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LEARNING OBJECTIVES

1. *Explain the criteria for determining ECRI's annual Top Ten Patient Safety Concerns.*
2. *Discuss all current endoscope-related risks that could affect a hospital's determination of Spaulding classification and reprocessing level.*
3. *List and explain the eight common reprocessing steps required for an endoscope protocol.*

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SELF-STUDY SERIES

Nine years is enough!

Conquering flexible scope reprocessing issues

by Sandra Beauclair, BSN, RN, CNOR

In 2010, the ECRI Institute (formerly the Emergency Care Research Institute) published its first annual *Top 10 Patient Safety Concerns for Healthcare Organizations* report (aka Top 10 List). The purpose of the report was, and still is, to help healthcare organizations identify possible sources of danger or difficulty with health technologies and to recommend steps to minimize adverse events. Unfortunately, patient safety related to inadequate reprocessing of flexible endoscopes has been a top 10 patient safety concern for healthcare organizations every year since 2010. The 2017 and very recent 2018 reports listed more global "Inadequate Cleaning of Complex Reusable Instruments Can Lead to Infections (#2)," and "Device cleaning, disinfection and sterilization (#8)," both of which you can surmise include flexible endoscopes.

Six factors are considered in the ECRI Institute's final decisions about which of the many safety concerns will be listed in the Top 10 Lists. First is the ***severity*** of the hazard; is it likely to cause a serious injury or death? Second is the ***frequency*** of occurrence. Will it occur often? Third is the ***breadth*** of the hazard. If the hazard does occur, what are the consequences? Will it affect many people and one facility or many people across many facilities? Fourth, ***insidiousness***; is the hazard difficult to recognize? Will it snowball into multiple errors before it is identified or corrected? Fifth is ***profile***. Will the hazard 'go public' and have a negative effect on the facility's reputation? Will the hazard become the focus of regulatory and accrediting agencies? And finally, is the hazard ***preventable***? Will raising awareness prevent or reduce future events? For the safety concern of flexible endoscope reprocessing, the answer to all six questions is a resounding yes![1]

Scope infections are political

In past decades it was rare to hear of infections associated with endoscopic procedures, including gastrointestinal procedures. The few that were noted in literature were linked to standard endoscope reprocessing or equipment failures. This is no longer the case. In 2015, there were two deaths reported to the U.S. Food and Drug Administration due to infection with carbapenem-resistant Enterobacteriaceae (CRE) associated with endoscopic retrograde cholangiopancreatography (ERCP) procedures.[2]

In 2013, two hospitals reported antibiotic-resistant infections in patients who had undergone procedures with a closed-channel duodenoscope, a device used to diagnose and treat conditions of the pancreas and bile duct. After publication of these and other infectious outbreaks related to contaminated duodenoscopes, Senator Patty Murray, the ranking member of the Senate Health, Education, Labor, and Pensions (HELP) Committee, initiated an investigation into the duodenoscope-linked infections. They discovered that between 2012 and the spring of 2015, 250 patients worldwide were affected by 25 different instances of antibiotic-resistant infections related to contaminated closed-channel duodenoscopes.[3]

Although the infections noted in the HELP Committee's 2016 report were specific to closed-channel duodenoscope reprocessing, the reality is that flexible endoscopes in general present reprocessing challenges. There are suction, water, air delivery, and biopsy ports, plus connectors and accessories that must be thoroughly cleaned. For example, at the tip of each duodenoscope is an elevator

mechanism, which allows instrumentation passed through the working channel to be directed and manipulated. The elevator mechanism is a moveable part that poses a major cleaning challenge for the person tasked with that responsibility.

Does current scope-related risk warrant reclassification?

Endoscopic procedures are considered minimally invasive, which is good for patients because the endoscope can be used for diagnostic purposes (e.g., colonoscopy), early treatment of pre-cancerous conditions (e.g., polypectomy), or for therapeutic procedures such as the removal of gallstones, all without cutting large openings into the body. These newer procedures can minimize patient discomfort, provide early diagnosis, and result in faster recovery times.

In 2002, an endoscopic system based on HDTV technology was introduced. That technology made it possible to make "extremely accurate diagnoses.[4] Now, physicians are using flexible endoscopes like the duodenoscope to perform amazing procedures. The technology continues to advance, but their status in Spaulding's classification system has not been updated to reflect newer devices and interventional techniques.

In the early 1970's Dr. Earl Spaulding devised a logical risk classification system that has since been used for sorting contaminated reusable medical devices into one of three reprocessing categories. Category 1, Critical Devices, are instruments that enter sterile tissue or the vascular system. They require sterilization (steam sterilization is the preferred method). Category 2, Semi-critical Devices, are those that encounter mucous membranes or non-intact skin. Sterilization is recommended, but if that is not possible, high-level disinfection is acceptable for devices that cannot tolerate sterilization; they should be free of all microbes, although after reprocessing there may be a small number of bacterial spores that remain. Category 3, Non-critical Devices, contact intact skin but not mucous membranes. They only need to be washed with warm water and a detergent unless shared between patients, in which case they should be low-level disinfected.[5] For many years, flexible endoscopes have been classified in Spaulding's Classification System as Category 2 Semi-critical Devices. This may no longer be appropriate, for several reasons.

For one thing, duodenoscopes are introduced into sterile body areas. Also, procedures are now being performed with flexible endoscopes that disrupt intact mucous membranes. For example, polypectomies performed during colonoscopies break the mucous membrane to cut out polyps. In these circumstances, and given the risk of antibiotic-resistant organisms transferring from one patient to another through use of endoscopes, should the flexible endoscope be considered a semi-critical device or a critical device? Should high-level disinfection or sterilization be used? These are questions that every healthcare facility must answer to address their level of patient safety risk and determine appropriate reprocessing protocols.

In addition, flexible endoscopes have been shown to be high-risk devices because of their confirmed direct links to healthcare-associated infections. These devices frequently have high levels of bacterial contamination. Their design poses substantial challenges to adequate cleaning. And we know that unless the device is clean it cannot be sterilized or adequately disinfected.

Reprocessing considerations

Flexible endoscopes are heat-sensitive, meaning most cannot be steam sterilized. Currently there are few options for terminal flexible scope sterilization: ethylene oxide, hydrogen peroxide (H_2O_2) gas or vapor, or vaporized hydrogen peroxide and ozone (O_3). H_2O_2 processes are shorter than ethylene oxide processes, which require 12-hour aeration phases for each cycle. However, duodenoscopes are not validated for H_2O_2 low-temperature sterilization.

There are numerous automated systems and chemistries that can be used to achieve high-level disinfection of flexible endoscopes, including use of high-level disinfectants based on glutaraldehyde, peracetic acid or orthophthalaldehyde. Although high-level disinfection is less robust than low-temperature sterilization, when all reprocessing steps (including pre-cleaning) are done correctly, HLD can be effective.

Liquid chemical sterilization with a peracetic acid-based sterilant is an effective alternative for heat-sensitive critical and semi-critical devices. Critical devices must be used immediately after being processed this way, and semi-critical devices can be used immediately or stored in the same manner as devices that are high-level disinfected.

Liquid chemical sterilization using peracetic acid is also safer for staff and patients than aldehyde-based liquid processes. The available system does not require specialized ventilation in the processing area, and because each device is thoroughly and consistently rinsed with treated water at the end of each cycle, there is virtually no risk of residual substances on devices. In contrast, when glutaraldehyde, which has adherent properties, is not thoroughly rinsed from endoscopes, it can cause reactions in sensitive technicians and glutaraldehyde-induced colitis in patients. Whichever methods are ultimately used by a facility for its endoscopes, safety must be assured by following all IFU to the letter.

Reprocessing steps: no shortcuts allowed

There are 20 million endoscopy procedures performed annually in the United States.[6] This translates to about 384,000 procedures performed per week. Yet despite their many clinical benefits, the ECRI Institute reports that endoscope failures continue to expose patients to infection risk.[1,6] Studies of endoscope reprocessing methods have provided significant evidence that the cause of this risk is failure to adhere to reprocessing guidelines.[7]

Are you able to identify the yellow objects in the 'patient ready' duodenoscope shown in the image at right?

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

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These are three tiny gallstones! This scope had been reprocessed; it was considered ready for the next procedure. Thankfully, the stones were discovered before the scope was used on the next patient.

Multiple professional organizations have provided standards or guidelines for reprocessing flexible endoscopes. There are minor differences among the organizations' documents but they all agree that reprocessing flexible endoscopes is a multi-step process that requires strict adherence to manufacturers' written instructions for use (IFU). This applies not only to the endoscope manufacturer, but for the IFU of each tool/chemistry/system (e.g., detergent/disinfectant, cleaning accessories and automated equipment) used for effective reprocessing. They also stress that reprocessing staff should be trained and competent. Although individual details may vary, these are the recommended steps for reprocessing flexible endoscopes:

1. **Pre-cleaning at the point of use** (POU). Immediate pre-cleaning of the endoscope and associated reusable accessories helps prevent the formation of biofilm. All-in-one POU products are available. They come with prepared enzymatic solutions and sponges that are effective, convenient and easy to use.
2. **Transport to the decontamination area/room**. During transport the endoscope should be in an enclosed, splash-resistant container that provides protection for the device and staff. It should be labeled with a biohazard label.
3. **Leak-testing** is performed in the decontamination area/room. This step is necessary as it detects damage to the external surfaces and internal channels of the endoscope, which when not detected can impede adequate disinfection or sterilization and can lead to more damage. Leak testing may be done manually or with automated leak testing equipment.
4. **Device cleaning** may be performed manually and/or with automated equipment. Meticulous attention to detail is critical when cleaning manually, to assure successful high-level disinfection or sterilization. Manual cleaning requires the technician to meticulously brush and flush the lumen, ports, channels and accessories following the device manufacturer's written IFU.

   If an automated endoscope reprocessor (AER) is used, it must be used according to the AER manufacturer's IFU. In addition to washing, rinsing (before and after) and high-level disinfecting, some AERs perform leak-testing.
5. **Cleaning verification testing** should be performed before high-level disinfection or sterilization to assure that the device is clean. There are different tests available that identify different soils. For example, there is a test that detects residual adenosine triphosphate (ATP) however, the purchase of additional equipment is necessary. Another more convenient, self-contained test is a protein detection test. Residual soil detection testing is a useful tool because the tests can detect soil not visible to the naked eye and therefore, not seen during visual inspection.
6. **Visual inspection** follows manual cleaning and residual soil detection testing. The endoscope and accessories should be inspected for residual soils and defects before high-level disinfection or sterilization. The use of a lighted magnifier helps to identify small defects in complex devices.
7. **High-level disinfection/sterilization.** Departments are responsible for documenting and following their own protocols, including their choice of HLD/sterilization method for each endoscopic device and that equipment's IFU.
8. **Storage/reuse.** Regardless of the reprocessing method, reprocessed endoscopes must be stored to prevent recontamination, protect the device from damage, and promote drying. There are storage cabinets designed specifically for flexible endoscope storage that prevent recontamination, provide protection and promote drying.

Steps to a better endoscope reprocessing protocol

No two facilities are the same. Each has their own inventory of devices, procedures performed with those devices, and personnel involved with reprocessing. To implement the best reprocessing practices for their needs, each facility should assemble a multidisciplinary team to review the appropriate standards and guidelines and conduct a risk assessment of their facility. As written policies and procedures are formalized, apply the facility's specific risk concerns to endoscope reprocessing decisions, and implement a quality management program to keep everyone on course.

Reprocessing staff should have all manufacturers' written IFU, along with professional and regulatory standards and guidelines, available in their departments. Adequate training and routine competency evaluations are a must to assure that all steps are being performed optimally, and internal audits should occur regularly to ensure that reprocessing staff, and staff at the POU, are competent and compliant.

Flexible endoscope reprocessing is still a patient safety issue in 2018, but there is hope. Technological innovation, clinical research, and proper risk assessment will continue to inform and improve practices. If every hospital works toward continuous improvement and is accountable for their reprocessing quality, it will not remain on the Top 10 List. **HPN**

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Sandra Beauclair, BSN, RN, CNOR, is a senior clinical education specialist for STERIS University, and is responsible for overseeing the continuing education program at STERIS Corporation's STERIS University. She is a member of the Association of periOperative Registered Nurses (AORN), Society of Gastroenterology Nurses and Associates (SGNA), Association for Professionals in Infection Control and Epidemiology (APIC), International Association of Healthcare Central Service Materiel Management (IAHCSMM).

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Conquering flexible scope reprocessing issues

Circle the one correct answer:

1. **The purpose of the ECRI Top 10 List is to help healthcare organizations identify possible sources of danger or difficulty with health technologies and to recommend steps to minimize adverse events.**
   A. True
   B. False

2. **Before the HELP investigation, infections associated with endoscopic procedures were linked to**
   A. Standard reprocessing failures
   B. Patients undergoing ERCP procedures
   C. Equipment failure
   D. A and C

3. **ECRI has listed inadequate reprocessing of flexible endoscopes and other complex devices in the Top Ten Patient Safety Concerns since 2010.**
   A. True
   B. False

4. **Name four of the six factors ECRI considers when making their final decision about which safety concerns will be published in their annual report.**
   A. Profile, preventable, insidiousness, bothersome
   B. Breadth, severity, profile, preventable
   C. Frequency, severity, inconvenience, profile
   D. None of the above

5. **Spaulding's Category 1, Critical Devices, are instruments that enter sterile tissue or the vascular system.**
   A. True
   B. False

6. **Flexible endoscope reprocessing standards and guidelines agree that reprocessing staff should be trained and competent, and that:**
   A. Reprocessing should use only manual processes.
   B. All manufacturers' written IFUs should be strictly adhered to.
   C. The first step in the reprocessing cycle is precleaning in the decontamination area/room.
   D. Cleaning can only be done at the POU

7. **Flexible endoscope cleaning is challenging because of the complexity and delicate nature of endoscopes. Cleaning is performed manually and/or with a(n). _____.**
   A. Steam sterilizer
   B. Washer/disinfector
   C. Liquid chemical sterilizer
   D. Automated endoscope reprocessor

8. **Since the introduction of HDTV technology what tool used by sterile processing departments has not been updated to account for newer minimally invasive procedures?**
   A. The Spaulding Risk Classification System
   B. SGNA's Guideline for Use of High-Level Disinfectants & Sterilants in the Gastroenterology Setting
   C. AORN Guideline for Processing Flexible Endoscopes
   D. ANSI/AAMI ST91: 2015 Flexible and semi-rigid endoscope processing in healthcare facilities.

9. **Flexible endoscopes are heat-sensitive and most cannot be steam sterilized. Low-temperature alternatives for these devices include:**
   A. Dry steam
   B. H2O2 gas/vapor processes
   C. Liquid chemical sterilization with peracetic acid
   D. b and c

10. **When storing reprocessed endoscopes, it is important to _____**
    A. Prevent kinks, promote drying and protect from recontamination.
    B. Promote drying, prevent recontamination, protect the controls
    C. Prevent recontamination, promote drying and protect devices
    D. b and c

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