5 UPDATES TO FLEXIBLE ENDSOCPE REPROCESSING

AORN presents and explains what it means for hospitals.
Real-time video and small cameras led to the development and release of the first flexible endoscopes in the 1960s. Scopes soon became a recognized diagnostic tool in the 1980s, at the same time germ and virus transmission became a top healthcare concern. Previously, cleaning instruments between procedures was recognized as important, but as data was collected and sterilization practices were outlined by leaders like Dr. Earle Spaulding, today’s version of instrument reprocessing was born. Systems, including automated endoscope reprocessors (AERs), were later developed to supplement manual reprocessing.

These practices have become more stringent to reduce infection, typically motivated by government and clinical association input, including the U.S. Centers for Disease Control and Prevention (CDC), Association of periOperative Registered Nurses (AORN), American Society for Gastrointestinal Endoscopy (ASGE) and Society for Healthcare Epidemiology of America (SHEA). These approaches were not pushed to the forefront of patient conversation until 2014, spurred by publicly known infection outbreaks linked to tainted scopes. Clinicians understand the probability of procedures resulting in a scope-related infection is relatively low; yet, 91 percent of these infections could have been prevented with proper reprocessing measures in place. With this in mind, facilities began taking a harder look at their practices. Associations also did. The most recent adjustment to guidelines was by AORN, which presented the changes during its April 2016 Surgical Conference and Expo.

Introduction

While the overall theme of AORN’s guideline update remains focused on implementing evidence-based practices to reduce infection, a renewed look at new technology and data in mind resulted in five key alterations. They include:

- Meticulous manual cleaning is a required step unless the mechanical processor has been FDA-cleared to process the endoscope without prior manual cleaning
- Mechanical cleaning in addition to manual cleaning is preferred and reiterated
- Drying cabinets become a staple
- Storage policies should be reevaluated
- Visual inspection, including using of lighted magnification and flexible borescopes for inspection of internal channels
- Microbiologic culture surveillance programs reconsidered
These alterations do not necessarily impact surgical teams, but they do reiterate the importance of precleaning scopes in the OR after procedures and of scopes being transported in closed containers.

"After weighing the benefits and the potential harms of not following the guideline recommendations, we are quite confident that those who read our guidelines will want to implement best practices and ensure they are following our recommendations to the letter," detailed Sharon A. Van Wicklin, MSN, RN, CNOR, CRNFA(E), CPSN-R, PLNC, senior perioperative practice specialist at AORN.

OR managers can be charged with spearheading these updates to ensure these steps and the additional changes are correctly implemented consistently at all reprocessing locations and ORs. They could result in case delay due to the extra time associated with the steps, so an increase in inventory might be weighed against set demand. AORN recommends a team approach and a hard look at supporting data when deciding.

**Manual Cleaning Verified with Testing**

AORN now states: “Manual cleaning of flexible endoscopes should be verified using cleaning verification tests when new endoscopes are purchased and at established intervals, (such as after each use or daily).”

Manually cleaning flexible endoscopes is a key part of reprocessing, and to reinforce the consistency and thoroughness of the process, verification testing offers an unbiased approach to assess cleanliness. Commonly, a quick glance or visual review is all that is given to verify manual cleaning is complete, however, while the human eye can see remaining large particles, microorganisms cannot be detected, even with magnification.

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**Coarse Size of Bacteria Relative to a Red Blood Cell, a Hair, and a Grain of Coarse Sand**


The human eye can typically see particulates up to 0.1 micrometer (mm) in size without magnification, which is about five times smaller than a
grain of salt. A lighted microscope helps humans see things as small as 500 nanometers (nm), such as larger bacteria. Most bacteria and all viruses are even smaller. “There is a need for rapid testing methods to detect residual soil and verify the adequacy of manual cleaning, which is the most important step in processing flexible endoscopes,” said Van Wicklin. “Cleaning verification tests include adenosine triphosphate (ATP) and chemical reagent tests for detecting clinically relevant soils. Periodic verification of cleaning effectiveness may help reduce errors in manual cleaning and improve cleaning effectiveness.”

Available rapid indicators for protein, blood and carbohydrates can test scopes in five minutes or less. If testing confirms bioburden has been removed, then the scopes can be mechanically cleaned.

### Mechanical Cleaning to Supplement Manual Cleaning

AORN now states: “After manual cleaning and when compatible with the endoscope manufacturer’s instructions for use (IFU), flexible endoscopes and accessories should be either mechanically cleaned and mechanically processed by exposure to a high-level disinfectant or a liquid chemical sterilant or should be mechanically cleaned and sterilized.”

IFUs should be followed foremost, but AORN also recommends mechanical cleaning supplement manual cleaning, unless using a mechanical processor that has been FDA-cleared to eliminate the manual cleaning step. This is typically done with an AER, that repeats the manual cleaning process in a machine with reduced risk of human error; the scopes are cleaned, disinfected with an HLD, or sterilized with a liquid chemical sterilant, rinsed and typically dried with forced air. The HLD or liquid chemical sterilant should always be compatible with IFUs and FDA cleared.

AORN reports, in addition to reducing human error in reprocessing, mechanical cleaning also increases efficiency, minimizes exposure to biohazardous materials and is easily monitored for consistency.

One challenge with using a device, not just AERs, is the potential for device malfunction, which can result in unfiltered water contaminating the devices or HLD failure. This can be detected with a PCR test, which can take from one to 48 hours to show results, or a culture test, which can take 24-48 hours, but the time associated with these tests creates reluctance.
Drying Cabinets Become a Staple

AORN now states: “Flexible endoscopes should be stored in a drying cabinet.”

The authors elaborated, saying, “The collective evidence shows that optimal storage of flexible endoscopes facilitates drying, decreases the potential for contamination and provides protection from environmental contaminants.”

These cabinet manufacturers recognized that unless all bioburden is eliminated during reprocessing, which experts say is impossible to guarantee, the bacteria can multiply during storage, especially in a damp or wet environment. These specialized cabinets are the result; they circulate HEPA-filtered air throughout the cabinet, and forced air is directed through the scope’s channels to make sure the scope is continuously dry.

Reevaluate Storage Policies

In addition to integrating drying cabinets into storage protocol, AORN guides facilities to reevaluate how endoscope storage is managed. It now states: “A multidisciplinary team that includes infection preventionists, endoscopy and perioperative RNs, endoscopy processing personnel, endoscopists, and other involved personnel should establish a policy to determine the maximum storage time that processed flexible endoscopes are considered safe to use without reprocessing.”

“Recommendations from research studies were also not in agreement and have shown that when correctly processed, flexible endoscopes may be safe to use for 48 hours to 56 days after processing.”

For years, safe storage time for flexible endoscopes following reprocessing has been debated and studies offer conflicting results. “During our review of the evidence we found that recommendations from professional organizations for maximum storage times for flexible endoscopes were not in agreement and the recommended storage times ranged from three hours to one month,” explained Van Wicklin. “Recommendations from research studies were also not in agreement and have shown that when correctly processed, flexible endoscopes may be safe to use for 48 hours to 56 days after processing.”

Contributing factors in the debate are often recognized as frequency of use, compliance with the manufacturer’s IFUs, storage conditions, patient population and types of procedures. “Since these factors and other relevant variables differ from facility to facility then the maximum safe storage time is best determined by a multidisciplinary facility team; however, AORN has provided an extensive evidence review to assist the team in making this important decision,” Van Wicklin said.
Microbiologic Culture Surveillance Programs Reconsidered

Reviewing storage policies was one of two directives set forth by AORN requiring a multidisciplinary team. The other was creation of a multidisciplinary team as a result of inconclusive data to ensure scope-related infections are prevented. AORN recommends: “A multidisciplinary team that includes infection preventionists, endoscopists, endoscopy processing personnel, microbiologists, laboratory personnel, risk managers, and other involved individuals should evaluate the need to implement a program for regular microbiologic surveillance cultures of flexible endoscopes and mechanical processors.”

Some professional associations recommend regular microbiological surveillance, and there is data to show it may reinforce best practices, while offering opportunity to correct mistakes. However, these guidelines vary, the tests’ high sensitivity might make results unreliable, and quarantining scopes until culture tests have been obtained can lead to patient care delays. “Microbiological culturing is resource-intensive, and requires additional expenditures for microbiological testing and additional time for personnel to collect and process samples,” Van Wicklin added. “Culturing for bacterial load is impractical for many endoscopy centers that may not have access to microbiology laboratories.” Some facilities rely on external laboratory testing, which can be expensive.

Conclusion

Preventing infections related to flexible endoscopes is a multifaceted challenge, but facilities can protect patients by following manufacturer IFUs and staying abreast of association guidelines, facilities can develop realistic policies to protect patients. Multidisciplinary teams are a staple to creating these robust solutions because they approach problems as an institution, versus as a department.

Disclosures

This paper was written by Rebecca Rudolph-Witt, editor of Surgical Products, in collaboration with Association of periOperative Registered Nurses (AORN). For more information about the guideline changes, please refer to AORN. Healthmark Industries was a silent sponsor of the paper, providing no input.
References:


