

Microbiological Surveillance of Flexible Endoscopes

A Method for Verifying Reprocessing Efficacy in Clinical Practice

by Bradley Catalone, Ph.D.

Flexible endoscopes are sophisticated medical devices used to perform more than 15 million procedures annually in the United States.¹ Like many medical devices, flexible endoscopes are reusable and must be reprocessed to render them safe for use on subsequent patients. Studies have indicated that the viable bioburden on flexible endoscopes after patient use ranges from 10⁶ to 10⁹ colony forming units.^{2,3} Proper reprocessing requires removal or inactivation of these microorganisms to ensure patient safety and minimize the risk of nosocomial infection. Reported iatrogenic infections due to flexible endoscopy are rare.⁴ In gastrointestinal endoscopy, the estimated rate of transmitting infectious organisms is 1 in 1.8 million procedures.⁵ Reported cases of iatrogenic transmission from endoscopy have involved breaches in currently accepted guidelines for cleaning and disinfection, use of contaminated reprocessing equipment, and use of defective equipment.^{6,7}

Despite the publication of consensus reprocessing guidelines,^{7,8} breaches in standard reprocessing practices continue to be reported. Recent reprocessing failures have resulted in notification letters being sent to potentially affected patients. These failures in endoscope reprocessing have also been highlighted in the popular media.^{9,10,11} Although the risk of nosocomial infection from endoscopy is rare, these reported incidents emphasize the need for methods to assure compliance with existing guidelines and to identify reprocessing failures in a timely manner.

Currently, effective endoscope reprocessing can only be assured through strict adherence to established guidelines. Endoscope reprocessing is a multi-step procedure that requires manual cleaning, and manual or automated high-level disinfection. As a result, the efficacy of endoscope reprocessing is dependent upon the performance of both personnel and automated equipment. Although aspects of the reprocessing procedure can be monitored (e.g., disinfectant concentration, contact time, and temperature), there are no standardized methods for verifying the efficacy of endoscope reprocessing in clinical practice. Without adequate quality assurance methods to monitor the efficacy of reprocessing, there is very little to indicate personnel and equipment failures in clinical practice.

One proposed approach for monitoring the efficacy of endoscope reprocessing is to perform routine microbiological surveillance cultures. However, there are currently no standard protocols for performing microbiological surveillance of endoscopes and the value of such an approach has not been widely accepted. Furthermore, routine environmental monitoring of endoscopes is not a recommended practice according to “The Multi-society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes.” The culturing of clinical endoscopes is only recommended as part of an epidemiological investigation where the endoscope may be a potential source of nosocomial disease transmission.⁸ Despite this, many healthcare facilities are choosing to implement microbiological surveillance of endoscopes as part of their quality assurance program. A recent survey by Moses and Lee indicated that 17% of responding facilities performed surveillance cultures of endoscopes.¹²

Elements of a Microbiological Surveillance Program for Endoscope Monitoring

Purpose

In order for a microbiological surveillance program to be valuable, the purpose, benefits and limitations of such a program must be understood. The primary purpose of microbiological surveillance is to provide assurance of endoscope reprocessing efficacy. There are two points in the process that may be routinely monitored, but it is important to understand that they provide different information regarding reprocessing efficiency. First, endoscopes may be cultured immediately after reprocessing. This approach evaluates the efficacy of the reprocessing procedure for removal and inactivation of viable bioburden from the endoscope. Second, endoscopes may be sampled after a period of storage to evaluate the effectiveness of channel drying and the contribution of environmental contamination during storage. For example, microbial growth in endoscope channels during storage could indicate that the channels were not properly dried and contained residual moisture.

Microbiological surveillance cultures are not intended as real-time verification of reprocessing efficacy, nor are they appropriate as release testing of endoscopes for patient use.

Because cultures take a minimum of 24 to 48 hours to incubate, and there is a clinical demand for reuse of these medical devices in the mean time, surveillance culture results will likely not be obtained until after the endoscope is used on the next patient. While not appropriate for instrument release criteria, surveillance cultures may be useful as part of a broader quality assurance program to identify reprocessing failures and limit the potential risk of nosocomial infection.

Sample Size

Sampling every endoscope or random sampling of endoscopes may not be the most value-added approach for selecting endoscopes to be monitored. The microbiological surveillance procedure for culturing endoscopes at the facility should establish the number and rationale for selection of endoscopes to be cultured. The surveillance program may want to specifically target the most frequently used endoscopes and endoscopes that have proven the most difficult to effectively reprocess in the past. However, it may be beneficial to include monitoring of every endoscope at least annually.

Sampling Frequency

The selected monitoring interval should be based upon the history of reprocessing efficacy. Initially, the monitoring frequency should be higher to generate sufficient data to provide assurance of effective reprocessing. For example, facilities may want to monitor flexible endoscopes on a monthly basis to establish a baseline of information and determine if the results warrant any modifications to current reprocessing practices. Once effective reprocessing has been established, the frequency of monitoring may be decreased. However, additional monitoring sessions should be included to evaluate any changes to the process: including, new reprocessing chemicals, equipment, or personnel.

Sample Site Selection

Microbiological surveillance cultures are not practical for determining the total bioburden present on an endoscope. The entire endoscope is not sampled as part of routine surveillance. Instead, sampling locations that represent the greatest challenge to cleaning and disinfection should be selected. In general, samples should be taken from locations that are exposed to the highest bioburden, are the most difficult to clean and disinfect, and represent the greatest risk to patient safety. In most cases, this will be the suction and instrument channel of flexible endoscopes. If results indicate that these locations were effectively reprocessed, this provides some assurance that the entire endoscope was effectively reprocessed. Other sampling locations, such as the air/water channel, auxiliary water channel, and elevator wire channel should be periodically monitored to ensure established reprocessing guidelines are being followed.

Microorganism Recovery

Microbiological surveillance culture methods should be selected to recover a broad range of microorganisms and not target species-specific microorganisms. Routine surveillance cultures that include methods to target species-specific pathogens, such as *Mycobacterium tuberculosis* or Hepatitis C Virus, require unique assays that are both cost and time prohibitive. The use of growth media that will support the recovery of many types of organisms provides some assurance that the results are representative of the sampling location bioburden. In contrast, endoscope culturing for relevant pathogens would be appropriate as part of an epidemiological investigation.

Methods and Validation

Microbiological surveillance of flexible endoscopes requires the use of appropriate and validated methods. Selection of appropriate sampling and assay methods is essential for the results to be meaningful. Sampling and assay methods should also be validated to recover microorganisms from the surface being sampled. Without method validation, there is no assurance that culture results are representative of the microbial bioburden from the sampled surface. Unfortunately, standard methods for surveillance cultures have not been established. Published studies evaluating residual viable bioburden from patient-used endoscopes have been performed by either flushing the internal channels with sterile water^{3,13,14} or using a flush-brush-flush method.^{15,16}

Endoscope Sampling

Endoscope sampling methods require extensive manipulation and handling of the endoscope. In addition, endoscope sampling will likely be performed in an open environment where airborne particulates may contaminate the sample. These factors make the procedure inherently prone to generating false positive results. Sampling personnel should be properly trained in aseptic technique and endoscope handling to minimize the potential for sample contamination. Due to the extensive manipulation of the endoscope and the potential for endoscope contamination during the sampling process, all sampled endoscopes should be reprocessed prior to patient use.

Considerations

Before embarking on a microbiological surveillance program for endoscopes, obtain input and approval from the Infection Control Committee or personnel responsible for determining infection control policies and procedures. In addition, no surveillance cultures should be taken unless acceptance criteria for culture results are clearly established and a defined course of action is specified for results exceeding established limits. Because surveillance culture results are traceable to a specific endoscope at a point in time and

the results will not be available until after the endoscope was likely used on a subsequent patient, it is critical to determine prior to entering into the surveillance program what actions will be required to address issues of possible nosocomial infection risk for individual patients should surveillance results exceed established limits.

It is also essential that personnel responsible for obtaining endoscope samples be trained in aseptic technique for sampling large, bulky instruments. The individuals actually reprocessing the endoscopes may not be the best candidates for taking such samples, since they are likely insufficiently trained in microbiological technique. It is largely the ease of obtaining false positives, and the resources consumed in investigating and following up false positives that have dissuaded most infection control experts and professional societies from recommending routine surveillance culturing of endoscopes.

Success Stories

While some opponents have argued that microbiological surveillance is of little value relative to the cost and resources required to implement such a program, two long-term surveillance programs have provided evidence of substantial clinical benefit. In one case, surveillance culture results were utilized to identify an automated endoscope reprocessor as the source of repeated endoscope contamination. In addition, routine surveillance cultures were used to identify deficiencies in reprocessing practices and implement corrective action, which improved future reprocessing efficacy.¹⁴ The other published surveillance study identified endoscopes that proved most difficult to reprocess, a damaged endoscope, and breaches in proper reprocessing procedures.¹³ The reprocessing failures that were identified as part of these studies would likely have been undetectable by traditional monitoring of the reprocessing procedure.

Summary

The decision whether or not to initiate a surveillance program is dependent upon on your answers to the following questions: Can we adequately train our staff to obtain cultures without sample contamination? Do we have a sampling environment where aseptic sampling can be performed? What protocol will we use for obtaining the samples? What microorganisms will we optimize our methods to recover? What is the appropriate surveillance interval? What rationale will we use to select endoscopes for sampling? What acceptance criteria or limits will we establish for culture results? What course of action is planned for both negative and positive results? What will the program cost us?

Surveillance monitoring has proven to provide value in many endoscopy units. However, the pitfalls of entering into such a program without adequate training and appropriate planning has convinced most infection control experts and professional societies against universally recommending the practice. †

References

1. Seeff L, Richards T, Shapiro J, et al. How Many Endoscopies are Performed for Colorectal Cancer Screening? Results From CDC's Survey of Endoscopic Capacity. *Gastroenterology* 2004; 127: 1670-1677.
2. Chu N, McAlister D, Antonoplos P. Natural bioburden levels detected on flexible gastrointestinal endoscopes after clinical use and manual cleaning. *Gastrointestinal Endoscopy* 1998; 137-142.
3. Alfa M, DeGagne P, Olson N. Worst-case soiling levels for patient-used flexible endoscopes before and after cleaning. *American Journal of Infection Control* 1999; 27: 392-401.
4. Spach D, Silverstein F, Stamm W. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. *Annals of Internal Medicine* 1993; 118: 117-128.
5. Kimmey M, Burnett D, Carr-Locke D, DiMarino A, Jensen D, Katon R, et al. Transmission of infection by gastrointestinal endoscopy. *Gastrointestinal Endoscopy* 1993; 36: 885-888.
6. Nelson D. Infectious disease complications of GI endoscopy: Part II, exogenous infections. *Gastrointestinal Endoscopy* 2003; 57: 695-711.
7. Mehta, AC, Prakash, UBS, Garland R, Haponik E, Moses L, Schaffner W, and G Silvestri. American College of Chest Physicians and American Association for Bronchoscopy consensus statement: Prevention of flexible bronchoscopy-associated infections. *Chest* 2005; 128: 1742-1755.
8. Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. *Gastrointestinal Endoscopy* 2003; 58(1): 1-8.
9. Glionna, JM. Unsterile devices prompt warnings: use of dirty endoscopes in colon and throat exams can pass along infections activists say. *The Los Angeles Times*, Los Angeles, CA, Feb 13, 2003, p B1.
10. Fahy, J, and Spice B. Monroeville hospital urges 200 colonoscopy patients to get checked for hepatitis, HIV. *The Pittsburgh Post-Gazette*, Pittsburgh, PA, March 31, 2005.
11. Torassa U. Endoscope hygiene a growing problem but experts say it's unlikely a patient would get hepatitis. *San Francisco Chronicle*, San Francisco, CA, September 10, 2004.
12. Moses F, Lee J. Current GI endoscope disinfection and QA practices. *Digestive Diseases and Sciences* 2004; 49: 1791-1797.
13. Moses F, Lee J. Surveillance cultures to monitor quality of gastrointestinal endoscope reprocessing. *The American Journal of Gastroenterology* 2003; 98: 77-81.
14. Tunuguntla A, Sullivan M. Monitoring quality of flexible endoscope disinfection by microbiologic surveillance cultures. *Tennessee Medicine* 2004; 97: 453-456.
15. Alfa M, Olson N, DeGagne P, Jackson M. A survey of reprocessing methods, residual viable bioburden, and soil levels in patient-ready endoscopic retrograde cholangiopancreatography duodenoscopes used in Canadian Centers. *Infection Control and Hospital Epidemiology* 2002; 23: 198-206.
16. Isenberg H, ed. *Clinical Microbiology Procedures Handbook*. Washington, D.C: American Society for Microbiology; 1994.

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