Virtual Tour of Central Processing

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Sterilization Practices in Healthcare Facilities

- Overview
- Physical facilities
- Cleaning, Packaging, Loading, Storage
- Monitoring

A Rational Approach to Disinfection/Sterilization

EH Spaulding believed 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) that kills all but high numbers of bacterial spores

NONCRITICAL – objects that touch only intact skin require low level disinfection

Sterilization

Complete elimination or destruction of all forms of microbial life. It is accomplished by 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
Sterilization Procedures

- Heat - steam, dry heat
- ETO
- Radiation (industry)
- Liquid chemical sterilant
- Low temperature (Plasma, Gas, Vapor)

Steam Sterilization

- Advantages
  - Non-toxic
  - Cycle easy to control and monitor
  - Inexpensive
  - Rapidly microbiocidal
  - Least affected by organic/inorganic soils
  - Rapid cycle time
  - Penetrates medical packing, device lumens
- Disadvantages
  - Deleterious for heat labile instruments


- Alternatives to ETO-CFC
  - ETO-CO₂, ETO-HCTC, 100% ETO
- New Low Temperature Sterilization Technology (LTST)
  - Hydrogen Peroxide Gas Plasma
  - Ozone
  - Vaporized hydrogen peroxide
Central Processing

- Goal
  - Orderly processing of medical and surgical instruments to protect patients from infections while minimizing risks to staff and preserving the value of the items being reprocessed
  - Ensure consistency of sterilization practices requires a comprehensive program that ensures operator competence and proper methods of cleaning and packaging instruments, loading the sterilizer, operating the sterilizer, and monitoring the entire process

Central Processing
Physical Facilities

- Facility ideally divided into three areas:
  - Decontamination-reusable items are received, sorted, and decontaminated; negative pressure; 6AC/hr. Personnel wear gloves when handling contaminated instruments; face masks, eye protection, and gowns/aprons when splashing may occur.
  - Packaging-used for inspecting, assembling, and packaging clean, but not sterile, material.
  - Sterilization and storage-limited access area with a controlled temperature and relative humidity.
Cleaning

- Items must be cleaned using water with detergents or enzymatic cleaners before processing.
- Cleaning reduces the bioburden and removes foreign material (organic residue and inorganic salts) that interferes with the sterilization process.
- Cleaning and decontamination should be done as soon as possible after the items have been used.

Bioburden on Surgical Devices

- Bioburden on instruments used in surgery (Nystrom, 1981)
  - 62% contaminated with $<10^1$
  - 82% contaminated with $<10^2$
  - 91% contaminated with $<10^3$
- Bioburden on surgical instruments (Rutala, 1997)
  - 72% contained $<10^1$
  - 86% contained $<10^2$

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
Cleaning

- All used items sent to Central Processing area should be considered contaminated (unless decontaminated in the area of origin)
- Used items handled with gloves (forceps or tongs are sometimes needed to avoid exposure to sharps)
- Decontaminated by a mechanical or manual method to render them safer to handle

Washer/Disinfector


- Five Chambers
  - Pre-wash: water/enzymatic is circulated over the load for 1 min
  - Wash: detergent wash solution (150°F) is sprayed over load for 4 min
  - Ultrasonic cleaning: basket is lowered into ultrasonic cleaning tank with detergent for 4 min
  - Thermal and lubricant rinse: hot water (180°F) is sprayed over load for 1 min; instrument milk lubricant is added to the water and is sprayed over the load
  - Drying: blower starts for 4 min and temperature in drying chamber 180°F

Washer/Disinfector

Removal/Inactivation of Inoculum (Exposed) on Instruments


<table>
<thead>
<tr>
<th>WD Conditions</th>
<th>Organism</th>
<th>Inoculum</th>
<th>Log Reduction</th>
<th>Positives</th>
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</thead>
<tbody>
<tr>
<td>Routine</td>
<td>MRSA</td>
<td>2.6x10^7</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td>VRE</td>
<td>2.6x10^7</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td><em>P. aeruginosa</em></td>
<td>2.1x10^7</td>
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<tr>
<td>Routine</td>
<td><em>M. terrae</em></td>
<td>1.4x10^8</td>
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<tr>
<td>Routine</td>
<td>GS spores</td>
<td>5.3x10^6</td>
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<td>11/14</td>
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<td>VRE</td>
<td>2.5x10^7</td>
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</tr>
<tr>
<td>No Enz/Det</td>
<td>GS spores</td>
<td>8.3x10^6</td>
<td>5.5</td>
<td>8/10</td>
</tr>
</tbody>
</table>
**Washer/Disinfector**

Removal/Inactivation of Inoculum (Non-Exposed) on Instruments


<table>
<thead>
<tr>
<th>WD Conditions</th>
<th>Organism</th>
<th>Inoculum</th>
<th>Log Reduction</th>
<th>Positives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine</td>
<td>MRSA</td>
<td>$2.6 \times 10^7$</td>
<td>Complete</td>
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</tr>
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<td>Routine</td>
<td>VRE</td>
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<tr>
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</tr>
<tr>
<td>Routine</td>
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<td>$1.2 \times 10^8$</td>
<td>7.6</td>
<td>6/8</td>
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<td>Routine</td>
<td>GS spores</td>
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<td>12/12</td>
</tr>
<tr>
<td>No Enz/Det</td>
<td>VRE</td>
<td>$2.4 \times 10^7$</td>
<td>Complete</td>
<td>0/10</td>
</tr>
<tr>
<td>No Enz/Det</td>
<td>GS spores</td>
<td>$8.7 \times 10^6$</td>
<td>1.6</td>
<td>10/10</td>
</tr>
</tbody>
</table>

Washer/disinfectors are very effective in removing/inactivating microorganisms from instruments

**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

Loading

- All items to be sterilized should be arranged so all surfaces will be directly exposed to the sterilizing agent
- Other basic principles:
  - Allow for proper steam circulation
  - Nonperforated containers should be placed on their edge
  - Peel packs should be placed on edge

Packaging/Load Configuration

- Packaging materials should be compatible with the sterilization process
- Packaging (rigid containers, peel pouches, wraps) should provide a barrier to microorganisms and moisture and should be sufficiently strong to resist punctures and tears.
- Items should be placed loosely into the basket, shelf, or cart so as not to impede contact between the sterilant and the microorganism.
Objectives of Monitoring the Sterilization Process

- Assures probability of absence of all living organisms on medical devices being processed
- Detect failures as soon as possible
- Removes medical device involved in failures before patient use

Sterilization Monitoring

Sterilization monitored routinely by combination of mechanical, chemical, and biological parameters

- Mechanical - cycle time, temperature, pressure. Monitors one location in the sterilizer.
- Chemical - heat or chemical sensitive inks that change color when germicidal-related parameters present. Identifies processed from unprocessed medical devices.
- Biological - *Bacillus* spores that directly measure sterilization. Integrates all parameters of the process.
Monitoring of Sterilizers

- Use mechanical, chemical and biological (B) monitors to ensure the effectiveness of the sterilization process
- Each load should be monitored with mechanical and chemical indicators
- If the mechanical, chemical or B indicators suggest inadequate processing, the items should not be used
- B indicators should be used at least weekly with spores intended specifically for the type of sterilizer

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

Biological Monitors

- Steam - *Bacillus stearothermophilus*
- Dry heat - *B. subtilis*
- ETO - *B. subtilis*
- New low temperature sterilization technologies
  - Plasma sterilization (Sterrad) - *B. stearothermophilus*
  - Peracetic acid - *B. stearothermophilus*
Positive Biological Indicators (BI)

- Objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the sterilizer or the sterilization process is defective as determined by maintenance personnel or inappropriate cycle settings (e.g., time, temperature). ASAP, repeat BI test in three consecutive sterilizer cycles. If BI positive, items nonsterile and supplies since last negative BI recalled and reprocessed.

- If additional spore tests remain positive, the items must be considered nonsterile and the items from the suspect load (s) should be recalled and reprocessed.
Parametric Release

- Declaring a product sterile, based on physical and chemical process data rather than on the basis of sample testing or biological indicator results.
- US, biological monitors used once a day/week (except with implantable objects), chemical indicators used in every package.

Storage

- Time-related shelf life-safe storage times for sterile packs vary with the porosity of the wrapper and storage conditions (e.g., 1 year, plastic wrapped pack)
- Event-related shelf life-product remains sterile until some event causes the item to become contaminated (e.g., tear in packaging, packaging become wet)
- Closed or covered cabinets are ideal but open shelving may be used for storage

Storage of Sterile Items

- Event-related shelf life recognizes that the product remains sterile until an event causes it to become contaminated (e.g., tear, wetness). Packages should be evaluated before use for lose of integrity.
- Time-related shelf life (less common) considers items remain sterile for varying periods depending on the type of material used to wrap the item/tray. Once the expiration date is exceeded the pack should be reprocessed.
Storage of Sterile Items

- Sterile storage area should be 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.
- Sterilized items should be labeled with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and the expiration date (if applicable).

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.

Conclusions

- All sterilization processes effective in killing spores.
- Cleaning removes salts and proteins and must precede 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.

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Thank you

References