Disinfection and Sterilization

APIC Certification Review Course
Spaulding Classification for Medical Devices

- Dr. Earle H. Spaulding devised a rational approach to disinfection and sterilization of patient-care items or equipment.
- He believed that the nature of disinfection could be understood more readily if instruments and items for patient care were divided into three categories based on the degree of risk of infection involved in the use of the item.

<table>
<thead>
<tr>
<th>Category</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>(high risk) devices enter sterile tissue or bloodstream – <strong>Sterilization</strong></td>
</tr>
<tr>
<td>Semi-critical</td>
<td>devices in contact with intact mucous membranes or skin that is not intact – <strong>High-level disinfection</strong></td>
</tr>
<tr>
<td>Non-critical</td>
<td>devices touch intact skin – <strong>Low level disinfection</strong></td>
</tr>
</tbody>
</table>
Definitions

- **Cleaning**: removal of all soil from objects/surfaces
- **Decontamination**: removal of all pathogenic microorganisms from objects to ensure they are safe to handle
- **Disinfection**: elimination many or all pathogenic organisms with the exception of bacterial spores
- **Sterilization**: complete elimination, destruction of all microbial life

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 (crevices, hinges, lumens)
- Temperature and pH of the disinfection process
Categories of Chemical Disinfectants

- Alcohols
- Halogens – chlorine, iodophor
- Phenols
- Quaternary ammonium compounds
- Aldehydes - glutaraldehyde, formaldehyde
- Peroxygens – hydrogen peroxide, peracetic acid

Selecting a Disinfectant

- Broad Spectrum
- Fast acting
- Not affected by environmental factors
- Nontoxic
- Surface compatibility
- Residual effect of treated surface
- FDA and EPA
- Easy to Use
- Odorless
- Economical
- Solubility
- Stability
- Cleaner
- Nonflammable
Disinfection and Sterilization Levels:

- **STERILE**
- **HIGH-LEVEL**
- **INTERMEDIATE-LEVEL**
- **LOW-LEVEL**

**Low-Level Disinfection**

- May kill:
  - most vegetative bacteria
  - some fungi
  - Some viruses
  - Generally (10 minutes)

- Quaternary (Quats) are low level disinfectants
  - Noncritical medical devices
  - Environmental surfaces
Processing Non-Critical Items

NON-CRITICAL - objects will not come in contact with mucous membranes or skin that is not intact. Objects that touch only intact skin can be expected to be contaminated with some microorganisms and only require low-level disinfection.

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

Intermediate-Level Disinfection

• May kill:
  – tubercle bacilli,
  – vegetative bacteria,
  – most viruses
  – most fungi
  – may not necessarily kill bacterial spores
• Phenolics, alcohols, and iodophors are examples of intermediate-level disinfectants
• Non-critical medical devices
  – Environmental surfaces
High-Level Disinfection

- A process (usually liquid chemicals or wet pasteurization) that eliminates:
  - many or all pathogenic microorganisms on inanimate objects
  - except large numbers of bacterial spores
  - short exposure times (<30 minutes)
- Compounds include
  - Aldehydes
  - Hydrogen peroxide
  - Peracetic acid

Processing Semi-Critical Items

- **SEMI-CRITICAL** - objects that touch mucous membranes or skin that is not intact require a disinfection process that kills microorganisms except high numbers of bacterial spores requires **high-level disinfection**.

- Examples:
  - Respiratory therapy
  - Anesthesia equipment
  - GI endoscopes
  - Endocavitary probes
  - Tonometers
Chemical Sterilants

- Chemicals used to destroy all forms of:
  - Microbiological life
  - Fungal and bacterial spores
  - Prolonged exposure times (6-10 hours)

High-level disinfectants when used as a sterilant may not convey the same level of sterility assurance as other methods (sterilizers).

Processing Critical Items

- CRITICAL - objects which enter normally sterile tissue or the vascular system or through which blood flows should be free from ALL microorganisms, including bacterial spores and must be **Sterile**.

- **Examples**
  - Surgical instruments
  - Cardiac catheters
  - Urinary catheters
  - Implants
  - Probes used in sterile body sites
Agents for Chemical Sterilization of Critical Items

Use for temperature sensitive devices
- 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%)
- Glutaraldehyde (1.12%) and Phenol/phenate (1.93%)
- Ortho-phthalaldehyde – OPA (0.55%)

Question #1

- According to the Spaulding Classification system, a larynscope blade should be disinfected by the following method:
  - A. Cleaning followed by HLD
  - B. Cleaning followed by chlorexidine for 20 min.
  - C. Cleaning followed by ultrasonic washer
  - D. Alcohol disinfection
Question #2

Which chemical agent should be used in an area where blood might be on the floor?
A. Alcohol
B. Halogen
C. Phenolic
D. Quat

Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

Prions
Spores
Mycobacteria
Non-Enveloped Viruses
Fungi
Bacteria
Enveloped Viruses
Environmental Pathogens Facts

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Survival</th>
<th>Environmental Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>C. Difficile</td>
<td>Months (spores)</td>
<td>3+</td>
</tr>
<tr>
<td>VRE</td>
<td>Days to weeks</td>
<td>3+</td>
</tr>
<tr>
<td>MRSA</td>
<td>Days to weeks</td>
<td>2-3+</td>
</tr>
<tr>
<td>Acinetobacter</td>
<td>33 days</td>
<td>2-3+</td>
</tr>
<tr>
<td>P. Aeruginosa</td>
<td>7 hours</td>
<td>1+</td>
</tr>
</tbody>
</table>

Central Processing Department

Factors in effective cleaning and decontamination:
- Water quality
- Acceptable washing method
- Cleaning agent
- Proper rinsing and drying
- Proper storage
- Practices to prevent personal injury
- Layout of the department
Cleaning

- Defined as the physical removal of all visible soil, dust, and other foreign materials.
- Effective cleaning will reduce microbial contamination on environmental surfaces & equipment.
- Cleaning is the *first and most* important step before disinfection or sterilization can occur.

Presoaking

- Prevents soils & proteins from drying on the instruments
- Softens soils and assists with their removal
- Presoaking the instruments should ideally occur immediately following the surgical procedure
Manual Cleaning

- Follows presoaking
- Instruments washed under water - reduce aerosolization
- Wear proper personal protective equipment sort
- Some washers may allow you to eliminate manual cleaning all together

Washer Disinfectors

- Mechanically cleans instruments using a spray action called impingement
- Impingement is the water force making contact with the instrument.
- Several cycle processes; final step is heated air drying which expedites drying time for sterilization
Ultrasonics for Delicate Instruments (e.g. eye instruments)

- Effectiveness is based on cavitation: sonic waves generate minute bubbles on instrument surface
- Bubbles then expand, become unstable, then collapse or implode
- Implosion generates very localized vacuum areas that literally dislodges the soil

Enzymatic Detergents

- Detergents – dislodge and disperse soils from a surface being cleaned
- Enzymatic detergents - enzymes and a surfactant
Types of Sterilizers

**Thermal (Heat)**
- Moist (Tabletop, Gravity, & High Speed Vacuum)
- Dry

**Chemical**
- ETO
- HLD Chemicals
- Ozone
- Radiation
Steam Gravity Sterilization

- Low cost, quick turnover, no toxic chemicals, accommodates large loads
- Steam enters the chamber by gravity & displaces air (so steam can penetrate load)
- Takes longer for steam to reach required temperature
- 4 key parameters; steam, pressure, temperature, time

Steam Pre-vacuum Sterilization or High Speed Vacuum

- Low cost, quick turnover, no toxic chemicals, accommodates large loads
- Air is removed by a pump then steam is rapidly introduced
Flash Sterilization

Acceptable only for items:
- Urgently needed
- Cleaned well
- Used close to point of sterilization
- Adequately covered or protected from contamination
- AAMI guidelines for implants
- AORN guidelines for implants
- Single instruments only (not trays)


Flash Sterilization

Considerations:
- Risk of pt. burns from hot instruments
- Recontamination of instruments during transport
- Keep logs of all flashing
- Monitor times used, procedures, who, and why – use as Performance Improvement
- Monitor staff performance
Dry Heat Sterilization

- Gravity
- Mechanical Convection – more efficient and temperature is more uniform

Low Temperature Sterilization

Ethylene oxide (EtO);
- Used for heat & moisture sensitive devices
- Lengthy aeration time must follow each cycle to allow removal of harmful residuals before opening chamber doors
- EtO is a carcinogen
- Alarms, ventilation, and training of staff promote safe use of this agent
Question #3

When purchasing a new sterilizer, which of the following would be most important?

1. Instruments to sterilize
2. Moisture resistance
3. Time for processing
4. Level of sterilization required
5. Safety of employees

A. 1, 3, 5  C. 2, 3, 4, 5
B. 1, 2, 3, 4  D. All of the above
Sterilization Monitoring: Biological Indicators (BI)

- Challenges the sterilization process against a Bacillus spore
- Use BI daily if sterilizer is used frequently
- Use a BI for every implant and EtO run
- Placement
- Procedures: notification, instruments, used?, documentation & report

Bacillus species for BI

- Steam, H202 vapor, Peracetic acid: 
  - Geobacillus stearothermophilus
- ETO, Dry Heat- bacillus atrophaeus
- Gamma Radiation – B. pumilus
Biological Indicators (BI)

- Following the autoclave cycle, the BI is placed in an incubator
- Rapid readout 1-3 hours, or 24 hours
- Control positive
- Positive test = sterilization process has failed
- Pull instruments

Sterrad Documentation: Note the Control is positive but the Biological is negative
Sterilization Monitoring: Chemical Indicators (CI)

- The CI is a *temperature* indicator that signals the item has been exposed to sterilization process.
- A CI is affixed to outside of package and used with every load.
- An indicator is also placed inside the pack to verify steam penetration.

Chemical Indicator (CI) placed in the tray prior to sterilization.
Examples of Bowie Dick Tests

Sterilization Monitoring: Mechanical Indicators

- Cycle time, temperature, & pressure is displayed on the sterilizer gauges with each instrument load
- Printout or graph also measures these indicators
Minimum Effective Concentration (MEC) Test Strips

- Dilution of chemical occurs during routine use
- Test strips depend on frequency use of chemical e.g. use daily, then test daily
- Do not use test strips beyond expiration date.
- Test & document when opening a new bottle; refer to manufacturer’s protocol

Question #4

- **Which type of indicator gives you the most evidence that your instruments are sterile?**
  A. Chemical
  B. Biological
  C. Bowie-dick
  D. Mechanical
Creutzfeldt-Jakob Disease (CJD)

Infectious prion in CNS tissue & CSF
- Responsible for brain tissue destruction.
- Do not pre-clean instruments
- Appropriate PPE
- Sterilization
  - Steam 30-60” at 132°C,
  - 1 N. sodium hydroxide for 60” then steam at 121°C for 30-60”, or
  - Pre-vacuum for 18” at 134° - 138° C

Time Related vs. Event Related Sterilization

- Time related- expiration date
- Event related sterilization – package must be intact, dry, clean
Storage of Clean/Sterile supplies

- Store at least 8-10 inches from the floor & 18 inches from the ceiling
- Solid bottom shelf

Reuse of Sterile, Single Use Medical Devices

- Manufacturers cite “single use only” (e.g. cardiac catheterization catheters, orthopedic bits/blades, DVT sleeves)
- Significant financial savings
- Risk of infection and injury
- Consider regulatory, medical, ethical, legal, & economic issues
Question #5

- **Heat and moisture sensitive items are best sterilized by:**
  - A. ultrasonic cleaning
  - B. steam
  - C. ethylene oxide
  - D. plasma

Question #6

To facilitate drying and to reduce microbial contamination and proliferation in an endoscope, you should:

- A. blow dry with compressed air, rinse with tap water, and hang vertically to dry
- B. blow compressed air through the channel and rinse with 70% ethyl or isopropyl alcohol
- C. rinse with tap water and blow compressed air through the channels
- D. rinse with alcohol, hang vertically to dry, and store in a case to keep clean
Summary: Variables Impacting the Disinfection/Sterilization Process

- Amount soil
- Resistance - spores v. vegetative bacteria (e.g. *Pseudomonas*, *Staphylococcus*)
- Disinfection concentration/potency
- Physical/chemical factors (temperature, pH, humidity, water hardness)
- Protein (feces, pus, blood, serum, etc.)
- Exposure duration to the germicide
- Biofilms
- Cleaning: manually, ultrasonic cleaner, washer-decontaminator, washer-sterilizer with a detergent

References

**Guidelines:**

- AORN
- AAMI
- Disinfection and Sterilization
- Isolation
- CJD
- Environmental Infection Control in Health-Care Facilities
- APIC web site: Practice Guidance section
Disinfection and Sterilization
Resource for ICPs:
www.disinfectionandsterilization.org

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Answers to Questions

- 1. A
- 2. C
- 3. D
- 4. B
- 5. C
- 6. B