological parameters

- **Physical** - cycle time, temperature, pressure
- **Chemical** - heat or chemical sensitive inks that change color when germicidal-related parameters present
- **Biological** - *Bacillus* spores that directly measure sterilization
<table>
<thead>
<tr>
<th>Sterility Indicators Table</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Before Exposure</strong></td>
</tr>
<tr>
<td><strong>(Do not use)</strong></td>
</tr>
<tr>
<td><strong>Steam Autoclave</strong></td>
</tr>
<tr>
<td>Tape</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Strip</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Peel Pack</strong></td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Ethylene Oxide (ETO. gas)</strong></td>
</tr>
<tr>
<td>Tape</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Strip</strong></td>
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<td><strong>Strip</strong></td>
</tr>
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</tbody>
</table>

*6/23/97*
Super Rapid Readout Biological Indicators
Commercially available

BI (blue cap)
• Monitors 270°F and 275°F gravity –displacement steam sterilization cycles
• 30 minute result (from 1 hour)

BI (brown cap)
• Monitors 270°F and 275°F dynamic-air-removal (pre-vacuum) steam sterilization cycles
• 1 hour result (from 3 hours)
Semicritical Medical Devices
Rutala et al. AJIC 2016;44:e47

- Semicritical
  - Transmission: direct contact
  - Control measure: high-level disinfection
  - Endoscopes top ECRI list of 10 technology hazards, >130 outbreaks (GI, bronchoscopes)
    - 0 margin of safety
      - Microbial load, $10^7$-$10^{10}$
      - Complexity
      - Biofilm
  - Other semicritical devices, rare outbreaks
    - ENT scopes, endocavitary probes (prostate, vaginal, TEE), laryngoscopes, cystoscopes
    - Reduced microbial load, less complex
Semicritical Items

- Endoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitary probes
- Tonometers
- Laryngoscopes
High-Level Disinfection
No Margin of Safety

0 margin of safety

Microbial contamination $10^7$-$10^{10}$: compliant with reprocessing guidelines 10,000 microbes after reprocessing:

maximum contamination, minimal cleaning ($10^2$)/HLD ($10^4$)
### High-Level Disinfection of “Semicritical Objects”


**Exposure Time ≥ 8m-45m (US), 20°C**

<table>
<thead>
<tr>
<th>Germicide</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde</td>
<td>≥ 2.0%</td>
</tr>
<tr>
<td>Ortho-phthalaldehyde</td>
<td>0.55%</td>
</tr>
<tr>
<td>Hydrogen peroxide*</td>
<td>7.5%</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
<td>1.0%/0.08%</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
<td>7.5%/0.23%</td>
</tr>
<tr>
<td>Hypochlorite (free chlorine)*</td>
<td>650-675 ppm</td>
</tr>
<tr>
<td>Accelerated hydrogen peroxide</td>
<td>2.0%</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>0.2%</td>
</tr>
<tr>
<td>Glut and isopropanol</td>
<td>3.4%/26%</td>
</tr>
<tr>
<td>Glut and phenol/phenate**</td>
<td>1.21%/1.93%</td>
</tr>
</tbody>
</table>

*May cause cosmetic and functional damage; **efficacy not verified*
## Transmission of Infection by Endoscopy


<table>
<thead>
<tr>
<th>Scope</th>
<th>Outbreaks</th>
<th>Micro (primary)</th>
<th>Pts Contaminated</th>
<th>Pts Infected</th>
<th>Cause (primary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper GI</td>
<td>19</td>
<td>Pa, <em>H. pylori</em>, <em>Salmonella</em></td>
<td>169</td>
<td>56</td>
<td>Cleaning/Disinfection (C/D)</td>
</tr>
<tr>
<td>Sigmoid/Colonoscopy</td>
<td>5</td>
<td><em>Salmonella</em>, HCV</td>
<td>14</td>
<td>6</td>
<td>Cleaning/Disinfection</td>
</tr>
<tr>
<td>ERCP</td>
<td>23</td>
<td><em>P. aeruginosa</em> (Pa)</td>
<td>152</td>
<td>89</td>
<td>C/D, water bottle, AER</td>
</tr>
<tr>
<td>Bronchoscopy</td>
<td>51</td>
<td>Pa, Mtb, Mycobacteria</td>
<td>778</td>
<td>98</td>
<td>C/D, AER, water</td>
</tr>
<tr>
<td>Totals</td>
<td>98</td>
<td></td>
<td>1113</td>
<td>249</td>
<td></td>
</tr>
</tbody>
</table>

Based on outbreak data, if eliminated deficiencies associated with cleaning, disinfection, AER, contaminated water and drying would eliminate about 85% of the outbreaks.
Reason for Endoscope-Related Outbreaks


- Margin of safety with endoscope reprocessing minimal or non-existent
- Microbial load
  - GI endoscopes contain $10^{7-10}$
  - Cleaning results in 2-6 log$_{10}$ reduction
  - High-level disinfection results in 4-6 log$_{10}$ reduction
  - Results in a total 6-12 log$_{10}$ reduction of microbes
  - Level of contamination after processing: $4\log_{10}$ (maximum contamination, minimal cleaning/HLD)
- Complexity of endoscope and endoscope reprocessing
- Biofilms-unclear if contribute to failure of endoscope reprocessing
Noncritical Medical Devices

- Noncritical medical devices
- Transmission: secondary transmission by contaminating hands/gloves via contact with the environment and transfer to patient
- Control measures: hand hygiene and low-level disinfection
- Noncritical devices (stethoscopes, blood pressure cuffs, wound vacuum), rare outbreaks
Effective Surface Decontamination

Product and Practice
**Exposure time ≥ 1 min**

<table>
<thead>
<tr>
<th>Germicide</th>
<th>Use Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl or isopropyl alcohol</td>
<td>70-90%</td>
</tr>
<tr>
<td>Chlorine</td>
<td>100ppm (1:500 dilution)</td>
</tr>
<tr>
<td>Phenolic</td>
<td>UD</td>
</tr>
<tr>
<td>Iodophor</td>
<td>UD</td>
</tr>
<tr>
<td>Quaternary ammonium (QUAT)</td>
<td>UD</td>
</tr>
<tr>
<td>QUAT with alcohol</td>
<td>RTU</td>
</tr>
<tr>
<td>Improved hydrogen peroxide (HP)</td>
<td>0.5%, 1.4%</td>
</tr>
<tr>
<td>Peracetic acid with HP (C. difficile)</td>
<td>UD</td>
</tr>
</tbody>
</table>

UD=Manufacturer’s recommended use dilution; others in development/testing-electrolyzed water; polymeric guanidine; cold-air atmospheric pressure plasma (Boyce Antimicrob Res IC 2016. 5:10)
Thoroughness of Environmental Cleaning

Carling P. AJIC 2013;41:S20-S25

Mean = 32%

>110,000 Objects

DAILY CLEANING
TERMINAL CLEANING
Implement evidence-based practices for surface disinfection
- Ensure use of safe and effective (against emerging pathogens such as C. auris and CRE) low-level disinfectants
- Ensure thoroughness of cleaning (new thoroughness technology)

Use “no touch” room decontamination technology proven to reduce microbial contamination on surfaces and reduction of HAIs at terminal/discharge cleaning

Use new continuous room decontamination technology that continuously reduces microbial contamination
“NO TOUCH” APPROACHES TO ROOM DECONTAMINATION

(UV/VHP~20 microbicidal studies, 12 HAI reduction studies; will not discuss technology with limited data)

Enhanced Disinfection Leading to Reduction of Microbial Contamination and a Decrease in Patient Col/Infection


All enhanced disinfection technologies were significantly superior to Quat alone in reducing EIPs. Comparing the best strategy with the worst strategy (i.e., Quat vs Quat/UV) revealed that a reduction of 94% in EIP (60.8 vs 3.4) led to a 35% decrease in colonization/infection (2.3% vs 1.5%). Our data demonstrated that a decrease in room contamination was associated with a decrease in patient colonization/infection. First study which quantitatively described the entire pathway whereby improved disinfection decreases microbial contamination which in-turn reduced patient colonization/infection.
Antisepsis
Antiseptic Agents
(used alone or in combination)

- Alcohols, 60-95%
- Chlorhexidine, 2% and 4% aqueous
- Iodophors
- PCMX
- Triclosan
Antiseptics

- Hand Hygiene-improvement and compliance monitoring
- Preoperative showers
- Preoperative skin preparation
- Surgical hand scrub
- Skin preparation prior to insertion of catheters
- Routine daily bathing of patients
Summary of Best Antiseptics


- **Preoperative showers** - CHG is preferred; significant impact on SSIs not proven
- **Preoperative skin preparation** - alcohol-containing products (with CHG or iodophor)
- **Surgical hand scrub** - alcohol-containing products reduce bacteria on hands best
- **Vascular access site preparation** - alcohol preparation containing >0.5% CHG
- **Routine daily bathing of patients** - CHG appear to be more effective than standard soap and water
Disinfection, Sterilization and Antisepsis

- Provide overview of disinfection, sterilization and antisepsis
  - Indications and methods for sterilization, high-level disinfection and low-level disinfection
  - Cleaning of patient-care devices
  - Sterilization
  - Disinfection (high-level and low-level disinfection)
  - Antisepsis
Summary

- D/S evidenced-based recommendations must be followed to prevent exposure to pathogens that may lead to infection
- Antiseptics must be used optimally to prevent infections that originate from the skin and patient contact
THANK YOU!

www.disinfectionandsterilization.org