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SPECIAL REPORT

A Perspective on Surgical Site Infection Prevention

Endoscope Reprocessing in 2014: Why Is the Margin of Safety So Small?



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Flexible endoscopes become heavily contaminated with bioburden (eg, blood, body fluids, other potentially infectious materials) during use. In a busy clinical practice, the same device may be used multiple times within an eight- to 12-hour period. The complexity of these devices with their multiple ports and channels poses a challenge for personnel tasked with cleaning and reprocessing the instruments for the next patient use. Rigid endoscopic devices that enter intrinsically sterile spaces undergo cleaning and then a traditional steam sterilization regimen; these instruments are classified as critical devices.^{1,2}

Flexible endoscopes and equipment, which come into intimate contact with intact mucous membranes, are classified as semicritical devices, so reprocessing involves cleaning and then high-level disinfection. This process kills all vegetative microorganisms, mycobacteria, selective non-lipid-containing and lipid-containing viruses, and fungal spores; however, high-level disinfection does not kill all bacterial spores.

Numerous recent reports highlight the infection risks of endoscopic equipment that is improperly reprocessed. The rise in drug-resistant pathogens, such as carbapenem-resistant Enterobacteriaceae (CRE), makes it even more important that sterile processing personnel ensure thorough and complete reprocessing takes place. Current standards of practice for endoscope reprocessing are vulnerable

to human error, including inadequate, delayed, or incomplete reprocessing. Personnel and administrators should be aware of these challenges and take steps to ensure that all endoscopic instruments are reprocessed according to current standards of practice. Additionally, it is important to be transparent with patients and explain the risk of bacterial transmission that is associated with endoscopic procedures, regardless of how minimal that risk may be.

INFECTIONS INVOLVING ENDOSCOPIC EQUIPMENT

The Centers for Disease Control and Prevention,³ American Society for Gastrointestinal Endoscopy, Society for Healthcare Epidemiology of America,⁴ Society of Gastroenterology Nurses and Associates,⁵ and AORN⁶—in collaboration with multiple organizations and industry experts—have developed and disseminated guidelines or standards of practice that address the appropriate cleaning and reprocessing of semicritical flexible endoscopic equipment.

The cleaning and reprocessing of flexible endoscopic equipment encompasses three major components:

- mechanical cleaning after use,
- high-level disinfection, and
- postprocessing of the endoscopic device.

Each component has several steps that, if followed meticulously, are designed to reduce the risk of

postprocessing contamination, which could lead to transmission of a health care–associated pathogen to the next patient on whom the device is used. The vulnerability of the process, however, is fraught with the potential for human error or intrinsic design features of the endoscopic device that restrict or limit thorough disinfection.

Kimmey et al⁷ estimated that the risk of acquiring a health care–associated infection after an endoscopic procedure is approximately one in 1.8 million procedures. Currently, infection preventionists consider this number to be inaccurate, in part because of inadequate (if any) surveillance documenting infection after an endoscopic procedure or the probable risk of

cross-contamination leading to colonization of the patient, who often presents with little or no symptoms. Several recent publications, cited in the

following sections, highlight the risk of acquiring an infection after undergoing flexible gastrointestinal endoscopy or bronchoscopy. The emergence of selective multidrug-resistant microbial populations has accelerated concerns that the current standards of practice involving high-level disinfection may no longer be adequate, especially when reprocessing endoscopic devices.

Carbapenem-Resistant Enterobacteriaceae

Since the late 1990s, reports of strains of *Escherichia coli*, *Klebsiella pneumoniae*, and other Enterobacteriaceae that produced carbapenemase enzymes have emerged as significant pathogens. These organisms express resistance to the broad-spectrum carbapenem antibiotics in the health care environment (eg, acute care, extended care, nursing homes).⁸ Since 2000, observed CRE that produce *K pneumoniae* carbapenemase (KPC) have been responsible for several reported infections in the United States.⁸⁻¹² However, since 2009, an *E coli* variant of CRE, a New Delhi metallo- β -lactamase

(NDM)-producing organism, has emerged as a significant health care–associated pathogen. According to Thaden et al,⁹ these organisms are now considered a global threat, with mortality rates ranging from 48% to 71% in high-risk patient populations. The CRE are now designated as reportable to state public health laboratories, which collect and transfer the data to the Centers for Disease Control and Prevention as part of a national surveillance effort. In 2010, the first reported endoscopic-associated transmission of a carbapenem-resistant KPC was documented in a hospital in France.¹⁰ Retrospective analysis of 17 patients who underwent gastroscopy with the

same endoscope revealed cross-contamination involving six patients, two of whom eventually developed an infection.¹⁰ Naas et al¹⁰ suggested that two

separate steps in instrument reprocessing may have been delayed, overlooked, or truncated, resulting in persistent contamination of the endoscope:

- the prewashing (ie, mechanical cleaning) stage may have been delayed, and
- the endoscope was not adequately dried after high-level disinfection before reuse.

Since 2013, there have been three reported occurrences of possible CRE cross-contamination involving a total of 144 patients, of which 41 people eventually became culture positive for CRE. One case involved cross-contamination of eight patients after bronchoscopy.¹¹ Two separate bronchoscopes were implicated in the outbreak, and flushing solution from the channels of each bronchoscope revealed heavy contamination (1,000 colony-forming units per milliliter). An audit of the various reprocessing steps revealed no deviation from standard practice. When the bronchoscopes were submitted to the manufacturer for testing and evaluation, however, defects were noted on the

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internal channel surfaces of both instruments. Although no obvious deviation was noted in the standard of practice for reprocessing the bronchoscopes, it is unknown why the internal surface defects were able to sequester microbial contamination away from the standard mechanical cleaning and disinfection process.

Two reported cases involved cross-contamination after endoscopic retrograde cholangiopancreatography (ERCP).¹³ Seven cases of KPC infection were identified at one endoscopy center where the patients underwent ERCP within a 60-day period with the same duodenoscope. Forty-six of 51 additional patients who underwent ERCP at this facility were screened by stool culture, and three additional patients were identified as being colonized but not infected with KPC.

The investigators identified a possible selective flaw in the reprocessing of endoscopes used for ERCP. The facility had not followed the manufacturer's instructions for use when cleaning the elevator component of the duodenoscope. Standard brushing is not adequate because of the intricate nature of the elevator component at the terminal end of the scope. In addition to thorough brushing of the terminal end of the channel adjacent to the elevator component, the elevator itself should be manipulated to allow the brush to access all surfaces, including the base of the elevator apparatus. The authors suggested that the buildup of biofilm (ie, biofilm) serves to sequester (ie, protect) surface contamination from the bactericidal activity of traditional high-level disinfection.

A second outbreak involved nine patients who were culture positive for an NDM-producing *E coli* after undergoing ERCP at the same institution. Fifty patients who underwent ERCP with the same duodenoscope returned for rectal surveillance cultures; as a result, an additional 23 NDM-producing *E coli* were recovered from colonized patients.

Genetic similarity between the recovered strains was determined by molecular testing. Cultures obtained from the terminal elevator portion of the duodenoscope documented genetic clonality with recovered patient strains.¹⁴ Although the report suggests that no lapses in endoscope reprocessing were identified through retrospective review, incomplete reprocessing in combination with intricate design characteristics likely contributed to multiple patients being exposed to an endoscopic device contaminated with NDM-producing *E coli*.

A recent report by a German investigator suggests that our current knowledge of endoscope-related infections may actually be the tip of the iceberg. Before the current reporting requirements for CRE, most device-related outbreaks may have been missed because

they may have been associated with traditional gut microflora.¹⁵ Ultimately, incomplete reprocessing in combination with intricate design characteristics may contribute to multiple patients being exposed to an endoscopic device contaminated with NDM-producing *E coli*.

THE UNDERLYING CHALLENGES OF ENDOSCOPE REPROCESSING

The resultant status of CRE as a reportable infectious agent to public health officials has highlighted the issue of endoscope contamination and cross-transmission of multidrug-resistant pathogens. Recent reports also have highlighted the problematic nature of endoscope reprocessing and the effect of inadequate, delayed, or incomplete reprocessing on the proliferation of highly resistant and potentially lethal pathogens.

As noted earlier in the case of the duodenoscope, the root cause of the problem is inadequate brushing of the terminal portion of the device housing the elevator components.¹⁴ The intricate design of the elevator makes it difficult to access all surfaces

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effectively. Also, in some cases, adequate flushing pressures may not be achieved by an automatic endoscope reprocessor¹⁴; therefore, manual flushing is warranted. Failure to remove the bioburden or residual organic material from these intricate surfaces can lead to the development of a biofilm, which will diminish the effectiveness of high-level disinfection. The process of manual cleaning alone can reduce the internal and external bioburden by 3 to 4 logs (ie, the relative number of live microbes eliminated from a surface by disinfecting or cleaning is reduced by 1,000 [3- \log_{10} reduction] to 10,000 [4- \log_{10} reduction]).¹⁶ Although the duodenoscope may present a unique scenario involving an intricate and difficult-to-clean elevator surface, all endoscopes are susceptible to biofilm formation if the devices are inadequately reprocessed.^{17,18}

A secondary issue is delayed reprocessing of endoscopes, whereby the endoscope is allowed to sit idle and soiled for an extended period, sometimes hours, before it is reprocessed.¹⁹ An alternative strategy in circumstances when immediate reprocessing is not possible is to soak the instrument in an appropriate enzymatic detergent according to the manufacturer's instructions for use until the endoscope can be mechanically cleaned and high-level disinfection can be performed. There are no recommendations or guidelines, however, on whether delayed reprocessing and extended soaking may adversely affect the integrity of the endoscope or increase the bioburden on the external or internal surfaces of the device. In the absence of a valid evidence-based guideline, personnel should make every effort possible to complete endoscope reprocessing in a timely and efficacious manner.

A third consideration is the tendency to truncate reprocessing steps, thereby generating errors. A recent publication analyzed lapses in endoscope reprocessing that were reported in the literature, media, and governmental reports between January 2005 and June 2012 in a wide geographic area in the United States.²⁰ The analysis included results from public and private health care facilities and outpatient surgical centers, revealing the following errors:

- generally not complying with established, published guidelines;
- failing to preclean selective endoscopes before reprocessing;
- not performing or allowing an inadequate duration of high-level disinfection;
- using expired disinfectants;
- allowing dirty endoscopes to dry before they are cleaned;
- inadequately brushing channels or skipping channel cleaning entirely;
- improperly cleaning the elevator component of duodenoscopes;
- improperly storing contaminated endoscopes;
- incorrectly programming automatic endoscope reprocessors;
- being unaware of or failing to report malfunctioning automatic endoscope reprocessors; and
- insufficiently documenting personnel competency to perform endoscope processing.

This report should in essence be viewed as a clarion call for all health care professionals who are engaged in reprocessing of endoscopic devices. It also should give pause to supervisory personnel and hospital administrators, because any or all of these deficiencies can (and will) have a significant effect on the health and well-being of patients and personnel alike. In addition to outbreaks of CRE associated with deficiencies in the processing of duodenoscopes, transmission of microbial pathogens via contaminated endoscopes has been noted recently, including *Clostridium difficile*, *E coli*, *Pseudomonas aeruginosa*, *Proteus mirabilis*, *Serratia* species, *Staphylococcus aureus*, and methicillin-resistant *S aureus*.²⁰⁻²² In several instances, lapses in endoscope reprocessing resulted in serious patient injury.²⁰⁻²² In one example, retained reprocessing chemicals used during high-level disinfection were responsible for chemical injury in exposed patients.²⁰ In another instance in which lapses occurred, patients who acquired a multidrug-resistant *K pneumoniae* infection had a longer length of hospital stay and a

five times higher mortality rate than other patient cohorts.²⁰ In almost all instances of inadequate reprocessing, investigators have noted retained debris (ie, bioburden) within the lumens of the affected devices.^{21,22}

The initial projection that the risk of acquiring a health care–associated infection after an endoscopic procedure was one in 1.8 million procedures⁷ may be an underestimation given the volume of critical exposures currently reported in the academic and commercial literature. The true number is pure conjecture because no validated surveillance program is in place to track such outcomes. Petersen has noted that “despite federal guidance and widespread adoption of multi-society guidelines for cleaning and high-level disinfection, these practices are often referred to as the Achilles heel for safety.”^{23(p997)} It would appear that current standards of practice for endoscope reprocessing are highly vulnerable to human error, and although future developments in the total automation of endoscopic reprocessing will greatly improve the efficiency and turnaround time of the process, it is unlikely to eliminate some of the basic risks that are associated with contaminated devices, especially involving instruments with intricate design features.

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PATIENT CARE TRANSPARENCY

In February 2014, the Centers for Disease Control and Prevention organized a conference call to discuss the current increase in outbreaks of CRE infection related to the use and reprocessing of duodenoscopes. Numerous stakeholders participated in this conference call²⁴:

- Association for Professionals in Infection Control and Epidemiology,
- Society for Healthcare Epidemiology of America,

- American Society for Gastrointestinal Endoscopy,
- Society of Gastroenterology Nurses and Associates,
- Association for the Advancement of Medical Instrumentation, and
- US Food and Drug Administration.

The meeting also addressed the challenges associated with duodenoscope reprocessing, compliance with current recommended practices for reprocessing, and the reasons for unrecognized lapses in the standards of practice for reprocessing endoscopic devices. It is evident that changes need to be made in the manner in which personnel assess the adequacy of reprocessing for duodenoscopes

and other endoscopes, and whether that involves microbiological surveillance or non-culture (eg, adenosine triphosphate assay) technique remains to be determined; currently,

there is not a standardized or accepted threshold for either methodology.

There is no disagreement, however, on the need for patient care transparency. Based on current experience, patients should be made aware during the informed consent process of the risk of bacterial transmission associated with endoscopic procedures, regardless of how minimal that risk may be. In addition, when confronted with an episode of documented cross-contamination, personnel must make every effort to

- identify any and all patients who may have undergone a procedure with the contaminated device,
- inform the patient of his or her probability of risk,
- describe the expected care that the patient will receive if needed, and
- discuss the degree of follow-up that will occur as a result of the exposure.

In many cases, the patient will be asked to submit a stool or blood sample for surveillance purposes.

Although a negative culture often is reassuring to the patient and practitioner, it does not completely eliminate the need for postexposure follow-up, especially if the exposure involved a viral agent such as hepatitis C.

Recent global experiences with CRE have served to accelerate a national dialogue on endoscope reprocessing and the failure of health professionals to effectively minimize the risk of cross-contamination. Although the pace of reprocessing at a busy endoscopy practice often can be overwhelming, there is never an excuse for lapses in reprocessing that place patients or personnel at risk for exposure to a health care–associated pathogen or any preventable injurious event after endoscopy. [AORN](#)

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