STERILIZATION OF REUSABLE MEDICAL DEVICES IN THE HEALTH CARE SETTING

1999

1999
STERILIZATION OF REUSABLE MEDICAL DEVICES IN THE HEALTH CARE SETTING

STUDY GUIDE

Disclaimer

AORN and its logo are registered trademarks of AORN, Inc. AORN does not endorse any commercial company's products or services. Although all commercial products in this course are expected to conform to professional medical/nursing standards, inclusion in this course does not constitute a guarantee or endorsement by AORN of the quality or value of such products or of the claims made by the manufacturers.

No responsibility is assumed by AORN, Inc. for any injury and/or damage to persons or property as a matter of product liability, negligence or otherwise, or from any use or operation of any standards, guidelines, recommended practices, methods, products, instructions, or ideas contained in the material herein. Because of rapid advances in the health care sciences in particular, independent verification of diagnoses, medication dosages, and individualized care and treatment should be made. The material contained herein is not intended to be a substitute for the exercise of professional medical or nursing judgment.

The content in this publication is provided on an "as is" basis. TO THE FULLEST EXTENT PERMITTED BY LAW, AORN, INC. DISCLAIMS ALL WARRANTIES, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OF THIRD PARTIES' RIGHTS, AND FITNESS FOR A PARTICULAR PURPOSE.

2170 South Parker Road, Suite 400
Denver, CO 80231-5711
(800) 755-2676
www.aorn.org

Video produced by Cine-Med.

Sterilization of Reusable Medical Devices in the Health Care Setting

TABLE OF CONTENTS

LEARNING OUTCOME

After completing this study guide and viewing the accompanying video, the perioperative registered nurse (RN) and other perioperative team members will have increased their knowledge of evidence-based, best practices for sterilizing surgical instruments. The perioperative RN and other health care team members will be able to apply these practices in the clinical setting to help minimize the risk for infections and to promote patient safety.

EDUCATIONAL OUTCOMES

The participant will be able to

- use the Spaulding classification to determine the required level of processing for reusable surgical instruments,
- remove gross soil from reusable surgical instruments and devices at the point of use,
- describe methods for sterilizing instruments,
- address health concerns related to exposure to sterilizing agents, and
- transport and store sterilized instruments.

INTRODUCTION

Surgical site infections (SSIs) are among the most common health care–associated infections, accounting for 31% of health care–associated infections among hospitalized patients.[1] As many as one in 20 surgical patients develops an SSI during hospitalization.[2] The Centers for Disease Control and Prevention estimated that 157,500 SSIs were associated with inpatient surgeries in 2011.[3]

Health care–associated infections can have serious consequences for patients and their families. Pain, increased use of antibiotics, longer hospital stays, and delayed wound healing caused by SSIs can all negatively affect patient outcomes.[2] The mortality rate associated with SSI is 3%.[3]

Surgical site infections are also associated with significant financial costs. A systematic review of literature published between 1998 and 2014 estimated an average treatment cost of between $10,433 and $25,546 for each SSI.[4] This translates to approximately $13,300 to $35,400 in 2018 dollars.[1] The cost of treating an SSI can exceed $90,000 if it involves a prosthetic joint or an antimicrobial-resistant organism.[4]

An important factor in the prevention of SSIs is the use of sterile devices for surgical and other invasive procedures. Sterilizing instruments is a multistep process. It begins with the removal of gross soil at the point of use and continues thorough cleaning; decontamination; inspection; packaging; and, finally, the process of sterilization itself. Each step of the process is critical for ensuring the sterility of items ultimately delivered to the sterile field for use on patients.[1]

This study guide and the accompanying video provide guidance for sterilizing reusable medical devices to perioperative RNs, other perioperative health care and service providers, sterile processing department team members, and team members of other departments in which invasive procedures are performed.[1]

INSTRUMENT CLASSIFICATIONS AND LEVELS OF PROCESSING

Many different types of reusable medical instruments are commonly used for surgery and other invasive procedures. There are also several different methods for processing reusable instruments. Select the appropriate method of processing for each device based on its intended use.[1]

Classification of Instruments

Reusable medical devices are typically classified as critical, semicritical, or noncritical according to the Spaulding classification system. Items that enter sterile tissue or the vascular system are classified as critical items. Critical items must be sterilized because they pose a high risk for spreading infection if they are contaminated. Common examples of critical items include surgical instruments, implants, and cardiac and urinary catheters. Steam sterilization is the preferred method for sterilization. Liquid chemical sterilants require considerably longer periods to achieve sterilization, and devices cannot be wrapped during processing. Only heat-sensitive critical devices incompatible with other methods of sterilization should be processed with liquid chemical sterilants.[5]

Patient Contact	Examples	Device Classification	Minimum Disinfection Level
Intact Skin		Non-Critical	Low Level or Intermediate Level Disinfection
Mucous Membranes or non-intact skin		Semi-Critical	High Level Disinfection
Sterile areas of the body, vascular system		Critical	Sterilization

Source: *Healthcare Purchasing News* (June 2014)

Items that come into contact with mucous membranes or nonintact skin are classified as semicritical items.[5] Semicritical items require a minimum of high-level sterilization using chemical disinfectants.[5] Sterilize semicritical items if they are validated for sterilization by the manufacturer.[1] All microorganisms must be eliminated, although some residual bacterial spores are not harmful.[5] Intact mucous membranes are generally resistant to infection by common bacterial spores.[5] However, emerging evidence shows that some pathogens can survive high-level disinfection, so semicritical items processed with high-level disinfection may pose a higher risk for spreading infection than sterilized items.[1] Examples of semicritical items include anesthesia equipment, gastrointestinal endoscopes, and bronchoscopes.[5]

Items that come into contact with intact skin, but not mucous membranes are classified as noncritical items. Intact skin is generally protective against most microorganisms, so sterility is not required. Noncritical items can be cleaned using intermediate-level and low-level disinfection. Examples of noncritical items are blood pressure cuffs and environmental surfaces.[5]

Always follow the manufacturer's instructions for use (IFU) when sterilizing reusable medical devices. This includes IFUs from the manufacturers of the device itself, the sterilization equipment, and the packaging materials. Items cannot be assumed to be clean or sterile unless the manufacturers' IFU are followed. The IFU should be readily accessible to personnel who perform sterile processing. If IFU from the device manufacturer, packaging manufacturer, and sterilizer manufacturer conflict, the device manufacturer's IFU should be followed. Device manufacturers perform validation studies to determine sterilization parameters required to achieve sterility for their specific device. Sterilizing and packaging manufacturers may not have validated parameters for every surgical device.[1]

Levels of Processing

Sterilization destroys all microorganisms, including bacterial spores.[5,6] Methods of sterilization include steam, dry heat, ethylene oxide gas, hydrogen peroxide gas plasma, ozone, hydrogen peroxide vapor, and some chemical sterilants.[5,6] The time required to achieve sterilization varies depending on the method.[5]

High-level disinfection destroys all microorganisms except for high numbers of bacterial spores. Methods include pasteurization and some chemical sterilants.[5]

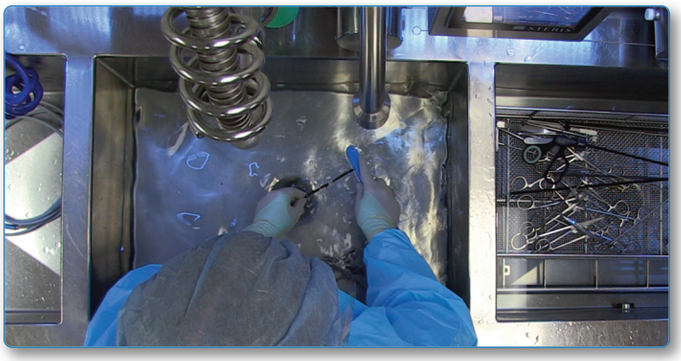
Intermediate-level disinfection destroys vegetative bacteria, mycobacteria, most viruses, and most fungi, but not bacterial spores. Intermediate-level disinfection can be performed with an Environmental Protection Agency (EPA)-registered hospital disinfectant that includes a claim regarding tuberculocidal activity on the label.[5]

Low-level disinfection destroys vegetative bacteria, some fungi, and some viruses, but not mycobacteria or bacterial spores. Low-level disinfection can be performed with an EPA-registered hospital disinfectant with no tuberculocidal claim or with 70% to 90% alcohol.[5]

CLEANING

Clean and decontaminate instruments as soon as possible after use. Moisten and remove gross soil at the point of use to prevent drying of blood and to limit the formation of biofilm. Blood or other bioburden can be difficult to remove from instruments that are allowed to dry. The effectiveness of sterilization or disinfection can be compromised if instruments are not thoroughly cleaned. Blood and organic material can also cause corrosion, rusting, and pitting if allowed to dry on surgical instruments.[7]

Clean and decontaminate all instruments opened onto the sterile field, regardless of whether they were used. Scrubbed team members may touch and contaminate instruments on the sterile field without being aware of it, and used instruments may come into contact with unused instruments. Contamination of unused instruments can easily occur without anyone noticing.[7]



Open and disassemble instruments composed of more than one piece to ensure that cleaning solutions make contact with all surfaces. Instruments cannot be thoroughly cleaned if contact with all surfaces is inhibited, and improperly cleaned instruments cannot be adequately sterilized or disinfected.[7]

When preparing used instruments for transport to the designated decontamination area, separate sharp instruments from other instruments and place them in puncture-resistant containers.[8] Separating and containing sharp instruments reduces the risk for injury to the personnel handling the instruments during cleaning and decontamination.[7] Protect delicate instruments (eg, fiberoptic cords, microsurgical instruments) during transport to the decontamination area by placing them on top of heavier instruments or placing them in separate containers.[7]

LOCATIONS FOR STERILIZATION

Sterilization should be performed in an area specifically intended, designed, and equipped to carry out sterilization processes. Requirements for sterilization do not change for different locations. Satellite processing areas should be functionally equivalent to the central processing area, with the same requirements for personnel, environments, procedures, supplies, equipment, and quality assurance measures.[1]

Sterilizers should be located in a clean work area or room with restricted access.[1,9] Sterilization should not be performed in an operating room or procedure room.[1] It is important to physically separate patient care areas from sterile processing areas to minimize the risk for cross contamination.[1] Sterilizers should also be physically separated form high-traffic hallways, sinks, containers for linens and trash, or any other potential source of contamination.[1]

Sterile processing areas should have cleaning and decontamination areas separated by a wall with a door or pass-through, a partial wall or partition at least 4 ft high, or a distance of at least 4 ft between the instrument-washing sink and the area used to prepare instruments for sterilization.[1,9] The area should have separate sinks for washing hands and washing instruments and should contain decontamination equipment and storage space for personal protective equipment and cleaning supplies.[1]

Functional workflow and traffic patterns should be established to create and maintain physical separation between the decontamination and sterilization areas and to define requirements for access, movement of personnel, and attire. Control of traffic patterns can help to protect personnel, equipment, supplies, and instruments from sources of potential contamination. Functional workflow patterns should begin in the cleaning and decontamination area and flow through preparation and packaging to sterilization processing and, finally, to sterile storage and the point of use. A functional workflow pattern can help to prevent clean or sterile items from reentering a contaminated area.[1]

METHODS OF STERILIZATION

Saturated Steam Under Pressure

Saturated steam sterilization is the preferred method of sterilization for heat- and moisture-stable items that have been validated for this method, unless otherwise indicated by the manufacturer. It is reliable, consistent, effective, and inexpensive with a large margin of safety. Steam sterilizes most porous and nonporous materials relatively rapidly.[1]

Steam sterilizers come in a variety of sizes, capacities, and designs. When operating a steam sterilizer, always follow the manufacturer's IFU for that specific sterilizer. Air removal is critical for steam sterilization. The medical device manufacturer's IFU may recommend a specific type of cycle or specify cycle parameters than must be achieved based on validation of a specific method for air removal.[1]

Packages containing phacoemulsification hand pieces may be sterilized in an upright position to allow for free drainage of the channel during steam sterilization unless the manufacturer's IFU specifies a different position. Evidence indicates this position helps to achieve optimal sterilization conditions (ie, steam contact) in the middle of the hand piece channel.[1]

After steam sterilization, remove the rack containing the sterilized items from the chamber, and then leave it untouched until the items cool. At the end of a steam sterilization cycle, a package may contain moisture that migrates out of the package as water vapor during cooling. Touching the package at this time may create a moist area that can act as a wick and draw bacteria from the hands. The time required for cooling can vary depending on the temperature of the items at the end of the cycle; the density and composition of materials; the packaging material; the availability of heating, ventilation, and air conditioning in the cooling area; and the ambient temperature

and humidity. Higher-density items retain more heat and may require more time to cool. Containers made of plastic may require extended cooling times to ensure moisture is removed from the container. The temperature of sterilized items may be measured with a calibrated infrared thermometer or similar device.[1]

Ensure sterilized items are cool before using them in patient care to prevent potential thermal injuries. This is particularly important when using items processed by immediate use steam sterilization. Items that are only warm to the touch can still cause thermal injuries if they are applied with pressure or remain in contact with the patient for an extended period.[1]

Do not place warm or hot items on cool or cold surfaces. Placing hot and cold objects together can cause moisture to condense inside and outside the package. This can compromise the integrity of packaging materials and the sterility of the package contents. It the sterilizer has a sterilization rack, allow items to cool on the rack.[1]

Inspect packages for integrity, moisture, and appropriate changes in the chemical indicator on the outside of the package when removing items from the cooling rack. Resterilize the items if there is any question about their sterility.[1]

Loads or packages found wet after a complete terminal sterilization cycle that includes drying may indicate a problem with the steam supply, sterilizer function, or load configuration. Investigate any wet loads or wet packs and take necessary corrective action. Investigation should include the

- date and time of the load,
- load configuration,
- number and description of trays reported as wet,
- cycle parameters,
- type of sterile barrier system used,
- personnel who packaged the items,
- contents of the tray,
- configuration of the tray,
- weight of the tray, and
- sterilizer performance.[1]

Immediate Use Steam Sterilization

Immediate use steam sterilization (IUSS) should only be used if all the following criteria are met:

- The device and sterilizer manufacturers' written IFU both include instructions for IUSS.

- The device manufacturer's written instructions for cleaning, cycle type, exposure times, temperature settings, and drying times are readily available and followed.
- Items are placed in a containment device that has been validated for IUSS and cleared by the US Food and Drug Administration (FDA) for this purpose.
- Items are placed in a manner that allows steam to contact all surfaces of the instrument.
- The written IFU from the rigid container manufacturer are followed.
- Measures are taken to prevent contamination during removal from the sterilizer and transfer to the sterile field.[1]

The same processing steps, including cleaning, decontaminating, and transporting sterilized items, should be followed regardless of the sterilization cycle used. Avoid eliminating or modifying critical steps in the process, regardless of time pressures. Abbreviating, modifying, or omitting critical steps places patients at risk for surgical infections.[1]

Items processed by IUSS should be used immediately, not stored for future use, and not held from one procedure to another. Immediate use steam sterilization should not be used for implantable devices except in emergencies when no other option is available.[1]

Low-Temperature Hydrogen Peroxide

Some medical devices may be damaged by exposure to the high temperatures associated with steam sterilization. Sterilization methods using low-temperature hydrogen peroxide (eg, vapor, gas plasma combination, ozone combination) should be used for items sensitive to heat and moisture when indicated by the device manufacturer. Different models of hydrogen peroxide sterilizers with different chamber sizes and cycles are available. Each model has

specific operating instructions and limitations on the types of items that may be sterilized. Always follow the manufacturer's IFU for operation, monitoring, and maintenance. Failure to follow the manufacturer's IFU can damage the sterilizer, fail to achieve sterility in processed items, or expose personnel to chemical sterilants.[1]

Ensure items to be sterilized are clean, thoroughly dry, and packaged in sterilization wraps, pouches, trays, or containers approved by the FDA for use in hydrogen peroxide sterilizers. Liquids, powders, and paper-based packaging materials are not suitable for low-temperature hydrogen peroxide gas plasma sterilization. Excess moisture can decrease the effectiveness of some gaseous chemical sterilants.[1]

Follow the IFU from the sterilizer and device manufacturers when placing items in the sterilizer chamber. Correct placement helps ensure contact between the items and the sterilant.[1]

Items processed using low-temperature hydrogen peroxide do not require additional aeration because the residuals and by-products are oxygen and water.[1]

Peracetic Acid

SYSTEM1® Liquid Chemical Sterilant Processing System. Reprinted with permission from STERIS Corporation.

Peracetic acid is an oxidizing agent and effective biocide at low temperatures. In FDA-approved products, it is effective in the presence of organic matter. Instrument processing systems that use peracetic acid may be used for devices that can be immersed, are approved for this type of sterilization by the device manufacturer, and cannot be sterilized using terminal sterilization methods.[1]

Items that have not been validated for a liquid peracetic acid sterilant processing system may not be compatible with the sterilant or the process, which may result in damage or ineffective sterilization. Always follow the manufacturer's written IFU for operation, monitoring, and maintenance. Verify the correct selection of adapters, and connect the device to the adapters as recommended by the manufacturers of both the device and the processing system to ensure proper contact between the liquid sterilant and the lumen of the sterilized item.[1]

Items processed in liquid chemical sterilant systems should be transported to the point of use immediately and should not be stored for later use or held from one procedure to another.[1]

3M™ Steri-Vac™ Sterilizer/Aerator GS8-1D©

Ethylene Oxide

Sterilization processes based on ethylene oxide are effective for sterilization of items sensitive to moisture and heat, when used according to both the device and sterilizer manufacturers' IFU.[1]

Risk of inhalation is highest when the chamber has not been aerated.[1] For this reason, the EPA requires hospitals and health care facilities to use a single-chamber process that combines sterilization and aeration in a single unit.[1,10] Items sterilized with ethylene oxide may not be transferred to a separate aerator.[1] Aeration is intended to reduce vapors and residue to safe levels.[1] Some manufacturer's IFU call for extended aeration times.[1] Do not open the sterilizer chamber or handle the load contents until aeration is complete.[1]

Select sterilizer cycle parameters according to sterilizer and device manufacturers' IFU. Factors influencing cycle parameters include the size and composition of items, preparation and packaging, density of the load, and the type

of sterilizer and aerator. Ensure all items, including item lumens, are clean and dry before packaging them for sterilization. Soil on items can inhibit sterilization. Ethylene oxide reacts with water and can form toxic by-products. Use baskets or loading carts when placing items in ethylene oxide sterilizers to allow for free circulation and penetration of the sterilant.[1]

Dry Heat

Dry heat sterilization is a slow process that kills microorganisms by direct heat transfer. Items that are impenetrable to moist heat and that can withstand the high temperatures involved may be sterilized with this method when indicated by the device manufacturer. Dry heat sterilizers vary in design and performance characteristics. Always follow the manufacturer's written IFU for operation, monitoring, and maintenance.[1]

Use only packaging and container materials validated to withstand high temperatures. Packaging material that has not been validated for high temperatures may char and compromise the integrity of the sterile items. Most types of tape are not designed for the temperatures required for dry heat sterilization. The adhesive may melt, resulting in loss of adhesion and sticky or baked-on residues.[1]

Place items within the sterilizer chamber according to the manufacturer's IFU. Correct placement of items facilitates effective sterilization.[1]

When a dry heat sterilization cycle is completed, both the sterilizer chamber and the items within are very hot. Do not touch them or remove them from the sterilizer until they have cooled.[1]

HEALTH CONCERNS FOR EXPOSURE TO STERILIZING AGENTS

Exposure to hydrogen peroxide can potentially have the following effects:

- Hydrogen peroxide is corrosive to skin, eyes, and mucus membranes at concentrations >10%.
- Eye contact can result in ulceration or perforation of the cornea.
- Contact with skin can cause irritation and temporary bleaching and may cause severe burns with blisters.
- Vapors, mists, or aerosols of hydrogen peroxide can cause upper airway irritation, inflammation of the nose, hoarseness, shortness of breath, and a sensation of burning or tightness in the chest.
- Inhalation of high concentrations can result in severe mucosal congestion of the trachea and bronchi and delayed accumulation of fluid in the lungs.
- Survivors of severe inhalational injury may sustain permanent lung damage.[1]

The Occupational Safety and Health Administration (OSHA) sets a limit of 1 part hydrogen peroxide per 1 million parts air (1 ppm) average airborne exposure in the workplace for any 8-hour work shift in a 40-hour work week.[11]

Ozone is available as an FDA-cleared sterilant in combination with hydrogen peroxide.[1] Exposure to ozone can result in headaches, dryness of the throat and mucus membranes of the nose and eyes, and reduced pulmonary function.[1] The OSHA limit for ozone exposure is 0.1 ppm average airborne exposure in the workplace for any 8-hour work shift in a 40-hour work week.[11]

Potential effects of exposure to peracetic acid include

- inflammation and occasionally blistering of the skin, with burns and ulcerations from prolonged exposure;
- lacrimation and extreme discomfort and irritation of nasal membranes;
- red, watering, and itching eyes;
- toxic effects to blood, kidneys, lungs, liver, mucus membranes, heart, cardiovascular system, upper respiratory system, skin, eyes, central nervous system, and teeth; and
- general deterioration of health by accumulation in one or many organs caused by repeated or prolonged exposure.[1]

The American Conference of Governmental Industrial Hygienists recommends a limit for peracetic acid of 0.4 ppm average airborne exposure in the workplace for any 8-hour work shift in a 40-hour work week.[1,11]

Ethylene oxide is a known carcinogen.[1] Potential health hazards of ethylene oxide, in addition to risk for cancer, include the following:

- Inhaling ethylene oxide at high concentrations can cause nausea, vomiting, and neurological disorders.
- Ethylene oxide in solution can severely irritate and burn skin, eyes, and lungs.
- Ethylene oxide may damage the central nervous system, liver, and kidneys.
- Ethylene oxide may cause cataracts.
- Ethylene oxide is extremely reactive and flammable, increasing risk of chemical accidents. Static electricity can cause ignition.

- Emission into the atmosphere can cause community exposure.[1]

The OSHA limit for ethylene oxide is 1 ppm average airborne exposure in the workplace for any 8-hour work shift in a 40-hour work week.[11]

Health care organizations are required by OSHA to establish a program for monitoring occupational exposure to ethylene oxide. Personnel with potential for exposure should wear ethylene oxide–monitoring badges. Documentation of employee monitoring must be maintained in an employee's health record for the duration of employment and for an additional 30 years after employment ends.[1]

Burns are the most common hazard associated with dry heat sterilization. Always use appropriate personal protective equipment (eg, insulated gloves, transfer handles).[1]

TRANSPORTING STERILE ITEMS

Protect sterile items from contamination, damage, or tampering during transport to a designated storage area or to the point of use. Mishandling or tampering with sterile packages can damage their integrity. Control of conditions during transport and storage reduce the risk for contamination and damage.[1]

Contain sterile packages in a sterile barrier system during transport. Sterile barrier systems are designed to protect the contents of the package from contamination until the item is used. Cover or enclose transport carts and bins. Covering or enclosing carts and bins helps to protect sterile items during transport. Carts should have solid bottom shelves to protect the packages from contaminants on the floor. Transport carts, containers, and reusable covers should be fluid resistant and should be cleaned and disinfected after each use.[1]

Keep sterile items separated from contaminated items, trash, and food during transport, to minimize potential contamination of the sterile items.[1]

STORING STERILE ITEMS

Store sterile items in a controlled environment and under controlled conditions. Handling, air movement, humidity, temperature, and dust can contribute to contamination. Limiting exposure of sterile items to these factors decreases the potential for contamination and degradation.[1]

Store sterile items in a manner that protects the integrity of the sterile barrier system. Keep racks, bins, and containers clean and dry on shelving that allows air circulation and ease of environmental cleaning. Shelves, racks, and cabinets in a sterile storage room may be closed or open. The bottom shelf of an open shelving unit should be solid. Use closed cabinets or covered carts for sterile items stored outside a designated sterile storage room. Do not store sterile items under sinks or in other areas where they might become wet.[1]

Access to sterile supply areas should be limited to authorized personnel.[1]

Health care organizations should establish processes for determining the shelf life of sterilized items. The shelf life should be event-related unless otherwise specified by the expiration date on the label from the packaging system's manufacturer. Events that could compromise the sterility of a package include multiple incidents of handling, leading to seal breakage or loss of package integrity; penetration by moisture; and exposure to airborne contaminants.[1]

QUALITY

Health care organizations should establish quality assurance and performance improvement programs to evaluate and monitor sterilization processes in all areas of the facility where sterilization is performed. Quality assurance and performance improvement programs can help to identify problems and assist team members in evaluating and improving the quality of patient care and in formulating plans for corrective action. These programs can also provide data that an organization can

use to determine whether benchmark goals are being met. Quality management programs provide mechanisms for evaluating the effectiveness of programs, compliance with manufacturers' IFU, sterilization policies and procedures, and function of equipment.[1]

Health care organizations should appoint interdisciplinary teams that have the responsibility and authority to implement quality assurance and performance improvement programs related to sterilization processes.[1]

Monitoring is a critical component of quality assurance. Failure to follow recommended practices can compromise the quality of sterilization. Chemical, physical, and biological indicators should be used to monitor sterilization processes. External and internal chemical indicators specific for the sterilization method should be used with each package to verify that conditions necessary for sterilization have been achieved within each specific package. A chemical indicator with a passing result does not guarantee sterility, rather it identifies that conditions for sterilization have been met in that location in the sterilized container; a failing result can identify procedural errors or sterilization equipment malfunctions.[1]

Internal indicators should be read before the tray or items are placed on the sterile field. If there is any question of inadequate processing, the items should not be used.[1]

Use biological indicators specific to each sterilization method and exposure time. Biological indicators are used to monitor sterilizer efficacy and are intended to demonstrate whether the conditions within the sterilizer, specific to the sterilization method, were adequate to be lethal to resistant spores. Testing with biological indicators should be performed weekly at a minimum, and preferably each day the sterilizer is used for steam and dry heat sterilizers. Low-temperature sterilization processes should be tested more frequently. An interdisciplinary team should determine the frequency for testing. Positive biological indicator results should be reported immediately and corrective action taken.[1]

Include a biological indicator with all loads containing implants. Quarantine the implants until the results of the biological indicator are known.[1]

Review physical monitors (eg, time, temperature, pressure, humidity, sterilant concentration) at the end of each cycle. Verify that all sterilization parameters were met for every cycle and every sterilization method.[1]

Facility engineering personnel should monitor and control the steam supply system to steam sterilizers with volumes greater than 2 cubic feet.[1]

Sterilizer Failures

Investigate, document, and report all sterilizer failures (eg, wet packs, failed chemical or physical indicators) to the affected department (eg, operating room, emergency department), an infection preventionist, the quality assurance or risk management department, and through the organizational chain of command. Take immediate corrective actions in cases of sterilizer failure.[1]

The interdisciplinary team should investigate sterilization failures in a standardized format, which can include actions to

- immediately quarantine any potentially affected items;
- remove the affected sterilizer from use until function is restored and qualification testing is completed;
- confirm the process failure (eg, rule out false positive);
- inform key stakeholders;
- conduct a complete and thorough investigation of the cause of failure;
- prepare a list of potentially exposed patients;
- assess the effect of the failure on patients' risk for infection;
- notify regulatory agencies, if required;
- develop a detailed plan to prevent similar failures in the future; and
- complete an after-action report.[1]

Environmental Impact

Health care organizations should assess the environmental impact of sterilization processes and equipment. An interdisciplinary team should evaluate the environmental impact of decisions regarding purchase and use of sterilization equipment.[1] Some organizations have achieved cost savings by implementing a strategy for shutting down idle steam sterilizers.[12]

Leadership

Health care organizations should assign responsibility and authority for leadership of the sterile processing team to qualified personnel. Leaders should be knowledgeable about sterilization processes, monitor adherence to professional standards and regulatory requirements related to sterilization, provide oversight for systematic data collection and surveillance, maintain safe working conditions for personnel, and maintain a staffing plan for sterilization personnel.[1]

SUMMARY

Using sterile instruments during surgical and other invasive procedures is important for preventing SSIs. Only personnel with documented competency should perform tasks related to sterilization, and perioperative teams must engage in interdisciplinary collaboration to ensure sterilization is performed correctly. Team members in the perioperative setting, in the sterile processing department, and in every department where invasive procedures take place play a role in ensuring that all critical, and when possible semi-critical, reusable medical devices are properly sterilized. Conscientiously following the steps and protocols for cleaning, decontamination, and sterilization reduces the risk for infection and improves outcomes for the patients in our care.

REFERENCES

1. Guideline for sterilization. In: *Guidelines for Perioperative Practice*. Denver, CO: AORN, Inc; 2019:973-1002.
2. Tanner J, Dumville JC, Norman G, Fortnam M. Surgical hand antisepsis to reduce surgical site infection. *Cochrane Database Syst Rev.* 2016;(1):CD004288.
3. Surgical site infection (SSI) event. Centers for Disease Control and Prevention. https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf. Accessed June 25, 2019.
4. Berrios-Torres SI, Umscheid CA, Bratzler DW, et al. Centers for Disease Control and Prevention guideline for the prevention of surgical site infection, 2017. *JAMA Surg.* 2017;152(8):784-791.
5. Rutala WA, Weber DJ. Disinfection and sterilization: an overview. *Am J Infect Control.* 2013;41(5 Suppl):S2-S5.
6. Guideline for disinfection and sterilization in healthcare facilities, 2008: update May 2019. Centers for Disease Control and Prevention. https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf. Accessed June 25, 2019.
7. Guideline for cleaning and care of surgical instruments. In: *Guidelines for Perioperative Practice*. Denver, CO: AORN, Inc; 2019:401-440.
8. Guideline for sharps safety. In: *Guidelines for Perioperative Practice*. Denver, CO: AORN, Inc; 2019:869-896.
9. Guideline for design and maintenance of the surgical suite. In: *Guidelines for Perioperative Practice*. Denver, CO: AORN, Inc; 2019:73-104.
10. Ethylene oxide (ETO): hospitals and healthcare facilities must use a single chamber when sterilizing medical equipment with ETO. US Environmental Protection Agency. https://archive.epa.gov/pesticides/reregistration/web/html/ethylene_oxide_fs.html. Published March 2010. Accessed July 17, 2019.
11. OSHA occupational chemical database. Occupational Safety and Health Administration. https://www.osha.gov/chemicaldata/. Accessed June 25, 2019.
12. McGain F, Moore G, Black J. Hospital steam sterilizer usage: could we switch off to save electricity and water? *J Health Serv Res Policy.* 2016;21(3):166-171.

POST-TEST

STERILIZATION OF REUSABLE MEDICAL DEVICES IN THE HEALTH CARE SETTING

Multiple choice. Please choose the word or phrase that best completes the following statements.

1. Which level of instrument processing is able to destroy all microorganisms, including bacterial spores?
   a. High-level disinfection
   b. Intermediate-level disinfection
   c. Low-level disinfection
   d. Sterilization
   e. All of the above
2. According to the Spaulding classification, which item would be classified as "critical" for purposes of determining the level of sterilization, disinfection, and processing?
   a. Anesthesia laryngoscope
   b. Blood pressure cuff
   c. Bronchoscope
   d. Surgical instrument tray
3. Which instruments on a sterile field should be cleaned and decontaminated after a surgical procedure?
   a. All instruments opened onto the sterile field
   b. Only instruments touched by the scrubbed team
   c. Only instruments used in the procedure that show visible signs of contamination
   d. Only instruments used in the procedure or that come into contact with a used instrument
4. Why is steam sterilization the preferred method for sterilizing reusable heat- and moisture-stable items, assuming the items are manufacturer-validated for sterilization by this method?
   a. It is inexpensive.
   b. It is reliable, consistent, and effective with a large margin of safety.
   c. It sterilizes most porous and nonporous materials relatively rapidly.
   d. All of the above
5. Which of the following statements about allowing instruments to cool after steam sterilization is most accurate?
   a. Higher-density items may require extended cooling times.
   b. Higher-density items cool more rapidly.
   c. Items are cool enough for use on patients if they are warm, but not hot, to the touch.
   d. Items can be monitored for cooling by touching their packaging periodically.
   e. Items can be placed on a cold surface to facilitate more rapid cooling.
6. Which of the following types of instruments are suitable for immediate use steam sterilization (IUSS)?
   a. Implantable devices
   b. Items that may be held from one procedure to another
   c. Items to be stored for future use
   d. Items to be used immediately
   e. All of the above
7. Which of the following sterilizing agents is a known carcinogen?
   a. Ethylene oxide
   b. Hydrogen peroxide
   c. Ozone
   d. Peracetic acid
   e. All of the above
8. Carts used for transportation of sterile items should be cleaned and disinfected
   a. after every use.
   b. daily.
   c. weekly.
   d. monthly.

9. Which of the following statements about storage of sterile items is accurate?
   a. Shelving in sterile storage areas should allow air circulation.
   b. Sterile items should not be stored under sinks.
   c. Sterile items stored outside of designated sterile storage rooms should be kept in closed cabinets or covered carts.
   d. The bottom shelf of open shelving units should be solid.
   e. All of the above

10. Which of the following statements about the use of biological indicators to monitor sterilization processes is accurate?
   a. Loads with implants should always include biological indicators.
   b. Low-temperature sterilization processes require less frequent monitoring than steam sterilization.
   c. Steam sterilizers should be tested with biological indicators monthly.
   d. The same standardized indicators should be used for all sterilization methods.

POST-TEST ANSWERS

STERILIZATION OF REUSABLE MEDICAL DEVICES IN THE HEALTH CARE SETTING

1. d
2. d
3. a
4. d
5. a
6. d
7. a
8. a
9. e
10. a