An Overview of 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
Disclosure: Advanced Sterilization Products and Clorox

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
  - Disinfection and sterilization 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

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).

Disinfection and Sterilization

Processing “Critical” Patient Care Objects

| Classification: | Critical objects enter normally sterile tissue or vascular system, or through which blood flows. |
| Object: | Sterility. |
| Level germicidal action: | Kill all microorganisms, including bacterial spores. |
| Examples: | Surgical instruments and devices; cardiac catheters; implants; etc. |
| Method: | Steam, gas, hydrogen peroxide plasma, vaporized hydrogen peroxide, ozone or chemical sterilization. |
### Critical Objects
- Surgical instruments
- Cardiac catheters
- Implants

### Sterilization of “Critical Objects”
- Steam sterilization
- Hydrogen peroxide gas plasma
- Ethylene oxide
- Peracetic acid (0.2%)-chemical sterilization
- Ozone
- Vaporized hydrogen peroxide
- Steam formaldehyde

### Chemical Sterilization of “Critical Objects”

<table>
<thead>
<tr>
<th>Germicide</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde (≥ 2.0%)</td>
<td>650-675 ppm</td>
</tr>
<tr>
<td>Hydrogen peroxide-HP (7.5%)</td>
<td>0.55%</td>
</tr>
<tr>
<td>Peracetic acid-PA (0.2%)</td>
<td>1.21%/1.93%</td>
</tr>
<tr>
<td>HP (1.0%) and PA (0.08%)</td>
<td>1.0%/0.08%</td>
</tr>
<tr>
<td>HP (7.5%) and PA (0.23%)</td>
<td>7.5%</td>
</tr>
<tr>
<td>Glut (1.12%) and Phenol/phenate (1.93%)</td>
<td>7.5%/0.23%</td>
</tr>
</tbody>
</table>

Exposure time per manufacturers’ recommendations

### Processing “Semicritical” Patient Care Objects
- Classification: Semicritical objects come in contact with mucous membranes or skin that is not intact.
- Object: Free of all microorganisms except high numbers of bacterial spores.
- Level germicidal action: Kills all microorganisms except high numbers of bacterial spores.
- Examples: Respiratory therapy and anesthesia equipment, GI endoscopes, endocavitary probes, etc.
- Method: High-level disinfection

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

### High Level Disinfection of “Semicritical Objects”

<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 (12 m)</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>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

<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</td>
<td>UD</td>
</tr>
<tr>
<td>Accelerated hydrogen peroxide</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

UD=Manufacturer’s recommended use dilution

Methods in Sterilization

Sterilization of “Critical Objects”

Steam sterilization
Hydrogen peroxide gas plasma
Ethylene oxide
Peracetic acid (0.2%)-chemical sterilization
Ozone
Vaporized hydrogen peroxide
Steam formaldehyde

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

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 disinfecter
- Manual
### Sterilization

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

### “Ideal” Sterilization Method

<table>
<thead>
<tr>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highly efficacious</td>
</tr>
<tr>
<td>Rapidly active</td>
</tr>
<tr>
<td>Strong penetrability</td>
</tr>
<tr>
<td>Materials compatibility</td>
</tr>
<tr>
<td>Non-toxic</td>
</tr>
<tr>
<td>Organic material resistance</td>
</tr>
<tr>
<td>Adaptability</td>
</tr>
<tr>
<td>Monitoring capability</td>
</tr>
<tr>
<td>Cost-effective</td>
</tr>
</tbody>
</table>

Schneider PM. Tappi J. 1994;77:115-119

### 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

### New Trends in Sterilization of Patient Equipment

#### Alternatives to ETO-CFC
- ETO-CO₂, ETO-HCFC, 100% ETO

#### New Low Temperature Sterilization Technology
- Hydrogen Peroxide Gas Plasma
- Vaporized hydrogen peroxide
- Peracetic Acid
- 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
### Hydrogen Peroxide Gas Plasma Sterilization

**Disadvantages**
- Cellulose (paper), linens and liquids cannot be processed
- Sterilization chamber is small, about 3.5ft³ to 7.3ft³
- 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

### Steris System Processor

**Advantages**
- Rapid cycle time (30-45 min)
- Low temperature (50-55°C) liquid immersion sterilization
- Environmental friendly by-products (acetic acid, O₂, H₂O)
- Fully automated
- No adverse health effects to operators
- Compatible with wide variety of materials and instruments
- Suitable for medical devices such as flexible/rigid scopes
- Simulated-use and clinical trials have demonstrated excellent microbial killing

**Disadvantages**
- Potential material incompatibility (e.g., aluminum anodized coating becomes dull)
- Used for immersible instruments only
- Biological indicator may not be suitable for routine monitoring
- One scope or a small number of instruments can be processed in a cycle
- 0.2μ bacterial filters may not be suitable for producing sterile water from tapwater
- More expensive (endoscope repairs, operating costs) than HLD
- Point-of-use system, no long-term storage

### 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 4.88ft³
- Medical devices restrictions based on lumen internal diameter and length—see manufacturer’s recommendations, e.g., SS lumen 1mm diameter, 125mm length
- Not used for liquid, inners, 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
## Sterilization Practices

### 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

### 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.

### 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 pouches; 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

### Failure to Follow Disinfection and Sterilization Principles

**Scenario:**

Hospital A discovered that for the past 3 days all surgical instruments were exposed to steam sterilization at 132°C for 0 minutes rather than the intended 4 minutes. A central processing technician turned the timer to 0 minutes in error.
Failure to Follow Disinfection and Sterilization Principles

- Method for assessing patient risk for adverse events
- Although exposure events are often unique, can approach the evaluation of potential failure using a standardized approach
- Propose a sequence of 14 steps that form a general approach to a possible failure of disinfection/sterilization (D/S)
- D/S failure could result in patient exposure to an infectious agent

Disinfection and Sterilization

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Summary

Disinfection and sterilization guidelines must be followed to prevent exposure to pathogens that may lead to infection

Thank you