Module F

PRINCIPLES OF DISINFECTION AND STERILIZATION IN THE DENTAL SETTING

Statewide Program for Infection Control and Epidemiology (SPICE)
UNC School of Medicine

OBJECTIVES

• Describe the principles of disinfection and sterilization
• Provide an overview of current methods for disinfection and sterilization
• Discuss training and quality control methods and required documentation

PRINCIPLES

• Factors influencing the efficacy of disinfection and sterilization
  • How well the object is cleaned
  • Type and amount of material
  • Solution concentration
  • Exposure time
  • Design of object
  • Temperature and pH of disinfectant
PRINCIPLES

Management of reusable contaminated items:
- Handle as little as possible
- Use appropriate PPE
- Remove gross soil or debris at the point of use (gauze sponge moistened with water/disinfectant wipe for example)
- Immediately contain and transport to the decontamination area or soiled utility room where cleaning procedures can be accomplished away from patient care
PRINCIPLES

• Transport of contaminated items:
  • Must be contained. 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
    • Must have a bio-hazard label or be red in color (never 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

CLEANING INSTRUMENTS

MANUAL

• Medical equipment/devices MUST be pre-cleaned prior to high level disinfection or sterilization
• Contaminants such as dirt, blood or other body fluids, if present, can act as a barrier
• ALWAYS REMEMBER:
  • Do not use a high-level disinfection or sterilant solution to "hold" instrument
  • A fluid-resistant gown should be worn
  • Wear puncture-resistant heavy-duty utility gloves
  • Wear face protection (eyes and mouth) to protect against splashes

AUTOMATED

Benefits:
  • Improve efficacy of cleaning process
  • Reduce handling of sharp instruments
  • Reduce risk of employee exposure

Follow manufacturer’s recommendations:
  • Dilution
  • Temperature
  • Water hardness
  • Use

After cleaning, rinse with water
KNOWLEDGE CHECK

Which of the following statements is true?

1. Manual cleaning of objects is safer than automated cleaning
   ✔️  e-cleaning is the most important factor in processing objects
2. Pre-cleaning is the most important factor in reprocessing objects
3. Objects do not need to be pre-cleaned if they are going to be sterilized
4. Household dishwashers can be used for pre-cleaning of instruments.

METHODS USED FOR DISINFECTION AND STERILIZATION

SPAAULDING CLASSIFICATION

Spaulding Classification of Surfaces:

- **Critical** – Objects which enter normally sterile tissue or the vascular system and require sterilization
- **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
- **Non-critical** – Objects that contact intact skin but not mucous membranes, and require low-level disinfection
**PROCESSING CRITICAL INSTRUMENTS**

- Critical Items:
  - Penetrate or enter normally sterile tissue or spaces, including the vascular system (Surgical instruments, cardiac catheters, IV devices, urinary catheters)
  - High risk of transmitting infection if handled improperly
  - Must be sterilized between uses or used as single-use disposable devices

*Goal:* Sterility = devoid of all microbial life

**METHODS**

- Four activities involved in the sterilization and disinfection of critical objects
  - Sterilization/Disinfection *(Steam, dry heat, liquid chemical)*
  - Monitoring
  - Packaging *(Wrapping, record keeping, loading)*
  - Storage

**STERILIZATION**

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

= high temperature
= low temperature
STEAM STERILIZATION

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

STEAM STERILIZATION

• 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:
    • Exposure: 30 minutes
    • Temperature: 121°C
  • Pre-vacuum:
    • Exposure: 4 minutes
    • Temperature: 132°C
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

LIQUID CHEMICAL STERILANTS/DISINFECTANTS

- Liquid chemical sterilants/disinfectants
- Only for heat-sensitive critical and semi-critical devices
- Exposure can be harmful to providers and patients
- Can not be stored
- Heat tolerant or disposable alternatives are available

STERILIZATION REVIEW

- 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
- Items immersed in chemo-sterilizer solutions should be used immediately
KNOWLEDGE CHECK

Patient care equipment and devices should be disinfected/sterilized based on:

1. Items intended use
2. What the item is going to come in contact with (mucous membranes or non-intact skin)  
   a. 1 and 4
3. The number of patients you have scheduled for the day  
   b. 2 and 4
   c. 1 and 2
4. What the physician tells you to do.  
   d. 3 and 4

MONITORING

- The Joint Commission (TJC)
- Centers for Medicare and Medicaid Services (CMS)
- 10A NCAC 41.0206 (NC Rule .0206)

STERILIZATION MONITORING

Sterilization monitored routinely by combination of physical, chemical, and biological parameters
STERILIZATION MONITORING

Physical - cycle time, temperature, pressure

• Assessment of:
  • Time
  • Temperature
  • Pressure via gauge

• Documentation:
  • Maintain monitor log
  • Computer readout

STERILIZATION MONITORING

Chemical - heat or chemical sensitive inks that change color when germicidal-related parameters reached

• 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

STERILIZATION MONITORS

Biological - Bacillus spores that directly measure sterilization

Steam - *Geobacillus stearothermophilus*

Dry heat - *B. atrophaeus* (formerly *B. subtilis*)

Ethylene oxide (ETO) - *B. atrophaeus*
MONITORING REVIEW

- Monitor each load with physical and chemical (internal and external) indicators.
- Use biological indicators to monitor effectiveness of sterilizers at least weekly with spores intended for the type of sterilizer.
- Use biological indicators for every load containing implantable items
- Policy for management of positive BI indicator

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

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.
PACKAGING

• Once cleaned, dried and inspected items, requiring sterilization must be:
  • Wrapped or placed in rigid containers
  • Arranged in trays or baskets per Association of Medical Instrumentation (AAMI) guidelines (hinged instruments should be opened for example)
• Follow manufacturer’s instructions for preparation
• Wrapping done to prevent gaps and tenting
• Wrapping material must:
  • Allow penetration of sterilant, be compatible with sterilizer, be puncture resistant, durable and have FDA clearance
• Choices in wrapping products include:
  • Peel packs, rigid containers, roll stock (self seal) and woven or nonwoven sterile wraps

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
• Peel packs:
  • Be used, filled and opened according to the pouch manufacturer’s instructions
  • Be of a size and strength to accommodate the item being packaged
  • Be closed so that all pouch seals are smooth (i.e., without folds, bubbles or wrinkles)
  • Be written only on the non-porous side of the pouch
SUMMARY METHODS

• 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

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.

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
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

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SEMI-CRITICAL INSTRUMENTS

- Examples of **Semi-Critical** Items:
  • Mouth Mirrors
  • Cheek retractors
  • Handpieces*
  • Reusable dental impression trays
  • Amalgam condensers

*Although dental handpieces are “by definition” considered a semi-critical item, they should always be heat-sterilized between uses
HIGH-LEVEL DISINFECTANTS

<table>
<thead>
<tr>
<th>Germicide</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde (Cidex)</td>
<td>≥ 2.0%</td>
</tr>
<tr>
<td>Ortho-phthalaldehyde (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* (Perac)</td>
<td>1.0% / 0.08%</td>
</tr>
<tr>
<td>Hydrogen Peroxide and peracetic acid* (Endospore a)</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>Peracetic 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 ≥8 – 45 min (US) and temperature 20‐25°C; *May cause cosmetic and functional damage

PROCESSING SEMI-CRITICAL INSTRUMENTS

Methods for processing:
A common method of high level disinfection is immersion in either Glutaraldehyde (Cidex®) or Ortho-phthalaldehyde (Cidex OPA®)

Manufacturer’s instructions for dilution and quality control testing must be followed. Must use correct test strip for solution!

- 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
### SPAULDING CLASSIFICATION

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### ROLE OF THE ENVIRONMENT

![Graph showing survival of pathogens over time]

### 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>
PROPERTIES OF AN IDEAL DISINFECTANT

• Broad Spectrum
• Fast Acting
• Non Toxic
• Surface Compatibility
• Easy to Use
• Acceptable odor
• Economical

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

Contaminated reusable items should be:
1. Handled as little as possible
2. Placed in a bio-hazard labeled container and left in room until end of work day
3. Pre-cleaned in sink in the exam room
4. Transported immediately after use and not left in the patient care area

Select correct one
a. 1 and 3
b. 3 and 4
c. 1 and 4
d. 1, 2, 3, 4

Select correct one
**TRAINING AND 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

**ADDITIONAL RESOURCES**

- CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities

- Guidelines for Infection Control in Dental Health-Care Settings — 2003
  [https://www.cdc.gov/mmwr/PDF/rr/rr5217.pdf](https://www.cdc.gov/mmwr/PDF/rr/rr5217.pdf)

- Summary of Infection Prevention Practices in Dental Settings; Basic Expectations of Care
  [https://www.cdc.gov/oralhealth/infectioncontrol/pdf/safe-are2.pdf](https://www.cdc.gov/oralhealth/infectioncontrol/pdf/safe-are2.pdf)

**QUESTIONS?**