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Learning Objectives

1. *Discuss the need for following best practice guidelines on reprocessing of reusable medical devices in any surgical setting.*
2. *Describe national resources for standards, recommendations and guidelines relating to medical device reprocessing.*
3. *Explain the reason for following the manufacturer's written validated instructions for use.*
4. *State why immediate-use steam sterilization should be avoided and/or used with caution.*

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SELF-STUDY SERIES *Sponsored by* 3M Health Care

Reprocessing in the ambulatory surgery setting

by Rose Seavey MBA, BS, RN, CNOR, CRCST, CSPDT

In the last thirty plus years healthcare has had a major shift from the acute, inpatient hospital setting to ambulatory settings. Today, over three fourths of surgical procedures are performed in outpatient settings such as freestanding or hospital based ambulatory surgery centers (ASC), physician offices and other dedicated settings.[1]

Any patient having surgery or an invasive procedure has a right to efficient and safe care, including medical device reprocessing, no matter where that care is provided. Unfortunately, long-standing best practices in reprocessing reusable medical devices are not always followed. This has resulted in reprocessing of reusable medical devices becoming a big focal point for regulatory and accreditation surveys. One of the major focuses of the Centers for Medicare and Medicaid Services (CMS) and The Joint Commission (TJC) is prevention of healthcare associated infections (HAI).[2,3] The Joint Commission's National Patient Safety Goals includes implementing evidence-based practices for preventing surgical site infections (SSI).[4]

The need for efficient, effective reprocessing procedures

Recently there have been many reports of patients in jeopardy of serious infection resulting from reusable medical devices that were inadequately cleaned, sterilized, or disinfected.[5] According to reports in the media, the large outbreaks do not appear to be in hospitals, but rather ambulatory settings.

"Dirty instruments have been showing up in hospitals and outpatient surgery centers with disturbing regularity. In 2009, the Department of Veterans Affairs admitted that 10,737 veterans in Florida, Tennessee and Georgia were given endoscopies or colonoscopies between 2002 and 2009 with endoscopes that may have been improperly cleaned. Some of those patients later tested positive for HIV, hepatitis C, or hepatitis B. Several lawsuits filed against the VA by veterans are currently working their way through the courts, and attorneys expect many others to follow. Investigation of a 2008 hepatitis C outbreak that sickened at least six people in Las Vegas revealed that an outpatient surgery center was improperly cleaning endoscopes and reusing biopsy forceps designed for a single use. Following that outbreak, a Centers for Medicare and Medicaid Services (CMS) pilot program inspected 1500 outpatient surgery centers and cited 28 percent for infection control deficiencies related to equipment cleaning and sterilization."[6]

CMS found many lapses in equipment reprocessing which included:

- Single-use devices inappropriately reprocessed
- High-level disinfectants (HLD) not prepared, tested, or replaced appropriately
- Instruments not precleaned prior to sterilization or HLD
- Monitoring devices (chemical and biological indicators) not appropriately used in sterilizer loads.[7]

Assign dedicated infection preventionist

Reprocessing areas differ in their physical design, location, equipment, and in the level of personnel expertise, competence and training. Smaller facilities sometimes find it challenging to meet all these big regulations with their limited resources.

According to the Centers for Disease Control and Prevention (CDC), ASCs and other ambulatory care settings do not always have sufficient or dedicated resources to support infection prevention and surveillance activities. Therefore, it is now recommended that every outpatient setting have at least one individual with training as a dedicated Infection Preventionist (IP).[1]

The IP should be employed by or regularly available to the facility. The IP should be involved in the development and ongoing improvement of IP policies (including medical device reprocessing policies) that are based on regulations, evidence-based guidelines, and national published standards.[1]

Reference national standards and guidelines in your policies

The main evidence-based and /or professional guideline documents that every IP, Operating Room (OR) and reprocessing professional in the healthcare organization should have access to are:

- The Association for periOperative Registered Nurses (AORN) *Perioperative Standards and Recommended Practices*, 2012
- The Association for the Advancement of Medical Instrumentation's (AAMI) *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012
- The CDC's Guideline for Decontamination and Sterilization in Healthcare Facilities which was last published in 2008
- The CDC's Guide to Infection Prevention For Outpatient Settings: Minimum Expectations for Safe Care, 2011

These documents are regularly updated to reflect the most current research and expert opinions resulting in best practices, so it is critical that the most current editions are obtained. It is essential that all reprocessing policies and procedures (P&P) be developed and referenced using the most current published recommended standards and guidelines.

Keeping up with new technologies in reprocessing is one of the reasons we must follow published standards. Joe Lewelling, vice-president of standards development for AAMI explains "Standards capture the state of the art, they're not pushing the state of the art. Standards alone don't solve problems - people have to use the standards."[5]

Follow long standing best practices

As a consultant, I have been told many times that a facility may not always follow AORN, AAMI or CDC standards because they are recommendations or guidelines and not "the law". However, in most cases, these recommendations are considered the minimal standard of care and failing to follow them could be considered malpractice in a court of law. Published guidelines are built on sound principles, research, scientific data, and opinions of experts in the field — making them best practices. My response is always –'Don't you want best practices for your patients, not just run of the mill practices? What if the patient was you or one of your loved ones?'

Follow manufacturer's instruction for use

AORN, AAMI, and the CDC state that following the manufacturers' instructions for use (IFU) of the specific medical device, cleaning/disinfection solution, sterilizer and containment device is required to ensure the sterilization and/or high-level disinfection of reusable device.[8,9,10,11]

In order for a manufacturer to take a reusable medical device to market, they must first get clearance from the Food and Drug Administration (FDA). Part of the FDA's 510(k) submission is the labeling regulations, which state that the manufacturer must supply the user with complete, comprehensive, validated and written instructions for use (IFU) which includes handling, cleaning, disinfection, testing, packaging and sterilization of each device. These IFU are validated for proven results of cleaning and sterilization efficacy. If you do not follow these precisely you are putting your patients at risk.

In a memo from the CMS to state survey agency directors regarding sterilization practices, "If manufacturers' instructions are not followed, then the outcome of the sterilizer cycle is guesswork, and the ASC's practices should be cited as a violation of 42 CFR 416.44(b)[5]."[12] According to CMS, the facility's infection control P&P should discuss what to do when there are discrepancies between a manufacturer's instructions for use (IFU) of a device and a manufacturer's IFU for the sterilizer.[13]

Use IUSS (aka flash sterilization) with caution

Our industry has changed the term "Flash Sterilization", to the new term "Immediate-use Steam Sterilization". The science behind sterilization tells us that we cannot sterilize in a "flash". There are many steps involved in the sterilization process including the need for adequate cleaning and the need for validated sterilization exposure time and temperature according to the device(s) IFU. There is a published multi-society endorsed IUSS position statement which can be downloaded for free at http://www.aami.org/publications/standards/ST79_Immediate_Use_Statement.pdf.

IUSS "is broadly defined as the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. Immediacy implies that a sterilized item is used during the procedure for which it was sterilized in a manner that minimizes its exposure to air and other environmental contaminants. A sterilized item intended for immediate use is not stored for future use, nor held from one case to another."[14]

CMS assessment of IUSS

A CMS memo was sent to all state survey agency directors on the subject of "Flash Sterilization Clarification – FY 2010 Ambulatory Surgery Centers (ASC) Surveys." This message spelled out CMS's position on flash sterilization for ASCs which frequently and sometimes routinely use this sterilization process.[2]

CMS implemented the following set of questions for surveyors to use when assessing the appropriateness of the ASC sterilization practices relating to IUSS:

The questions that surveyors will ask are as follows:

1. Is the sterilizer labeled for this cycle by the manufacturer?
2. What is the sterilizer manufacturer-recommended load for that cycle?
3. Is the containment device used labeled by its manufacturer for use in that cycle?
4. For what load is the containment device recommended by its manufacturer?
5. Is the chemical indicator used labeled for use in this cycle by its manufacturer?
6. If a biological indicator is used, is it labeled for use for this cycle by its manufacturer?
7. If the cycle is used frequently, is it checked regularly with a biological indicator?[2]

AORN's guidance on IUSS

In AORN' 2012 recommended practices for sterilization, recommendations VII.a.2. states, "Immediate-use sterilization should be performed only if all of the following conditions are met:

- The device manufacturer's written instructions include instructions for IUSS.
- The device manufacturer's written instructions for cleaning, cycle type, exposure times, temperature settings, and drying times (if recommended) are available and followed.
- Items are placed in a containment device that has been validated for IUSS and cleared by the FDA for this purpose and in a manner that allows steam to contact all instrument surfaces.
- The containment device manufacturer's written instructions for use are followed.
- Measures are taken to prevent contamination during transfer to the sterile field.
- Items subjected to IUSS are used immediately and not stored for later use or held from one procedure to another."[9]

In recommendation VII.e., AORN explains that rigid sterilization containers should be validated by the manufacturer for IUSS cycles. Rigid containers help to protect devices, reduce the risk of contamination during transport to the point of use and make aseptic presentation easier.[9] In addition, TJC has been known to cite healthcare facilities for not using containment devices for IUSS.[15]

*See **SELF-STUDY SERIES** on page 40*

Self-Study Test Answers: 1. B, 2. A, 3. A, 4. B, 5. A, 6. B, 7. A, 8. A, 9. A, 10. A

Staff should be competent in all reprocessing procedures

Cleaning and sterilizing instruments was once very basic, but due to the technology explosion reprocessing is now a very complex process and involves many complicated steps that cannot be skipped or rushed. Therefore sterilization and decontamination duties should only be performed by competent personnel with demonstrated knowledge and documented competences in all aspects of reprocessing: decontamination, preparation, packaging, sterilization, sterile storage, and handling of sterile items. Competencies should be documented and performed at least annually.[8,9]

"Personnel involved in reprocessing should be knowledgeable and capable of exercising critical thinking and judgment, and should implement standardized practices. The supervising organization is responsible for ensuring appropriate training, education, and competency of staff and ensuring that the necessary related resources are provided."[14]

Key recommendations in the CDC guidelines for infection prevention states ASCs should assign responsibilities for reprocessing of medical equipment to healthcare professionals with appropriate training.[11] It is also recommended that all personnel performing sterile processing activities be certified as a condition of employment. At a minimum, all personnel should successfully complete a sterile processing certification examination within two years of employment and should maintain that certification throughout their employment.[8]

Available education and certification resources include the Certification Board for Sterile Processing and Distribution (CBSPD) at www.sterileprocessing.org and the International Association of Healthcare Central Service Materiel Management (IAHCSMM) at www.iahcsmm.org.

Leaders must provide equipment, supplies, resources

Sterilization is a complex process requiring environmental controls, appropriate equipment and supplies; adequate space; qualified, competent personnel who are provided with ongoing training and personal protective equipment (PPE); and monitoring for quality assurance. TJC standard LD.04.01.11 says "The leaders provide for equipment, supplies, and other resources."[4] Hence, it is up to the leadership of the facility to ensure all of these resources are available for the staff.

Reprocessing single-use devices by a third-party

Facilities can save costs and reduce medical waste by reprocessing and reusing single-use devices (SUDs) that have been approved for reprocessing by the FDA. Nevertheless, before any medical devices can be reprocessed and reused, a third-party or healthcare organization reprocessor must meet the same FDA requirements that apply to the original equipment manufacturers, including:

- Submitting documents for premarket notification or approval
- Registering reprocessing firms and listing all products
- Submitting adverse event reports
- Tracking devices whose failure could have serious outcomes
- Correcting or removing from the market unsafe devices
- Meeting manufacturing and labeling requirements.[16]

What ASCs can do now to improve reprocessing

In an effort to address concerns regarding disease transmission due to improper reprocessing, AAMI and the FDA held a Medical Device Reprocessing Summit in October 2011. After the summit, AAMI published a priority issues report that included "10 Things Your Organization Can Do Now to Improve Reprocessing". Following is a summary of this top 10 list:

1. Follow the basics (cleaning and disinfection/sterilization)
2. Have the right tools (IFU, cleaning implements, and equipment)
3. Create a multidisciplinary committee (review issues and set a plan)
4. Share lessons learned (learn from other facilities)
5. Written procedures (reprocessing program built on published best practices)
6. Standards matter (know the current standards)
7. Purchasing (consider reprocessing before purchasing)
8. Separate and standardize functions and locations (create standardized job descriptions)
9. Training (train, train and retrain)
10. Assessment (check for compliance routinely)[5]

For a complete copy of the reprocessing summit report with complete explanation of the "10 Things Your Organization Can Do Now to Improve Reprocessing" go to www.aami.org/reprocessing.

Conclusion

Every patient has the right to efficient and safe care in any setting. Established long standing best practices for reprocessing should be consistently followed to decrease the risk of serious infection resulting from inadequately reprocessed reusable medical devices. As with any facility, ASCs should ensure the validated manufacturers' IFUs are available and constantly followed and that the staff reprocessing these devices is competent in their duties. It only takes one negligent mistake to make a big change in a patient's life. Always remember: safety isn't expensive — it's priceless! HPN

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Rose Seavey MBA, BS, RN, CNOR, CRCST, CSPDT is the President/CEO of Seavey Healthcare Consulting, LLC, and formerly the Director of the Sterile Processing Department at The Children's Hospital of Denver. Seavey served on the Association of periOperative Registered Nurses (AORN) Board of Directors from 2008-2010. She was honored with AORN's award for Outstanding Achievement in Mentorship in 2012 and the Outstanding Achievement in Clinical Nurse Education in 2001.

In 2003 Seavey served as President of the American Society of Healthcare Central Service Professionals (ASHCSP) and was awarded the National Educator of the Year award in 2002.

Seavey is the author of the book tilted Sterile Processing In Healthcare Facilities: Preparing for Accreditations Surveys, *published by AAMI. She was elected to the AAMI National Nominating Committee for 2011-2014 and co-chairs the AAMI Working Group for Hospital Steam Sterilizers. She is a member of several AAMI working group committees developing recommended practices. In addition, she has lectured and authored many articles on various topics relating to perioperative services and sterile processing, locally, nationally and internationally.*

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Reprocessing in the ambulatory surgery setting

Circle the one correct answer:

1. **Reprocessing of reusable medical devices is an increasingly smaller focus for regulatory and accreditation surveys.**
   A. True B. False
2. **CMS states that every outpatient setting should have at least one individual with training as a dedicated Infection Preventionist (IP).**
   A. True B. False
3. **All reprocessing policies and procedures should be developed and referenced using the most current published recommended standards and guidelines.**
   A. True B. False
4. **Not all FDA cleared reusable medical devices have a written IFU for reprocessing.**
   A. True B. False
5. **The term "Flash sterilization" has nationally been changed to "Immediate-use steam sterilization".**
   A. True B. False
6. **IUSS items can be held from one procedure to another if not used for the procedure for which it was sterilized.**
   A. True B. False
7. **Rigid sterilization containers should be used for IUSS items.**
   A. True B. False
8. **Sterilization and decontamination duties should only be performed by competent personnel with demonstrated knowledge and documented competences in all aspects of reprocessing.**
   A. True B. False
9. **Single-use devices should not be reprocessed unless the reprocessor meets the FDA requirements that apply to the original equipment manufacturers.**
   A. True B. False
10. **Established long standing best practices for reprocessing should be consistently followed to decrease the risk of serious infection resulting from inadequately reprocessed reusable medical devices.**
    A. True B. False

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