Gastroenterology & Endoscopy News

In the News

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Gastro Groups Aim For Cleaner Scopes After Deadly Outbreak

By Ashley Taylor

The outbreak of superbug infections linked to contaminated duodenoscopes that sickened at least seven patients in Los Angeles and left two dead has spurred gastroenterology practices nationwide to implement measures to bolster their scope reprocessing practices.

The infections, involving carbapenem-resistant Enterobacteriaceae (CRE), were tracked back to contaminated duodenoscopes used for endoscopic retrograde cholangiopancreatography (ERCP) procedures in Los Angeles, Illinois and elsewhere. CRE reportedly has a mortality rate of at least 40% among patients who develop bloodstream infections with the microbe.

Before the latest outbreak, which officials say exposed as many as 179 patients at Ronald Reagan Medical Center to infection and as many as 67 more at nearby Cedars-Sinai Medical Center, infections had been attributable to lapses in adherence to cleaning protocols, which include manual washing and brushing in detergent followed by high-level disinfection. The latter may be done using an automatic endoscope reprocessor or ethylene oxide gas. But the recent infections—the latest reported March 4 at Cedars-Sinai—occurred without any known reprocessing slip-ups, casting doubt on the disinfection protocols themselves.

In mid-March, *USA Today* reported that the scopes involved in CRE outbreaks since 2013 underwent decontamination by automated endoscope reprocessors (AERs). The FDA has been reviewing the machines, which are rated to destroy 99.9999% of bacteria on scopes, for more than a year, according to the newspaper, but only recently asked the manufacturers of the devices for new data on their effectiveness.

Craig Smith, senior vice president of regulatory affairs and quality assurance for Cantel Medical, the parent company of AER manufacturer Medivators, said the FDA contacted his firm recently with a request for seven specific items. “What the FDA is wondering is, have manufacturers of AERs that have been cleared for several years done anything to revalidate scopes that are new to the market? Many of these scope reprocessors were cleared in the 1990s, and even longer ago, and there have been a lot of technological changes to scopes since then.”

Medivators has had “an ongoing validation program in place since before 1999,” Mr. Smith added.

As for the safety of duodenoscopes, Mr. Smith said, “I think that perhaps everyone acknowledges that the elevator wire channel is complex. If you have a scope that is not in good clinical condition and you don’t follow the manufacturer’s guidelines for pre-cleaning and disinfecting, I think everyone knows you could have problems.”

Mr. Smith said data from his company show that about 90% of duodenoscopes in use in the United States undergo an AER cycle.

The outbreak has triggered at least two lawsuits against Olympus. It also has prompted a flurry of reactions from government health agencies. In early 2014, following a 2013 CRE outbreak traced to a contaminated duodenoscope at an Illinois hospital, the FDA asked the three duodenoscope manufacturers Olympus, Pentax and Fujifilm to submit results of tests of their duodenoscope-cleaning protocols, the Reuters news agency reported. The FDA concluded that the tests were either improperly conducted or the disinfection protocols failed, but the agency did not report these findings.

After news of the California infections broke in February, the FDA issued a new safety alert that duodenoscopes, by their design, may be difficult to clean and therefore prone to infection. The report mentioned that the duodenoscope’s elevator, which moves up and down to maneuver instruments near the bile and pancreatic ducts, contains microscopic crevices that brush bristles may not be able to reach. Despite concerns over efficacy of manufacturers’ cleaning guidelines, the FDA recommended adhering to them.

Furthermore, reports have stated that the FDA had not approved one of the scopes in question, Olympus' most recent model TJF-Q180V; in fact, Olympus put in its 501(k) last year at the agency's request, CNN reported.

On March 4, the FDA updated its earlier safety communication to address this issue: "At this time, FDA has no evidence that the lack of a 510(k) clearance was associated with the infections," according to the agency. Infections were associated with duodenoscopes from all three manufacturers, not just the unapproved Olympus model, the update said. The FDA said it would not pull the scopes from the market out of concern that doing so would risk creating a duodenoscope shortage.

The FDA, which has rejected recalling the scopes, revisited the issue on March 12. In a "final guidance," the agency said it will require scope makers to demonstrate that reusable devices can be safely cleaned before it will approve new instruments. The policy does not apply to scopes already on the market, however.

Officials also sought to reassure clinicians and the public about the safety of the scopes. "Despite the recent concerns about multidrug-resistant bacteria infections associated with duodenoscopes, patients and health care providers should know that the risk of acquiring an infection from a reprocessed medical device is low," said William Maisel, MD, MPH, chief scientist at FDA's Center for Devices and Radiological Health.

Meanwhile, the Centers for Disease Control and Prevention (CDC) has released an interim protocol for facilities that want to test their scopes for evidence of contamination. Writing on the agency's blog, Michael Bell, MD, deputy director of CDC's Division of Healthcare Quality Promotion, said: "This is not a replacement for ongoing training and oversight to ensure that cleaning and disinfection steps are all performed correctly. But it might be a way to detect contamination, whether due to lack of adherence to manufacturer-recommended reprocessing practices or any other reason, and to prompt follow-up action to protect patients if needed."

How Practices Are Testing For Bacterial Activity

The endoscopy department at Brigham and Women's Hospital, in Boston, has added a step to its cleaning protocol for duodenoscopes. After manually cleaning the scopes, they now use a device to check for adenosine triphosphate (ATP) activity, which is a sign of live bacteria, before moving on to automatic reprocessing, said John Saltzman, MD, the hospital's director of endoscopy. If ATP activity is found "you can keep processing the scope to see if you've manually cleaned out everything that can be detected. This strategy has not been proven yet," Dr. Saltzman continued. "There's no data [telling] us that that necessarily adds anything more to what we have been doing."

St. Joseph's/Candler Healthcare, in Savannah, Ga., also tests for ATP production, said Nicholas Costrini, MD, PhD, MBA, director of gastroenterology at the institution. If concerns about bacterial contamination remain after testing, staff may try to culture swabs from the device in question, Dr. Costrini said.

Culturing Samples

In response to the infections, Gastroenterology Associates of Laredo, Texas, started culturing samples taken from the duodenoscope elevator, its channel and the fluid in the channel, to monitor bacterial exposure after each use, said Monte Allen, DO, one of the small practice's two physicians. The clinic plans to continue culturing swabs from the scopes for the next six months, then assess the data. Dr. Allen said he and his colleagues do not keep their duodenoscopes out of use while awaiting culture results.

ECRI Recommendations

In culturing their duodenoscopes, the Laredo practice is in line with recommendations from the ECRI Institute, a nonprofit health care standards organization. In early March, ECRI suggested that practices take swabs from each scope and culture them for 48 hours after reprocessing. Doing so takes duodenoscopes out of service for much longer than the hour or so that is typical for cleaning with an automatic reprocessor.<2029>One possible concern mentioned in the ECRI report about culturing duodenoscope samples for 48 hours before reusing the instruments is that practices might need to buy more endoscopes to keep up with demand. ECRI therefore recommends that if culturing after each reprocessing is impossible, practices culture their scopes over the weekend.

At Chicago's Loyola University Health Center, the endoscopy department has been revamping its duodenoscope cleaning procedure since the 2013 CRE outbreak at Advocate Lutheran General Hospital, in Illinois, said Neil Gupta, MD, MPH, the hospital's director of endoscopy and assistant professor at Loyola University of Chicago's Stritch School of Medicine. "It has been an ongoing process," Dr. Gupta said.

Loyola has been double-checking to ensure that it follows the Olympus guidelines, a process that includes having company employees retrain the technicians who clean the instruments.

Loyola is not culturing its scopes, however, out of concern for accuracy. "We're concerned about whether culturing the tip of the scope and having a negative culture truly means that that scope is not contaminated," Dr. Gupta said. "Traditionally, a negative culture means that nothing continued to grow out on the culture, but that doesn't mean that there isn't some

CRE on the scope, and that's one of the reasons that we have not implemented cultures yet: We don't know if that's an accurate way to ensure that the scope is correctly processed."


Close-up view of an ERCP endoscope tip.

More Frequent Reprocessing

At Yale-New Haven Hospital, in New Haven, Conn., the endoscopy department also cultured samples from its reprocessed scopes after the recent outbreak; how frequently it will do this in the future is unclear, said Priya Jamidar, MBChB, the hospital's director of endoscopy and professor at the Yale School of Medicine.

However, Yale has increased how often it reprocesses its duodenoscopes. Before the CRE outbreak, it reprocessed the scopes once per week if they were unused, or after each use. "We have started to reprocess all our scopes first thing in the morning before we do any ERCPs. We also reprocess scopes immediately after doing ERCPs," Dr. Jamidar said. "The scopes basically cut the queue and are at the head of the line compared with other scopes, so they're reprocessed immediately."

A 2014 study from the Medical University of South Carolina, in Charleston, found that duodenoscopes could be stored for as long as 21 days without developing growth of pathogenic bacteria (*Gastrointest Endosc* 2014 Dec 4. [Epub ahead of print]). Longer reprocessing intervals would save money, the authors pointed out.

Security Uncertain

Given that it's unclear if following manufacturers' reprocessing guidelines to the letter can prevent contamination, uncertainty reigns over what the best reprocessing methods are, with hospitals trying many different approaches.

"I think it's unclear to everyone what is the right thing to do with regard to culturing or with regard to gas sterilization [another disinfection method under consideration] because there are pros and cons to both," Dr. Gupta told *Gastroenterology & Endoscopy News*. After the 2013 infections, Advocate Lutheran switched from automatic reprocessing to ethylene gas sterilization and had no more infections (*JAMA* 2014:312;1447-1455). However, concerns have arisen about the wear and tear that sterilization with ethylene oxide gas causes to instruments and also about whether or not repeated exposure to the gas is safe for technicians.

Fine-tuning these reprocessing methods for best results, Dr. Jamidar said, is “a work in progress.”

FDA’s Recommendations for Facilities and Staff That Reprocess ERCP Duodenoscopes

Follow closely all manufacturer instructions for cleaning and processing.

- The FDA recommends adherence to general endoscope reprocessing guidelines and practices established by the infection control community and endoscopy professionals. In addition, it is important to follow specific reprocessing instructions in the manufacturer’s labeling for each device.
- Even though duodenoscopes are inherently difficult to reprocess, strict adherence to the manufacturer’s reprocessing instructions will minimize the risk for infection. Deviations from the manufacturer’s instructions for reprocessing may contribute to contamination. The benefit of using cleaning accessories not specified in the manufacturer’s instructions, such as channel flushing aids, brushes, and cleaning agents, is not known.
- Report problems with reprocessing the device to the manufacturer and to the FDA.

Follow these additional general best practices:

- Meticulously clean the elevator mechanism and the recesses surrounding the elevator mechanism by hand, even when using an automated endoscope reprocessor (AER). Raise and lower the elevator throughout the manual cleaning process to allow brushing of both sides.
- Implement a comprehensive quality control program for reprocessing duodenoscopes. Your reprocessing program should include written procedures for monitoring training and adherence to the program, and documentation of equipment tests, processes and quality monitors used during the reprocessing procedure.
- Refer to the Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes: 2011 consensus document for evidence-based recommendations for endoscope reprocessing.