Disinfection and Sterilization

William A. Rutala, Ph.D., M.P.H.
University of North Carolina (UNC) Health Care System and UNC at Chapel Hill, NC

disinfectionandsterilization.org

Disinfection and Sterilization

- Provide overview of cleaning, disinfection and sterilization recommendations
- Review significant issues
  - Sterilization
  - Flash sterilization
  - Endoscope reprocessing

Surveillance, Prevention and Control of Infections

The Joint Commission, 2009

- Disinfection and Sterilization
  - The hospital implements infection prevention and control activities when doing the following: Cleaning and disinfecting medical equipment, devices, and supplies. Elements of Performance IC.02.02.01
  - The hospital implements infection prevention and control activities when doing the following: Sterilizing medical equipment, devices, and supplies. Elements of Performance IC.02.02.01

Disinfection and Sterilization in Healthcare Facilities

WA Rutala, DJ Weber, and HICPAC, www.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**.

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**.

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, ozone, VHP, or chemical sterilization.

Critical Objects

- Surgical instruments
- Cardiac catheters
- Implants

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 ≥ 8m-30m (US), 20ºC

Germicide	Concentration
Glutaraldehyde	≥ 2.0%
Ortho-phthalaldehyde (12 m US)	0.55%
Hydrogen peroxide*	7.5%
Accelerated hydrogen peroxide	2.0%
Hydrogen peroxide and peracetic acid*	1.0%/0.08%
Hydrogen peroxide and peracetic acid*	≥7.35%/≥0.23%
Hypochlorite (free chlorine)*	650-675 ppm
Glut and phenol/phenate	1.21%/1.93%
Glut and alcohol	3.4%/26% IPA

*May cause cosmetic and functional damage

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

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

Sterilization of "Critical Objects"

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

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

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^{o}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
- 0.2µ 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

Recommendations
Methods of Sterilization

- Steam is preferred for critical items not damaged by heat
- Follow the operating parameters recommended by the manufacturer
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat
- Use immediately critical items that have been sterilized by peracetic acid immersion process (no long term storage)

Flash Sterilization

Flash Sterilization
AORN, CDC Guidelines

- Flash sterilization used for items that must be used immediately
- Acceptable for processing items that cannot be packaged, sterilized and stored before use
- Because of the potential for serious infections, implanted surgical devices should not be flash sterilized unless unavoidable (e.g., orthopedic screws)
- Do not used flash sterilization for reasons of convenience, as an alternative to purchasing additional instrument sets, or to save time

Flash Sterilization

- Hospitals should comply with these recommendations (and expect surveyors to monitor and ensure compliance)

Flash Sterilization

- Professional organizations should develop a more permissive guideline on flash sterilization using the scientific literature that ensures patient safety
- History of Flash Sterilization
  - In 1942, Underwood defined flash sterilization as 3 minutes at 250ºF for instruments when there is an “extreme emergency”.
  - In 1969, Perkins redefined flash sterilization of an unwrapped item to the current definition of 270ºF for 3 minutes in a gravity sterilizer.
  - At the time there were no special biological indicators designed for flash sterilization, no flash sterilization containers, and the time/temperature was suboptimal.

Flash Sterilization

- Flash sterilization principles as defined by Underwood/Perkins and perpetuated by professional organizations are no longer applicable as the longstanding concerns have changed over the past 40 years. Historically, these issues included:
  - Lack of a timely biological indicator to monitor performance (now 1 hr) ;
  - Possibility for contamination of processed items during transportation to the Operating Rooms (containers ensure aseptic delivery to the OR);
  - Sterilization cycle parameters are minimal (extended exposure times) .
- And while no compromise with patient safety can be tolerated, principles regarding flash sterilization should be reassessed by professional organizations.
- Recommendation: comply with current recommendations

Flash Sterilization

- Properly managed instruments are instruments that are cleaned (no visible contamination) with detergents, monitored with physical/chemical/biological indicators, sterilized at an exposure time/temperature that reliably kills microorganisms, and used in a manner that minimizes contamination.
- Personnel should be formally trained.
- Recordkeeping with respect to items contained in each load, maintenance and QC should be maintained.

Flash Steam Sterilization Parameters

Type of Sterilizer	Load Configuration	Temperature, Time
Gravity displacement	Nonporous items only (metal, no lumens)	132°C, 3 m
	Nonporous and porous (rubber, plastic, lumens)	132°C, 10 m
Prevacuum	Nonporous items only	132°C, 3 m
	Nonporous and porous	132°C, 4 m

Flash Sterilization

- Records normally include
  - Patient's name
  - Surgery or procedure performed
  - Items/instruments
  - Exposure time and temperature
  - Chemical and biological indicator results

Flash Sterilization

- Hospitals should comply with these recommendations (and expect surveyors to monitor and ensure compliance)

Endoscopes/AERS

GI ENDOSCOPES AND BRONCHOSCOPES

- Widely used diagnostic and therapeutic procedure
- Endoscope contamination during use (GI 10^9 in/10^5 out)
- Semicritical items require high-level disinfection minimally
- Inappropriate cleaning and disinfection has lead to cross-transmission
- In the inanimate environment, although the incidence remains very low, endoscopes represent a risk of disease transmission

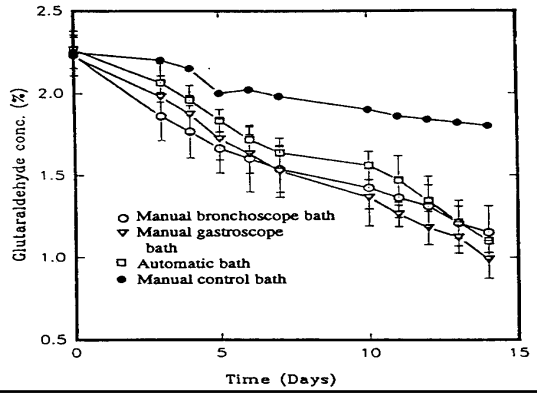
TRANSMISSION OF INFECTION

- Gastrointestinal endoscopy
  - >300 infections transmitted
  - 70% agents *Salmonella sp.* and *P. aeruginosa*
  - Clinical spectrum ranged from colonization to death (~4%)
- Bronchoscopy
  - 90 infections transmitted
  - *M. tuberculosis*, atypical *Mycobacteria*, *P. aeruginosa*

Spach DH et al Ann Intern Med 1993: 118:117-128 and Weber DJ, Rutala WA Gastroint Dis 2002;87

ENDOSCOPE DISINFECTION

- CLEAN-mechanically cleaned with water and enzymatic cleaner
- HLD/STERILIZE-immerse scope and perfuse HLD/sterilant through all channels for at least 12 min
- RINSE-scope and channels rinsed with sterile water, filtered water, or tap water followed by alcohol
- DRY-use forced air to dry insertion tube and channels
- STORE-prevent recontamination



Minimum Effective Concentration Chemical Sterilant

- Dilution of chemical sterilant occurs during use
- Test strips are available for monitoring MEC
- Test strips for glutaraldehyde monitor 1.5%
- Test strip not used to extend the use-life beyond the expiration date (date test strips when opened)
- Testing frequency based on how frequently the solutions are used. Check solution each day of use (or more frequently) using the appropriate indicator.
- Record results

ENDOSCOPE SAFETY

- Ensure protocols equivalent to guidelines from professional organizations (APIC, SGNA, ASGE)
- Are the staff who reprocess the endoscope specifically trained in that job?
- Are the staff competency tested at least annually?
- Conduct IC rounds to ensure compliance with policy
- Perform microbiologic testing of the endoscope or rinse water-no recommendation (unresolved issue)

Recommendations
Quality Control

- Provide comprehensive and intensive training for all staff assigned to reprocess medical/surgical instruments
- To achieve and maintain competency, staff should:
  - hands-on training
  - all work supervised until competency is documented
  - competency testing should be conducted at commencement of employment and regularly
  - review written reprocessing instructions to ensure compliance
  - Conduct infection control rounds in high-risk areas (GI)

Summary

- D/S guidelines must be followed to prevent exposure to pathogens that may lead to infection
- All sterilization processes effective in killing spores
- Cleaning must precede sterilization as it removes salts and proteins
- Follow the CDC/AORN guidelines for flash sterilization
- Delivery of sterile products for use in patient care depends not only on the effectiveness of the sterilization process but also on cleaning, disassembling and packaging of the device, loading the sterilizer, and monitoring

Disinfection and Sterilization

- Provide overview of cleaning, disinfection and sterilization recommendations
- Review significant issues
  - Sterilization
  - Flash sterilization
  - Endoscope reprocessing

Thank you

References

- Rutala WA, Weber DJ. CJD: Recommendations for disinfection and sterilization. Clin Infect Dis 2001;32:1348
- Rutala WA, Weber DJ. Disinfection and sterilization: What clinicians need to know. Clin Infect Dis 2004;39:702
- Rutala WA, Weber DJ, HICPAC. CDC guideline for disinfection and sterilization in healthcare facilities. www.cdc.gov
- Rutala WA. APIC guideline for selection and use of disinfectants. Am J Infect Control 1996;24:313
- Rutala WA, Gergen M, Weber DJ. Disinfection of a probe used in ultrasound-guided prostate biopsy. Infect Control Hosp Epidemiol 2007;28:916