An Overview of Disinfection and Sterilization in Healthcare

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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

disinfectionandsterilization.org

Disinfection and Sterilization in Healthcare Facilities

WA Rutala, DJ Weber, and HICPAC, cdc.gov

- 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).

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"

Glutaraldehyde (≥ 2.0%)
Hydrogen peroxide-HP (7.5%)
Peracetic acid-PA (0.2%)
HP (1.0%) and PA (0.08%)
HP (7.5%) and PA (0.23%)
Glut (1.12%) and Phenol/phenate (1.93%)

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"

Exposure Time ≥ 12 m-30m (US), 20°C

Germicide	Concentration
Glutaraldehyde	≥ 2.0%
Ortho-phthalaldehyde (12 m)	0.55%
Hydrogen peroxide*	7.5%
Hydrogen peroxide and peracetic acid*	1.0%/0.08%
Hydrogen peroxide and peracetic acid*	7.5%/0.23%
Hypochlorite (free chlorine)*	650-675 ppm
Accelerated hydrogen peroxide	2.0%
Glut and phenol/phenate**	1.21%/1.93%

*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

Exposure time ≥ 1 min

Germicide	Use Concentration
Ethyl or isopropyl alcohol	70-90%
Chlorine	100ppm (1:500 dilution)
Phenolic	UD
Iodophor	UD
Quaternary ammonium	UD
Accelerated hydrogen peroxide	0.5%

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 disinfector
- 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

- Highly efficacious
- Rapidly active
- Strong penetrability
- Materials compatibility
- Non-toxic
- Organic material resistance
- Adaptability
- Monitoring capability
- Cost-effective

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-CO_2, 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 3.5ft^3 to 7.3ft^3
- 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^{o}C) liquid immersion sterilization
- Environmental friendly by-products (acetic acid, O_2, H_2O)
- 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

Steris System Processor

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
- 0.2u 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

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, 4ft^3
  - 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 4.8ft^3
  - 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, 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

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 pouched; 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^{o}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

Failure to Follow Disinfection and Sterilization Principles

Rutala, Weber ICHE 2007;28:146

- 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

1. Confirm disinfection or sterilization reprocessing failure
2. Impound any improperly disinfected/sterilized items
3. Do not use the questionable disinfection/sterilization unit (e.g., sterilizer, automated endoscope reprocessor) until proper functioning can be assured
4. Inform key stakeholders
5. Conduct a complete and thorough evaluation of the cause of the disinfection/sterilization failure
6. Prepare a line listing of potentially exposed patients
7. Assess whether disinfection/sterilization failure increases patient risk for infection
8. Inform expanded list of stakeholders of the reprocessing issue
9. Develop a hypothesis for the disinfection/sterilization failure and initiate corrective action
10. Develop a method to assess potential adverse patient events
11. Consider notification of state and federal authorities
12. Consider patient notification
13. Develop long-term follow-up plan
14. Perform after-action report

FIGURE 1. Protocol for exposure investigation after a failure of disinfection and sterilization procedures

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