Endoscopic procedures are gaining popularity worldwide and the use of flexible endoscopes is on the rise. Although endoscopic examinations are generally regarded as low risk, scopes that remain contaminated after reprocessing may transmit microbes between patients sometimes resulting in infection. Since reusing endoscopes is only considered safe when strict reprocessing guidelines are followed, further research and monitoring are warranted to improve endoscope reprocessing policies and practices.

Current endoscope reprocessing guidelines comprise sequential steps beginning with bedside pre-cleaning, or removing visible external soil with detergent solution by scrubbing, suctioning, and flushing through the working channels of the endoscope. The next step is high-level disinfection (HLD) of the scopes in automated endoscope reprocessors approved by the Food and Drug Administration (FDA) using specialized HLD solutions. The final step is to thoroughly dry the equipment generally with an alcohol flush followed by forced air exposure, and to store the equipment in an upright dangling position to permit drip drying of any moisture lingering in internal channels. When performed meticulously, experts assert that these guidelines should work well; research confirms that most cases of transmitting microbes to patients via contaminated scopes have resulted from not adhering to reprocessing guidelines.

“Despite federal guidance and widespread adoption of multi-society guidelines for cleaning and HLD, endoscope reprocessing is often referred to as the Achilles heel for safety in our gastrointestinal endoscopy suites,” says Bret Petersen, MD, a specialist in gastroenterology and hepatology at Mayo Clinic in Rochester, Minn. “The instruments are quite complex and to reprocess them adequately with appropriate attention day after day and in procedure after procedure requires diligence through a multi-step sequence often done in fast-paced environments by staff with perhaps less training and professional background than others.”

Another barrier to consistently successful endoscope reprocessing is the complexity of the scopes themselves. Most contemporary endoscopes are designed with various channels that are difficult to clean and provide an excellent place for bacteria to form stubborn biofilms. What’s worse, many of the bacterial strains that contaminate endoscopes are resistant to antibiotics.

“The primary issues are the length, the different internal channels, and the slender caliber of many endoscopes,” says Petersen. “Some scopes are more difficult to clean due to different moving parts that have crevices around their joint or hinges that are a bit more prone to harboring infection and therefore require extra attention. If things are caught inside the channel – even microscopic organisms – and allowed to dry inside the channel, they’re more difficult to remove so it makes the timeliness of reprocessing also important.”

Moreover, according to Petersen, another reason that endoscopes are difficult to reprocess between patients is that they cannot be heat sterilized. “Autoclave sterilization requires manufacture from different materials than are currently used and may be feasible with further development but they just haven’t been developed yet,” he says. “Another possibility is sterilizing endoscopes with ethylene oxide but gas sterilization has a very slow and long turnaround – it requires overnight processing plus aeration to get rid of the gas so it would only allow you to use an instrument once in a day which is cost prohibitive. In theory they could...
be sterilized with chemicals but these chemicals can be hard on the materials and require extremely long reprocessing cycles which again becomes cost prohibitive."

Recently, rapid indicator tests are receiving interest as they can potentially gauge endoscope cleanliness in real time during various stages of reprocessing. These tests are also used along with microbial culturing of scope surfaces after HLD. Rapid indicators detect organic residues such as blood, protein, and adenosine triphosphate (ATP), which is deemed an indirect marker of bioburden as it is found in all living cells and thus serves as a localized sign that viable organisms and cells have recently died. Organic residues not removed during manual cleaning can chemically impair the effectiveness of the disinfecting solution used in HLD.

Microbial culturing of scope surfaces is also sometimes performed after HLD to assess cleanliness. However, culturing requires long incubation periods that often conclude after the endoscope has already been used in subsequent patients. Culturing is also limited by lack of standardized sampling techniques and methods, and difficulty interpreting results, which are often skewed by environmental contaminants.

“The whole cleaning process includes cleaning right after the endoscopy, then a manual cleaning process where all of the organic debris is removed, followed by HLD,” says Pritish Tosh, MD, an infectious disease specialist who recently conducted a study in rapid indicator testing in endoscope reprocessing at Mayo Clinic in Rochester, Minn., with colleagues headed by Kavel Visrodia, MD, an internal medicine specialist. “The real Achilles heel here is that manual cleaning process and what our study was looking at was how easy it was to see whether manual cleaning has been done correctly. The current recommendations are to clean until there is no visible debris and we found that in endoscopes that are free of visible debris several tested positive for organic compounds. This organic matter is of concern because if it’s there it can inactivate the HLD solution that occurs next, making it ineffective. In
order to ensure that the endoscopes are able to get cleaned and go through HLD appropriately, we need to be ensured that we can get rid of the organic debris that is present.”

In the study, Visrodia, Tosh and colleagues evaluated contamination levels of clinically used endoscopes using visual inspection and rapid indicator tests before and after manual cleaning. Visrodia, et al. also sought to determine which rapid indicator instruments and methods were best for ensuring adequacy, and for guiding training, quality monitoring, and quality improvement efforts, in endoscope reprocessing.

The researchers visually inspected endoscopes for noticeable residue and acquired samples for rapid indicator testing to measure contamination levels after both bedside and manual cleaning. External components of the endoscopes including the control handle, biopsy port, distal end and elevator, were individually swabbed, and each suction/biopsy channel was tested for blood and protein and ATP during 37 encounters with 12 unique endoscopes.

According to test results, all bedside-cleaned endoscopes had high levels of ATP and detectable blood or protein, whether or not any residue was visible. Although there was no visible residue on any endoscopes after manual cleaning, 82 percent of endoscopes tested had at least one positive rapid indicator test. ATP levels exceeded the nominal benchmark of 200 relative light units on at least one endoscope component after cleaning in eight of 14 reprocessing cycles (57 percent), including seven of 10 samples at the biopsy ports, which appeared to be the site of greatest potential risk for persistent contamination. In other words, only 18 percent of endoscopes passed all rapid indicator tests after manual cleaning. The researchers also noted that cross tabulations showed reliance on only one rapid indicator or on samples obtained from only one component resulted in false negatives.

The authors of the study concluded that flexible endoscopes are highly contaminated after gastrointestinal procedures and often remain contaminated after manual cleaning, as detected by rapid indicators, and that the study findings underscore the value of rapid indicators in identifying contaminated endoscopes that have passed visual inspection. The authors noted that early detection of endoscope contamination may allow reprocessing issues to be identified and prevent patient exposure and that testing of different components using more than one indicator may be necessary to ensure that contamination is consistently detected before endoscopes are disinfected and used in patients. They added that the findings should influence reprocessing guideline updates such as the need for routine monitoring to verify cleaning effectiveness, they added, and they called for additional research to validate specific monitoring protocols and ensure patient safety.
“There are several different avenues being explored on how best to ensure that endoscopes are ready for patient use,” says Tosh. “One of the avenues we are exploring is the potential use of rapid indicators either for protein, blood or ATP which is a marker of biologic activity. In our studies and studies being done by others we are looking into the feasibility of these indicators – how easy they are to use, how reliable they are, and how well they correlate with culture results. Hopefully through further studies we can arrive at cleaning recommendations and a testing protocol so that we can ensure that every scope is ready for patient use. As soon as we have further studies not just from ourselves but from colleagues across the discipline, we will have a good sense of which indicators to use, at what point in processing and how often.”

In a commentary written in response to the study authored by Visrodia et al. Petersen wrote that the study “confirms long-standing presumptions that significant quantities of organic soil remain on endoscopes following bedside pre-cleaning and that visual inspection alone is an insufficient guide to the adequacy of manual cleaning prior to HLD.” He also wrote that most important realization appears to be that the long narrow channels and the biopsy ports of endoscopes represent areas of highest risk and are therefore the most useful sites for assessment during cleaning and HLD. The second most important realization, according to Petersen, is that rapid ATP assays appear to identify the greatest proportion of high or unacceptable results following manual cleaning compared with protein or blood testing. Since ATP testing seemed to be the most effective indicator, Petersen also disapproved of the study authors’ guidance to use multiple rapid indicator tests, particularly given the lack of solid data validating an association between these intermediate rapid indicator tests and terminal culture results. “Some of these tests are partially validated and some of them are not validated yet,” he says. “Of the multiple tests that they used, the incremental benefit from some of them was very modest other than ATP testing and if we’re using them for spot checking a process or a department or a staff person once a week that might be feasible. If we’re using them daily or for every procedure it again becomes impractical. Even ATP testing, which is backed by some relatively strong data to support its use and is being gradually adopted by a number of centers, would greatly benefit from some stronger data to correlate the test results after washing and before HLD with the results of cultures after HLD. Those correlates in a clinical setting haven’t been done. ATP testing is so far the most encouraging test.”

Both Petersen and Visrodia et al. agree that new studies employing ATP testing of the intermediate steps in reprocessing and terminal culturing are indispensable and should be supported by organizations that encourage and fund these practices. “More research is needed to fill knowledge gaps and develop workable solutions that ensure patient safety and are operationally feasible,” Visrodia et al. stated in a reply to Petersen’s commentary. “Our findings suggest that the current practice of visual inspection is not adequate for assessing endoscope cleanliness. Rapid indicator testing may be useful while researchers continue to evaluate methods for reducing the risk of endoscope-related infection.”

In his commentary Petersen also called for improved design of the most intricate endoscopes to ensure infection prevention and control in the delivery of safe endoscopy services. “Given the common-place role of gastrointestinal endoscopy and the low but uncertain potential for transmission of clinical disease or subclinical alteration of the gut microbiome, research funding in all aspects of endoscope reprocessing and industry efforts for redesign of the most complex instruments should become high priorities,” he wrote. “In general, infections related to endoscopes are rare but consequential when they do occur,” says Tosh. “There have been some outbreaks related to improperly reprocessed endoscopes including some that have resulted in infections with multi-drug-resistant organisms. Because of this, it’s important for healthcare facilities across the country and across the world to ensure that their scopes are clean and ready for their patients.”

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References

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8. Ibid.