DISCLOSURES
2022

- Consultations
  - PDI (Professional Disposables International)

- Honoraria
  - PDI

- Other
  - Kinnos, Ideate Medical
Provide overview of disinfection, sterilization and antisepsis

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

- Provide overview of disinfection, sterilization and antisepsis
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  - Disinfection (high-level and low-level disinfection)
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Update: May 2019

William A. Rutala, Ph.D., M.P.H.\(^1,2\), David J. Weber, M.D., M.P.H.\(^1,2\), and the Healthcare Infection Control Practices Advisory Committee (HICPAC)\(^3\)

\(^1\)Hospital Epidemiology
University of North Carolina Health Care System
Chapel Hill, NC 27514

\(^2\)Division of Infectious Diseases
University of North Carolina School of Medicine
Chapel Hill, NC 27599-7030
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.
Disinfection, Sterilization and Antisepsis

- Provide overview of disinfection, sterilization and antisepsis
  - Indications and methods for sterilization, high-level disinfection and low-level disinfection
  - Sterilization
  - Cleaning of patient-care devices
  - Disinfection (high-level and low-level disinfection)
  - Antisepsis
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, implants
    • Enormous margin of safety, rare/no outbreaks
    • ~85% of surgical instruments <100 microbes
    • Washer/disinfector removes or inactivates 10-100 million
    • Sterilization kills 1 trillion spores
Risk of Infection Transmission via Surgical Instruments—Essentially Zero
Pre-Cleaning in the Operating Room
Point-of-Use

- Point-of-use pre-cleaning by clinicians or technicians post-procedures is critical to removing bioburden and debris
- Ideally, instruments should arrive in Central Processing free on visible contamination (results in greater efficiency in CP)
- Wetting and wiping instruments and keeping lumens flushed throughout surgery prevents drying of debris. Soiled instruments that will not be reused should be allowed to soak in a basin of sterile water for the remainder of the procedures.
- Keep instruments moist (e.g., enzymatic sprays, foams, gels) until manual cleaning
Cleaning

○ Manual

○ **Mechanical** cleaning machines-automated equipment may increase productivity, improve cleaning effectiveness, and decrease worker exposure
  - Utensil washer-sanitizer
  - Ultrasonic cleaner
  - Washer sterilizer
  - Dishwasher
  - Washer disinfecter
Cleaning

- Items must be cleaned using water with detergents or enzymatic cleaners (single use) 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.
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; borescope

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 $10^{-6}$
Washer/Disinfector

Five Chambers

- Pre-wash: water/enzymatic is circulated over the load for 1 min
- Wash: detergent wash solution (150°F) is sprayed over the load for 4 min
- Ultrasonic cleaning: basket is lowered into ultrasonic cleaning tank with detergent for 4 min
- Thermal and lubricant rinse: hot water (180°F) is sprayed over the load for 1 min; instrument milk lubricant is added to the water and is sprayed over the load
- Drying: blower starts for 4 min and temperature in drying chamber 180°F
# 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>
Washer/disinfectors are very effective in removing/inactivating microorganisms from instruments.
Cleaning Indicators for Washers

- Monitor the automated washer and instrument cleaning chemistry functionality
- Complete soil removal of the dried test soil pattern is a “pass”
- Indicator includes proteins, lipids, and polysaccharides to mimic common challenging test soils
Heat resistant
• Steam sterilization

Heat sensitive
• Ethylene oxide
• Hydrogen peroxide gas plasma
• Ozone and hydrogen peroxide
• Vaporized hydrogen peroxide
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
Sterilization-SAL $10^{-6}$
Robustness
“Dirty” (non-cleaned) Instruments with Blood and Bacteria
**Effectiveness of the Microbicidal Activity of Steam Sterilization in the Presence of Blood on “Dirty” Instruments**


<table>
<thead>
<tr>
<th>Test Organism</th>
<th>Method of Sterilization</th>
<th>Instruments “dirty” (non-cleaned) with or without blood²</th>
<th>Instrument Quantitation (Mean)</th>
<th>% Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Geobacillus stearothermophilus</em> (spores)</td>
<td>Steam Sterilization</td>
<td>Dirty</td>
<td>~1.56x10⁵</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dirty with blood (spores mixed with blood not sandwich²)</td>
<td>~1.99x10⁵</td>
<td>0/12 (0)</td>
</tr>
<tr>
<td><em>Mycobacterium terrae</em></td>
<td>Steam Sterilization</td>
<td>Dirty</td>
<td>~4.25x10⁶</td>
<td>0/10 (0)</td>
</tr>
</tbody>
</table>

¹Study conditions not representative of practice or manufacturer’s recommendations.

²Sandwich consists of “dirty” or non-cleaned instrument, then an inoculum of spores or vegetative bacteria, and lastly overlaid with blood after inoculum dry. One *G. stearothermophilus* experiment was done with the spores mixed with the inoculum and then placed on the dirty instrument.
Steam sterilization is the most effective sterilization technology with the largest margin of safety, followed by ETO and hydrogen peroxide gas plasma.

### Table 1. Effectiveness of the Microbicidal Activity of Sterilization Technologies in the Presence of Blood on “Dirty” Instruments

<table>
<thead>
<tr>
<th>Test Organism</th>
<th>Method of Sterilization</th>
<th>Instruments “Dirty” (Undeaned) With or Without Blood</th>
<th>Instrument Quantitation (Mean)</th>
<th>No. of Positives/No. of Runs (% Positive)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Geobacillus stearothermophilus</em></td>
<td>Steam Sterilization</td>
<td>Dirty</td>
<td>(~1.56\times10^5)</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dirty with blood (spores mixed with blood not sandwich)</td>
<td>(~1.99\times10^5)</td>
<td>0/12 (0)</td>
</tr>
<tr>
<td><em>ETO</em></td>
<td>Dirty</td>
<td>(~1.53\times10^5)</td>
<td>0/10 (0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>(~2.35\times10^5)</td>
<td>0/11 (0)</td>
<td></td>
</tr>
<tr>
<td><em>HPGP</em></td>
<td>Dirty</td>
<td>(~1.58\times10^5)</td>
<td>5/10 (50)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>(~2.35\times10^5)</td>
<td>9/15 (60)</td>
<td></td>
</tr>
<tr>
<td><em>Mycobacterium terrae</em></td>
<td>Steam Sterilization</td>
<td>Dirty</td>
<td>(~4.25\times10^6)</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td><em>P. aeruginosa</em></td>
<td>HPGP</td>
<td>Dirty</td>
<td>(~1.81\times10^6)</td>
<td>3/15 (20)</td>
</tr>
<tr>
<td><em>Bacillus atrophaeus</em> (spores)</td>
<td>ETO</td>
<td>Dirty</td>
<td>(~2.30\times10^7)</td>
<td>6/10 (60)</td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>(~4.08\times10^7)</td>
<td>9/10 (90)</td>
<td></td>
</tr>
<tr>
<td><em>MRSA</em></td>
<td>ETO</td>
<td>Dirty</td>
<td>(~2.62\times10^6)</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>(~1.72\times10^6)</td>
<td>0/10 (0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HPGP</td>
<td>Dirty</td>
<td>(~1.10\times10^6)</td>
<td>4/10 (40)</td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>(~1.27\times10^6)</td>
<td>4/10 (40)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Steam sterilization</td>
<td>Dirty</td>
<td>(~2.56\times10^6)</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>(~5.20\times10^6)</td>
<td>0/10 (0)</td>
<td></td>
</tr>
<tr>
<td><em>VRE</em></td>
<td>ETO</td>
<td>Dirty</td>
<td>(~2.27\times10^6)</td>
<td>0/10 (0)</td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>(~3.59\times10^6)</td>
<td>0/10 (0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HPGP</td>
<td>Dirty</td>
<td>(~2.63\times10^6)</td>
<td>3/10 (30)</td>
</tr>
<tr>
<td></td>
<td>Dirty with blood</td>
<td>(~2.34\times10^6)</td>
<td>9/10 (90)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Steam sterilization</td>
<td>Dirty</td>
<td>(~1.90\times10^6)</td>
<td>0/10 (0)</td>
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Indications and methods for sterilization, high-level disinfection and low-level disinfection

Sterilization

Cleaning of patient-care devices

Disinfection (high-level and low-level disinfection)

Antisepsis
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
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 $10^4$)
HBV and HCV transmission during endoscopy and use of semicritical medical devices can occur, but it is rare (3)

No articles related to possible transmission of HIV via medical device

Greatest evidence of transmission associated with GI endoscopes/bronchoscopes (~130 outbreaks) likely due to microbial load and complexity.

Several other semicritical medical devices are associated with infections related to inadequate reprocessing
## High-Level Disinfection of “Semicritical Objects”

Rutala, Weber. AJIC 2019;47:A3-A9

<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
ENDOSCOPE REPROCESSING: CHALLENGES

Complex [elevator channel]-10^7-10^10 bacteria/endoscope

Surgical instruments-<10^2 bacteria
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
Gastrointestinal Endoscopes
A Need to Shift From Disinfection to Sterilization?

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

More than 10 million gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both. Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.

In this issue of JAMA, Epstein and colleagues report findings from their investigation of a cluster of New Delhi metallo-β-lactamase (NDM)-producing Escherichia coli associated with gastrointestinal endoscopy that occurred from March 2013 to July 2013 in a single hospital in northeastern Illinois. During the 5-month period, 9 pa-

First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-level disinfection. High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible. However, no low-temperature sterilization technology is US Food and Drug Administration (FDA)-cleared for gastrointestinal endoscopes such as duodenoscopes.

Second, more health care-associated outbreaks and clusters of infection have been linked to contaminated endoscopes than to any other medical device. However, until now,
EH Spaulding believed that how an object will be disinfected depended on the object’s intended use (modified).

CRITICAL - objects which directly or secondarily (i.e., via a mucous membrane such as duodenoscope, cystoscope, bronchoscope) enter normally sterile tissue or the vascular system or through which blood flows should be sterile.

SEMICRITICAL - objects 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 - objects that touch only intact skin require low-level disinfection (or non-germicidal detergent).
### Processing “Noncritical” Patient Care Objects

<table>
<thead>
<tr>
<th>Classification:</th>
<th>Noncritical objects will not come in contact with mucous membranes or skin that is not intact.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Object:</td>
<td>Can be expected to be contaminated with some microorganisms.</td>
</tr>
<tr>
<td>Level germicidal action:</td>
<td>Kill vegetative bacteria, fungi and lipid viruses.</td>
</tr>
<tr>
<td>Examples:</td>
<td>Bedpans; crutches; bed rails; EKG leads; bedside tables; walls, floors and furniture.</td>
</tr>
<tr>
<td>Method:</td>
<td>Low-level disinfection</td>
</tr>
</tbody>
</table>
Evidence environment contributes

- Role-MRSA, VRE, *C. difficile*
- Surfaces are contaminated—~25%
- EIP survive days, weeks, months
- Contact with surfaces results in hand contamination; contaminated hands transmit EIP to patients
- Disinfection reduces contamination
- Disinfection (daily) reduces HAIs
- Rooms not adequately cleaned (puts next patient at infection risk)
### 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>PA with HP, 4% HP, chlorine (C. difficile spores)</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)
A Bundle Approach to Surface Disinfection (prevents infection to new patient)

- Develop policies and procedures
- Select cleaning and disinfecting products
- Educate staff-environmental services and nursing
- Monitor compliance (thoroughness of cleaning, product use) and feedback
- Implement “no touch” room decontamination technology and monitor compliance (and new strategies)
Disinfection, Sterilization and Antisepsis

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  - Sterilization
  - Cleaning of patient-care devices
  - Disinfection (high-level and low-level disinfection)
  - Antisepsis
Antiseptic Agents
(used alone or in combination)


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

JM Boyce. AJIC 2019.47:A17-A22

- **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 appears to reduce infections (CLABSI) in ICU
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  - 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.