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LEARNING OBJECTIVES

- **Identify the various risk factors contributing to flexible endoscope high-level disinfection failure.**
- **Identify strategies to mitigate risk factors that contribute to flexible endoscope high-level disinfection failure.**
- **Describe the process of conducting a risk assessment of flexible endoscope-related disease transmission within a healthcare facility.**

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SELF-STUDY SERIES

Safer scopes

Developing internal quality assurance processes for flexible endoscopes

by Rebecca (Becca) Bartles, MPH, CIC, FAPIC

The literature is filled with case reports of patient infections linked to contaminated flexible endoscopes, implicating a wide range of scope types and designs.¹⁻⁷ A number of recent outbreaks in the U.S. have resulted in multiple deaths due to multi-drug resistant organism transmission via flexible endoscopes.^{3,8} Although this topic may not be as prevalent in the news today as it was just a year or two ago, the same problems continue to plague our endoscopy labs. How does an organization make sense of this risk and develop a quality assurance process that will reliably result in adequately disinfected flexible endoscopes? This article will address that question, but first we will review the problem and its history in greater detail.

In 1957, Dr. Earle Spaulding of Temple University proposed the Spaulding Classification, a now widely used system for determining the appropriate disinfection or sterilization processes for various types of patient equipment. Flexible endoscopes have historically been classified as “semi-critical” items, meaning that they come in contact with non-intact skin or mucus membranes but do not penetrate them. According to the Spaulding Classification, semi-critical devices should undergo high-level disinfection (HLD), a process that kills all microorganisms with the exception of a large number of bacterial spores and prions. At the time, this was an appropriate classification for flexible endoscopes, because the instruments were relatively simple and not used for complex procedures. Technology has changed, though, and flexible endoscopes have become exceedingly more complex. Today’s flexible endoscopes are commonly used

to penetrate mucus membranes, but the recommendations for these scopes have not changed.

In an ideal scenario, HLD could still be a sufficient technique for reprocessing flexible endoscopes. Unfortunately, endoscope reprocessing rarely happens in an ideal scenario. There are a number of factors that can make high-level disinfection insufficient. The primary factor is manual cleaning. In order for a scope to be effectively high-level disinfected, all organic material should be removed via a thorough manual cleaning process. If this does not occur, microorganisms can develop biofilm and survive the HLD portion of the process in a protected environment. The greater the complexity of the scope, the more difficult thorough manual cleaning becomes.

Inappropriate disinfection can also result in reprocessing failure. Although the invention of automated endoscope reprocessors (AERs) has reduced some of the potential for user error during the HLD step, there are still ways in which this step can fail. For example, using the wrong disinfectant, according to the AER manufacturer’s instructions for use (IFU), can result in inadequate HLD.

Finally, the manufacturer’s IFUs are often incredibly long, detailed processes that lend themselves to human error. When combining complex devices, difficult instructions, and human beings, the potential for error is great. Dr. William Rutala addressed this issue in his 2015 article “ERCP Scopes: What Can We Do to Prevent Infection?”⁹ He demonstrated the very small (if not non-existent) margin of safety in HLD of flexible endoscopes by calculating the potential log reduction of bacteria at each step of the process. After use on a patient, the working channel of flexible scopes can contain from 7 to 10 log₁₀ enteric microorganisms after use. Manual cleaning can reduce this burden



Dr. Earle Spaulding, 1953

Image Courtesy of the U.S. National Library of Medicine

by 2 to 6 log₁₀ and HLD by another 4 to 6 log₁₀. If the minimum log reduction is achieved at each step, the endoscope could still potentially contain a 4 log₁₀ enteric microorganism burden.

The literature – and lack of answers

Over the last couple of years, much research has been done to better understand flexible endoscope contamination rates. A number of studies reflect an inherent rate of positive bacterial cultures in flexible endoscopes after HLD (ranging from .6 to 60 percent),^{10,11} despite adherence to manufacturers' HLD instructions. This ongoing risk of scopes harboring bacteria after standard HLD warrants additional risk mitigation strategies. Although many advisory documents exist regarding endoscope reprocessing, none offer a consensus on a single strategy to eliminate this risk.

In August of 2015, the FDA recommended that facilities using duodenoscopes consider the use of supplemental measures to help reduce the risk of infection transmission.¹² These measures included microbiological culturing, ethylene oxide sterilization, use of a liquid chemical sterilant reprocessing system, and repeat high level disinfection. Following these recommendations, researchers began assessing each strategy to determine its potential for reducing transmission risk.

One multicenter study tested the efficacy of repeat HLD in a randomized trial and determined no significant impact on positive bacterial cultures.¹³ Although microbiologic culturing is an important strategy, it is not feasible (due to both cost and time) to utilize this mitigation strategy on each flexible endoscope before each use, and that is the only way to ensure a negative scope. Both ethylene oxide sterilization and liquid chemical sterilant reprocessing still require adequate mechanical cleaning before sterilization in order to be effective. In the case of incomplete manual cleaning or presence of biofilm, these practices may not be any more effective than HLD.



Photo courtesy of Becca Bartles

Conducting a flexible scope risk assessment

In light of the lack of effective supplemental measures and continued reports of positive bacterial cultures in fully reprocessed endoscopes, facilities should consider utilizing a risk assessment methodology to determine the best mitigation strategy to ensure patient safety. Conducting a risk assessment allows a facility to understand the detail and degree of risk associated with their endoscopes. Although the process is generally laborious and requires significant resources, the result is accurate, organization-specific information for making optimal decisions.

The first step in a flexible endoscope risk assessment is inventory creation. Depending on the size of an organization, this could be a daunting task. An inventory should be a line listing of each endoscope owned by the organization, along with a number of key attributes (serial number, manufacturer, model number, etc.). Having a comprehensive inventory allows the risk assessment team to identify risks based on type and volume of scopes within the facility.



Photo courtesy of Becca Bartles

The second step in the risk assessment is risk identification. Each scope category (duodenoscopes, gastroscopes, colonoscopes, endobronchial ultrasound scopes, etc.) should be reviewed to determine if there are unique risks because of scope structure, design, or type of use. ERCP scopes are considered higher risk because of the difficulty involved in cleaning the elevator mechanism. Other scope types can present similar challenges, like small channels that cannot be brushed. Age of scope and frequency/volume of use should also be considered, particularly if the scope has not received regular preventative maintenance. In addition, risks present in all flexible endoscopes should be identified (e.g., increased risk of biofilm development if bedside cleaning is not conducted immediately following the procedure) so that a mitigation strategy can be developed for each risk.

The third step in the risk assessment is research and literature review. Probably the most daunting, it is a worthwhile endeavor to read about what other organizations have done to try to address this problem. A number of advisory guidelines that address quality control in endoscopes are available as reference, though there are notable differences between them. Acquiring a comprehensive understanding of the epidemiology of the problem can support the team in identifying effective solutions.

The final step in the risk assessment process is to determine the mitigation strategies that will be utilized. Each risk should have an aligned mitigation strategy. Below is an example of the strategies that were used by one large, highly-integrated health system. See table, next page.

Implementing recommendations

The work of conducting a risk assessment can be intense, and it may end up going to waste if a careful effort is not made to ensure implementation of each recommendation. Higher-yield mitigation strategies are often higher-cost as well, so these will require planning and a cost-benefit analysis to ensure approval of funding.

One example of a high-yield, literature-supported mitigation strategy for reducing the risk of endoscope infection transmission is the use of ATP testing during reprocessing. As previously described, both HLD and sterilization processes will be ineffective if an endoscope has not been manually cleaned appropriately. All bioburden should be removed from an endoscope prior to HLD or sterilization. Many facilities have begun to utilize ATP testing after manual cleaning to ensure that bioburden has been removed before moving forward with HLD or sterilization. This technology provides the individual cleaning the scope with an immediate indication of whether or not a substantial amount of bioburden remains on the scope, allowing them to re-clean before continuing reprocessing if needed. Although a strategy of this type requires a financial investment, the case is easily made for return on investment in the form of patient safety and cost avoidance.

Each risk mitigation strategy, along with its rationale should be evaluated to determine cost to the organization and expected return on investment. Sharing this information with senior leadership

Risk Mitigation Strategy	Rationale
Always use an automated endoscope reprocessor or sterilizer (excludes downtime procedures).	Studies have shown that automated endoscope reprocessors are significantly more effective at high-level disinfection than manual soak processes.
Always reprocess the scope within 1 hour of use. Exceptions should be minimized and accompanied by manufacturer's delayed reprocessing recommendations. Exceptions should be documented for use in annual scope review.	This is the manufacturer's recommendation. Allowing scopes to sit for greater than 1 hour with biological material can result in development of biofilm, which significantly decreases cleaning and disinfection effectiveness.
Utilize ATP testing following manual cleaning to ensure the bioburden is reduced enough for effective high-level disinfection. Scopes with a reading of >200 RLU should be manually cleaned again. If <200 RLU cannot be achieved after the second manual cleaning, the scope should be sent to the repair facility with a request for comprehensive review (including boroscope).	ATP has been shown to be a reliable indicator of manual cleaning effectiveness. Utilizing ATP after manual clean and before high level disinfection adds a comfort level that bioburden has been reduced enough to make HLD effective.
Conduct an annual review of scope use, including frequency/volume of use, type of use, and accumulated QC data to determine if replacement or rebuild is warranted.	Conducting an annual review will allow departments to ensure that their fleet is well maintained, in working order, and updated as appropriate.
Do not irrigate the auxiliary water channel w/simethicone or methane blue/ indigo carmen.	These products can be difficult to remove from channels that cannot be brushed. This can provide a reservoir for bacterial growth.

along with the recommendations can assist in illuminating the business case for what might otherwise be seen as “just another way to spend money.”

Conclusion

Although the vast majority of healthcare facilities in the United States are continuously focused on improving patient safety, flexible endoscope infection transmission remains an ongoing risk. Although a comprehensive (and future) solution will likely involve redesign of scopes and reprocessing practices, it is imperative that facilities that utilize these scopes ensure the most effective mitigation strategies are in place NOW. Conducting a comprehensive risk assessment will assist facilities in determining their areas of greatest risk and identifying the right mitigation strategies to keep their patients safe. **HPN**

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CONTINUING EDUCATION TEST • JUNE 2018

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Circle the one correct answer:

1. The average level of enteric microorganism contamination in an endoscope after patient use is 7 to 10 log₁₀.
A. True
B. False
2. The Spaulding Classification is a system used to determine the appropriate disinfection or sterilization process for patient equipment.
A. True
B. False
3. Microbiological culturing can provide an immediate determination of an endoscope's level of contamination.
A. True
B. False
4. ATP testing is a literature-supported mitigation strategy for assessing the bioburden within an endoscope after manual cleaning.
A. True
B. False
5. Manual cleaning is not an important part of the high level disinfection process.
A. True
B. False
6. In August 2015, the FDA recommended that facilities not worry about the risk of infection transmission from endoscopes.
A. True
B. False
7. The first step in a flexible endoscope risk assessment is creating an inventory.
A. True
B. False
8. It is not important to identify the return on investment when implementing a risk mitigation strategy.
A. True
B. False
9. Design and structure of endoscopes can affect the efficacy of manual cleaning.
A. True
B. False
10. If manufacturer's instructions for use are followed during reprocessing, there should be no concern that an endoscope might still harbor bacteria afterwards.
A. True
B. False

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