Module F

Principles of Disinfection and Sterilization in the outpatient setting

Objectives

• State the principles of disinfection and sterilization
• List the current methods for disinfection and sterilization per CDC guideline recommendations

Order of resistance of microorganisms to disinfectants

Hardest to Kill
- Prions (Creutzfeldt-Jakob Disease (CJD), mad cow disease)
- Spores (C. difficile)
- Mycobacteria (Tb)
- Non-enveloped viruses (norovirus)
- Fungi (Candida)
- Vegetative bacteria (MRSA, VRE)
- Enveloped viruses (HIV, HBV)

Easiest to Kill

Where are you processing your instruments?

Management of contaminated items

• Contaminated reusable items should be handled as little as possible
• When handling contaminated items appropriate PPE should be used
• Gross soil or debris should be removed at the point of use (gauze sponge moistened with water/disinfectant wipe for example)
• Soiled items should be immediately contained and transported to the decontamination area or soiled utility room where cleaning procedures can be accomplished away from patient care

Transport of contaminated items

• Contaminated items must be contained during transport. The type of container depends on the item being transported:
  • Puncture-resistant, leak-proof, closable containers must be used for devices with edges or points capable of penetrating container or skin
  • All containers must have a bio-hazard label or be red in color
  • Contaminated items should never be transported via gloved hands alone.
• Items should be kept moist during transport by adding a towel moistened with water (not saline) or a foam, spray or gel product specifically intended for this use
• Avoid transporting contaminated items in a liquid
• Reusable collection containers for holding contaminated items should be made of material that can be effectively decontaminated
• Use separate collection containers for contaminated versus re-processed or clean items
Factors influencing the efficacy of disinfection and sterilization processes

- Cleaning of the object
- Organic and inorganic load present
- Type and level of microbial contamination
- Concentration and exposure time to the disinfectant/sterilant
- Nature of the object
- Temperature, pH, and water hardness

Cleaning instruments manual

- Soak in enzymatic or non-enzymatic detergent
- Wear the appropriate PPE
- Keep instruments submerged in solution and scrub with brush
- Thoroughly rinse the instrument
- Allow instrument to dry

Cleaning instruments automated

- Types:
  - Ultrasonic cleaner
  - Instrument washer
  - FDA regulated instrument washer (household dishwasher NOT recommended)
- Benefits:
  - Improved efficacy
  - Reduced employee exposure to splash and sharps

Spaulding Classification

Spaulding Classification of Surfaces:
1. Critical – Objects which enter normally sterile tissue or the vascular system and require sterilization
2. semi-critical – Objects that contact mucous membranes or non-intact skin and require high-level disinfection, which kills all but high-levels of bacterial spores
3. non-critical – Objects that contact intact skin but not mucous membranes, and require low-level disinfection

Processing Critical Instruments

- Penetrate or enter normally sterile tissue or spaces, including the vascular system
- Surgical instruments, cardiac catheters, IV devices, urinary catheters
- Must be sterilized between uses or used as single-use disposable devices
- Goal: Sterility = devoid of all microbial life
Sterilization

The complete elimination or destruction of all forms of microbial life by either physical or chemical processes.

Methods of sterilization

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

Steam Sterilization

- Advantages
  - Non-toxic
  - Cycle easy to control and monitor
  - Inexpensive
  - Rapidly microbicidal
  - Rapid cycle time
  - Least affected by organic/inorganic soils
  - Penetrates medical packing, device lumens

- Disadvantages
  - Deleterious for heat labile instruments
  - Inappropriate for heat-sensitive instruments
  - Inappropriate for moisture-sensitive instruments
  - Dulling
  - Rusting
  - Potential for burns

Steam Sterilization

- Steam under pressure (autoclaving)
  - Gravity displacement
  - Pre-vacuum

Process times for packaged items

<table>
<thead>
<tr>
<th>Method</th>
<th>Exposure (minutes)</th>
<th>Temperature Range</th>
<th>Dry Time (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam autoclave</td>
<td></td>
<td></td>
<td>Depends on the item being sterilized</td>
</tr>
<tr>
<td>• Gravity</td>
<td>30</td>
<td>121°C</td>
<td></td>
</tr>
<tr>
<td>• Prevacuum</td>
<td>4</td>
<td>132°C</td>
<td></td>
</tr>
</tbody>
</table>
Dry Heat Sterilization

- Transfers heat energy from air inside the oven to the instruments
- Requires higher temperatures
- Good for items that are likely to dull or rust in the autoclave,
- Good for powders, cellulose and ink
- Packaging must be able to withstand high temperatures

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

Conclusions . .

- 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 could interfere with the sterilization process.

Packaging

- Peel packs
- Rigid containers
- Self seal roll stock
- Sterile wraps woven and non-woven
- Must be FDA approved

Loading

- Place items/packages correctly and loosely into the sterilizer so as not to impede penetration of the sterilant
- Peel packs and non-perforated containers should be placed on their edge

Monitoring
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 reached
- Biological - Bacillus spores that directly measure sterilization

Biological Monitors

- Steam - Geobacillus stearothermophilus
- Dry heat - B. atrophaeus (formerly B. subtilis)
- Ethylene oxide (ETO) - B. atrophaeus

Recommendations

Monitoring of Sterilizers

Following a single positive biological indicator from steam sterilization:
- Remove the sterilizer from service and review sterilizer instructions
- Retest the sterilizer
- If spore test negative, put the sterilizer back in service
- If the spore test is positive: do not use until it has been inspected; and recall (to the extent possible) all items processed since the last negative spore test; challenge in three consecutive empty sterilization cycles.
- Single positive biological indicator (BI) from other than steam sterilization: treat as non-sterile all items back to last load tested with negative indicator

Monitoring of Sterilizers

- Internal Chemical Indicator
  - Validates the sterilant penetrated the pack or tray
  - Advantage of the pack control monitor is that it is inside each pack in multiple locations
  - Detect local problem

Recommendations

Monitoring of Sterilizers
**Record-Keeping**

Maintain sterilization records (physical, chemical and biological)
For each sterilization cycle record
- the type of sterilizer and cycle used;
- the load identification number;
- the load contents;
- the exposure parameters (time and temperature);
- the operator’s name or initials; and
- the results of physical, chemical, and biological monitoring.

**Summary**

**Sterilization Recommendations . . .**

- Steam is preferred for critical (and semi-critical) items not damaged by heat
- Always follow manufacturer’s operating instructions
- Use an “FDA cleared” container, wrapping or packaging system that is compatible with the type of sterilization process used
- Do not overload the chamber

**Recommendations**

**Storage of Sterile Items**

- Ensure the sterile storage area is a 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.
- Label sterilized items with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and if applicable the expiration date.

**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. moisture).
- Packages should be evaluated before use for loss of integrity. Repack and reprocess if compromised.
- If time related storage of sterile items is used, label the pack at the time of sterilization with an expiration date. Once this date expires, reprocess the pack.

**Storage in healthcare facilities**

*General guidelines*

- All patient care items must be stored at least 8” off the floor
- Open rack storage should have a bottom shelf (plexi-glass for example)
- Stored at least 18” below the ceiling or the sprinkler head (according to fire code)
- Stored at least 2” inches from outside wall
- Items should be stored in areas of limited traffic
- Stored in an area with controlled temperature and humidity
- Outside shipping containers and corrugated cartons should not be used as storage containers
- Items should not be stored under sinks or exposed water/sewer pipes
- Windowsills should be avoided
- Closed or covered cabinets are preferred

**Spaulding Classification**

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3. **Non-critical** – Objects that contact intact skin but not mucous membranes, and require low-level disinfection
Semi-Critical objects contact mucous membranes or non-intact skin and require high level disinfection

Goal:
High-level disinfection = free of all microorganisms except high numbers of bacterial spores

<table>
<thead>
<tr>
<th>High-Level Disinfectants</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde (Cidex)</td>
<td>≥ 2.0%</td>
</tr>
<tr>
<td>Ortho-phthaladehyde (Cidex OPA)</td>
<td>0.55%</td>
</tr>
<tr>
<td>Hydrogen Peroxide* (Sporox)</td>
<td>7.5%</td>
</tr>
<tr>
<td>Hydrogen Peroxide and peracetic acid* (Peract)</td>
<td>1.0% / 0.08%</td>
</tr>
<tr>
<td>Hydrogen Peroxide and peracetic acid* (Endospore *)</td>
<td>7.5% / 0.23%</td>
</tr>
<tr>
<td>Hypochlorite (free chlorine)* (Sterilox ©)</td>
<td>650-675 ppm</td>
</tr>
<tr>
<td>Accelerated hydrogen peroxide (Resert XL)</td>
<td>2.0%</td>
</tr>
<tr>
<td>Peroacetic Acid (Steris 20)</td>
<td>0.2%</td>
</tr>
<tr>
<td>Glutaraldehyde and isopropanol (Aldahol III)</td>
<td>3.4% / 26%</td>
</tr>
<tr>
<td>Glutaraldehyde and phenol/phenate (Sporicidin)</td>
<td>1.21% / 1.93%</td>
</tr>
</tbody>
</table>

Exposure time ≥21-45 min (US) and temperature 20-25°C;
*May cause cosmetic and functional damage

Semi-critical instruments

- Examples of semi-critical devices
  - Endocavity probes
  - Tonometers
  - Diaphragm fitting rings
  - Vaginal speculums
  - Endoscopes
  - Respiratory therapy equipment
  - Anesthesia equipment

Processing Semi-critical instruments

Methods for processing:
The most common used in outpatient facilities is immersion in either Glutaraldehyde (Cidex*) or Ortho-phthaladehyde (Cidex OPA*)

Manufacturer’s instructions for dilution and quality control testing must be followed:

- Submerge the test strip into the solution prior to each use to monitor minimum effective concentration (MEC)
- Remove excess by standing upright on paper towel
- Read results according to manufacturer’s instructions (recommended time period and change in color of the test strip)
- Document findings

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Non-Critical objects contact intact skin but not mucus membranes and require low level disinfection

Liquid Disinfectants

<table>
<thead>
<tr>
<th>Disinfectant Agent</th>
<th>Use Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl or isopropyl alcohol</td>
<td>70% - 90%</td>
</tr>
<tr>
<td>Chlorine (bleach)</td>
<td>100 ppm</td>
</tr>
<tr>
<td>Phenolic</td>
<td>UD</td>
</tr>
<tr>
<td>Iodophor</td>
<td>UD</td>
</tr>
<tr>
<td>Quaternary ammonium compound (QUAT)</td>
<td>UD</td>
</tr>
<tr>
<td>Improved/Accelerated hydrogen peroxide</td>
<td>0.5%, 1.4%</td>
</tr>
</tbody>
</table>

UD = Manufacturer’s recommended use dilution

Cleaning Recommendations

Clean and disinfect surfaces using correct technique
- Clean to dirty
- Prevent contamination of solutions
  - Don’t use dried out wipes
- Physical removal of soil (elbow grease)
- Contact time
- Monitor the cleaning/disinfection process

Other Environmental Issues

Blood and Body Fluid Spills
- Promptly clean and decontaminate
- Use appropriate PPE
- Clean spills with dilute bleach solution (1:10 or 1:100) or an EPA-registered hospital disinfectant with a TB or HIV/HBV kill claim.

Knowledge check

- Patient care equipment and devices should be disinfected/sterilized based on:
  1. Items intended use
  2. What the item is going to be in contact with, for example, mucus membranes or non-intact skin
  3. The number of patients you have scheduled for the day
  4. What the physician tells you to do
     1. 1 and 2
     2. 1 and 3
     3. All of the above

Recommendations

Quality Control

- Provide comprehensive and intensive training for all staff assigned to reprocess medical/surgical instruments
- To achieve and maintain competency:
  - Staff receive hands-on training
  - Work with supervision until competency is documented
  - Competency testing should be conducted at commencement of employment and no less than annually
- Training and competencies should be documented
Recommendations for Quality Control

• Conduct infection control rounds no less than annually and more often if high risk area (GI clinic, Urology, Endoscopy)
• Ensure all products used for disinfection and/or sterilization have been approved by infection prevention
• Follow manufacturer instructions for use (IFUs) for preparation and packing of items

Questions?