Sterile Reprocessing

Two-Day Healthcare-Associated Infections Workshops
Louisiana Office of Public Health
2017

Objective and Outline

By the end of the presentation, attendees will be able to:

- Standardize reprocessing methods by device type
  - Critical devices
  - Semi-critical devices
  - Noncritical devices
  - Case studies

Key Terms

**Critical Devices**
- Confer a high risk for infection if they are contaminated with any microorganism
- Enter sterile tissue or the vascular system
- Devices included:
  - Surgical instruments
  - Cardiac and urinary catheters
  - Implants
  - Ultrasound probes used in sterile body cavities

**Semi-Critical Devices**
- Contact mucous membranes or nonintact skin
- Devices included:
  - Respiratory therapy and anesthesia equipment
  - Some endoscopes
  - Laryngoscope blades
  - Esophageal manometry probes
  - Cytoscopes
  - Anorectal manometry catheters
  - Diaphragm fitting rings

**Noncritical Devices**
- Come in contact with intact skin but not mucous membranes
- Devices included:
  - Noncritical patient care items: intact skin acts as an effective barrier to most organisms; therefore, the sterility of items coming in contact with skin is "not critical"
  - Noncritical environmental surfaces: frequently touched by hands; potentially could contribute to secondary transmission

**Biofilm**
- Microbial masses attached to surfaces that are immersed in liquids
- May be resistant to disinfectants by multiple mechanisms, e.g. genotypic variation of the bacteria, microbial production of neutralizing enzymes, and physiological gradients within the biofilm
Key Terms

Cleaning
- Removal of foreign material (e.g., soil, organic material) from objects and is normally accomplished using water with detergents or enzymatic products
- Reduces the bioburden and removes foreign material that interferes with the sterilization process

Disinfection
- Process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects
- Disinfected by liquid chemicals or wet pasteurization

Sterilization
- Destroys or eliminates all forms of microbial life and is carried out by physical or chemical methods
- Examples:
  - Steam under pressure
  - Dry heat
  - Ethylene Oxide gas
  - Hydrogen peroxide gas plasma
  - Liquid chemicals

Key Terms

High-level disinfectant
- Chemical germicide that has been cleared by the FDA as capable of destroying all viruses, vegetative bacteria, fungi, mycobacterium and some, but not all, bacterial spores


15-Step Protocol for Exposure Investigation After a Failure of Disinfection and Sterilization Processes
1. Confirm failure of disinfection or sterilization reprocessing
2. Immediately embargo any possibly improperly disinfected/sterilized items
3. Do not use the questionable disinfection/sterilization unit (e.g., sterilizer, automated endoscope reprocessor) until proper functioning has been assured
4. Inform key stakeholders
5. Conduct a complete and thorough evaluation of the cause of the disinfection/sterilization failure
6. Prepare a line listing of potentially exposed patients
7. Assess whether the disinfection/sterilization failure increases a patient's risk for infection
8. Inform expanded list of stakeholders of the reprocessing issue
15-Step Protocol for Exposure Investigation After a Failure of Disinfection and Sterilization Processes

9. Develop a hypothesis for the disinfection/sterilization failure and initiate corrective action
10. Develop a method to assess potential adverse patient events
11. Consider notification of appropriate state and federal authorities (e.g., health department, FDA)
12. Consider patient notification
13. If patients are notified, consider such patients require medical evaluation for possible postexposure therapy with appropriate anti-infectives. In addition, appropriate follow-up to detect infection (e.g., HIV, hepatitis B, hepatitis C) should be offered, if warranted.
14. Develop a detailed plan to prevent similar failures in the future
15. Perform after-action report


Sterilization Cycle Verification

- A sterilization process should be verified before it is put into use
- Biological and chemical indicator testing is done for ongoing quality assurance testing
- When three consecutive cycles show negative biological indicators and chemical indicators with a correct end point response, you can put the change made into routine use


Physical Facilities

- The central processing area(s) should ideally be divided into at least three areas: Decontamination, Packaging, and Sterilization and Storage
- Physical barriers should separate the decontamination area reusable contaminated supplies are received, sorted, and decontaminated
- American Institute of Architects 959 recommends negative pressure and no fewer than six air exchanges per hour
- Floors and walls should be made of materials that can be chemically cleaned or disinfected
- Ceilings and walls should be made of non-shedding materials

Cleaning

- Surgical instruments are generally presoaked or prerinsed to prevent drying of blood and tissue
- Pre-cleaning in patient-care areas may be needed on items are heavily soiled with feces, sputum, blood, or other material
- PPE for personnel working in decontamination area: 1) rubber or plastic gloves when handling contaminated instruments and devices, 2) face masks, eye protection such as goggles or full-length face shields, 3) appropriate gowns when exposure to blood and contaminated fluids may occur
- Use engineering tools such as forceps to retrieve sharps
Sterile Reprocessing


Packaging
- Complex instruments should be prepared and sterilized according to device manufacturer’s instructions and test data
- Factors contributing to maintaining sterility of surgical instruments include rigid containers, peel-open pouches, roll stock or reels, and sterilization wraps

Loading
- Arrange so all surfaces will be directly exposed to the sterilizing agent
- Basic principles:
  - Allow for proper sterilant circulation
  - Perforated trays should be placed so the tray is parallel to the shelf
  - Nonperforated containers should be placed on their edge
  - Small items should be loosely placed in wire baskets
  - Peel packs should be placed on edge in perforated or mesh bottom racks or baskets


Storage
- Safe storage times for sterile packs vary with the porosity of the wrapper and storage conditions
- Supplies wrapped in double-thickness muslin comprising four layers, or equivalent, remain sterile for at least 30 days
- Medical and surgical supplies should not be stored under sinks or in other locations that can become wet
- Closed or covered cabinets are ideal but open shelving may be used


Monitoring
- Chemical indicators should be used in conjunction with biological indicators but should not replace them because they indicate sterilization at marginal sterilization time
- Chemical indicators are affixed on the outside of each pack to show that the package has been processed through a sterilization cycle
- Biological indicators monitor the lethality of a given sterilization process
- If patient-care items were used before retrieval, the infection control professional should assess the risk of infection in collaboration with central processing, surgical services, and risk management staff
- Document sterilization records including chemical and biological indicator test results, sterilizer maintenance and wrapping, and load numbering of packs
The Joint Commission (TJC): Chemical Sterilization and High-Level Disinfection in Health Care Facilities

- Chemical sterilants should be used in an area that is properly ventilated.
- When general room ventilation is not adequate, a self-contained, freestanding system* or a local exhaust hood should be installed to capture chemical vapor during processing.
- When an outside exhaust system is not available, a ductless fume hood* can be used to deliver vapor to a filter system that chemically inactivates the vapor; then, clean, filtered air is returned to the room.
- Filters for these systems should be replaced in accordance with the manufacturer's recommendations.

* A ductless fume hood is simply a freestanding system that captures the toxic fumes and vapors and returns clean air to the room. Other names for ductless fume hoods are vapor control systems and disinfection soak stations.

Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes, Society of Gastroenterology Nurses and Associates (SGNA), 2012

Core Components of an Education Program

- Standard precautions
- Personal protective equipment
- OSHA rules on occupational exposure to bloodborne pathogens
- Reprocessing procedures for endoscopes and accessory equipment
- Mechanisms of disease transmission
- Maintenance of a safe work environment
- Safe handling of high level disinfectants and sterilants
- Procedures for waste management
Quality Control Documentation
- Procedure date and time
- Patient's name and medical record number
- The endoscopist
- The endoscope’s model and serial number or other identifier
- The automated endoscope reprocessor (if used) model and serial number or other identifier
- The staff member(s) reprocessing the endoscope

Infection Control Measures
- Disinfection and sterilization of medical equipment
- Proper use of PPE
- Personal hygiene
- Engineering controls
- Cleaning and disinfection of environmental surfaces
- Administrative monitoring and support
- Training and continuing education
- Written protocols

Endoscope Reprocessing Protocol
- Precleaning
- Leak testing
- Manual cleaning
- Rinse after cleaning
- High level disinfection (manual or automated)
- Rinse after high level disinfection
- Drying
- Storage

Endoscope Storage
- Store in a manner that will protect from contamination
- Hang in a vertical position to facilitate drying
- Clean, well ventilated, dust free area
- Prevent damage to the exterior of the instrument by protecting it from physical impact

- 9 patients with NDM-producing E. coli were identified in northeastern Illinois from March – July 2013
- 8 treated at the same hospital
- Case-control study was conducted with 27 controls selected randomly
- History of undergoing endoscopic retrograde cholangiopancreatography (ERCP) at hospital A was strongly associated with case status (OR = 78.0)
- 91 patients were notified that they had potential exposure; 50 patients returned for rectal surveillance cultures
- Hospital A changed ERCP endoscope reprocessing from automated high-level disinfection to gas sterilization with ethylene oxide; no new cases identified


- Clusters were investigated that involved M. tuberculosis and M. intracellulare or imipenem-resistant Pseudomonas aeruginosa (IRPA)
- Cluster 1: November-December 1996
  - Bronchial specimens from 5 patients yielded M. tuberculosis; index case had an AFB smear and culture positive specimens
  - Subsequent four cases were contaminated through bronchoscopy
- Cluster 2: March-April 1998
  - 7 cases identified with M. avium-intracellulare; all underwent bronchoscopy at the same facility with the same bronchoscope
  - Bronchoscope was mycobacterial culture negative
- Cluster 3: August-October 1998
  - 18 patients grew IRPA post bronchoscopy
  - Facility switched to STERIS

CASE STUDY

A case study of a real-time evaluation of the risk of disease transmission associated with a failure to follow recommended sterilization procedures

- 2011: Sterile Processing Department staff at an Ohio hospital identified two steriset Sterilization Containers containing reprocessed surgical instruments in which a steam chemical integrator strip indicated that sterilization had not been achieved
- Operating room staff did not routinely document the results of integrator strips placed inside each Steriset Container
- Up to 72 patients may have undergone operations using instruments that had been autoclaved on the gravity cycle
A case study of a real-time evaluation of the risk of disease transmission associated with a failure to follow recommended sterilization procedures

Initial Actions
- Consultation on the exposure risk associated with this incident
- Initial need: provide timely information for hospital administrators, infection control personnel, and exposed patients
- Hypothesis: sterilization may be achieved inside the Steriset Container on a gravity cycle

Setting
- Hospital performed a wide range of surgical procedures
- Reviewed processes of cleaning and disinfection in a machine washer/disinfector

Evaluation of the effectiveness of the washer/disinfector
- Case-control processing of instruments: cases underwent manufacturer's instructions and controls were contaminated in an identical fashion, but not processed in the washer/disinfector

Evaluation
- Four test methods were used to assess sterilization inside the Steriset Containers
- Calculates risk of MRSA and hepatitis B virus

Results
- MRSA transmission was determined to be 1 in 100 trillion when doing the processing correctly

Conclusion
- Risk is negligible when cycle is performed correctly
- Real time assessments help with decision-making and disclosure to patients!

Moral of the story: follow manufacturers’ guidelines!!

Summary
- Infection Control measures should be applied to sterile processing measures
- Education of bloodborne pathogens and donning/doffing PPE is essential
- Quality control and documentation is necessary
- Adhere to evidence-based guidelines when devising your protocols
- Follow manufacturers’ guidelines
Questions?

I swear, I did not overload that sterilizer!

Zorns Holdener