High-level Disinfection and Sterilization Toolkit

Healthcare Associated Infections Antimicrobial Resistance Program

Background

West Virginia Bureau for Public Health's Healthcare-associated Infections and Antimicrobial Resistance (HAI/AR) Program is dedicated to protecting patients and healthcare personnel by promoting safety and quality. Preventing healthcare associated infections (HAIs) and reducing antimicrobial resistance (AR) are top priorities. HAIs are infections that people acquire while they are receiving treatment for medical or surgical conditions in a healthcare setting and can be acquired anywhere healthcare is delivered. For many years HAIs have been a recognized public health threat associated with morbidity, mortality, and increased healthcare costs, and yet many are preventable.

Introduction [4]

Each year in the United States, approximately 46.5 million surgical procedures and over five million invasive medical procedures, like endoscopies, are performed. Each of these procedures involves a medical device or surgical instrument contacting a patient's tissue or mucous membranes, creating a potential pathway for infection. Disinfection and sterilization are the essential, non-negotiable processes that ensure these instruments do not transmit infectious pathogens to patients. By destroying or eliminating harmful microorganisms, these decontamination methods form a critical line of defense in patient safety, preventing countless HAIs.

This toolkit is designed to provide healthcare facilities with recommendations for developing and maintaining a reliable system for reprocessing reusable medical devices, minimizing infection risks for both patients and staff.

Must Know Terms [4]

Sterilization: A process that destroys or eliminates all forms of microbial life. In healthcare facilities, this is accomplished through physical or chemical methods, including steam under pressure, dry heat, ethylene oxide gas, hydrogen peroxide gas plasma, and liquid chemical sterilants.

Disinfection: A process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects.

High-level Disinfection: A process that kills all microorganisms, with the exception of large numbers of bacterial spores.

Intermediate-level Disinfection: A process that is fatal for mycobacteria, vegetative bacteria, most viruses, and most fungi, but does not necessarily kill bacterial spores.

Low-level Disinfection: A process that can kill most vegetative bacteria, some fungi, and some viruses in a practical period of time.

Cleaning: The essential first step involving the removal of visible soil from objects and surfaces. It is typically accomplished manually or mechanically using water with detergents or enzymatic products.

Decontamination: The process of removing pathogenic microorganisms from objects so they are safe to handle, use, or discard.

United States Food and Drug Administration (FDA): Regulates liquid chemical sterilants and high-level disinfection used on critical and semicritical medical devices.

United States Environmental Protection Agency (EPA): Regulates disinfectants used on noncritical environmental surfaces and gaseous sterilants.

Occupational Safety and Health Administration (OSHA): Regulates occupational safety, including setting permissible exposure limits for chemicals like ethylene oxide and formaldehyde and enforcing the Bloodborne Pathogens Standard.

The Spaulding Classification: Matching the Method to the Risk [4]

The Spaulding Classification categorizes medical items based on the degree of infection risk involved in their use.

1. **Critical Items:** These items pose a high risk of infection if contaminated. They are defined as objects that enter sterile tissue or the vascular system. Because any microbial contamination could transmit disease, these items must be sterile.
    - **Examples:** Surgical instruments, cardiac catheters, urinary catheters, implants, and ultrasound probes used in sterile body cavities.
    - **Required Level:** Sterilization.
2. **Semicritical Items:** These items come into contact with mucous membranes or nonintact skin. While they should be free from all microorganisms, small numbers of bacterial spores are permissible, as intact mucous membranes are generally resistant to them.
    - **Examples:** Respiratory therapy and anesthesia equipment, endoscopes, laryngoscope blades, cystoscopes, and diaphragm fitting rings.
    - **Required Level:** high-level disinfection (minimum).

3. **Noncritical Items:** These are items that only come into contact with intact skin, which acts as an effective barrier to most microorganisms.
    - **Examples:** Bedpans, blood pressure cuffs, crutches, and computers.
    - **Required Level:** Low-level disinfection.

Factors Influencing Efficacy of Disinfection and Sterilization [4]

The effectiveness of any germicidal process is dependent on a combination of interrelated factors.

- **Number and Location of Microorganisms:** A higher initial number of microbes requires a longer exposure time to achieve destruction. Locations like crevices, joints, and lumens are harder to disinfect because they impede sterilant penetration.
- **Innate Resistance of Microorganisms:** Microorganisms vary widely in their resistance to chemical germicides and sterilization processes. This resistance can be ranked in descending order:
    1. Prions
    2. Bacterial spores
    3. Coccidia
    4. Mycobacteria
    5. Nonlipid or small viruses
    6. Fungi
    7. Vegetative bacteria
    8. Lipid or medium-sized viruses
- **Concentration and Potency of Germicides:** The concentration of the disinfectant directly impacts its efficacy.
- **Physical and Chemical Factors:**
    - **Temperature**: Efficacy generally increases with temperature, but excessive heat can degrade some disinfectants.
    - **pH**: The pH of the solution can enhance or diminish the activity of a germicide. Glutaraldehyde is activated in alkaline solutions, while hypochlorites are more active in acidic solutions.
    - **Relative Humidity**: This is a critical factor for gaseous sterilants like Ethylene Oxide.
    - **Water Hardness**: Can reduce the effectiveness of some disinfectants.
- **Organic and Inorganic Matter:** Materials like blood, serum, pus, and salts can inactivate germicides or shield microbes from contact. Meticulous cleaning is the only way to mitigate this factor.

- **Duration of Exposure:** Items must be exposed to the germicide for the minimum contact time specified by the manufacturer and cleared by the FDA or EPA.
- **Biofilms:** Microorganisms can form biofilms—accumulated masses of bacteria and extracellular material—that adhere tightly to surfaces and are highly resistant to removal and disinfection.

The Critical First Step: Meticulous Cleaning [1,4]

Cleaning is the non-negotiable foundation upon which all successful disinfection and sterilization processes are built. It is the single most important, and most frequently overlooked, step in reprocessing. Residual organic material not only inactivates germicides, as noted by the Centers for Disease Control and Prevention (CDC), but as Association for Professionals in Infection Control and Epidemiology (APIC) guidance highlights, it can also harbor and protect dangerous biofilms, which are up to 1,000 times more resistant to disinfectants than free-floating bacteria. An instrument that looks "clean" to the naked eye can still retain biofilm, making meticulous manual friction and enzymatic breakdown essential first steps to ensure patient safety.

Rationale for Cleaning

The primary functions of meticulous cleaning are to:

- Reduce the number and type of viable microorganisms, known as the bioburden, on the item.
- Remove foreign material, including organic residue and inorganic salts, that acts as a physical barrier, preventing the sterilant or disinfectant from reaching the device surface.
- Prevent the drying or baking of soil onto instruments, a condition that makes effective removal more difficult.

Cleaning Methods

Cleaning can be performed through manual or mechanical means, often in combination.

- **Manual Cleaning:** This method is essential for cleaning intricate devices and is typically used for fragile or complex instruments. It relies on two key components: friction (rubbing or scrubbing the soiled area with a brush) and fluidics (the use of fluids under pressure to remove soil from internal channels).
- **Mechanical Cleaning:** Automated equipment improves cleaning effectiveness and increases productivity. Common types of automatic cleaners include ultrasonic cleaners

(which use cavitation to dislodge soil), washer-decontaminators, and washer-disinfectors.

Cleaning Agents

Specialized cleaning agents are used to break down and remove soil from instruments.

- **Detergents:** Neutral or near-neutral pH detergents are commonly used as they provide soil removal and are compatible with a wide range of medical device materials.
- **Enzymatic Cleaners:** These products often contain proteases, enzymes that are highly effective at breaking down proteinaceous organic material like blood and pus. Some formulations may also contain lipases (for fats) and amylases (for starches).
- **Rinsing:** After cleaning, it is critical to thoroughly rinse instruments to remove all cleaning agent residues. These residues can interfere with subsequent disinfection or sterilization processes and, if left on an instrument, have been associated with adverse patient reactions.

High-level Disinfection Process and Chemical Agents [1, 3-4]

High-level disinfection is the required minimum standard for reprocessing semicritical devices, particularly complex instruments like flexible endoscopes, which have been linked to more healthcare-associated outbreaks than any other medical device. The bioburden on a used gastrointestinal endoscope can range from 100,000 to 10 billion CFU/mL, with the highest levels found in the suction channels. Meticulous cleaning alone can reduce this, but high-level disinfection is essential to eliminate the remaining pathogenic threat. It is crucial to distinguish the process of high-level disinfection from the agent used. While some chemical agents are classified as "chemical sterilants," they are used to achieve high-level disinfection with shorter, specific contact times that are not intended to destroy high numbers of bacterial spores. This section details the high-level disinfection process for endoscopes and the chemical agents used to achieve it.

High-level Disinfection Process for Endoscopes

A standardized, multi-step protocol is essential for the safe reprocessing of flexible endoscopes.

1. **Pre-cleaning (Point-of-Use)**: Immediately after the procedure, wipe the exterior of the endoscope. Flush the internal channels with an enzymatic detergent to prevent blood and organic material from drying.

2. **Leak Testing:** Test each flexible endoscope for leaks according to the manufacturer's instructions. This is critical to detect damage that could allow fluid entry, leading to device failure and inadequate reprocessing.
3. **Manual Cleaning:** Meticulously and manually clean the endoscope by immersing it in an enzymatic cleaner and brushing all internal channels and external surfaces. All removable parts must be detached and cleaned separately.
4. **High-level Disinfection:** Fully immerse the cleaned endoscope in an FDA-cleared high-level disinfection, ensuring all channels are filled. Immersion must be for the specified time and at the specified temperature noted on the product's label.
5. **Rinsing:** After disinfection, thoroughly rinse the endoscope and all its channels with sterile, filtered, or tap water to remove toxic or irritating disinfectant residue.
6. **Drying:** Flush the channels with 70-90% alcohol, followed by forced-air drying if indicated in the manufacturers' instructions. This final step is crucial to prevent recontamination from waterborne organisms that may be present in the rinse water.
7. **Storage:** Store the reprocessed endoscope in a way that prevents recontamination and promotes drying, such as by hanging it vertically in a designated clean storage cabinet.

Chemical Agents for High-level Disinfection

The following agents are commonly used for high-level disinfection. The agent selected should be based on which best balances efficacy, device compatibility, turnaround time, and occupational safety.

- Glutaraldehyde
- Ortho-phthalaldehyde
- Hydrogen peroxide
- Peracetic Acid
- Peracetic Acid and Hydrogen Peroxide

Chemical Agent Preparation, Testing, and Replacement

Adhering to the manufacturer's instructions for use for chemicals utilized in high-level disinfection is a foundational requirement to ensure the effectiveness and safety of medical device reprocessing.

Compliance with manufacturer instructions for high-level disinfection chemicals focuses on three critical areas:

1. **Preparation (dilution and activation)**: To ensure the chemical is effective, facilities must adhere to procedures for preparing the solution.

2. **Testing for appropriate concentration**: Because high-level disinfectants degrade or become diluted during use, routine testing confirms efficacy.
    - Facilities are required to routinely test the liquid sterilant/high-level disinfectant to ensure the minimal effective concentration (MEC) of the active ingredient is met.
    - This testing involves checking the solution each day of use (or more frequently, depending on facility policy and chemical usage volume) using the appropriate chemical indicator.
    - The MEC is the minimum concentration of the germicide necessary to achieve the claimed microbicidal activity. The solution must be discarded if the chemical indicator shows the concentration is less than the MEC.
    - The results of this potency testing must be formally documented.
3. **Replacement (reuse-life and expiration)**: Chemicals must be replaced not only when their concentration falls below the MEC, but also based on time limits.
    - Manufacturer instructions must be followed for the replacement of the chemical, either when efficacy is lost or upon reaching the defined expiration date.
    - The liquid sterilant/high-level disinfectant must not be used beyond the reuse-life recommended by the manufacturer (e.g., 14 days for *ortho-phthalaldehyde*).
    - Documentation should include the expiration dates for chemical disinfectants and potency test strips. Opened liquid chemical containers should be labeled with the date opened and the use-by date.
    - Furthermore, when using FDA-cleared high-level disinfection, staff must adhere to the manufacturer's recommended exposure time and temperature to ensure effective disinfection, as these parameters are linked to the chemical's efficacy.

Automated Endoscope Reprocessors

Automated Endoscope Reprocessors (AERs) are machines that are designed to clean, disinfect, and sometimes sterilize flexible endoscopes between patient use. They standardize and automate disinfection, reducing personnel exposure to chemicals. However, they are not a substitute for manual cleaning. Failures can occur if incorrect channel connectors are used or if the AER cannot adequately flush certain channels.

Transvaginal Ultrasound Probes

Transvaginal probes, also known as endocavitary probes (vaginal or rectal), are classified as semicritical devices.

Reprocessing of transvaginal ultrasound probes falls under the critical domain of high-level disinfection protocols, necessitating rigorous oversight due to potential cross-contamination risks and challenges related to specific microbial pathogens. Risks include:

- **Viral Contamination**: The human papilloma virus has been reported to contaminate both endovaginal and endorectal ultrasound probes.
- **Sheath/Cover Failure**: Although guidelines recommend using a single-use sheath or condom on the probe prior to use, the CDC recommends that the probe still be high-level disinfected after each use due to the high risk of probe cover failures such as perforations.

Adherence to manufacturer's reprocessing protocol is critical.

Sterilization Methods, Practices, and Monitoring [1,4]

Sterilization is a critical component of infection prevention and control. Its primary purpose is to eliminate the risk of disease transmission by destroying all forms of microbial life on medical instruments and devices. This process directly prevents HAIs, particularly surgical site infections, which represent one of the most common and costly complications of medical care. The meticulous application of sterilization principles is not merely a procedural requirement but a fundamental commitment to patient safety. This section details sterilization methods, practices, and monitoring that ensure sterility.

Sterilization Methods

- **Steam Sterilization (Autoclave):** Steam sterilization is the most widely used, dependable, and cost-effective method for reprocessing medical devices that are stable to heat and moisture. The process uses saturated steam under pressure to achieve sterilization.
    - The effectiveness of steam sterilization depends on four critical parameters: steam, pressure, temperature, and time. Different types of steam sterilizers are used, including gravity-displacement autoclaves, where incoming steam displaces the heavier, residual air, and dynamic-air-removal systems (e.g., prevacuum), which use a vacuum pump to actively remove air before steam is introduced.

- **Ethylene Oxide (ETO) Gas Sterilization:** Ethylene oxide is a low-temperature gas sterilization method used for items that are sensitive to heat and moisture. It is compatible with a wide range of medical materials and can penetrate packaging and device lumens.
    - Effective ETO sterilization is dependent on four parameters: gas concentration, temperature, relative humidity, and exposure time. Despite its effectiveness, ETO poses significant occupational and environmental hazards. It is toxic, carcinogenic, and flammable. A crucial part of the ETO process is a lengthy aeration period (typically eight to 12 hours) to allow the toxic gas residuals to dissipate from sterilized items before they are safe to handle or use on a patient.
- **Hydrogen Peroxide Gas Plasma:** Hydrogen peroxide gas plasma is a newer low-temperature sterilization technology that is safe for the environment and for healthcare personnel. The process involves injecting hydrogen peroxide vapor into a chamber, which is then excited by a radio frequency to create a plasma state. This plasma generates microbicidal free radicals (e.g., hydroxyl radicals) that destroy microorganisms.
- **Liquid Chemical Sterilization (Peracetic Acid Immersion System):** This method utilizes an automated, microprocessor-controlled machine that sterilizes heat-sensitive, immersible instruments by immersing them in a 0.2% peracetic acid solution at approximately 50-55°C. Peracetic acid is a highly biocidal oxidizing agent that is effective even in the presence of organic material.

Transportation of Instruments to Reprocessing Area

The transport of instruments to the reprocessing area requires adherence to facility policies and procedures to prevent cross-contamination and exposure to infectious materials.

Container and Cart Specifications

Soiled instruments must be transported to the decontamination area in a closed container or enclosed transport cart. To ensure safety, the following criteria is recommended:

- Leakproof to prevent fluids from spilling.
- Puncture-resistant to prevent sharp injuries.
- Sufficient size to contain all contents adequately.
- Properly labeled.

Preparation for Transport

Preparation for decontamination should begin at the point of use before the instruments are moved:

- **Timing:** Contaminated instruments should be transported to the reprocessing area as soon as possible after use.
- **Instrument State:** Hinged instruments should be placed in an open position.
- **Pre-treatment:** To prevent organic material from drying, instruments can be treated with an instrument cleaner. Spray enzymatic products may be applied after the procedure is completed but prior to transporting the instruments.

Sterilization Practices

Ensuring the sterility of an item involves a sequence of standardized practices within the reprocessing area;

1. **Packaging:** After cleaning, items must be placed in packaging that allows for penetration of the sterilant and maintains sterility until the point of use. Common materials include woven or nonwoven sterilization wraps, paper-plastic peel pouches, and rigid sterilization container systems.
2. **Loading:** Items must be loaded into the sterilizer chamber to allow for free circulation of the sterilant. For example, peel packs should be placed on their edge, and hinged instruments should be opened.
3. **Storage:** The shelf life of a sterilized package is event-related, meaning sterility is maintained indefinitely unless an event compromises the barrier. Sterile items must be stored in a clean, dry, controlled environment at least eight to 10 inches from the floor, at least 18 inches below ceiling sprinkler heads, and two inches from exterior walls.

Sterilization Monitoring

Sterilization monitoring relies on a combination of three methods to verify process efficacy.

- **Mechanical/Physical Monitoring:** This involves assessing the sterilizer's cycle time, temperature, and pressure by reviewing the gauges, displays, or computer printouts for each load. The operator verifies that all parameters meet the preset cycle requirements.
- **Chemical Monitoring:** Chemical indicators use heat- or chemical-sensitive inks that change color upon exposure to specific sterilization parameters.
    - External indicators are placed on the outside of each package to show that the item has been exposed to the sterilization process.

    - Internal indicators are placed inside each package in the area least accessible to the sterilant to verify its penetration.
    - Specialty Indicators: A specific type, the Bowie-Dick test, is used daily in dynamic-air-removal (prevacuum) steam sterilizers. It is not a sterility indicator but a test to ensure the vacuum pump is effectively removing air from the chamber, which is essential for proper steam penetration.
- **Biological Monitoring:** This is the most definitive method for assessing the lethality of a sterilization process. Biological Indicators (BI) contain a standardized population of highly resistant bacterial spores.
    - **Spore Type:** *Geobacillus stearothermophilus* spores are used for steam, hydrogen peroxide gas plasma, and peracetic acid. *Bacillus atrophaeus* spores are used for Ethylene Oxide and dry heat.
    - **Frequency:** Sterilizers should be monitored with a BI at least weekly and for every load that contains an implantable device.

Protocol for a Positive BI

A positive BI from a steam sterilizer requires immediate and systematic action.

1. Immediately take the sterilizer out of service.
2. Notify the department supervisor and the Infection Control department.
3. Review the mechanical and chemical indicators for the failed load. If they also suggest a failure, the entire load must be recalled and reprocessed.
4. If the physical and chemical indicators were acceptable, quarantine the sterilizer and repeat the BI test in three consecutive empty cycles.
5. If all three repeat BIs are negative, the sterilizer can be returned to service.
6. If any repeat BI is positive, the sterilizer must remain out of service until it has been inspected and repaired. All items processed since the last known negative BI must be recalled and reprocessed.
7. In the event of an infection breach the local and state health departments must be notified for additional guidance including additional testing and/or patient notification if necessary.

The Reprocessing Environment and Workflow [1-4]

The physical setting should be designed to support a one-way workflow from "dirty" to "clean" to prevent cross-contamination.

- **"Dirty" Area and Supplies**

        - Ideally, physically separate the "dirty" preprocessing area from the "clean" area.
        - Ensure a clear traffic flow pattern from soiled to clean.
        - Provide adequate space for device inspection.
        - Maintain negative air pressure relative to adjoining spaces in accordance with manufacturers' instructions for use.
        - **Required Supplies and Safety Equipment:**
            - Handwashing sink separate from reprocessing sink.
            - Readily available supply of appropriate Personal Protective Equipment (PPE).
            - Eyewash station within a 10-second travel distance of chemicals, with documented weekly maintenance.
            - Readily available spill kits and Safety Data Sheets (SDS) for all chemicals.
- **"Clean" Area**
    - Maintain positive air pressure relative to adjoining spaces.
    - Store disinfected and sterilized instruments in a manner that protects them from damage and recontamination.
    - For endoscopes, store them hanging vertically in a dedicated, clean, well-ventilated cabinet to facilitate drying and prevent damage.

Infection Prevention and Control Practices [3-4]

The reprocessing area requires attention to infection prevention and control practices to prevent cross-contamination and ensure safety.

1. Hand Hygiene

Proper hand hygiene is crucial throughout the reprocessing area, particularly when moving between contaminated and clean work spaces.

- **Dedicated Sinks**: Staff should have access to a handwashing sink that is separate from the reprocessing sink(s) used for cleaning devices.
- **Accessibility**: Hand hygiene stations, including soap and water sinks and alcohol based hand rub (ABHR), should be readily available throughout the reprocessing area.

2. PPE

The appropriate PPE must be used based on the task being performed, especially given the handling of hazardous chemicals and potentially infectious materials.

- **Availability**: A readily-available supply of PPE is required, including gloves, gowns, eye and face protection.
- **Decontamination Area**: PPE is required in the decontamination area where exposure to blood and other potentially infectious materials (OPIM) is likely.
- **Handling Chemicals**: PPE must be worn to preclude exposure to infectious agents or chemicals. Staff should use PPE to minimize skin or mucous membrane contact when handling hazardous chemicals.

3. Environmental Services

Environmental services are essential in reprocessing areas to prevent contamination and ensure that sterilization and high-level disinfection processes are effective.

- **Cleaning and Disinfection**: Routine cleaning is required, and prompt cleaning and decontamination of spills of blood or OPIM are mandated.
- **Surfaces:** Reprocessing surfaces must be smooth, made of cleanable materials, and durable enough to withstand frequent use of disinfectant solutions.
- **Chemical Safety**: An SDS must be readily available for all chemicals used in the area. Spill kits must also be readily available.
- **Eyewash Stations**: An eyewash station must be installed within a 10-second travel distance from where hazardous chemicals are used. Documentation of maintenance, such as flushing, should be maintained for eyewash stations.

Leadership and Program Management [1-4]

A successful reprocessing program requires visible and tangible support from all levels of leadership.

- **Leadership Accountability and Resource Allocation**
    - Ensure the governing body is accountable for the success of infection prevention and reprocessing activities.
    - Allocate sufficient human and material resources to support consistent, high-quality reprocessing and minimize infection risk.
    - Ensure staffing levels are adequate to allow for sufficient time to perform all reprocessing steps correctly, avoiding delays.
- **Program Oversight and Empowerment**
    - Assign qualified, trained individuals to manage the infection prevention and reprocessing program.

    - Empower and support the authority of those managing the program to ensure its effectiveness.
- **Policy Development and Review**
    - Develop reprocessing policies with a multidisciplinary team.
    - Ensure policies are written, based on evidence-based guidelines, and reviewed regularly.
    - Policies should address the selection, transport, cleaning, high-level disinfection/sterilization, and storage of all reusable equipment, including "loaner" instruments.

Personnel Training, Education,Competency and Certification 2-3, 5

All personnel involved in reprocessing must receive ongoing education, training, and competency assessments.

- **Initial and Ongoing Training**
    - Provide job-specific infection prevention training before personnel perform their duties and at least annually thereafter.
    - Training must be based on the manufacturer's instructions for each device, chemical, and piece of reprocessing equipment.
    - Include training on the rationale for each of the essential reprocessing steps.
- **Competency Assessment**
    - Develop processes to ensure all personnel are competent to adhere to requirements.
    - Conduct and document competency assessments:
        - Initially upon hire.
        - Periodically (e.g., annually).
        - Whenever new equipment, chemicals, or device models are introduced.
        - For each specific type of device reprocessed (e.g., different endoscope models).
- **Accessible Resources**
    - Ensure written, evidence-based policies and procedures are readily available to staff.
    - Ensure manufacturer's instructions for all equipment, devices, and chemicals are readily available in the reprocessing area.
- **Professional Certification**
    - Is a patient-safety investment.

- Represents the knowledge and skills of employees to properly clean, disinfect, and sterilize medical instruments to prevent the spread of infections.
- Builds professional credibility and a commitment to strengthen infection control excellence.
- Many healthcare organizations encourage and often require certification.

CDC Project Firstline [6]

Project Firstline is an easily accessible on-line learning platform that supports education for all healthcare workers. There are a variety of educational resources including videos, interactive scenarios, toolkits, and webinars to help meet the learning needs of all healthcare professionals. More information about Project Firstline can be found at the following link https://www.cdc.gov/project-firstline/about/index.html

Device-associated Infections [4]

Device-associated infections are a major concern in healthcare settings, resulting from the potential introduction of pathogens when medical devices contact a patient's non-intact skin, sterile tissue, mucous membranes, or the bloodstream.

Reprocessing Errors and Failures [1, 3-4]

When a reprocessing error or failure occurs, facilities must activate a protocol to mitigate the risk of disease transmission.

Protocol for Breach or Failure

- Facilities must have established policies and procedures detailing how to respond to reprocessing errors or failures, especially if equipment was used on a patient.
- A multi-disciplinary team, typically including infection prevention and control staff, reprocessing personnel, risk management staff and others as indicated, should review the event to determine necessary corrective steps and assess the risk of disease transmission.
- If a suspected breach of disinfection or sterilization procedures involves potential patient exposure, the decision to notify patients must be made in consultation with the facility leadership and state and local health departments.

- Any potential error or failure related to medical devices must be reported to the device manufacturer and the FDA MedWatch Safety Information and Adverse Event Reporting program.

Documentation and Tracing

- Comprehensive documentation is essential for quality assurance and patient tracing, particularly in the event of a reprocessing failure that necessitates a "look back".
- A log must be maintained that documents the instrument reprocessed, date, technician who performed the task, and results of all monitoring.
- Sterile packs must be labeled with a load number that identifies the sterilizer used, the cycle number, and the date of sterilization to ensure traceability.

Additional information regarding the West Virginia Office of Epidemiology and Prevention Services Infection Control Breach Referral Protocol can be found at the following link: https://oeps.wv.gov/media/571/download?inline

Special Considerations 1-4, 7-11

While standard sterilization protocols are effective for the vast majority of medical devices, certain instruments, materials, and infectious agents pose unique and significant challenges. These situations require specialized knowledge and adherence to reprocessing guidelines to ensure patient and staff safety.

Loaned Instruments

Loaned instruments, which are devices provided temporarily by manufacturers, equipment suppliers, or other healthcare facilities, must be managed under policies that ensure they meet the same reprocessing standards required for facility-owned equipment.

IUSS

This process, formerly known as "flash" sterilization, is a modification of conventional steam sterilization for items that are needed for immediate use and cannot be packaged, sterilized, and stored. IUSS is considered acceptable for processing cleaned patient-care items that will be used immediately, such as an instrument that is inadvertently dropped during a procedure. However, IUSS **should not be used** for reasons of convenience, as an alternative to purchasing additional instrument sets, or to save time.

Single-use Medical Devices

Single-use devices (SUDs) are medical items labeled by the manufacturer for use on a single patient during a single procedure and do not include instructions for reprocessing.

While the general standard is that SUDs should not be reprocessed, specific regulatory pathways exist for facilities that choose to reuse them.

- **Regulatory Status**: If a healthcare facility or third-party reprocessor elects to reuse a single-use device, the FDA considers that entity to be the manufacturer. Consequently, the facility is regulated under the same standards as the original equipment manufacturer.
- **Requirements**: To reuse an SUD, the reprocessing entity must comply with FDA regulatory requirements and receive FDA clearance to reprocess that specific device. The reprocessor must demonstrate that the device is as safe and effective as it was when new.
- **Verification**: Facilities utilizing third-party reprocessors should maintain documentation confirming that the reprocessor is registered with the FDA and cleared to process the specific devices in use.

Preventive Maintenance

Preventive maintenance of reprocessing equipment and medical devices is a foundational element of infection prevention. It ensures that the machinery used to clean and sterilize instruments functions correctly and that the medical devices themselves remain intact and safe for patient use. This process involves adherence to manufacturer instructions, documentation, and verification following repairs.

Supply of Equipment

Facilities must maintain a sufficient supply of equipment to allow adequate time for all reprocessing steps, including drying, to be correctly performed.

Contracted Procedural Services

Leadership bears the ultimate accountability for infection prevention and patient safety, a responsibility that mandates the allocation of sufficient human and material resources to ensure that the selection, use, and reprocessing of all medical equipment—including items managed by contracted service providers—meet regulatory and safety standards. Furthermore, administrators are responsible for empowering infection prevention programs to oversee these

external relationships and for ensuring robust documentation and response protocols are in place to address and investigate any reprocessing breaches or failures.

Surgical Attire Outside of Reprocessing Areas

Personnel who work in reprocessing areas should adhere to guidance concerning surgical attire, particularly when moving outside of their designated work zones.

General Guidance for Scrub Attire Outside the Facility

- Personnel should change into street clothes whenever they go outside of the building.

Attire Within the Reprocessing Area

- The Sterile Processing Department (SPD) is typically defined as a semi-restricted space.
- Surgical attire (scrubs) is generally recommended in all major areas of the SPD, including decontamination, high-level disinfection, assembly/packaging, sterilization, and sterile storage.

Handling Contamination and Movement

- If reprocessing staff are wearing surgical attire that has been penetrated by blood, body fluids, or OPIM, the attire must be removed immediately or as soon as possible and replaced with clean attire.
- In the decontamination area of the SPD, where exposure to blood and OPIM is likely, appropriate PPE is required.
- PPE, such as gowns, should be worn to protect skin and prevent the soiling of surgical attire during procedures or activities that could cause contact with blood, body fluids, secretions, or excretions.
- When a reprocessing staff member completes a task, disposable PPE should be removed and discarded before leaving the reprocessing area. This practice protects the environment and prevents the potential transmission of infections.

Reprocessing of Creutzfeldt-Jakob Disease (CJD) Contaminated Devices

CJD is a rare, fatal brain disorder caused by an abnormal infectious protein known as a prion. Prions are exceptionally resistant to conventional disinfection and sterilization procedures. Instruments used on high-risk tissues (e.g., brain, spinal cord, eye) of patients with known or suspected CJD require special handling. Since neurosurgical instruments pose the greatest risk of contamination due to the high burden of infectious proteins, procedures must ensure that transmission of these particles is minimized.

Disinfection and Sterilization of Dental Instruments

Ensuring the safety of dental instruments relies on meticulous reprocessing, encompassing both cleaning and sterilization or high-level disinfection, guided by the instrument's classification and manufacturer's instructions. Critical dental items, which penetrate soft tissue or bone (e.g., surgical burs, extraction forceps, periodontal scalers), have the highest risk of infection transmission and must be sterilized or discarded after each use. Semicritical items, which contact mucous membranes or non-intact skin (e.g., mouth mirrors, amalgam condensers, reusable impression trays), should also be heat sterilized if they are heat-tolerant. If a semicritical item cannot tolerate heat, it must, at a minimum, receive high-level disinfection. Notably, dental handpieces and associated attachments, even though considered semicritical, should be heat sterilized between patients due to the documented contamination of their internal surfaces during use. Thorough pre-cleaning is foundational, as debris and organic contamination like blood and saliva can shield microorganisms and compromise the effectiveness of the sterilization or disinfection process.

Central to a robust dental infection prevention program is sterilization monitoring, which uses a combination of mechanical, chemical, and BI to confirm the process effectively achieved sterilization conditions. Mechanical monitoring involves checking sterilizer gauges, displays, and printouts for appropriate pressure, temperature, and exposure time for every load. Chemical indicators should be used both externally (if the internal one is not visible) and internally in every package to verify the sterilizing agent penetrated and reached the instruments inside; if the expected color change did not occur, the instruments must not be used. Finally, biological monitoring, or spore testing, directly assesses the process's lethality by using highly resistant microorganisms and should be performed at least weekly to monitor sterilizers. Maintaining accurate mechanical, chemical, and biological records is an important component of the infection prevention program, ensuring accountability and aiding in recall if a sterilization failure, such as a positive spore test, occurs.

Sterilization of Ophthalmic Surgical Instruments

Adherence to specialty-specific guidelines for the cleaning and sterilization of intraocular surgical instruments is crucial for patient safety. The small volume of the eye and its acute sensitivity to contaminants mean that improper instrument cleaning or sterilization practices pose a significant risk to patients. Improper cleaning and sterilization is the most commonly identified cause of Toxic Anterior Segment Syndrome (TASS), a severe, sight-threatening inflammatory reaction.

TASS is defined as a rare ophthalmologic condition that results in an inflammatory reaction within the anterior chamber of the eye.

- **Cause and Pathogenesis**: TASS is caused when a chemical agent enters the anterior chamber of the eye during surgery.
- **Clinical Association**: It is commonly associated with cataract surgery, but it can occur subsequent to any anterior eye surgery.
- **Outcome**: If TASS is not treated properly, the inflammatory response that ensues can lead to severe visual impairment.

Disinfection and Sterilization for the Outpatient Podiatry Settings

The CDC's *Guide to Infection Prevention for Outpatient Podiatry Settings*, addresses the unique procedural risks inherent to foot and ankle care with the following points:

- **Procedural Risks:** Podiatry involves distinct infection risks, such as the generation of inhalational nail dust, the frequent use of reusable instrumentation (e.g., nippers, burrs, curettes), and invasive procedures performed on extremities often compromised by poor circulation or diabetes. Identifying hazards and implementing standard precautions to protect both patients and healthcare personnel is necessary to prevent outbreaks similar to those previously linked to podiatric care, including cases of *Proteus mirabilis*, methicillin-resistant *Staphylococcus aureus* (MRSA), and Hepatitis B.
- **Disinfection and Sterilization:** Podiatry relies heavily on reusable medical devices that are classified as critical or semicritical and require reprocessing in between uses.
    - Written policies for reprocessing are based on evidence-based guidelines and manufacturer instructions.
    - Purchasing decisions for new devices involve infection prevention consultation to ensure the facility has the capability to reprocess them correctly.
    - Sterilization monitoring is performed correctly, including the use of biological and chemical indicators, to prevent the use of contaminated instruments.
- **Management of Off-site Care Challenges:** Podiatrists frequently provide care in off-site settings, such as nursing homes or assisted living facilities, where maintaining sterile environments is challenging. Protocols should be established to ensure that the same standard of care is delivered regardless of location. This includes defining procedures for the safe transport of contaminated instruments and ensuring that proper hand hygiene and sharp disposal resources are available remotely.
- **Program Development and Auditing:** A comprehensive patient safety program should include:

    - **Tailored Policy Development**: Written policies that reflect the specific services and patient population of the facility.
    - **Risk Assessments**: Conducting annual facility risk assessments to prioritize resources and focus on high-risk areas.
    - **Surveillance and Auditing**: Using tools like the CDC's *Infection Prevention Checklist for Outpatient Podiatry Settings* to audit staff adherence to hand hygiene, PPE use, and environmental cleaning.
    - Competency Training: Education and competency-based training for staff, particularly regarding job-specific tasks like instrument cleaning and sterilization.
- **Outbreak Response and Reporting:** In the event of an infection breach or outbreak, the local and state health departments must be notified for additional guidance including additional testing and/or patient notification if necessary.

Links To Training

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