Insight and Perspectives

a publication of Endurance Insurance's Healthcare Practice

We are pleased to offer our latest installment of *Insight and Perspectives*. This newsletter is dedicated to sharing healthcare news, trends and developments impacting our brokers and insureds.

This installment features Charlotte Guglielmi's article on *Reducing the Risk of Infections from Flexible Endoscopes*, as we continue to bring you practical information on current risk management topics.

As always, we appreciate your continued support and thank you for selecting Endurance to be a part of your risk and insurance programs.

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Our U.S. and Bermuda teams provide healthcare professional liability coverage to non-profit and for-profit hospitals and other healthcare organizations.

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Reducing the Risk of Infections from Flexible Endoscopes

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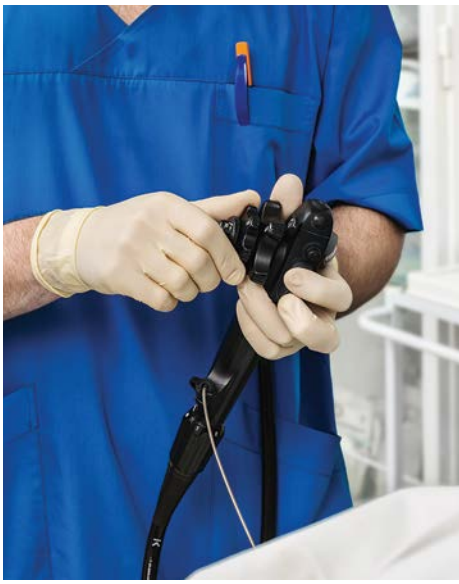

Endoscopy-related transmission of infections has received much attention from medical professionals and healthcare regulators over the past several years. In particular, cases related to duodenoscopes – devices used in endoscopic retrograde cholangiopancreatography (ERCP) procedures – have been associated with the transmission of carbapenem-resistant Enterobacteriaceae (CRE). The U.S. Food and Drug Administration convened special meetings with contamination experts and issued additional guidance in 2015 for effectively reprocessing endoscopes used for ERCP[1] and a U.S. Senate Committee reported extensively on this same topic.[2]

Causes of Endoscopic Infections

However, the issue is not limited to just duodenoscopes. All types of flexible endoscopes can become contaminated with microorganisms, secretions and blood during use. Complicating the cleaning of endoscopes is their intricate design, which includes narrow lumens and multiple internal channels.

Infections caused by inadequate reprocessing of endoscopes, particularly in the pre-cleaning stage, were listed as the number one concern in the Top 10 Technology Hazards for 2016 by The ECRI Institute.[3] Both manufacturers and providers of endoscopic services need to address these concerns to reduce the risk of infections, improve patient safety, and mitigate liability exposures.

Steps to Safe Endoscope Reprocessing

In 2016, the Society of Gastroenterology Nurses and Associates (SGNA) published updated standards for infection prevention in reprocessing flexible gastrointestinal endoscopes and outlined appropriate steps to follow in managing endoscopes.[4] The SGNA standards can be a valuable resource for assessing reprocessing practices and identifying opportunities for improvement.

The SGNA guidelines also identify contributing factors that add to the difficultly in reprocessing endoscopes. These factors can be assigned to the following categories:

- Endoscope Design: The complexity of the endoscope design and the variability in the cleaning procedures between manufacturers in relationship to the difficulty of thoroughly cleaning the scopes and the impact of occult damage harboring microorganisms

Continued over

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- Staff: Personnel (staff) factors that influence the quality of reprocessing
- Reprocessing: Reprocessing factors that are prone to human error include a high number of steps in the process, delays in reprocessing, and inadequate pre-cleaning and drying.
- Technology Errors: Malfunction of the equipment used for reprocessing endoscopes, use of incorrect connectors and unrecognized problems with the water supply

With an abundance of literature on the topic of endoscope reprocessing, sorting through all of the information can be a daunting and confusing task. A valuable resource is the work done by The Association of periOperative Registered Nurses (AORN). AORN staff reviewed 3,397 pieces of published literature and identified 418 of them containing the strongest evidence for safe endoscope reprocessing. These publications were incorporated into the endoscope processing guideline released in February 2016 by AORN, which shares the following six evidence-based recommendations that clinicians should follow for safer cleaning procedures.[5]

1. Record the times that the endoscopy procedure is completed and the cleaning is initiated
2. Mechanically clean and process flexible endoscopes by exposure to high-level disinfectant or a liquid chemical sterilant or mechanically clean and sterilize
3. Implement cleaning verification tests
4. Store clean endoscopes in a drying cabinet
5. Have an expert team determine maximum recommended storage time
6. Ensure that cleaning and processing is conducted by individuals who have received training and completed competency verification activities related to endoscope processing

AORN guidelines include the rated evidence and detailed explanations for each of the recommended practices as well as a collection of implementation tools with policy templates.[6]

The Human Factor: Staff Competency

There is consensus in the medical expert community that staff competency is an essential area that needs to be addressed to reduce infections caused by the improper handling of flexible endoscopes. Education of staff in the operating rooms and procedure areas as well as the central processing department is critical to improved patient safety. Educational content needs to be up to date and leadership must make these resources readily available. Staff members need to know the steps necessary to carry out endoscope reprocessing as well as how to access key procedure information that includes endoscope manufacturer's information for use (IFU) for each type of endoscope instrument.

The AORN guideline for processing flexible endoscopes contains helpful staff competency validation tools. Validation of competency for scope reprocessing should occur during the hiring process, prior to placing new instrumentation into service, and whenever changes in processes are introduced. Continuous reinforcement of initial learning is essential. In addition to traditional in-service training, an example of a useful learning tool is the "teach-back" which is a single page tool that includes the topic, a statement of the focus, learning, and the steps to complete the task in compliance with facility policy.

As an example, the Perioperative Education team at Beth Israel Deaconess Medical Center in Boston has created a teach-back to assist their staff with the difficult task of preparing flexible endoscopes for transfer. The guideline includes the six steps outlined by the manufacturer along with photographs of each step.

Conclusion

Meticulous compliance with best practices, continued education and awareness, engagement of staff at all levels and continued partnerships with endoscope suppliers provide the keys to preventing infections caused by contaminated flexible endoscopes. ◄

1. FDA. Effective Reprocessing of Endoscopes used in Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures. May 2015. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GastroenterologyUrologyDevicesPanel/UCM445592.pdf
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3. Top 10 Technology Hazards for 2016. ECRI. https://www.ecri.org/Resources/Whitepapers_and_reports/2016_Top_10_Hazards_Executive_Brief.pdf
4. Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes. SGNA., 2016. https://www.sgna.org/Education/Standards-Practice-Guidelines
5. 6 new evidence-based practices for implementing more effective processing of flexible endoscopes. AORN Periop Insider Weekly Newsletter. January 14, 2016 https://www.informz.net/InformzDataService/OnlineVersion/Pub/bWFpbGluZ0luc3RhbmNlSWQ9MjAwOTU1NQ==
6. 2016 Guidelines for Perioperative Practice. Guideline for processing flexible endoscopes. AORN. 657-757. 2016. http://www.aornstandards.org/content/1/SEC34.extract (AORN member login needed for access to full Guidelines)