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LEARNING OBJECTIVES

1. Explain the differences of the sterility assurance levels for HLD as opposed to sterilization.
2. Discuss recommendations for the disinfection and sterilization of flexible endoscopes.
3. Explain the difference in storage time between high-level disinfected and sterilized scopes.
4. Discuss steps to take when transitioning from HLD to sterilization of flexible endoscopes.

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SELF-STUDY SERIES

Scopes require higher level of disinfection

by Susan Klacik, BS, AS, FSC, ACE, CHL, CIS, CRCST

The objective of healthcare is to provide the highest level of quality outcomes for patient care. Seeking this higher level often occurs with the introduction of research and new technology. Often this new technology includes medical devices that are complex and difficult to clean and sterilize or disinfect. Flexible endoscopes are among this category. Through the use of scopes, patients can be diagnosed and treated with minimally invasive techniques and experience a reduced recovery time.

Many flexible endoscopes have a complex design and are processed using HLD. Based on recent investigations of patient outbreaks related to flexible endoscopes, it is time to look into moving from high-level disinfection (HLD) to sterilization. This article will examine the benefits of moving from HLD to sterilization for flexible endoscopes that are used directly or secondarily to enter normally sterile tissue. Regardless of the disinfection or sterilization modality used, it is important that scopes are thoroughly cleaned before being subjected to a disinfection or sterilization process. Without adequate cleaning, sterilization or disinfection cannot occur. Performing a cleaning verification test after cleaning and before disinfection or sterilization verifies the effectiveness of the cleaning process, ensuring the scope is prepared for the next critical step.

Sterility assurance levels for HLD vs. sterilization

The decision of whether to use HLD or sterilization to reprocess a particular device is based on the Spaulding classification scheme. There are distinct differences between HLD and sterilization. The biggest and most important distinction is sterility assurance level or SAL.

Spaulding divided medical instruments and equipment into three categories (critical, semicritical, and noncritical) on the basis of the risk of infection from contamination on the item (Spaulding, 1972). The Centers for Disease Control and Prevention (CDC) uses this scheme to describe the level of disinfection or

sterilization needed after decontamination and before patient use:

a) Critical devices are instruments or objects that are introduced directly into the human body, either into or in contact with the bloodstream or other normally sterile areas of the body, and products with sterile fluid pathways. Critical items present a high risk of infection transmission if contaminated and must be sterile at the time of use.

(Note: Unless contraindicated, steam sterilization is the preferred processing method. Low-temperature processes (e.g., ethylene oxide (EO) sterilization and other processes with exposure temperatures lower than steam sterilization) can be used to sterilize some heat-labile devices when time between uses allows such processes to be used.)

b) Semicritical devices are instruments or objects that contact intact mucous membranes or nonintact skin of the patient during use, but do not usually penetrate the blood barrier or other normally sterile areas of the body. Semicritical devices should be sterilized, if possible. However, if sterilization is not feasible, the device, at a minimum, must be subjected to a HLD process that would be expected to destroy all microorganisms except for small numbers of bacterial spores. In most cases, meticulous physical cleaning followed by HLD provides reasonable assurance that enough pathogens have been eliminated and the device is safe for patient use.

c) Noncritical devices are instruments or objects that usually contact only the intact skin of the patient. Depending on the particular item and degree of contamination, cleaning with a detergent and warm water could be appropriate. Disinfection is a process that kills pathogenic and other microorganisms by physical or chemical means. Disinfection destroys most recognized pathogenic microorganisms but not necessarily all microbial forms, such as bacterial spores. Sterilization results in an instrument free from all viable microorganisms including bacterial spores.

The Food and Drug Administration (FDA) defines the performance requirements of both HLD and sterilization. According to the FDA, high-level disinfecting chemicals and processes must be able to demonstrate the ability to kill 6 logs (1×10^6 or 1,000,000 organisms) of various test organisms under the specified use conditions, including exposure time, defined by the manufacturer. Sterilization is a validated process used to render a medical device free from viable microorganisms. Sterilization processes are required to kill all types of microorganisms including the most resistant bacterial spores. During the sterilizer validation process, sterilizers are tested and validated using viable resistant bacterial spores. This validation process, commonly referred to as the “overkill” process, is performed by determining the amount of exposure time required to kill 6 logs of bacterial spores, then doubling this exposure time resulting in the equivalent of 12 logs of kill (1,000,000,000,000 spores) to provide a large margin of safety.

The overkill sterilization method is based on the concept that the sterilization process will be able to kill a known resistant microbiological challenge plus provide an additional safety factor, and can be used to demonstrate an SAL. Said another way, an SAL is a value indicating the probability of a single viable microorganism survivor after a sterilization process. For example, an SAL of 10^{-6} is the probability that one in one million bacteria will survive after exposure to a sterilization process.

HLD processes are required to kill 6 logs of less resistant test organisms, while sterilization processes are designed to kill 12 logs of more resistant bacterial spores. According to ANSI/AAMI ST58 and the FDA’s guidance document *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, “Disinfection processes do not ensure the margin of safety associated with sterilization processes.”

Recommendations for disinfection, sterilization of flexible endoscopes

Flexible endoscopes have been classified as semicritical devices according to the Spaulding Classification since they are instruments that contact intact mucous membranes of the patient during use, but do not usually penetrate the blood barrier or other normally sterile areas of the

body. As explained in ANSI/AAMI ST79, according to the Spaulding classification “Semicritical devices should be sterilized, if possible. However, if sterilization is not feasible, the device, at a minimum, must be subjected to a HLD process that would be expected to destroy all microorganisms except for large numbers of bacterial spores. In most cases, meticulous physical cleaning followed by HLD provides reasonable assurance that the items are free of pathogenic microorganisms.” Over the years, flexible endoscopes have undergone HLD. Based on outbreaks and research, the sterilization of flexible endoscopes that are used directly or secondarily to enter normally sterile tissue needs to be considered. Sterilization of certain flexible endoscopes is possible with EO and other low temperature sterilization modalities.

ANSI/AAMI ST91 Flexible and semi-rigid endoscope processing in health care facilities

The ANSI/AAMI ST91 Flexible and semi-rigid endoscope processing in health care facilities standard provides guidance on how to process flexible and semi-rigid endoscopes for patient use. Section 8 on terminal sterilization by gaseous chemical sterilization processes recommends sterilization of these scopes. “With the infection risk that endoscopes present to the patient, terminal sterilization is the preferred method of microbial inactivation and the only option in sterile environments. Terminal sterilization is recommended for flexible and semi-rigid endoscopes that enter sterile body cavities. Terminal sterilization is required for all endoscope accessories that penetrate mucosa, such as biopsy forceps, sphincterotomes, etc. Steam sterilization is often not compatible with flexible and semi-rigid endoscopes, but should be used on compatible endoscopes whenever possible. Other compatible methods are ethylene oxide (EO), hydrogen peroxide (HP) gas, and ozone sterilization.”

AORN Guideline for processing flexible endoscopes

The 2016 AORN *Guideline for processing flexible endoscopes* recommends assembling a multidisciplinary team to conduct a risk assessment to determine if instruments that secondarily enter sterile tissue or the vascular system should be sterile. This guidance document provides evidence of the effectiveness of sterilization over HLD. Research has shown reduced bacterial sus-

ceptibility to high-level disinfectants and that sterilization is the only reprocessing method that has demonstrated effectiveness. This research includes the importance of thoroughly cleaning the scopes.

Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee Meeting

On May 14-15, 2015, the FDA held the Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee Meeting to address the effectiveness of reprocessing duodenoscopes and to further form rigorous, practicable reprocessing protocols that would enhance the safety margin of procedures using duodenoscopes. The purpose was to seek expert scientific and clinical opinion related to reprocessing of duodenoscopes based on available scientific information. The panel members were made up of healthcare, consumer and industry representatives. For two days the panel listened to presentations, testimony and other input. Dr. William Rutala, a renowned expert, discussed how endoscopes can cause healthcare-acquired infections (HAIs). His concerns include the narrow or nonexistent margin of safety associated with HLD of semicritical items due to microbial load and complexity. His suggested solutions to reduce the chance of an infection from these scopes included:

- Modification of the Spaulding classification scheme by the FDA (and professional organizations) to require sterilization of instruments that directly or secondarily enter normally sterile tissue
- Shifting from HLD to sterilization to protect the public health and prevent Endoscopic Retrograde Cholangiopancreatography (ERCP)-related outbreaks
- Implementation of enhanced methods for duodenoscope reprocessing
- Requiring manufacturers that submit instruments that secondarily enter normally sterile tissue to the FDA for clearance to offer a sterilization method

Medical Technology and HAIs Forum

Sterilizing flexible endoscopes was a recommendation from the Medical Technology and HAIs Forum that was held on September 29 and 30, 2016. The purpose of this forum was to continue to find solutions to reduce HAIs. It was a collaborative meeting with the foremost agencies concerned with HAIs, including AAMI, AHA, CDC, IAHCSSM, FDA/CDRH, and The Joint Commission. More than 100 invited stake-

holders that have a direct impact on the use of medical devices attended the forum. The objective was to identify the causes of device- and equipment-associated HAI transmissions and to identify solutions to the problem. Dr. William Rutala delivered a presentation that emphasized the risks associated with complex medical devices such as flexible endoscopes, stating that there should be an evaluation of the efficacy of current processing protocols. After a review of our current practices according to the Spaulding classification, which specifies how a medical device such as a flexible endoscope will be disinfected, Rutala suggested that HLD may not be appropriate for endoscopes, based on years of failures. He instead recommended sterilizing devices that pose a significant or potentially significant infection risk, such as gastrointestinal endoscopes and bronchoscopes.

Duodenoscopes

Over the past few years, there have been outbreaks from procedures using duodenoscopes. The organisms associated with these outbreaks were Carbapenem resistant *Enterobacteriaceae* (CRE). The duodenoscopes were used in ERCP procedures. These outbreaks got the attention of the FDA and CDC. Investigations showed the scope processing was performed according to the instructions for use (IFU) and best practices. This led the investigators to the conclusion that the duodenoscopes had the “potential to remain contaminated with pathogenic bacteria even after recommended reprocessing is performed.” Positive cultures were found to be associated with the elevator guide wire channel and the elevator mechanism. The complex design of the duodenoscope makes it difficult to clean. When hospitals switched from processing the scopes using HLD procedures to terminal sterilization using EO gas, the infections ceased.

A study on the outbreaks of CRE related to duodenoscopes was conducted by Dr. Zachary Rubin and Dr. Rekha Murthy in 2016. They studied CRE outbreaks associated with ERCP procedures between 2013 and 2015 in the United States and Europe. Their study showed that even though the cleaning and reprocessing were done correctly, the scopes remained contaminated with CRE. They found that the cause of the infection transmission included a low margin of safety for gastrointestinal endoscopic procedures and complex design features of duodenoscopes. Their research concluded that the outbreaks were halted

with enhanced cleaning and surveillance measures and by adopting EO gas sterilization methods.

Storage time differences between high-level disinfected scopes and sterilized scopes

Flexible endoscopes that have undergone HLD are hung in scope cabinets. Research has shown high-level scopes become contaminated in as little as three hours in storage. Terminally sterilized (i.e., packaged) medical devices can be stored indefinitely so long as the storage is in an area of a healthcare facility designed to store clean and sterile items, and the packs are handled appropriately.

Storage time for flexible endoscopes is addressed in Standards and Guidelines. Previously AORN recommended a storage time for high-level disinfected scopes of five days. The 2016 AORN evidence-based Guideline for Processing Flexible Endoscopes now recommends that flexible endoscopes and accessories are stored in a manner that minimizes contamination and protects them from damage and that a multidisciplinary team establish a policy to determine the maximum storage time.

The storage time for high-level disinfected scopes is dependent upon many factors. In the *ANSI/AAMI ST91 Flexible and semi-rigid endoscope processing in health care facilities Standard*, it is recommended that hospitals perform a risk assessment to determine the maximum storage time for an endoscope before it needs to be reprocessed to use on the next patient. Variables to be included in the risk assessment are the complexity and type of endoscope, whether it is lumened or non-lumened, frequency of use, patient population, frequency, type, results of quality monitoring of processing and quality of final rinse water.

Society of Gastroenterology Nurses and Associates (SGNA) updated and published “Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes” in 2016. In this standard it is recommended that endoscopes are stored in an area that is clean, well-ventilated and dust-free in order to keep the endoscopes dry and free of microbial contamination. Endoscopes should be stored in accordance with the endoscope and storage cabinet manufacturers’ IFUs. SGNA recommends that endoscopes can be stored for seven days if they have been effectively reprocessed to remove all pathogens and almost all other microorganisms, and are stored

in a way that keeps them completely dry and free from environmental and human contamination.

Transitioning from HLD to sterilization of flexible endoscopes

For a healthcare facility to transition from HLD to sterilization for scopes that directly or secondarily enter normally sterile tissue, the first step is to develop a multi-disciplinary team. The first step for this team is to review how each scope is used. For any scopes that are going to be used to directly or secondarily enter normally sterile tissue, the next step is to check with the scope manufacturer’s IFU for validated methods of sterilization. There are a variety of low temperature sterilants and sterilization cycles, and it is important to select the correct sterilization modality and cycle. The sterilizer IFUs must be reviewed to assure compatibility. Packaging selection should be compatible with both the sterilizer and the scope IFUs. Quality monitors must be validated and labeled for the sterilization modality.

Healthcare facilities that are adopting sterilization should review the IFUs of new scopes before they are purchased, to assure they are compatible with the sterilization modalities available at the healthcare facility.

Conclusion

Flexible endoscopes are complex medical devices and the decision about whether to perform HLD or sterilization has traditionally been based on the Spaulding classification scheme. Because of the complex design of flexible endoscopes, recent outbreaks and new research, it is time to re-assess this model and shift this paradigm to sterilization of flexible endoscopes that directly or secondarily enter normally sterile tissue. There are some scopes that can undergo sterilization today. Future advancements and technology may produce more scopes that can be sterilized. Healthcare facilities should assemble a multi-disciplinary task force to review scope-processing practices and make recommendations for sterilization or disinfection. **HPN**

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CONTINUING EDUCATION TEST • JUNE 2020

Scopes require higher level of disinfection

Circle the one correct answer:

- An advantage to sterilization is that scopes do not need to be cleaned first.
A. True B. False
- The decision to use HLD or sterilization is based on the Spaulding classification.
A. True B. False
- According to the Spaulding classification, semicritical devices should be sterilized, if possible.
A. True B. False
- HLD must show a 6 log reduction of test organisms, whereas sterilization must show a 12 log reduction of bacterial spores.
A. True B. False
- Ethylene oxide (EO) cannot be used to sterilize endoscopes.
A. True B. False
- Methods to sterilize scopes include EO, vaporized hydrogen peroxide (HP) and ozone sterilization.
A. True B. False
- The reprocessing method that had the most successful elimination of CRE from duodenoscopes was EO.
A. True B. False
- The standard time for storing high-level disinfected scopes is 10 days.
A. True B. False
- When determining whether to sterilize or disinfect endoscopes, a multi-disciplinary team should be assembled.
A. True B. False
- Before sterilizing endoscopes, the IFUs for the endoscope, sterilizer and packaging must be reviewed.
A. True B. False

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