News

Endoscope Reprocessing: The Importance of Being Proactive

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ECRI Institute's Accident and Forensic Investigation (AFI) Group provides specialized services to investigate, analyze, and prevent incidents, injuries, and deaths related to medical device failures and organization systems and processes. This column draws from the AFI Group's broad experience to discuss the risk management implications of medical-device-related incidents.

Endoscopes that are suspected of being contaminated despite having undergone reprocessing raise a multitude of risk management issues. These events may harm patients, alarm hundreds or even thousands of others, consume time and resources to investigate, increase the risk of litigation, and diminish trust in the organization. And unfortunately, they continue to happen. What can risk managers do to avoid these incidents and their wide-ranging consequences?

A Proactive Approach

"Hospitals should be diligent in addressing risks related to endoscope reprocessing before a contamination—or even worse, a patient infection—occurs," says Scott R. Lucas, PhD, PE, program manager, engineering, ECRI Institute's AFI Group. "They should not be learning about these problems after an infection," Chris Lavanchy, engineering director, ECRI Institute's Health Devices Group, agrees; "rather, they should be investigating concerns, proactively, with staff." But therein lies the paradox. If an organization is not currently experiencing patient infections as a result of endoscopic procedures, how is it to know that it has a flaw in its reprocessing process? It is often an increase in patient infection rates or a positive culture from periodic microbiological sampling that triggers an investigation. "While we may not be able to eliminate all hospital-acquired infections related to endoscopy, this risk can be mitigated with a proactive approach," says Lucas.

Endoscope reprocessing begins immediately after use on a patient and includes precleaning in the patient procedure room, transport to a decontamination or reprocessing room, manual cleaning, a disinfection cycle (often with an automated endoscope reprocessor), alcohol rinsing, drying, and storage. "Each stage in the process contains devices and accessories with associated processes that must be integrated according to each manufacturer's recommendations," says Lucas. "The next challenge is to develop and maintain policies considering these recommendations and ensure that staff are performing the reprocessing accordingly."

Collaboration among departments is key to ensuring that all elements are addressed. Such an approach may involve risk managers, infection preventionists, endoscope reprocessing technicians, clinical engineers, facilities and building management staff, and clinicians. "The risk manager can facilitate such collaboration and foster a culture of contamination prevention," says Lucas. In addition, clinical and facilities engineers should routinely work with vendors to maintain reprocessing equipment service requirements.

There are many types of endoscopes, and while the general premise of reprocessing them is the same, each has unique requirements. For example, many rigid scopes can be steam sterilized, whereas flexible scopes should be leak-tested and require specific channel adapters for channel flushing and automated reprocessing. Endoscope manufacturers provide reprocessing procedures in their manuals. If compatible automated endoscope reprocessors are not listed in the endoscope manual, it is up to the automated endoscope reprocessor manufacturer to ensure compatibility.

Periodic review of reprocessing procedures is one central component of a proactive approach. This should not be just a "paper" review, however; it also involves talking with staff and touring the reprocessing rooms. Questions to ask might include, "Are you able to follow the procedures? Do you feel the need to make changes? What issues are you running into? Does the facility workflow meet the personnel and facilities capabilities?" Lavanchy notes.

Small Changes, Potentially Big Impact

Change management is also key to a proactive approach. Effectively managing changes is necessary not just for new devices and reprocessing equipment but for other, smaller changes as well. For example, new disinfectants, soaking solutions, brushes for cleaning channels, or automated reprocessor equipment may require changes to reprocessing procedures. "There needs to be recognition that reprocessing is a complex process," says Lavanchy. "Because it's so complex, small changes can have a ripple effect, and they can be very significant."

Increases in workload can also have an impact. Causes of greater workload can include greater case volume; more devices, device types, or models; and changes in the types of procedures performed. An expanding workload may be difficult to recognize, especially if it happens gradually. "A gradual increase in workload can lead to procedural deviations or shortcuts, particularly if the staff feel pressure to reprocess the scopes faster," says Lavanchy. Communicating with reprocessing staff regularly will help identify these risks.

When Peripherals Are Central

Safe endoscope reprocessing is not just about what happens in the reprocessing room. Issues such as water filtration, facility design, transport, and storage can also play a role in contamination. "Often the contaminations that occur are from bacteria that are ubiquitous in the environment. For this reason, it is critical to be meticulous through the whole process," says Lucas.

"When using automated reprocessors or sterilizers, water filters are often viewed as peripheral to the process," says Lavanchy, "but the last step in reprocessing before drying and storage is a rinse cycle with purified water." If filters are improperly maintained, this rinse water could contaminate the endoscope. Filters are changed at regular intervals or as determined by appropriate hospital staff. There may be confusion about who is supposed to change water filters, and even a simple brand substitution could require a change to the frequency of filter replacement. Proactive steps can also be taken; for example, monitoring for differences in water pressure from one side of the filter to the other or monitoring the appearance of the filter can identify a clogged filter.

The hospital can also "make sure the facility design is encouraging good process," says Lavanchy. "You want dirty items moving progressively to areas that are cleaner." To that end, Lucas notes, "it's important to designate an appropriate work space for each stage of reprocessing. Infection preventionists and central sterile processing managers are particularly useful resources."

Reprocessed endoscopes are at risk of becoming contaminated during transport. One mitigation strategy is "minimizing the transport distance and designating a transport route that has limited personnel traffic," says Lucas. When major renovations are not possible, less extensive modifications, such as pass-throughs instead of doors, may reduce this distance. In addition, the containers in which the endoscopes are transported should be made of a hard plastic or metal and closed with a lid and should be disinfected after transporting a scope.

Storage conditions are important, too. Ideally, the room where endoscopes are stored should be dedicated to device storage, with appropriate environmental conditions; it should not be a high-traffic room. "Facilities modification is expensive," says Lavanchy, "but if discussion about renovation or new construction at the facility is already under way, endoscope reprocessing needs should be considered."

Room for Improvement

Ultimately, a proactive approach may help hospitals prevent issues from arising and spot them early when they do occur. "When we investigate a case, sometimes we don't

find the unequivocal source of contamination," says Lucas, "but often we find a discrepancy between a policy and procedure. There is always room for improvement."

For more information on endoscope reprocessing, see the Guidance Article Reprocessing of Flexible Endoscopes.

TOPICS AND METADATA

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