Best Practices for Cleaning, Disinfection, and Sterilization in Healthcare
Prof. William Rutala, University of North Carolina
Sponsored by WHO First Patient Safety Challenge, Clean Care is Safer Care

Best Practices for Cleaning, Disinfection and Sterilization in Healthcare
William A. Rutala, Ph.D., M.P.H.
University of North Carolina (UNC) Health Care System
and UNC at Chapel Hill, NC

Disinfection and Sterilization
Provide overview of disinfection and sterilization recommendations
Indications and methods for sterilization, high-level disinfection and low-level disinfection
Cleaning of patient-care devices
Sterilization practices
Disinfection practices

Disinfection and Sterilization in Healthcare Facilities
Overview
Last Centers for Disease Control and Prevention guideline in 1985
158 pages (>82 pages preamble, 34 pages recommendations, glossary of terms, tables/figures, >1000 references)
Evidence-based guideline
Cleared by HICPAC February 2003; delayed by FDA
Published in November 2008

disinfectionandsterilization.org

Disinfection and Sterilization
EH Spaulding believed that how an object will be disinfected depended on the object’s intended use.
CRITICAL - objects which 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).

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

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Processing “Critical” Patient Care Objects

<table>
<thead>
<tr>
<th>Classification:</th>
<th>Critical objects enter normally sterile tissue or vascular system, or through which blood flows.</th>
</tr>
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<tbody>
<tr>
<td>Object:</td>
<td>Sterility.</td>
</tr>
<tr>
<td>Level germicidal action:</td>
<td>Kill all microorganisms, including bacterial spores.</td>
</tr>
<tr>
<td>Examples:</td>
<td>Surgical instruments and devices; cardiac catheters; implants; etc.</td>
</tr>
<tr>
<td>Method:</td>
<td>Steam, ETO, hydrogen peroxide gas plasma, vaporized hydrogen peroxide, ozone or chemical sterilization.</td>
</tr>
</tbody>
</table>

Critical Objects

- Surgical instruments
- Cardiac catheters
- Implants

Sterilization of “Critical Objects”

- Steam sterilization
- Hydrogen peroxide gas plasma
- Ethylene oxide
- Ozone
- Vaporized hydrogen peroxide

Processing “Semicritical” Patient Care Objects

<table>
<thead>
<tr>
<th>Classification:</th>
<th>Semicritical objects come in contact with mucous membranes or skin that is not intact.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Object:</td>
<td>Free of all microorganisms except high numbers of bacterial spores.</td>
</tr>
<tr>
<td>Level germicidal action:</td>
<td>Kills all microorganisms except high numbers of bacterial spores.</td>
</tr>
<tr>
<td>Examples:</td>
<td>Respiratory therapy and anesthesia equipment, GI endoscopes, endocavitary probes, etc.</td>
</tr>
<tr>
<td>Method:</td>
<td>High-level disinfection</td>
</tr>
</tbody>
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Semicritical Items

- Endoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitary probes
- Tonometers
- Diaphragm fitting rings

High-Level Disinfection of “Semicritical Objects”

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<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>Glut and isopropanol</td>
<td>3.4%/0.66%</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

Processing “Noncritical” Patient Care Objects

Classification: Noncritical objects will not come in contact with mucous membranes or skin that is not intact.

Object: Can be expected to be contaminated with some microorganisms.

Level germicidal action: Kill vegetative bacteria, fungi and lipid viruses.

Examples: Bedpans; crutches; bed rails; EKG leads; bedside tables; walls, floors and furniture.

Method: Low-level disinfection (or detergent for housekeeping surfaces)

Low-Level Disinfection for “Noncritical” Objects

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<tr>
<th>Germicide</th>
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<td>Ethyl or isopropyl alcohol</td>
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<tr>
<td>Quaternary ammonium</td>
<td>UD</td>
</tr>
<tr>
<td>Accelerated hydrogen peroxide</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

UD=Manufacturer’s recommended use dilution (e.g., 1:504)

Methods in Sterilization

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### Sterilization of “Critical Objects”

- Steam sterilization
- Hydrogen peroxide gas plasma
- Ethylene oxide
- Ozone
- Vaporized hydrogen peroxide

### Cleaning

- Critical and semicritical 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.

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**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

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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 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 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>2.6x10⁷</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td>VRE</td>
<td>2.6x10⁷</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td>P. aeruginosa</td>
<td>2.1x10⁷</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td>M. terrae</td>
<td>1.4x10⁴</td>
<td>7.8</td>
<td>2/8</td>
</tr>
<tr>
<td>Routine</td>
<td>GS spores</td>
<td>5.3x10⁸</td>
<td>4.8</td>
<td>11/14</td>
</tr>
<tr>
<td>No Enz/Det</td>
<td>VRE</td>
<td>2.5x10⁷</td>
<td>Complete</td>
<td>0/10</td>
</tr>
<tr>
<td>No Enz/Det</td>
<td>GS spores</td>
<td>8.3x10⁸</td>
<td>5.5</td>
<td>8/10</td>
</tr>
</tbody>
</table>

Washer/disinfectors are very effective in removing/inactivating microorganisms from instruments

Sterilization

The complete elimination or destruction of all forms of microbial life and is accomplished in healthcare facilities by either physical or chemical processes

Steam Sterilization

- Advantages
  - Non-toxic
  - Cycle easy to control and monitor
  - Inexpensive
  - Rapidly microbicidal
  - Least affected by organic/inorganic soils
  - Rapid cycle time
  - Penetrates medical packing, device lumens
- Disadvantages
  - Deleterious for heat labile instruments
  - Potential for burns

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Newer Trends in Sterilization of Patient Equipment

- Alternatives to ETO-CFC
  - ETO-CO₂, ETO-HCFC, 100% ETO
- Newer Low Temperature Sterilization Technology
  - Hydrogen Peroxide Gas Plasma
  - Vaporized hydrogen peroxide
  - Ozone

Ethylene Oxide (ETO)

- Advantages
  - Very effective at killing microorganisms
  - Penetrates medical packaging and many plastics
  - Compatible with most medical materials
  - Cycle easy to control and monitor
- Disadvantages
  - Some states (CA, NY, TX) require ETO emission reduction of 90-99.9%
  - CFC (inert gas that eliminates explosion hazard) banned after 1995
  - Potential hazard to patients and staff
  - Lengthy cycle/aeration time
### Hydrogen Peroxide Gas Plasma Sterilization

**Advantages**
- Safe for the environment and health care worker; it leaves no toxic residuals
- Fast - cycle time is 28-52 min and no aeration necessary
- Used for heat and moisture sensitive items since process temperature 50°C
- Simple to operate, install, and monitor
- Compatible with most medical devices

**Disadvantages**
- Cellulose (paper), linens and liquids cannot be processed
- Sterilization chamber is small, about 3.5 ft³ to 7.3 ft³
- Endoscopes or medical devices restrictions based on lumen internal diameter and length (see manufacturer’s recommendations); expanded claims with NX
- Requires synthetic packaging (polypropylene) and special container tray

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### Ozone

**Advantages**
- Used for moisture and heat-sensitive items
- Ozone generated from oxygen and water (oxidizing)
- No aeration because no toxic by-products
- FDA cleared for metal and plastic surgical instruments, including some instruments with lumens

**Disadvantages**
- Sterilization chamber small, 4 ft³
- Limited use (material compatibility/penetrability/organic material resistance?) and limited microbicidal efficacy data

### V-PRO™1, Vaporized Hydrogen Peroxide

**Advantages**
- Safe for the environment and health care worker; it leaves no toxic residuals
- Fast - cycle time is 55 min and no aeration necessary
- Used for heat and moisture sensitive items (metal and nonmetal devices)

**Disadvantages**
- Sterilization chamber is small, about 4.8 ft³
- Medical devices restrictions based on lumen internal diameter and length—see manufacturer’s recommendations, e.g., 53 lumen 1 mm diameter, 125 mm length
- Not used for liquid, linens, powders, or any cellulose materials
- Requires synthetic packaging (polypropylene)
- Limited use and limited comparative microbicidal efficacy data
Conclusions

Sterilization

- All sterilization processes effective in killing spores
- Cleaning removes salts and proteins and must precede sterilization
- Failure to clean or ensure exposure of microorganisms to sterilant (e.g. connectors) could affect effectiveness of sterilization process

Recommendations

Methods of Sterilization

- Steam is preferred for critical items not damaged by heat
- Follow the operating parameters recommended by the manufacturer (times, temperatures, gas conc)
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat
- Aerate surgical and medical items that have been sterilized in the ETO sterilizer

Methods of Sterilization

- Dry heat sterilization (e.g., 340F for 60 minutes) can be used to sterilize items (e.g., powders, oils) that can sustain high temperatures

Sterilization Practices
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Packaging

- Once items are cleaned, dried, and inspected, items are wrapped or placed in a rigid container
- Arranged in tray/basket according to guidelines
  - Hinged instruments opened
  - Items with removable parts should be disassembled
  - Heavy items positioned not to damage delicate items
- Several choices to maintain sterility of instruments: rigid containers, peel pouch; sterilization wraps

Packaging

Sterilization Wraps

- An effective sterilization wrap would:
  - Allow penetration of the sterilant
  - Provide an effective barrier to microbial penetration
  - Maintain the sterility of the processed item after sterilization
  - Puncture resistant and flexible
  - Drapeable and easy to use
- Multiple layers are still common practice due to the rigors of handling

Recommendations

Storage of Sterile Items

- Sterile storage area should be well-ventilated area that provides protection against dust, moisture, and temperature and humidity extremes.
- Sterile items should be stored so that packaging is not compromised
- Sterilized items should be labeled with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and the expiration date (if applicable)

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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 Monitoring

Sterilization monitored routinely by combination of physical, chemical, and biological parameters

- Physical - cycle time, temperature, pressure
- Chemical - heat or chemical sensitive inks that change color when germicidal-related parameters present (Class 1-6)
- Biological - Bacillus spores that directly measure sterilization

Biological Monitors

- Steam - Geobacillus stearothermophilus
- Dry heat - B. atrophaeus (formerly B. subtilis)
- ETO - B. atrophaeus
- New low temperature sterilization technologies
  - HP gas plasma (Sterrad) - G. stearothermophilus
  - Ozone - G. stearothermophilus

Recommendations Monitoring of Sterilizers

- Monitor each load with physical and chemical (internal and external) indicators. If the internal indicator is visible, an external indicator is not needed.
- Use biological indicators to monitor effectiveness of sterilizers at least weekly with spores intended for the type of sterilizer (Class 6 CI not a substitute for BI).
- Use biological indicators for every load containing implantable items and quarantine items, whenever possible, until the biological indicator is negative.

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Recommendations
Storage of Sterile Items

- Event-related shelf life recognizes that the product remains sterile until an event causes it to become contaminated (e.g., tear, wetness). Packages should be evaluated before use for lose of integrity.
- Time-related shelf life (less common) considers items remain sterile for varying periods depending on the type of material used to wrap the item/tray. Once the expiration date is exceeded the pack should be reprocessed.

Semicritical Items

- Endoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitory probes
- Tonometers
- Diaphragm fitting rings

Disinfection Practices

Endoscopes/AERS

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ENDOSCOPE REPROCESSING
Multi-Society Guideline on Endoscope Reprocessing, 2011

- PRECLEAN-point-of-use remove debris by wiping exterior and aspiration of detergent through air/water and biopsy channels
- CLEAN-mechanically cleaned with water and enzymatic cleaner
- HLD/STERILIZE-immerscope and perfuse HLD/sterilant through all channels for exposure time (>2% glut at 20m at 20°C). If AER used, review model-specific reprocessing protocols from both the endoscope and AER manufacturer
- RINSE-scope and channels rinsed with sterile water, filtered water, or tap water. Flush channels with alcohol and dry
- DRY-use forced air to dry insertion tube and channels
- STORE-hang in vertical position to facilitate drying; stored in a manner to protect from contamination

High-Level Disinfection of "Semicritical Objects"

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Noncritical Items

Surface Disinfection
Noncritical Patient Care-CDC, 2008

- Disinfecting Noncritical Patient-Care Items
  - Process noncritical patient-care equipment with an EPA-registered disinfectant at the proper use dilution and a contact time of at least 1 min. Category IB
  - Ensure that the frequency for disinfecting noncritical patient-care surfaces be done minimally when visibly soiled and on a regular basis (such as after each patient use or once daily or once weekly). Category IB

Environmental Surfaces-CDC, 2008

- Disinfecting Environmental Surfaces in HCF
  - Disinfect (or clean) housekeeping surfaces (e.g., floors, tabletops) on a regular basis (e.g., daily, three times per week), when spills occur, and when these surfaces are visibly soiled. Category IB
  - Use disinfectant for housekeeping purposes where: uncertainty exists as to the nature of the soil on the surfaces (blood vs dirt); or where uncertainty exists regarding the presence of multi-drug resistant organisms on such surfaces. Category II

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Effective Surface Decontamination
Practice and Product

Low-Level Disinfection for “Noncritical” Objects

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UD=Manufacturer’s recommended use dilution

Effective Surface Decontamination
Practice and Product

Practice* NOT Product
surfaces not wiped

Thoroughness of Environmental Cleaning
Carling and coworkers, SHEA 2010

Role of the Environment in Transmission
Pathogens implicated in transmission via contaminated noncritical surfaces (survival in the environment and recovered from the environment)
- Bacteria
  - Oxacillin-resistant Staphylococcus aureus
  - Vancomycin-resistant Enterococcus spp.
  - Clostridium difficile
  - Acinetobacter and P. aeruginosa
- Viruses
  - Rotavirus
  - Norovirus
  - SARS coronavirus

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Risk of Acquiring MRSA, VRE, and *C. difficile* from Prior Room Occupants

- Admission to a room previously occupied by an MRSA-positive patient or VRE-positive patient significantly increased the odds of acquisition for MRSA and VRE (although this route is a minor contributor to overall transmission). Huang et al. Arch Intern Med 2006;166:1945.
- Prior environmental contamination, whether measured via environmental cultures or prior room occupancy by VRE-colonized patients, increases the risk of acquisition of VRE. Drees et al. Clin Infect Dis 2008;46:678.
- Prior room occupant with CDAD is a significant risk for CDAD acquisition. Shaughnessy et al. ICHE 2011:32:201

New Approaches to Room Decontamination

Summary

**UV and HP decontamination units have been demonstrated to be effective against various pathogens (including *C. difficile* spores) and offer an option for room decontamination.**

Disinfection and Sterilization

- Provide overview of disinfection and sterilization recommendations
  - Indications and methods for sterilization, high-level disinfection and low-level disinfection
  - Cleaning of patient-care devices
  - Sterilization practices
  - Disinfection practices

Summary

- Critical and semicritical items must be cleaned using water with detergents or enzymatic cleaners before processing.
- Disinfection and sterilization guidelines must be followed to prevent patient exposure to pathogens that may lead to infection
- Contaminated surfaces contribute to pathogen transmission and health care facilities may need to introduce control measures to ensure all surfaces are completely cleaned daily and terminally

Thank you
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References

- Rutala WA. APIC guideline for selection and use of disinfectants. Am J Infect Control 1996;24:313

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- February 8: Behavioural Change in Infection Prevention and Control, Prof. Andreas Voss
- March 7: Achievements in Improving Injection Safety Worldwide, Dr. Sahra Khamous
- April 17: Implementing Change: The Technical & Socio-Adaptive Aspects of Preventing Catheter-Associated Urinary Tract Infection, Prof. Saqib Jafar
- May 7: Keeping the Hand Hygiene Agenda Alive: Acting on Data and the Influence of Global Surveys, Prof. Oliver Pittet
- June 4: Economic Impact of Healthcare Associated Infections in Low and Middle Income Countries, Dr. A. Anand Mysore
- July 11: Patient Empowerment in Infection Control, Ciaran Kilpatrick

2012 WHO Teleclasses

- August 8: Processing Medical Devices in Settings with Limited Resources, Dr. Kaim Daron
- September 2: Successes and Challenges in Developing and Implementing Bundles for Infection Prevention, Prof. Dan Goldman
- October 4: The Role of Education in Low and Middle Income Countries, Prof. Sheela Mether
- November 7: Measuring Impact: Key to Infection Control Scale-Up and Sustainability, Prof. Jeppe Ruby
- December 5: New Developments in Infection Control for Renal Dialysis, Prof. Wee Seto

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