EDITORIAL

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Gastrointestinal Endoscopes
A Need to Shift From Disinfection to Sterilization?

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More than 10 million gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both.[1] Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.[1]

In this issue of *JAMA*, Epstein and colleagues[2] report findings from their investigation of a cluster of New Delhi metallo-β-lactamase (NDM)–producing *Escherichia coli* associated with gastrointestinal endoscopy that occurred from March 2013 to July 2013 in a single hospital in northeastern Illinois. During the 5-month period, 9 patients with positive cultures for NDM-producing *E coli* were identified, and a case-control study demonstrated that a history of undergoing an endoscopic procedure at this specific hospital was strongly associated with cases of NDM-producing *E coli*. Cultures obtained from the endoscope used on 5 of the case patients yielded an NDM-producing *E coli* from the elevator channel. The elevator channel is unique to side-viewing endoscopes, most often used to perform endoscopic retrograde cholangiopancreatography (ERCP). The elevator has a separate channel and provides orientation of catheters, guide wires, and accessories into the endoscopic visual field. This channel is complex in design and may be more difficult to disinfect completely.

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The *E coli* isolate was highly related (>92%) to all case patient isolates by pulsed-field gel electrophoresis. Endoscope reprocessing procedures were reviewed and no lapses were identified. Further, the automated endoscope reprocessor (AER) was functioning correctly and the duodenoscopes were not damaged. The facility notified the 226 patients who had potential exposure to a culture-positive endoscope. Twenty-seven additional case patients were identified by active surveillance who were colonized and had been exposed to a duodenoscope. No additional cases were identified after the hospital changed its endoscope reprocessing from automated high-level disinfection with orthophthalaldehyde to gas sterilization with ethylene oxide.

The key concern raised by this study is whether current US endoscope reprocessing guidelines are adequate to ensure a patient-safe gastrointestinal endoscope (one devoid of potential pathogens) or if endoscopes with their long, narrow channels, right-angle turns, difficult to clean and disinfect components, and heavy microbial contamination impossible to reliably high-level disinfect. To examine this concern and offer recommendations, understanding current knowledge on endoscope reprocessing is necessary.

First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-level disinfection.[3,4] High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible.[3] However, no low-temperature sterilization technology is US Food and Drug Administration (FDA)–cleared for gastrointestinal endoscopes such as duodenoscopes.

Second, more health care–associated outbreaks and clusters of infection have been linked to contaminated endoscopes than to any other medical device.[3,5] However, until now, these episodes have been traced to deficient practices such as inadequate cleaning, inappropriate disinfection, and damaged endoscopes or flaws in the design of endoscopes or AERs.[3] In addition, reprocessing failures have led to patient notifications and blood-borne pathogen testing in dozens of instances.[6]

Third, evidence-based endoscope reprocessing guidelines have been prepared by professional organizations and the Centers for Disease Control and Prevention (CDC). Although some data have demonstrated that rigorous adherence to these guidelines will result in a patient-safe endoscope,[3,4] other data have demonstrated that all of the steps associated with manual endoscope reprocessing are rarely performed and some essential steps (eg, brushing all endoscope channels and components) are commonly skipped.[7] Endoscope reprocessing was improved with the use of AERs because most steps were automated.[7]

Fourth, endemic transmission of infections associated with gastrointestinal endoscopes may be unrecognized due to inadequate surveillance of outpatient procedures, long lag time between colonization and infection, and a low frequency of clinical infection. Additionally, the risk for some procedures might be higher than others in which normally sterile areas are contaminated. In the cluster of cases identified by Epstein et al, the presence of an unusual pathogen (NDM-producing *E coli*) prompted an investigation and subsequent recognition that duodenoscopes were the source of the case patient isolates.[2]

Fifth, the margin of safety associated with reprocessing endoscopes is minimal. Endoscopes are heavily contaminated with microbes. The internal channel of gastrointestinal endoscopes may contain $10^{8\text{-}10}$ (8-10 $\log_{10}$) enteric microorganisms.[8] The cleaning step in endoscope reprocessing results in a 4 to 6 $\log_{10}$ reduction of microbes and the high-level disinfection step results in another 4 to 6 $\log_{10}$ reduction of mycobacteria, for a total 8 to 12 $\log_{10}$ reduction of microbes.[9] Thus, the margin of safety associated with cleaning and high-level disinfection of gastro-

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intestinal endoscopes is minimal (0-2 $\log_{10}$ margin of safety). Therefore, any deviation from proper reprocessing could result in the failure to eliminate contamination with a possibility of subsequent patient-to-patient transmission. This low margin of safety associated with endoscope reprocessing compares with the 17 $\log_{10}$ margin of safety associated with cleaning and sterilization of surgical instruments.[10,11]

What should be done to ensure the safety of these commonly used devices? The enforcement of best practices including equipment maintenance and routine audits with at least yearly competency testing of staff who use the reprocessing equipment is imperative. But if adherence to regulation is lax, more outbreaks will likely occur. Obtaining additional information on the frequency and level of microbial contamination of endoscopes that have been cleaned and high-level disinfected with strict adherence to current guidelines will be helpful in defining the extent of the problem. If endoscopes are found to be contaminated with potential pathogens (eg, enteric gram-negative bacilli), the clinical effects of such contamination need to be quantified.

In addition, better approaches to assess the effectiveness of cleaning and high-level disinfection are needed. Although microbiological cultures are the gold standard, they cannot be used as a real-time monitoring process. However, based on the study by Epstein et al, it would be reasonable to perform periodic microbiological surveillance of duodenoscopes to assess microbial contamination, although many questions remain. These include the following: (1) What cutoff should be used to define proper disinfection (eg, 0 pathogens or a higher number, such as <10 colony-forming units of enteric pathogens per channel)? (2) What sampling scheme should be used to evaluate gastrointestinal endoscopes (eg, all or a sample of endoscopes)? (3) Is the trigger for further action based on the level or the frequency of contamination (ie, percent of endoscopes contaminated)? (4) What actions should an endoscopy unit undertake if a positive trigger is reached based upon the level or frequency of contamination (ie, patient notification with an offer of blood-borne pathogen testing, ethylene oxide sterilization of positive endoscopes, or ethylene oxide sterilization of all endoscopes)? Real-time monitoring methods need to be developed and validated to assess the risk of infection.

Moreover, adequate resources must be provided by the manufacturers of endoscopes, AERs, high-level disinfectants, and sterilization technologies as well as federal authorities (CDC, FDA, and National Institutes of Health) to design and complete the necessary studies to determine the risks posed by current reprocessing of endoscopes and develop new reprocessing methods and practices. In addition, new endoscope reprocessing technologies need to be developed that reliably result in sterilization of gastrointestinal endoscopes via an FDA-cleared sterilization process, which would greatly improve the margin of safety. Alternatively, development of sterile disposable gastrointestinal endoscopes or a shift to other sterile diagnostic modalities should be considered. Ethylene oxide sterilization, which was used to terminate this cluster of endoscope-related infections,[2] is not a long-term satisfactory solution as it has not been FDA-cleared for sterilizing gastrointestinal endoscopes, many hospitals no longer have ethylene oxide, and the sterilization and aeration time is long (12-15 hours).

Finally, clinicians should be encouraged to report and publish cases of infectious diseases related to endoscopy, especially if current reprocessing methods were adhered to, so it can be determined if the report by Epstein et al[2] is the tip of the iceberg or an isolated occurrence. If the former, then revision of the endoscope reprocessing guidelines will be necessary to ensure patient safety. However, regardless of when these issues are resolved, endoscopy will remain an important diagnostic and therapeutic modality and should continue to be used while clinicians strictly adhere to current endoscope reprocessing guidelines.[3,4]

ARTICLE INFORMATION

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