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## Major article

## Reported gastrointestinal endoscope reprocessing lapses: The tip of the iceberg

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Instrument cleaning  
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**Background:** Most cases of microbial transmission to patients via contaminated endoscopes have resulted from nonadherence to reprocessing guidelines. We evaluated the occurrence, features, and implications of reprocessing lapses to gauge the nature and breadth of the problem in the context of widely available and accepted practice guidelines.

**Methods:** We examined peer-reviewed and non-peer-reviewed literature to identify lapses reported in North America during 2005 to 2012 resulting in patient exposure to potentially contaminated gastrointestinal endoscopes.

**Results:** Lapses occurred in various types of facilities and involved errors in all major steps of reprocessing. Each lapse continued for several months or years until the problem was discovered except for one that was described as a single incident. There were significant implications for patients, including notification and testing, microbial transmission, and increased morbidity and mortality. Only 1 reprocessing lapse was found in a peer-reviewed journal article, and other incidents were reported in governmental reports, legal documents, conference abstracts, and media reports.

**Conclusion:** Reprocessing lapses are an ongoing and widespread problem despite the existence of guidelines. Lack of publication in peer-reviewed literature contributes to the perception that lapses are rare and inconsequential. Reporting requirements and epidemiologic investigations are needed to develop better evidence-based policies and practices.

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Gastrointestinal (GI) endoscopes are used in bodily cavities that are heavily colonized with microorganisms.<sup>1</sup> Proper endoscope reprocessing, including thorough cleaning and high-level disinfection (HLD), is necessary between patients to minimize the risk of cross contamination.<sup>1</sup> Reprocessing guidelines for fiberoptic endoscopes were first published in 1978.<sup>2</sup> Since then, governmental and professional organizations have updated them and developed new guidelines for reprocessing specific types of endoscopes.<sup>1,3,4</sup>

Guideline nonadherence led to the use of improperly reprocessed endoscopes at Veterans Affairs (VA) medical facilities in Tennessee, Florida, and Georgia between 2003 and 2009, requiring notification of over 10,000 patients.<sup>5,6</sup> Other reprocessing lapses (“lapses”) have come to light following investigations into facilities’ practices.<sup>5–8</sup> In 2008, the United States Centers for Medicare and Medicaid Services (CMS) conducted unannounced inspections of infection control practices at 68 ambulatory surgical centers, over half of which performed endoscopies.<sup>7</sup> Among these facilities, 39 had deficiencies in infection control serious enough to warrant citation, and 19 failed to properly reprocess instruments. In 2010, an observational, multisite study revealed that only 48% of 183 GI endoscopes were properly reprocessed, even though managers at all sites asserted institutional adherence to guidelines and reprocessing personnel were aware of being observed.<sup>8</sup> Nonadherence was particularly high (99%) when manual methods were used to clean endoscopes.<sup>8</sup>

A study conducted at Beth Israel Deaconess Medical Center and Harvard Medical School found that GI endoscopy-associated

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complications resulting in an emergency department visit or hospitalization occurred after approximately 1% of 18,015 outpatient procedures, including screening colonoscopies.<sup>9</sup> Complications included fever and other potential signs of infection. Other researchers have reported numerous cases of postendoscopy infection associated with endoscope contamination, including transmission of multidrug-resistant organisms (MDROs).<sup>2,10–12</sup> Although the risk of infection following endoscopy is stated to be extremely remote by nearly all major guidelines including the 2008 Centers for Disease Control and Prevention/Healthcare Infection Control Practices Advisory Committee (CDC/HICPAC) Guideline for Disinfection and Sterilization in Healthcare Facilities and the 2011 Multisociety Guideline on Reprocessing Flexible GI Endoscopes,<sup>14</sup> existing risk estimates were recently found to be outdated, inaccurate, based on flawed methods, and too low.<sup>13</sup>

Since the introduction of reprocessing guidelines, there have been increases in the volume of endoscopic procedures, the complexity of endoscope design, and the economic pressures on institutions. Given the current challenges, we evaluated the occurrence, features, and implications of recently reported lapses.

## METHODS

Searches for scientific, peer-reviewed journal articles describing lapses were conducted via PubMed. Internet searches were performed to identify lapses published in media reports, including newspapers, magazines, press releases, or other articles. Government Web sites and reports were also reviewed, including sources from state departments of health, the Department of Veterans Affairs Office of Inspector General (VAOIG), CDC's Epidemic Intelligence Service, and the Food and Drug Administration (FDA). Whenever possible, multiple sources were obtained to compile information about a lapse because individual documents often contained incomplete information.

We sought to identify lapses reported between January 2005 and June 2012 in North America. Reports that met these search parameters and described a lapse resulting in patient exposure to a potentially contaminated GI endoscope were included. Lapses were defined as any incident involving 1 or more reprocessing errors resulting in the exposure of 1 or more patients. Errors included nonadherence to cleaning and disinfection guidelines, improper use of reprocessing equipment, or inadequate standard operating procedures or staff competence records for reprocessing. Endoscopes under consideration included colonoscopes, gastroscopes, duodenoscopes (eg, endoscopic retrograde cholangiopancreatography endoscopes), and endoscopes not otherwise specified.

## RESULTS

### *Geographic and facility spread*

Reported lapses occurred with various GI endoscopes and procedures at health care facilities throughout the United States and Canada (Tables 1 and 2). Public and private facilities, including hospitals, medical centers from large health systems, outpatient endoscopy centers, and outpatient surgical centers were involved (Tables 1 and 2). In some cases, multiple facilities within the same health system were implicated.<sup>5,14,15</sup>

### *Sources of reports*

Among the lapses identified, only 1 was published in a peer-reviewed journal,<sup>16</sup> whereas all others were described in media reports and related sources (Table 1) or government reports

(Table 2). Individual government documents and certain media reports described lapses at multiple health care facilities, including 4 reports published by state agencies (Table 2).<sup>17–20</sup>

Following the well-publicized lapses at 3 VA medical facilities, unannounced inspections of 36 VA medical facilities with 38 reprocessing units for colonoscopes were conducted by the VAOIG in 2009.<sup>5</sup> Among these units, 52.6% were found to have inadequate standard operating procedures or documentation of demonstrated staff competence for reprocessing (Table 2). Since then, the VAOIG has continued to monitor facilities and publish reviews that indicate whether processes are in place to ensure effective reprocessing. These recent reviews described additional lapses in the reprocessing of reusable medical equipment, including GI endoscopes.

Lapses were also readily identifiable in the FDA's Manufacturer and User Facility Device Experience (MAUDE) database, which consists of adverse event reports involving medical devices. These are voluntary reports or other reports submitted by device manufacturers, distributors, and health care facilities, typically following device malfunction or incidents resulting in serious patient injury or death. Recent MAUDE reports described postendoscopy complications, including infections or chemical colitis, attributed to reprocessing errors or defective equipment that was undetected prior to patient use. When the FDA reviewed MAUDE reports on endoscopes filed between January 1, 2007, and May 11, 2010, the agency found 80 reports of lapses and 28 reports of infection possibly because of inadequate reprocessing (Table 2).<sup>21</sup> Supplemental data and references documenting lapses described in MAUDE and VAOIG reports are available from the authors on request.

### *Duration and nature of errors*

Reports described errors in each of the major reprocessing steps, whereas general noncompliance with guidelines and manufacturer protocols was also cited. Steps were skipped or done improperly for entire endoscopes as well as for certain channels (Tables 1 and 2). Only 1 lapse was described as a single incident,<sup>22</sup> whereas multiple lapses continued for several years, exposing numerous patients to potentially contaminated endoscopes.<sup>23–27</sup> In some cases, the lapse duration was unknown, either because it was not disclosed or because investigators were unable to determine when the problems started.<sup>28,29</sup>

Many lapses were identified as a result of surveillance or inspections. The single lapse reported in a peer-reviewed journal was discovered during surveillance for deviations from reprocessing protocols.<sup>16</sup> Government reports also described improper reprocessing practices identified through inspections or mandatory adverse event reports.<sup>17,18</sup> Generally, states having multiple lapses, such as Pennsylvania, New Jersey, and California, had mandatory patient safety reporting requirements, whereas other states may not gather data or publicly report lapses.

Improper cleaning occurred on multiple occasions, and employees detected visually apparent residual matter on endoscopes during several of these lapses.<sup>18,30–34</sup> At 3 hospitals, residue on duodenoscopes was associated with bacterial infections.<sup>31,34</sup> At one of the hospitals, guidelines were violated over a period of 20 months when contaminated duodenoscopes were allowed to dry before cleaning.<sup>30,35</sup> MAUDE reports described multiple lapses involving detection of debris or residue in various endoscope channels or components. Other lapses described in MAUDE reports involved broken cleaning brushes that were left in endoscopes and found during subsequent procedures, occasionally after being expelled into patients.

Errors in disinfection often involved lack of HLD for entire endoscopes or certain channels.<sup>16,18,19,23,36–39</sup> For example, endoscopes at

**Table 1**  
Lapses published in media reports and related sources: North America, January 2005-June 2012

Type of health care facility	Location	Pub. Year	Type of endoscope	Errors	Estimated duration of lapse	Estimated patients				Microorganisms found
						Exposed	Notified	Tested	Tested positive	
Private hospital <sup>32,33</sup>	North Carolina	2012	GI endoscope NOS	No cleaning or sterilization for 1 channel	5 months	10	Yes	Yes (viral)	ND	ND
Outpatient endoscopy clinic <sup>26,71-73</sup>	Ontario	2011; 2012	GI endoscope NOS	Multiple reprocessing and chemical issues	9 years	6,800	Yes	Yes (viral)	408	Hepatitis B; hepatitis C
Academic medical center <sup>36,74</sup>	Louisiana	2011	GI endoscope NOS	No HLD	8 months	222	Yes	Yes (viral)	ND	ND
Private medical center <sup>38,75,76</sup>	Oregon	2011	Colonoscope	No HLD	ND	18	Yes	Yes (viral)	ND	ND
Academic medical center <sup>77-79</sup>	Louisiana	2011	GI endoscope NOS	Inadequate HLD temperature	8 weeks	360	Yes	Yes (viral)	ND	ND
Public hospital <sup>30,31,35,80</sup>	British Columbia	2010; 2011	Duodenoscope	Improper reprocessing; Endoscopes allowed to dry before cleaning	20 months	536	Yes	Yes (viral)	11	<i>Pseudomonas</i> ; hepatitis C*; HIV*
Public hospital and academic medical center <sup>23,81</sup>	Minnesota	2010	GI endoscope NOS	Improper HLD of 1 channel	3 years	2,600	Yes	No	ND	ND
Private medical center, hospital, and outpatient surgery center <sup>14,82,83</sup>	California	2010	Colonoscope	Improper HLD; Expired disinfectant	16 months	3,400	Yes	Yes (viral)	ND	ND
Private hospital <sup>24</sup>	Pennsylvania	2010	GI endoscope NOS	Improper HLD of 1 channel	5 years	75	Yes	Yes	ND	ND
Public hospital <sup>27,39,84</sup>	British Columbia	2010	Colonoscope; Gastroscope	No HLD for 1 channel	28 months	9,000	Yes	No	ND	ND
Two county hospitals and a regional cancer treatment center <sup>34,54,56</sup>	Florida	2009; 2010	Duodenoscope	Improper cleaning of elevator channel	≥8 months	191	Yes	Yes	13	<i>Klebsiella pneumoniae</i> (carbapenemase-producing); <i>Escherichia coli</i> (carbapenemase-producing); <i>Pseudomonas aeruginosa</i> ; <i>Proteus mirabilis</i> ; <i>Serratia</i>
Outpatient surgery center <sup>41,85,86</sup>	Georgia	2009; 2010	Colonoscope	Inadequate HLD time	17 months	1,300	Yes	Yes	ND	ND
Public hospital <sup>44,46</sup>	Newfoundland and Labrador	2009	GI endoscope NOS	Inadequate disinfectant amount; AER malfunction	17 months	2,900	ND	ND	ND	ND
Outpatient surgery center <sup>42,87</sup>	Nevada	2008; 2009	GI endoscope NOS	Inadequate HLD time	2 years	ND	Yes	Yes	ND	ND
GI facility NOS <sup>22</sup>	U.S. NOS	2008	Colonoscope	Improper storage of contaminated, damaged endoscope	Single incident	1	ND	ND	ND	ND
Public hospital <sup>25,50,52,88,89</sup>	Alberta	2007; 2008	Endoscope NOS	Improper cleaning and HLD; No disassembly	4 years	2,872 (300 due to endo-scopes)	Yes	Yes (viral)	ND	<i>Staphylococcus aureus</i> (methicillin-resistant)
Two private hospitals <sup>15,90,91</sup>	California	2006	Gastroscope	Improper reprocessing	>1 year	305	Yes	Yes	ND	ND
Private hospital <sup>92</sup>	West Virginia	2006	Endoscope NOS	Improper HLD	19 months	"100s"	Yes	ND	ND	ND
Private hospital <sup>37,93</sup>	Pennsylvania	2005	Colonoscope	No HLD of auxiliary channels	4 months	200	Yes	Yes (viral)	ND	ND
Private hospital <sup>94</sup>	Virginia	2005	GI endoscope NOS	Inadequate HLD time	10 days	144	Yes	Yes (viral)	ND	ND
Private hospital <sup>28,95</sup>	California	2005	GI endoscope NOS	Multiple equipment and operator issues	ND	2,116	Yes	Yes (viral)	ND	ND

AER, automated endoscope reprocessor; GI, gastrointestinal; HLD, high-level disinfection; ND, not disclosed; NOS, not otherwise specified.

\*Indicates previously identified cases that tested positive.

**Table 2**  
Lapses published in government reports: North America, January 2005-June 2012

Health care facilities						
Type of health care facility	Total No. inspected	No. with lapses	Locations	Reporting agency	Pub. Year	Errors
1 outpatient surgery center; 1 outpatient clinic; 5 hospitals <sup>20,96</sup>	NA	7 lapses; 5 facilities	Minnesota	MN Department of Health	2012	Improper cleaning and HLD; Reprocessing a single-use device; Used improper AER connector; Inadequate staff training
ND <sup>21</sup> Outpatient surgery centers and surgical practices <sup>7</sup>	NA 91	80* ≥3	US NOS New Jersey	FDA NJ Health Care Quality Institute	2011 2011	Inadequate reprocessing Improper reprocessing; Unchanged water and cleaning solution
ND <sup>18</sup>	107*	62*	Pennsylvania	PA Patient Safety Authority	2010	Improper cleaning, HLD, and documentation; Knowingly used incompletely reprocessed endoscope
Veterans Affairs medical facilities <sup>5</sup>	36 facilities; 38 units	20 units	Multiple US states	VAOIG	2009	Inadequate standard operating procedures or documentation of staff competence for reprocessing
Hospitals <sup>19</sup>	NA	3	California	CA Department of Health Services	2007	Improper sterilization and reassembly

AER, automated endoscope reprocessor; GI, gastrointestinal; NA, not applicable; ND, not disclosed; NOS, not otherwise specified; VAOIG, Veterans Affairs Office of Inspector General.

NOTE. Supplemental data and references documenting lapses described in MAUDE and VAOIG reports are available from the authors on request.

\*Indicates reports.

a large medical center received no HLD during an 8-month period.<sup>36,40</sup> At another large center, HLD was not performed on an endoscope channel for nearly 3 years because of misinformation from the manufacturer.<sup>23</sup> MAUDE reports discussed incorrect connectors used to attach endoscopes to automated endoscope reprocessors (AERs) or flushing aids, resulting in no HLD of certain channels. Other failures involved inadequate HLD time or temperature<sup>41-43</sup> and errors in disinfectant concentration or water quality during reprocessing.<sup>14,44,45</sup> At 1 hospital, only 25% of the required amount of disinfectant was used over a period of 17 months.<sup>46</sup> Expired disinfectant was used for over 1 year at each of 4 other facilities.<sup>14,47</sup> In addition, 1 MAUDE report described a lapse where water was used in place of disinfectant, and problems with endoscope flushing or rinsing were found when residual chemicals caused chemical colitis.

Improper endoscope storage was also reported.<sup>22</sup> One lapse involved patient exposure to a damaged, contaminated colonoscope that was hung unlabeled in a cabinet with clean endoscopes.<sup>22</sup> Other errors involved equipment problems, including AER malfunction or incorrect programming.<sup>46,48</sup> In some cases, inadequate staff training was recognized as an underlying problem.<sup>5,49</sup> VAOIG investigations revealed insufficient documentation of staff competency at several VA medical centers.<sup>5</sup> One state agency reported receiving 3 notifications when staff knowingly used incompletely reprocessed endoscopes on patients.<sup>18</sup>

Certain individual lapses involved multiple reprocessing errors.<sup>26,30,31,50</sup> At 1 private endoscopy clinic, reprocessing errors involved expired chemicals, inadequate cleaning and HLD, and cross contamination of clean and dirty endoscopes.<sup>26,51</sup> At a large general hospital, failure to preclean duodenoscopes contributed to problems cleaning them.<sup>31,35</sup> Multiple cleaning and HLD errors also occurred at another general hospital.<sup>25,50,52</sup>

### Effects on patient safety

The impact of lapses on patient safety was a focus of media reports, but not the peer-reviewed journal article or government reports, with the exception of MAUDE reports. Lapses discussed in the media typically involved exposure and notification of hundreds of patients, and several lapses involved more than 1,000 patients (Table 1). Patient notification often recommended testing for infection transmission; however, testing was typically done only for viruses such as HIV, hepatitis B, and hepatitis C rather than for enteric pathogens. In 1 lapse at a single provider's clinic, 6,800 patients were exposed to potentially contaminated GI endoscopes and offered only viral testing.<sup>26</sup> In 2 other lapses, thousands of patients treated at large medical facilities were notified about the lapse but not tested.<sup>23,53</sup> In each instance, national health authorities had asserted the risk of disease transmission was too low to warrant testing.<sup>23,53</sup>

Microorganisms were reported to have been transmitted by contaminated endoscopes.<sup>31,34</sup> Various types of microorganisms and occasionally multiple species were detected, including viruses and bacteria (Table 1). *Pseudomonas* spp was most common, and other bacterial pathogens included *Serratia* spp, *Proteus mirabilis*, and *Clostridium difficile* (Table 1). One MAUDE report described 9 patients who acquired *C difficile* after undergoing procedures with an endoscope that was found to have retained debris. Multidrug-resistant bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA) and *Klebsiella pneumoniae* carbapenemase (KPC)-producing *Klebsiella pneumoniae* and *Escherichia coli*, were detected following 2 lapses.<sup>25,34</sup> One of these lapses involving a contaminated duodenoscope resulted in 13 cases of multidrug-resistant *K pneumoniae* among 191 endoscopy patients, indicating a 7% attack

rate.<sup>34,54</sup> Two other lapses were associated with patients who tested positive for viruses. In 1 instance, 408 of 4,353 exposed patients who underwent laboratory testing for bloodborne pathogens tested positive for hepatitis B or C, including previously undiagnosed cases and 20 cases of active infection.<sup>26,55</sup> Viral transmission was attributed to patient lifestyles, yet reports did not provide substantiating data to rule out transmission from contaminated endoscopes.<sup>26</sup> In the other instance, 10 patients tested positive for hepatitis C and HIV after exposure to a contaminated duodenoscope; however, these cases had been previously diagnosed.<sup>55</sup> Nonetheless, these reports revealed that numerous patients were exposed to improperly reprocessed endoscopes that had been previously used on patients with viral infections.

Several lapses were associated with serious patient injury. On multiple occasions, reprocessing chemicals remaining in endoscopes caused colitis in exposed patients. MAUDE reports described a variety of patient complications after exposure to contaminated endoscopes, including abdominal pain, inflammation, and bacteremia. In other instances, patients who tested positive for microorganisms after a lapse required treatment and hospitalization.<sup>31,56</sup> At 1 hospital, an ill patient who had undergone endoscopy with a contaminated duodenoscope was hospitalized with a *Pseudomonas* infection.<sup>31</sup> The patient died soon after acquiring the infection as a result of the preexisting illness.<sup>31</sup> Following another lapse, patients who underwent endoscopies and acquired multidrug-resistant *K pneumoniae* were found to have longer hospital stays and 5 times higher mortality than other patients.<sup>34,54,56</sup>

## DISCUSSION

By looking beyond peer-reviewed literature for evidence, we identified numerous recent reprocessing lapses in North America, including several that were associated with patient infection, injury, or death.<sup>21,31,34,56</sup> Recent lapses have also been reported in other countries,<sup>10,11,57-61</sup> indicating that improper reprocessing is widespread and continues to occur despite the existence of reprocessing guidelines. Other researchers have acknowledged that most lapses never get publicly reported.<sup>2,6</sup> Reluctance by institutions to report lapses may contribute to the lack of peer-reviewed articles describing them. In addition, some journals do not publish case reports.<sup>62,63</sup> Lack of reporting in peer-reviewed journals contributes to the perception that lapses are rare and inconsequential.

Current endoscopy-associated infection (EAI) risk estimates are erroneously based on the number of infections reported in peer-reviewed articles.<sup>13</sup> As a result, numerous experts and organizations have asserted the risk of EAI is virtually nonexistent.<sup>1,3,4,12</sup> Based on existing estimates, fewer than a dozen EAIs would be expected to occur each year in the United States. However, multiple cases of EAI resulting from individual lapses have exceeded these estimates, indicating current estimates are inaccurate and far too low.<sup>13</sup>

Researchers have identified retained debris in lumened instruments, including endoscopes, as a result of inadequate reprocessing and complex device design.<sup>64,65</sup> A recent study found that protein residue and water remained on endoscope channels even after thorough cleaning.<sup>66</sup> Studies by Alfa et al found that 14% of patient-ready GI endoscopes had bacterial or fungal growth<sup>67</sup> and that up to 19% of manually cleaned channels tested positive for protein, hemoglobin, or carbohydrates.<sup>68</sup> Detailed outbreak investigations have implicated endoscopes as likely sources of microbial transmission.<sup>10,11,31,34,64</sup> Matching strains of MDROs were collected from patients and endoscopes following several of these lapses, indicating that MDROs may be transmitted by contaminated endoscopes.<sup>10,11,34,56</sup> With the exception of methicillin-resistant *Staphylococcus aureus*, the vast majority of MDROs are harbored in the GI tract and can be clinically silent for months to years before

causing extraintestinal infection. Endoscopies with contaminated devices may place patients at high risk for acquiring MDROs because bowel preparation alters colonic microflora,<sup>69,70</sup> thereby reducing patient resistance to colonization with MDROs.

At present, there is no central repository for reports on lapses and no requirement that local or federal officials maintain records or make them available to clinicians, researchers, or policy makers. Exposed patients are not routinely recalled for testing because the health risks are assumed to be very low.<sup>23,27</sup> This leads to a vicious cycle whereby institutions do not notify or test patients when a lapse is discovered because decision makers rely on erroneous risk estimates that have been propagated in the guidelines. Mandatory reporting of lapses to a national registry would support epidemiologic review and investigation and the consideration of new policies based on sound data.

Adherence to reprocessing guidelines needs to be improved.<sup>8</sup> In a multisite study that revealed poor adherence, staff reported that they did not like to do various reprocessing tasks, felt pressure to work quickly, and attributed health problems to working with endoscopes.<sup>8</sup> The link between reprocessing errors and factors that may influence health care worker behavior suggests that training and competency testing need to be supplemented with accountability measures and active surveillance of reprocessing effectiveness so that contaminated endoscopes can be identified before they are used on patients.

## Limitations

Because of the lack of a central repository or peer-reviewed journal articles describing lapses, ad hoc searches of media, government reports, and other online sources were used to identify them. Even when multiple reports on individual lapses were available, the information was frequently incomplete and difficult to interpret. Thus, the results of this review may not be generalizable. Furthermore, the information provided in media and government reports was neither scrutinized by peer reviewers nor edited for technical accuracy or clarity of communication. Data were sometimes reported using potentially inaccurate terms (eg, sterilization rather than HLD).

## Conclusion

Improper endoscope reprocessing is an ongoing and pervasive problem that has the potential to cause significant patient harm. Reprocessing guidelines should be revised to reflect the true risk of transmitting infections, including enteric pathogens and MDROs, when lapses occur. These revisions will require additional research because the magnitude of risk associated with particular types of lapses is unknown. As such, there is a need for a central repository of data pertaining to lapses and associated outcomes. Infection preventionists should recognize risks associated with improper reprocessing and continuously evaluate reprocessing effectiveness to ensure that endoscopes are clean and disinfected prior to use on every patient.

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