Disinfection & Sterilization
Objectives

• Define important components in cleaning, disinfection, and sterilization
• Identify methods for cleaning, disinfection, or sterilization
• List risks of failure to properly clean, disinfect, or sterilize equipment
• Discuss importance of coordinated approach
Definitions

- **Clean** - Remove **visible** foreign material
- **Decontamination** - Remove pathogenic organisms and make equipment safe for handling
- **Sterilization** - Kill all microbes
- **Sanitize** - Reduce microbial load on inanimate objects to relatively safe level
Important Difference

- **Disinfection**-Killing all microbiologic organisms with the exception of spores
- **Antisepsis**-Kill or reduce microbial load on living tissue
- **Agents that can kill microorganisms** include both disinfectants and antiseptics (*cide* or *cidal*)
  - Disinfectants – inanimate objects
  - Antiseptics – living tissue
Regulations

• Federal Insecticide, Fungicide, Rodenticide Act 1947 (FIFRA)

• Specified
  – Use Dilution
  – Contact Time
  – Method of Application
  – Safety Precautions
Regulations

• Environmental Protection Agency (EPA)
  – Disinfectants
  – Including High Level Disinfectants
  – Liquid Chemical Sterilants

• Food and Drug Administration (FDA)
  – Antiseptics
Regulations

• Occupational Safety and Health Administration (OSHA)
  – Bloodborne Pathogen Rule 1991
    • Require EPA registration
    • Disinfectant must be tuberculocidal
    • Rule amended in 1997 - disinfectants must be effective against HIV & HBV
Spaulding Classification System

• Critical – objects which penetrate sterile tissue or blood must be Sterile
• Semi-critical – objects that touch mucous membranes or non-intact skin require High level disinfection
• Non-critical – objects that only touch intact skin require Intermediate & Low level disinfection
4 Methods

- Sterilization – all microorganisms & spores
- High-level disinfection – all microorganisms except spores
- Intermediate-level disinfection – destroys most virus and most fungi but not spores
- Low-level disinfection – destroys vegetative bacteria, some viruses and fungi, but not spores or Mycobacteria
Influencing Factors

- Organic and inorganic load
- Type and level of microbial contamination
- Concentration and exposure time to germicide
- Physical nature of object
- Presence of biofilms
- Temperature and pH
- Relative Humidity
Biofilm

- Structured community of microorganisms
- Encapsulated in a complex matrix
- Adheres to a living or inert surface
- Often characterized by
  - surface attachment
  - structural heterogeneity
  - genetic diversity
  - complex community interactions
  - extracellular matrix of polymeric substances - AKA slime, sludge
Staphylococcus aureus biofilm
Critical Items

- Objects that enter normally sterile tissue or vascular system

Goals
- Sterility
  - Destroy all microorganisms including spores

Methods
- High temp – Steam
  - Heat tolerant items
- Low temp – ETO or H2O2 gas
  - Heat sensitive items
- Liquid chemical sterilants – H2O2, paracetic acid
  - Heat sensitive items
Ideal Sterilization Method

- Highly effective
- Rapid action
- Strong penetration
- Materials compatible
- Non-toxic
- Organic material resistance
- Adaptable
- Monitoring required
- Cost-effective

Schneider PM. Tappi J. 1994;77:115-119
Decontamination of Critical Items

- Dedicated area
- Negative air flow
- Required personal protective equipment
- Presoak to remove load
- Manual cleaning of fragile items
- Automated cleaning
  - Ultrasonic
  - Washers
- Detergents (sanitize)
  - Neutral pH
  - Enzymes
Clean instruments

• Dried
• Inspected
  – Cleanliness
  – Maintenance
  – Repair
• Packed or wrapped
  – AAMI approved rigid containers or wrappers
  – Association for the Advancement of Medical Instrumentation
Sterilization Monitoring

- Mechanical – cycle time, temperature, pressure (steam)
- Chemical – heat or chemical sensitive inks that change color when germicidal parameters reached
- Biological – *Bacillus* or *Geobacillus* spores that directly measure sterilization

Bowie-Dick test is for vacuum and done once a day. Not a sterilization monitor
Chemical monitor

- Chemical integrator
- Used for pack control to monitor conditions inside each pack or rigid container
- Failed indicator – immediately remove pack from procedure and reprocess
Biological Monitors

- Daily
- Steam – *Geobacillus stearothermophilus*
- Dry heat – *Geobacillus stearothermophilus*
- ETO – *Bacillus atrophaeus*
- Low temperature technologies (H2O2 gas) – *Geobacillus stearothermophilus*
- Adhere to Manufacturer’s Quality Controls recommendations

Steam biologic monitor
Failed Biologic Indicator

- Immediately take sterilizer out of service
- Notify director and infection control
- Quarantine all loads since failure and reprocess
- Begin investigation
  - Verify integrity of biologic indicator
  - Verify mechanical indicator (print out)
  - Verify operator input
    - Correct cycle selection
  - Verify correct plant operations
    - Loss of steam
    - Power loss
- Repeat biologic indicator in 3 consecutive runs
  - If any positive – call manufacturer for service
Flash Sterilization (immediate use sterilization)

Designed for the steam sterilization of unwrapped single items designated for immediate use

- Decontaminate item
- Use rigid covered immediate use container
- Do not wrap item
- All mechanical, biological and chemical monitors apply
- Never use for any implantable item
Immediate Use Sterilization

- Weigh costs of more instruments vs. patient safety
- Do not use for convenience or as an alternative to purchasing more instrument sets
- Establish guidelines and monitor use
  - Date & time
  - MD, case
  - Item
  - Reason
- Use only when there is insufficient time to process instrument completely in wrapped or rigid container
Low Temperature Sterilization

Used on heat and moisture sensitive equipment

- **ETO (ethylene oxide)**
  - Gas concentration, temperature, humidity
  - Long cycle, aeration required, toxicity

- **Hydrogen peroxide gas plasma (Sterrad)**
  - Requires synthetic packaging. No cellulose
  - Some devices with narrow long lumens cannot be processed (See manufacturer’s recommendations for length and diameter)

- **Peracetic Acid (Steris)**
  - Point of use. No storage allowed.
  - Small loads
  - Immersible instruments only
Single Use Device

- Hospital or third party reprocessor is regulated the same as original equipment manufacturer.
- A device labeled for single use is considered a new device if reprocessed. The reprocessor is considered the manufacturer.
- As a new device, all federal (FDA) controls regarding the manufacture and marketing of the device apply.
Storage of Sterile Items

- Event related shelf life – consider the product sterile until an event causes it to become contaminated. Packaging evaluated before use for integrity
  - Tear or opening in packaging
  - Water damage

- Time related shelf life – consider item sterile for set period based on wrapping/packaging material. Once expiration date is passed, item must be removed from service. Discard or reprocess. If manufacturer has placed expiration date on package, item has time related shelf life.
Storage of Sterile Items

• Segregated, protected area
• Covered shelving
• Solid surface bottom shelf
• Temperature control (68-75)
• Humidity control (30%-70%)
• Air exchange per hour
• 8-10 inches off floor
• 18 inches below ceiling
• 2 inches from outside wall
Semi-Critical Items

• Objects that come in contact with mucous membranes and non-intact skin

• Goals
  – High level disinfection
    • Free of all microorganisms except high numbers of spores

• Methods
  – Pasteurization
  – Liquid chemical sterilants – heat sensitive items
    • Gluteraldehyde
    • OPA (ortho-pthaldehyde)
Semi-Critical Items

• Pasteurization
  – 70°C (158°F) for 30 minutes
• Not just for food and drink
• Used on respiratory therapy and anesthesia equipment
High Level Disinfection

- Endoscopes
- Bronchoscopes
- Laryngoscope Blades
- Tonometers
- Cryosurgical instruments
- Endocavitary probes
  - Transesophageal
  - Transvaginal
  - Nasopharyngoscopes
## High Level Disinfection

<table>
<thead>
<tr>
<th>&gt;2.0% Glutaraldehyde</th>
<th>0.55% OPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>45 minute process</td>
<td>12 minute process</td>
</tr>
<tr>
<td>Well ventilated area with covered containers</td>
<td>Well ventilated area with covered containers</td>
</tr>
<tr>
<td>Deactivator required before disposal</td>
<td>No deactivator required</td>
</tr>
<tr>
<td>OSHA limit of 0.05ppm</td>
<td>No OSHA limit</td>
</tr>
<tr>
<td>Strong odor</td>
<td>Weak odor</td>
</tr>
<tr>
<td>$</td>
<td>3x$</td>
</tr>
<tr>
<td></td>
<td>Contraindicated for urological instruments used on patients with history of bladder cancer</td>
</tr>
</tbody>
</table>
Scopes

- Pre clean
  - Remove visible soiling
- Disinfect
  - Manual
  - Automated
- Rinse
  - Fresh water
    - No recommendation for sterile vs. potable
  - Manually rinse lumens
  - Flush with 70% isopropyl alcohol
- Dry
  - Air dry
- Store
  - Hanging freely (no touching)
  - In ventilated cabinet
Emerging Pathogens

“Standard disinfection and sterilization procedures for patient care equipment are adequate to sterilize or disinfect instruments or devices contaminated with blood and other body fluids from persons infected with emerging pathogens.”

(Rutala, W. A, Ph.D., MPH., 2004)

One exception – Creutzfeldt-Jakob Disease
Non-Critical Items

- Objects that will not come in contact with mucous membranes and non-intact skin

Goals
- Intermediate and low level disinfection
  - Free of all vegetative bacteria and some fungi and viruses

Methods
- EPA registered hospital disinfectant
  - Chlorine-based
  - Phenolics
  - Quaternary ammonium
  - Hydrogen Peroxide
  - 70-90% alcohol
Non-Critical Items

• Environmental Surfaces
  – Medical equipment
  – Furniture
  – Building environment

• Risks
  – High touch areas
    • Door handles
    • IV poles
    • Phones
    • Computers

  – Low touch areas
    • Toilet seats
Room disinfection Technologies

- EPA registered
- Sanitize specific surfaces
  - Copper alloy
- Sanitize entire room
  - UV irradiation
  - Ozone
- Some can sanitize room and contents of supply drawers
  - Hydrogen peroxide vapor
Bacteria per square inch

3,295

49

25,127
Survival Rates

- Influenza 24-48 hrs
- MRSA 63 days
- VRE 58 days
- *Acinetobacter* 33 days
- *C. diff* spore 5 months
- *Pseudomonas* 7 hours
- Hepatitis B 7 days
- Norovirus 12 days
- SARS 24-72 hrs
- Candida sp. 3 days
- Parainfluenza 10 hrs
Staff Competencies

• Provide comprehensive training for all staff assigned to process medical/surgical instruments

• To achieve and maintain competency
  – Hands on training
  – All work supervised until documented competency
  – Includes review of written instruction to assure compliance and uniformity
  – Conducted at hire and annually
Infection Prevention Role

• Periodic review of policies and procedures
• Annual review of disinfectants
• Regular review
  – Expired items
  – Flash sterilization logs
  – Sterilization monitor logs
  – HLD logs
  – Observations
    • Hand hygiene
    • Proper personal protective equipment
Pearls of Wisdom

If it can’t be CLEANED – it cannot be disinfected or sterilized.

ALWAYS adhere to manufacturer of device/instrument recommendations.

ALWAYS follow Disinfectant Manufacturer recommendations for storage and testing of solution.

Temperatures, humidity's, testing of strips, quality controls MUST be logged as required
References

• Centers for Disease Control and Prevention
  http://www.cdc.gov/ncidod/dhqp/guidelines.html

• Environmental Protection Agency
  http://www.epa.gov

• Food and Drug Administration
  http://www.fda.gov

• University of North Carolina
  http://www.disinfectionandsterilization.org