Microbial Surveillance of Flexible Endoscopes

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LEARNING OBJECTIVES

1. Define microbial surveillance and understand the current standards and professional society recommendations for performing microbial surveillance of flexible endoscopes
2. Review published studies stating contamination rates and findings
3. Outline the current methods available for performing microbial surveillance on endoscopes

Outbreaks of bacterial infection associated with endoscopes are often attributed to improperly reprocessed endoscopes; however, recent reports have identified carbapenem-resistant Enterobacteriaceae (CRE) transmission associated with persistently contaminated duodenoscopes for which no breaches in reprocessing were identified.1 Endoscope manufacturers, regulatory bodies and healthcare facilities are increasingly concerned about the spread of communicable diseases, including clinically relevant microorganisms, from reprocessed medical devices. Since it is well known that flexible endoscopes are a challenge to clean and disinfect/sterilize, microbial surveillance testing has become more widely implemented. The goal is to proactively monitor the effectiveness of processing of clinically-used scopes.

Specifically, numerous healthcare facilities have successfully implemented routine or periodic surveillance testing to assess the adequacy of duodenoscope reprocessing and to identify duodenoscopes with persistent contamination despite reprocessing.1

Objective 1: Define microbial surveillance testing and understand the current standards and professional society recommendations for performing microbial surveillance of flexible endoscopes

Microbial surveillance testing involves sampling endoscope channels and the distal end, and culturing those samples to identify any bacterial contamination that may be present on the scope after reprocessing.1

Figure 1: Technician performing endoscope surveillance sampling for testing

Although there are no specific requirements for endoscope microbial
surveillance sampling at this time, current national standards and professional society guidelines, such as ANSI/AAMI ST91, *Flexible and semi-rigid endoscope processing in health care facilities*; the Society of Gastroenterology Nurses and Associates’ (SGNA’s) *Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes*; and the Association of periOperative Registered Nurses’ (AORN’s) *Guidelines for Perioperative Practice: Flexible Endoscopes – 2018*, do discuss the value of conducting endoscope sampling as a means to identify reprocessing issues for endoscopes, and as a feedback mechanism to determine if there is a robust processing system in place. Endoscope sampling has been successful at identifying quality issues in facilities.

Specifically, ANSI/AAMI ST91 states that:

- No recommendation is made in the current version because of the timing of release; and
- Studies have identified the nature of microbial contamination likely to be found in improperly reprocessed endoscopes and have demonstrated the value of surveillance testing.

SGNA states that “microbiologic testing after reprocessing, during storage or before use is not required.” However, the FDA, Centers for Disease Control and Prevention (CDC) and American Society for Microbiology (ASM), along with other endoscope processing experts, recently released protocols on voluntary, standardized duodenoscope surveillance sampling and culturing (2018). Surveillance cultures can aid in identifying particular endoscope issues that hamper effective reprocessing.

AORN recommends that a multidisciplinary team (which includes infection preventionists, endoscopists, endoscopy processing personnel, microbiologists, laboratory personnel, risk managers and other involved personnel) should evaluate the need to implement a program for regular microbiologic surveillance culturing of flexible endoscopes and, specifically, duodenoscopes. This multidisciplinary team should also evaluate the method to use for sampling, the frequency of performing testing and established benchmark levels for the facility. The team should also discuss what to do with the results once obtained.

Additionally, the FDA provides a list of supplemental duodenoscope reprocessing measures that facilities can use in addition to current instructions.
for use (IFU) for additional risk mitigation. These strategies are listed as:

- Microbiological culturing;
- Ethylene oxide sterilization;
- Use of a liquid chemical sterilant processing system; and
- Repeat high-level disinfection (HLD).

As recently as August 29, 2019, the FDA published a safety alert entitled *The FDA is recommending transition to duodenoscopes with innovative designed to enhance safety: FDA safety communication.* Within this alert, the FDA listed two important recommendations for healthcare facilities:

- Institute a quality control program that includes sampling and microbiological culturing, and other monitoring methods; and
- Monitor reprocessing procedures. Examples of monitoring are sampling and culturing using the FDA/CDC/ASM Method.

ECRI Institute also has a statement about microbial surveillance of duodenoscopes. Included in their recommendations, facilities should consider instituting CRE surveillance testing by routinely culturing duodenoscopes. The options listed for how to do this include:

- Doing baseline cultures;
- Culturing every duodenoscope after reprocessing is complete and waiting to release the scope for use once negative test results are received; and
- If not doing this for every scope, then at least doing so weekly.

Therefore, although there are no direct requirements for performing routine microbial surveillance of flexible endoscopes, there are many recommendations to do so, in particular, for duodenoscopes.

**Objective 2: Review published studies stating contamination rates and findings**

Multiple published peer-reviewed articles have demonstrated significant incidences of residual microbial contamination in reprocessed endoscopes. High-level disinfected endoscopes should have no bacteria remaining in or on them after the HLD process; however, studies now demonstrate this is often not the case.

The FDA required post-market safety surveillance studies be performed in healthcare facilities by the major endoscope manufacturers. Interim results have been posted on the FDA’s website as of July 2019 and show a 5.0% (Olympus) and 4.9% (Pentax) positive culture rate for high-concern organisms across all types of duodenoscopes.

The most recent studies from the scope manufacturers show elevated rates of contamination, including the presence of high-concern organisms (defined as organisms that are more often associated with disease transmission, such as *E. coli* and *Pseudomonas aeruginosa*).

Additional, recent published studies from Ofstead and Associates found that flexible endoscopes were contaminated at alarmingly high rates. The following culture positive rates were found post-HLD or post-sterilization across several different studies:

- GI endoscopes: 60% in one study; 64% in another
- GI bronchoscopes and urology scopes: 71%
- Bronchoscopes: 58%
- Ureteroscopes: 13% (following sterilization, not HLD)

Other studies have found similarly high rates of contamination persisting after HLD. Researchers Saliou and Legemate demonstrated high failure rates with both GI scopes and ureteroscopes. Saliou et al. demonstrated that of 1100 microbial tests of GI endoscopes, a total of 264 endoscopes (34.6%) showed a level of contamination higher than the target. Also, in a study by Legemate et al., it was found that of 389 microbial samples, ureteroscope cultures were positive in 12.1%, of which urological pathogens were found in 2.3% and skin organisms 9.8%.

These two studies are just a sampling of data available in published literature that demonstrate significant rates of culture positive flexible endoscopes after HLD. This reinforces the need for routine, periodic monitoring of all types of flexible endoscopes.

**Objective 3: Outline the current methods available for performing microbial surveillance on endoscopes**

Per ANSI/AAMI ST90, a quality management system is required in healthcare facilities. This means assessing reprocessing areas to determine the adequacy and completeness of reprocessing. This includes ensuring training competency through a monitoring program and that the reprocessing steps outlined in the medical device IFU are carried out as specified. Doing so also helps with internal investigation if patient infections are linked to reprocessing. A monitoring program, including a microbiological surveillance program, would be part of this quality management system and evaluation of reprocessing practices.

**How does a facility implement microbial surveillance?**

There are currently two methods available for performing microbial surveillance on flexible endoscopes: traditional surveillance cultures and...
rapid gram-negative test kits.

Traditional culturing is performed according to the validated FDA/CDC/ASM method. This method provides a protocol for surveillance sampling and culturing of reprocessed duodenoscopes intended as a quality control measure of the adequacy of reprocessing. While the current instructions apply primarily for duodenoscopes, they can also be implemented for other flexible endoscopes, including other types of GI scopes, ultrasound scopes and bronchoscopes.

In general, endoscope samples are collected from the endoscope instrument suction channel, from the distal end and, if the endoscope has one, from the elevator recess. The sample taken from the instrument/suction channel is obtained by a Flush-Brush-Flush method where sterile water is flushed through the channel and then brushed and flushed again with sterile water. The effluent is collected into a sterile container to which Dey/Engley (D/E) neutralizing fluid is added. Additionally, when present, a sample of the elevator recess is taken. These samples are combined and sent to a laboratory for concentration and analysis.

Once samples are concentrated and plated, the plates must be incubated for 72 hours. If there is growth on the plates, then this must also be identified; therefore, this process routinely takes a week or more to get results and identification of any bacteria found in the testing. Culturing scopes by this traditional method will find all types of organisms, including both gram-positive and gram-negative bacteria.
Alternatively, rapid gram-negative test kits can be used as a screening tool to more rapidly assess the status of reprocessed flexible endoscopes. While not a replacement for traditional culture methods, the comparative simplicity and rapidity of results means that more endoscopes can be screened for possible contamination. When used as an adjunct to routine culturing, these tests can help increase the population and frequency of scopes tested.

These types of tests require only a 12-hour incubation period. Samples are taken by flushing sterile water through the biopsy port, which is collected at the distal tip. Swab methods are also available for this type of test, which allows a user to swab directly around the forceps elevator of a duodenoscope. A gram-negative test will pick up only gram-negative bacteria, which are mainly those identified as organisms of concern by the FDA/CDC/ASM method and those that have been implicated in endoscope-related outbreaks.

Typically, the system works by utilizing a unique enzyme detection method. A fluorometer checks for gram-negative bacteria down to 10 Colony Forming Units (CFU) by reading fluorescence given off by those bacteria that may be present in the recaptured sample. If the fluorometer reading gives a positive result for gram-negative bacteria, it is recommended to reprocess the endoscope following manufacturer guidelines prior to use. Testing can be performed directly in the endoscopy clinic or healthcare facility, thus not requiring sending the sample to a laboratory for testing or waiting days for a culture result.

Like traditional culturing, these rapid gram-negative tests detect gram-negative bacteria such as *E. coli*, *Pseudomonas aeruginosa*, and *Klebsiella* species, which have been associated with patient infections after endoscopic procedures. Additionally, multi-drug resistant strains of these organisms, such as CRE, are also demonstrated to be detected. Gram-negative bacteria act as indicators for bacterial contamination in endoscopes and reduce the risk of false positives associated with the gram-positive bacteria occurring normally as skin flora, such as *Staphylococcus epidermidis*.

The FDA states that a negative surveillance culture does not completely exclude the possibility of a contaminated duodenoscope; however, positive culture results should lead to some action as outlined in the FDA/CDC/ASM method. Any endoscope found to be contaminated with any level of high-concern organisms or unacceptable level of low-concern organisms should be reprocessed again with repeat post-reprocessing cultures obtained. The endoscope should not be used again until it has been demonstrated to be free of high-concern organisms and has an acceptable level of low-concern organisms.
**Conclusion**

Safe patient care requires that each endoscope is free from microbial contamination. Routine periodic microbial surveillance testing of flexible endoscopes is one quality assurance parameter that is recommended to be implemented as part of a quality management system and as a means to evaluate reprocessing practices. This process will increase patient safety by demonstrating that reprocessing practices are effective.

**REFERENCES**


2. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST91:2015, Flexible and semi-rigid endoscope processing in health care facilities.


