Disinfection & Sterilization

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Beth Ann Ayala is Director of Infection Control at University Health System in San Antonio. Infection Control and Prevention is an area she has worked in for the last seven years. Prior to that, were ten years of experience as a clinical microbiologist. She has a Bachelor of Science degree in Microbiology from Colorado State University and a Master of Science in Pathobiology/Microbiology from the University of Arizona. She also has a Master of Business Administration from Louisiana State University. Beth Ann finds Infection Control to be a fascinating field. She embraces the challenges and change occurring both at UHS and in the health care environment. She is currently on the board of the Texas Society for Infection Control and Prevention.

Presenting: *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 antisetics (*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

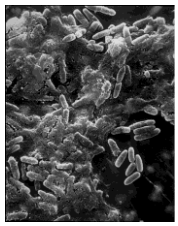
- Critical –objects which penetrate sterile tissue or blood must be **Sterile**
- Semi-critical –objects that touch mucous membranes or non-intact skin require **High level disinfection**
- Non-critical –objects that only touch intact skin require **Intermediate & Low level disinfection**

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



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

Decontamination room

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

Biological Monitors

- Daily
- Steam – *Geobacillus stearothermophilus*
- Dry heat – *Geobacillus stearothermophilus*
- ETO – *Bacillus atrophaeus*
- Low temperature technologies (H_2O_2 gas) – *Geobacillus stearothermophilus*

Steam biologic monitor

Failed Biologic Indicator

- Immediately take sterilizer out of service
- Notify director
- 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 positive – call manufacturer for service

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

Flash Sterilization

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

- Decontaminate item
- Use rigid covered container
- All mechanical, biological and chemical monitors apply
- Never use for any implantable item

Flash 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 (Sterris)
  - Point of use. No storage allowed.
  - Small loads
  - Immersible instruments only

Single Use Device

- FDA issued Single Use Device Guidance in August 2000.
- 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

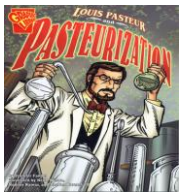
- Segregated, protected area
- Covered shelving
- Solid surface bottom shelf
- Temperature control (68-75)
- Humidity control (35%-75%)
- Air exchange per hour
- 8-10 inches off floor
- 18 inches below ceiling
- 2 inches from outside wall

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
  - Pastuerization
  - Liquid chemical sterilants - heat sensitive items
    - Gluteraldehyde
    - OPA (ortho-pthaldehyde)

Semi-Critical Items

- Pasteurization
  - 70^0 C (158^0 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

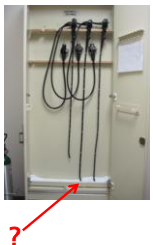
High Level Disinfection

>2.0% Gluteraldehyde
- 45 minute process
- Well ventilated area with covered containers
- Deactivator required before disposal
- OSHA limit of 0.05ppm
- Strong odor
- $

0.55% OPA
- 12 minute process
- Well ventilated area with covered containers
- No deactivator required
- No OSHA limit
- Weak odor
- 3x$
- Contraindicated for urological instruments used on patients with history of bladder cancer

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



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
    - 70-90% alcohol

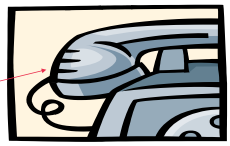
Non-Critical Items

- Environmental Surfaces
  - Medical equipment
  - Furniture
  - Building environment
- Risks
  - High touch areas
    - Door handles
    - IV poles
    - Phones
  - Low touch areas
    - Toilet seats

Bacteria/inch^2

3,295

49



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Survival Rates

- Influenza 24–48 hrs
- MRSA 9 weeks
- 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
  - Observations
    - Hand hygiene
    - Proper personal protective equipment

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