Keeping up with Duodenoscope and High-level Disinfection Best Practices

LEARNING OBJECTIVES
1. Discuss the highlights of the newly-released Association of periOperative Registered Nurses Guideline for Manual Chemical High-Level Disinfection
2. Describe the recommendations to implement a surveillance sampling and culturing protocol for duodenoscopes

IN HEALTHCARE, FOLLOWING BEST PRACTICES PROVIDES THE foundation for quality patient care; best practices are based upon research. This lesson plan presents highlights from two of the recently-released documents developed to advance the quality of patient care.

OBJECTIVE 1: DISCUSS THE HIGHLIGHTS OF THE NEWLY-RELEASED ASSOCIATION OF PERIOPERATIVE REGISTERED NURSES GUIDELINE FOR MANUAL CHEMICAL HIGH-LEVEL DISINFECTION

In January 2018, the Association of periOperative Registered Nurses (AORN) released its Guideline for Manual Chemical High-level Disinfection. This guideline is based on a comprehensive, systematic review of research- and non-research-based evidence. The guideline contains recommended best practices for safe and effective high-level disinfection (HLD) performed manually when automated methods are not possible. Research for this guideline consisted of 148 full-text sources that were independently evaluated and appraised according to the strength and quality of the evidence.

Twelve recommendations within the guideline address how to safely and effectively perform manual HLD, particularly by thoroughly cleaning and following manufacturer’s instructions for...
use (IFU). The preferred method of HLD is through an automatic process such as an automatic endoscope reprocessor (AER). Automated methods, such as AERs, improve cleaning effectiveness, increase efficiency and minimize personnel exposure to hazardous chemicals. Reusable semi-critical items that have been validated by the manufacturer for sterilization should be sterilized, if possible, because HLD poses a greater risk of disease transmission than items processed by sterilization.

The purpose of this guideline is to provide direction for:
- Performing safe and effective manual chemical HLD of reusable semi-critical items; and
- Preventing patient and healthcare worker injury associated with handling and use of liquid chemical high-level disinfectants.

The selection of HLD is very important, so it is necessary to review all available options. An interdisciplinary team should perform a risk assessment for HLD or sterilization to review semi-critical devices that secondarily enter sterile tissue or the vascular system.

HLD should be performed on the clean side of the department, in a low traffic area that is controlled and maintained to prevent environmental contamination, cross contamination and employee exposure, while also improving efficiency and enhancing process control and monitoring. Warning signs should be posted at the entrance to alert staff about the potential for exposure to hazardous chemicals.

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or a barrier that extends at least four feet above the sink rim. A one-way directional flow should be used to prevent recontamination of the item, while improving efficiency.

Point-of-use cleaning and proper transport must occur as medical devices are sent to the decontamination area for cleaning. All medical devices must be thoroughly cleaned because high-level disinfectants are inactivated or become less effective in the presence of organic material. In addition, some high-level disinfectants act as fixatives, meaning they may fix organic soil and blood to the surface of the item being disinfected.

As with all processes, following the manufacturer’s IFU for HLD helps ensure the effectiveness of the disinfection process. The medical device IFU must also be carefully followed; the manufacturer has validation performed to ensure the device can be effectively disinfected, and provides validated instructions for HLD.

Personal protective equipment (PPE) used for performing disinfection differs slightly from the PPE worn in the decontamination area. Masks and eyewear are required. Gloves should be chemical resistant and their selection should be based upon the recommendation of the HLD manufacturer. For the correct type of impervious gown/apron, the manufacturer’s safety data sheet (SDS) should be consulted. If a respirator is needed, that will also be listed in the SDS. Testing must be done to verify that the HLD is effective for use [e.g., use of a test strip or other testing device that is specific to the HLD and the active ingredient in the disinfectant, and cleared by the US Food and Drug Administration (FDA)]. A calibrated thermometer to verify the temperature and a timer to verify the exposure time should also be used.

Multi-part instrumentation should be disassembled, and the items should be completely immersed in the HLD solution. Moving parts should be actuated while immersed to ensure all surfaces are exposed to the high-level disinfectant. Lumened items should be flushed and completely filled with the high-level disinfectant.

After disinfection, the device should be safely and thoroughly rinsed with sterile water. Rinsing is an extremely important step to remove the high-level disinfectant. Thorough rinsing and flushing helps prevent patient injury associated with any disinfectant remaining on the device. Using sterile water reduces the potential for introducing microorganisms onto the disinfected device. Rinse sinks should be located as close as possible to the high-level disinfectant soaking container. After rinsing, if the device will be stored for future use, it should be dried using a clean, lint-free cloth, and lumens should be flushed with instrument air.

Once the disinfection process is
complete, the item should be protected from contamination and clearly identified as processed and ready for use; this will help prevent confusion and the accidental use of a contaminated device. Methods to protect the disinfected item from contamination are discussed. Guidance is also provided for transferring a medical device that has undergone HLD onto a sterile field.

A quality medical device processing program incorporates education and training. This new guideline states: “The healthcare organization should provide initial and ongoing education and competency verification activities. It is the responsibility of the healthcare organization to provide initial and ongoing education and to verify the competency of its personnel; however, the primary responsibility for maintaining ongoing competency remains with the individual.”

Providing patients with high-quality medical devices is the goal of this new AORN guideline. The recommendations, which are intended to be achievable, represent what is believed to be the best possible level of practice.

**OBJECTIVE 2: DESCRIBE THE RECOMMENDATIONS TO IMPLEMENT A SURVEILLANCE SAMPLING AND CULTURING PROTOCOL FOR DUODENOSCOPES.**

The FDA, Centers for Disease Control and Prevention (CDC) and the American Society for Microbiology (ASM), along with other endoscope culturing experts, have released a protocol for standardized duodenoscope surveillance sampling and culturing protocols titled *Duodenoscope Surveillance Sampling and Culturing Reducing the Risks of Infection.*

This document provides protocols for surveillance sampling and culturing of reprocessed duodenoscopes. The International Association of Healthcare Central Service Materiel Management (IAHCSMM) also participated in the development of this document.

This multi-agency document provides recommendations for healthcare facilities that choose to implement duodenoscope microbiological surveillance sampling and culturing. It was developed to detect organisms of concern, some of which have been associated with infectious outbreaks. These protocols are not intended to be used during a suspected outbreak linked to inadequately reprocessed endoscopes, and the results from following this protocol cannot be used to certify that an endoscope is sterile. Instead, it is intended as a quality control measure to demonstrate the effectiveness of reprocessing. Culturing information may be collected to monitor the facility specific procedures for reprocessing duodenoscopes and could be used to identify systematic errors in reprocessing or damaged endoscopes and equipment.

The document is divided into three sections. The first section provides an overview and introduction to the sampling and culturing protocols. The second section identifies the materials and methods for duodenoscope sampling and recommends that it be conducted by appropriate personnel who are familiar with handling duodenoscopes (e.g., Central Service/Sterile Processing (CS/SP) technicians or endoscopy staff). The third section provides four different methods to culture duodenoscopes, which are performed by appropriate microbiology laboratory staff; it also includes suggested initial limits for microbiological cutoffs based on expert opinion.

Additionally, two appendices are included in the document: Appendix 1 includes suggested volumes for endoscope channels of various sizes. Appendix 2 incorporates photographs of duodenoscope sampling to illustrate duodenoscope design features and sampling equipment. Tables are also provided for examples of establishing microbial limits for endoscope culturing by healthcare facilities and are presented as limits low- to moderate-concern organisms and high-concern organisms. Guidance is provided on how to interpret the culture results for high-concern organisms and low- to moderate-concern concern organisms. Suggested responses for a healthcare facility to follow are based on the culture results, with results classified into four categories: action, alert, modified action and no action. *Note: Except in areas where endoscope surveillance sampling and culturing is specifically required or regulated by state or local authorities, use of this protocol is not a mandatory component of a duodenoscope reprocessing program.*

Healthcare facilities that adopt endoscope surveillance sampling and culturing as a required policy should develop and follow their own written procedures, including any necessary remediation activities outlined in their policy. Samples from endoscopes are not considered clinical specimens from patients; they are being sampled for microbial culturing as a quality indicator. The decision to implement a duodenoscope surveillance sampling and culturing program should be made by a multidisciplinary task group that includes leadership from Endoscopy, CS/SP, Infection Prevention and Control, Risk Management, Clinical Microbiology or Laboratory Medicine, Gastroenterology/ Gastrointestinal Surgery, and management within a healthcare facility.

It is not recommended to transport the duodenoscopes to an offsite laboratory; such transport can allow for proliferation of microbes on the endoscope and increase the potential for environmental contamination of the endoscope.
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CONCLUSION

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RESOURCES


The duodenoscope multidisciplinary task group will need to determine the following matters as they relate to endoscope surveillance sampling and culturing in their institution:

- Frequency of sampling and culturing (including the choice of periodic sampling and culturing based on a period of time or number of procedures, or the option to sample and culture after every use of the device);
- Clinical use of duodenoscopes while awaiting culture results;
- Endoscopes to be sampled;
- Additional endoscope channels to be sampled;
- Endoscope handling after processing;
- How samples should be sent and received to the laboratory;
- Culture reporting format, identification of staff receiving culture results;
- Training and competency assessment for sampling and culturing staff;
- Duration of time to maintain endoscope culturing records;
- Threshold limits for low- to moderate-concern organisms;
- Frequency of review of this protocol; and
- Procedures to respond to endoscope culturing results, including when results exceed the predetermined microbial limits.

Obtaining samples is complex and will require two trained individuals – one to perform the sampling, maintain aseptic handling and perform brushing steps; the other to assist with opening packages and handling the unsampled portions of the endoscope. At least two samples should be collected and combined; an instrument channel sample (biopsy port to distal end) should be taken using a flush, brush, flush method, and an elevator recess sample should be taken by flushing and brushing of the elevator recess. For duodenoscopes with an open (unsealed) elevator wire channel, a third sample should be collected from the elevator wire channel by flushing that channel and combining the sample with the other two samples. Personnel should wear the appropriate PPE when handling the endoscopes for sampling.

As a facility develops its plan for endoscope surveillance sampling and culturing, it is recommended to include responses to the culturing results when results exceed the predetermined microbial limits. It is also recommended that healthcare facilities have a plan to include a risk/safety management response when high-concern organisms are cultured from reprocessed endoscopes. Examples of responses may include quarantine of endoscopes, retraining reprocessing staff on endoscope reprocessing protocols, conducting a risk/safety management response, and patient notification.

Endoscope surveillance sampling and culturing records should be maintained by the healthcare facility’s Infection Prevention and Control staff or other designated personnel, in accordance with the healthcare facilities record storage and retention policy.