COMMENTARY

Managing and Preventing Exposure Events from Inappropriately Reprocessed Endoscopes

David J. Weber, MD, MPH[1]

(See the article by Holodniy et al, on pages 649–656.)

Each year in the United States millions of invasive procedures are performed, including greater than 10,000,000 gastrointestinal endoscopic procedures (Table 1).[1,2] All invasive procedures involve contact by a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogens that can lead to infection. Failure to properly disinfect or sterilize equipment carries not only the risk associated with breach of host barriers but also the risk of person-to-person transmission (eg, hepatitis B virus [HBV]) and transmission of environmental pathogens (eg, *Pseudomonas aeruginosa*). Proper disinfection and sterilization are essential for ensuring that medical and surgical instruments do not transmit pathogens to patients.[3,4]

More than 55 years ago, Spaulding devised a rational approach to disinfection and sterilization of patient care items or equipment.[3-5] This classification scheme is so clear and logical it has been retained and refined and continues to be used when planning methods for disinfection and sterilization. Spaulding divided medical devices into 3 categories (ie, critical, semicritical, and noncritical) on the basis of the risk of infection involved in the use of the items. Critical devices are items that enter sterile tissue or the vascular system and include surgical instruments, implants, and intravenous or intra-arterial catheters. Items in this category should be purchased as sterile or should be sterilized by steam sterilization (preferred). Semicritical items are those that come into contact with mucous membranes or nonintact skin and include gastrointestinal endoscopes, bronchoscopes, laryngoscope blades and handles, and diaphragm-fitting rings. These medical devices should be free of all microorganisms (ie, mycobacteria, fungi, viruses, and bacteria), although small numbers of bacterial spores may be present. The minimal requirement for semicritical items is high-level disinfection using Food and Drug Administration (FDA)–cleared high-level chemical disinfectants. Noncritical items are those that come into contact with intact skin but not mucous membranes (eg, bedpans, blood-pressure cuffs, and bed rails). Such items should undergo low-level disinfection after use when shared by different patients. The Spaulding classification provides an excellent guide for disinfection and sterilization of medical devices, but it should be noted that the scheme is an oversimplification, and preventing transmission of infection by medical devices may require additional modifications.[4,6]

Multiple studies in many countries have documented a lack of compliance with established guidelines for disinfection and sterilization.[4] Failure to comply with scientifically based guidelines has led to numerous outbreaks.[4] Preventing and managing potential outbreaks when there is a breach in established methods of disinfection and sterilization is complex, may consume substantial amounts of personnel time and expense, and may lead to legal problems. In this issue of *Infection Control and Hospital Epidemiology*, Holodniy et al[7] describe the management of 4 potential outbreaks in Veterans Affairs medical centers (VAMCs), all resulting from failure to follow established guidelines for cleaning and disinfecting endoscopes. The breaches in disinfection led to 9,879 patients being tested in look-back programs for possible acquisition of human immunodeficiency virus (HIV), HBV, and hepatitis C virus (HCV). This excellent article raises a number of important issues.

First, what is the frequency of outbreaks and pseudo-outbreaks related to endoscopy? The incidence of infection associated with endoscopy has been reported to be very low (about 1 case per 1.8 million procedures).[8] However, as noted by Holodniy and colleagues, this number may be an underestimate because outbreaks may be unrecognized or never reported. The prolonged incubation period of the key bloodborne viruses (ie, HIV, HBV, and HCV) and the fact that initial infection may be asymptomatic would make detection of an infection from an endoscopic procedure difficult. Fur-

Affiliation: 1. Department of Medicine, University of North Carolina at Chapel Hill, North Carolina; and Department of Hospital Epidemiology, UNC Health Care, Chapel Hill, North Carolina.

Received March 21, 2012; accepted March 22, 2012; electronically published May 7, 2012.

 0899-823X/2012/3307-0002$15.00. DOI: 10.1086/666339

TABLE 1. Frequency of All Procedures and of Selected Endoscopic Procedures Performed in the United States

Procedure	Total Procedures	Inpatient Procedures, 2009	Outpatient Procedures, 2006
All procedures	101,262,000	47,962,000	53,300,000
Endoscopy of small intestine	4,562,000	1,095,000	3,467,000
Endoscopy of large intestine	6,266,000	525,000	5,741,000
Bronchoscopy	442,000	269,000	173,000
Cystoscopy	881,000	130,000	751,000
Hysteroscopy	...	NA	313,000
Arthroscopy of knee	...	NA	956,000

NOTE. NA, not available.

thermore, the true incidence of infections caused by contaminated endoscopes is unknown because there are no formal, prospective surveillance systems for these types of infection.[9] Nevertheless, more outbreaks have been associated with endoscopes than any other medical device.[9-16] Most outbreaks have involved gastrointestinal endoscopes,[9-14] followed by bronchoscopes.[9-12,15,16] However, outbreaks have been associated with cystoscopy and hysteroscopy.[11] As noted by Holodniy and colleagues, ear, nose, and throat (ENT) endoscopes have not been linked to patient-to-patient transmission of pathogens.

Second, why are endoscopes so frequently involved in outbreaks and pseudo-outbreaks? Because of the body cavities they enter, flexible endoscopes often acquire high levels of microbial contamination (bioburden) during each use.[4] For example, the bioburden on flexible gastrointestinal endoscopes after use has ranged from 10^7 to 10^{10} colony-forming units (CFUs)/mL, with the highest levels found in the suction channels. The average load on bronchoscopes before cleaning was 6.4×10^4 CFUs/mL. Unfortunately, most current flexible endoscopes are heat sensitive and must either be sterilized using a low-temperature method (eg, ethylene oxide) or be subjected to high-level disinfection (eg, glutaraldehyde, peracetic acid, and ortho-phthalaldehyde), methods that are less robust than steam sterilization. In addition to high bioburden, flexible endoscopes present a challenge for low-temperature sterilization and high-level disinfection because they have long, narrow lumens; cross-connections; mated surfaces; sharp angles; springs and valves; occluded dead ends; absorbent material; and rough or pitted surfaces. Excellent guidelines that provide detailed recommendations for the cleaning and disinfection or sterilization of endoscopes are available.[4,17,18] However, procedures for the cleaning and disinfection of endoscopes are complex, and the guidelines must be adapted for the specific endoscope and method of disinfection.

Third, what are the most common causes of such endoscope-associated outbreaks? Most outbreaks associated with endoscopy occur because of poor adherence to current disinfection guidelines. The causes of endoscopy-related outbreaks have been comprehensively detailed.[11,16] Contamination most commonly results from failure to properly perform the key steps in disinfection: appropriate cleaning, disinfection, rinsing, drying, and/or storage. Many recent outbreaks have resulted from contaminated automatic endoscope reprocessors or the use of damaged or malfunctioning endoscopes. Outbreaks have resulted from contaminated equipment, including rinse tanks, tubing, antibacterial filters on water lines, cleaning brushes, and biofilms in the reprocessor. Two of the breaches of standard disinfection practice reported by Holodniy and colleagues (ie, at VAMCs 1 and 2) involved failure to perform high-level disinfection. When disinfecting an endoscope, it is important to use an FDA-cleared sterilant or high-level disinfectant and follow the manufacturer's recommendation for use dilution, monitoring, and exposure duration. Disinfectants that are not FDA cleared and should not be used for reprocessing endoscopes include iodophors, chlorine solutions, alcohols, quaternary ammonium compounds, and phenolics. Two additional breaches reported by Holodniy and colleagues (ie, at VAMCs 3 and 4) involved the failure to properly replace or disinfect the auxiliary water tubing between patients. Current guidelines recommend that the water bottle (used for cleaning the lens and irrigation during the procedure) and its connecting tubing be subjected to high-level disinfection or sterilization at least daily,[4,18] although some organizations espouse more frequent exchange of water bottles and tubing. Sterile water should be used to fill the water bottle. The reprocessing of nonendoscopic devices, accessories, and attachments should adhere to the manufacturer's recommendations.

Fourth, how can errors in proper cleaning and disinfection of endoscopes be minimized? Key to preventing errors in the disinfection of endoscopes are detailed facility policies and procedures that are consistent with current disinfection guidelines.[4,18] These policies and procedures should be consistent with the cleaning and disinfection recommendations of the endoscope manufacturer and producer of the disinfectant (or automated endoscope reprocessor). If the recommendations conflict, the manufacturers of the endoscope and reprocessor should be contacted and the recommendations reconciled. Current guidelines recommend that personnel assigned to reprocess endoscopes should receive device-specific reprocessing instructions (ie, endoscope and automated endoscope reprocessor) to ensure proper cleaning

TABLE 2. Protocol for Exposure Evaluation after a Failure of Disinfection and Sterilization Procedures

1. Confirm disinfection or sterilization reprocessing failure
2. Impound any improperly disinfected/sterilized items
3. Do not use the questionable disinfection/sterilization unit (eg, sterilizer, automated endoscope reprocessor) until proper functioning can be assured
4. Inform key stakeholders
5. Conduct a complete and thorough evaluation of the cause of the disinfection/sterilization failure
6. Prepare a line listing of potentially exposed persons
7. Assess whether disinfection/sterilization failure increases patient risk for infection
8. Inform expanded list of stakeholders of the reprocessing issue
9. Develop a hypothesis for the disinfection/sterilization failure and initiate corrective action
10. Develop a method to assess potential adverse patient events
11. Consider notification of state and federal authorities
12. Consider patient notification
13. Develop a long-term follow-up plan
14. Perform after-action report

and high-level disinfection or sterilization. Competency testing of personnel who reprocess endoscopes should be performed and documented on a regular basis (eg, at start of use and annually). Temporary personnel should not be allowed to reprocess endoscopes until competency has been established. Other preventive measures include proper maintenance and repair of endoscopes, removal of damaged devices from use until repaired, performing routine testing of high-level liquid disinfectants to ensure at least the minimal effective concentration of the active ingredient, and use of a method that allows users to readily identify whether and when an endoscope has been reprocessed.[4,18,19] In addition to proper cleaning and disinfection of endoscopes, endoscopy personnel should follow safe injection practices to prevent outbreaks of bloodborne pathogens.[19,20]

Finally, how should healthcare facilities manage potential breaches of proper disinfection and sterilization of medical devices, including endoscopes? As with all potential breaches of medical practice that may place patients at risk, healthcare facilities should have a mechanism by which personnel can report these breaches to risk management without recrimination. Healthcare facilities should maintain a log for each endoscopic procedure indicating the patient's name and medical record number, the procedure, and the serial number or other identifier of the endoscope (and automated endoscope reprocessor, if used) to assist in an outbreak investigation.[4,18] A 14-step protocol for investigating possible exposures after a failure of disinfection and sterilization has been published (Table 2).[21] Important steps include confirming the disinfection/sterilization failure, impounding and reprocessing any potentially improperly disinfected items, assessing the risk of pathogen transmission to patients, and notification of key internal stakeholders and state and federal authorities. The outbreak evaluations described by Holodniy and colleagues in this issue exemplify management of potential exposure events. A key issue in potential exposure events is whether to contact patients and to initiate a look-back program. Assessing the likelihood of disease transmission can aid in this process.[21] Using the method of Rutala and Weber,[21] Holodniy and colleagues estimated the risk of acquiring a bloodborne pathogen during ENT endoscopy or colonoscopy as 7 in 10 trillion and 2.4 in 1 billion, respectively, for HIV and as 1 in 1 billion and 8 in 10 million, respectively, for HBV, with HCV intermediate between HIV and HBV. The risk of disease transmission should be viewed in light of the risk of dying from other causes. For example, the risk per year of dying in the United States for selected events is as follows (2007 risks): heart disease, 1 in 467; motor vehicle accident, 1 in 6,855; drowning, 1 in 874,817; bee/wasp sting, 1 in 5,579,431; dog bite, 1 in 9,415,305; fireworks injury, 1 in 30,129,071; and shark attack, approximately 1 in 300,000,000.[22,23(p37)] While there is no specific level of risk for which patient notification is required, healthcare facilities may choose not to inform patient of risks that are far below those faced in everyday life.[21] Of course, healthcare facilities may elect to inform patients of a possible exposure even if the risks of disease transmission are low and offer such patients postexposure testing, most commonly for bloodborne pathogens. Such look-back programs are difficult and expensive. Furthermore, if large numbers of patients are involved it is likely that patients unknowingly infected with bloodborne pathogens will be uncovered, as the prevalence of infection has been estimated as follows: for HBV, 2.6%–4.6%;[24] for HCV, 8.8%–12.8%;[24] and for HIV, 0.39%.[25] For viral diseases, quasispecies analysis can be performed to provide evidence of person-to-person transmission.[26] However, as testing of all possible sources is unlikely even quasispecies analysis usually cannot entirely exclude the possibility that an occult infection was acquired as a result of a failure of proper disinfection or sterilization.

In conclusion, Holodniy and colleagues are to be congratulated for publishing this important article detailing the look-back investigation of improperly reprocessed endoscopy equipment, for their careful and comprehensive exposure evaluation, and for assessment of the risk of bloodborne path-

ogen transmission. Prevention is always superior to treatment, and infection control professionals and their medical facilities should prospectively educate and implement recommendations for the proper cleaning and disinfecting of endoscopes.

ACKNOWLEDGMENTS

Potential conflicts of interest. D.J.W. reports no conflicts of interest relevant to this article. All authors submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest, and the conflicts that the editors consider relevant to this article are disclosed here.

Address correspondence to David J. Weber, MD, MPH, 2163 Bioinformatics, CB #7030, Chapel Hill, NC 27599 (dweber@unch.unc.edu).

The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Departments of Veterans Affairs, Health and Human Services, or the United States government. When this investigation was initiated, Ronald Valdiserri was the Chief Public Health Consultant in the Veterans Affairs Office of Public Health.

REFERENCES

1. Cullen KA, Hall MJ, Golosinskiy A. Ambulatory surgery in the United States, 2006. *Natl Health Stat Report* 2009;Jan 28(11): 1–25.
2. Centers for Disease Control and Prevention. National Hospital Discharge Survey: 2009 table, procedures by selected patient characteristics. http://www.cdc.gov/nchs/fastats/insurg.htm. Accessed February 20, 2012.
3. Rutala WA, Weber DJ. Disinfection and sterilization in health care facilities: what clinicians need to know. *Clin Infect Dis* 2004; 39:702–709.
4. Rutala WA, Weber DJ. Guideline for disinfection and sterilization in healthcare facilities, 2008. http://www.cdc.gov/hicpac/Disinfection_Sterilization/acknowledg.html. Accessed February 20, 2012.
5. Rutala WA, Weber DJ. Sterilization, high-level disinfection, and environmental cleaning. *Infect Dis Clin North Am* 2011;25: 45–76.
6. McDonnell G, Burke P. Disinfection: is it time to reconsider Spaulding? *J Hosp Infect* 2011;78:163–170.
7. Holodniy M, Oda G, Schirmer PL, et al. Results from a large-scale epidemiologic look-back investigation of improperly reprocessed endoscopy equipment. *Infect Control Hosp Epidemiol* 2012;33:649–656 (in this issue).
8. Schembre DB. Infectious complications associated with gastrointestinal endoscopy. *Gastrointest Endosc Clin N Am* 2000;10: 215–232.
9. Srinivasan A. Epidemiology and prevention of infections related to endoscopy. *Curr Infect Dis Rep* 2003;5:467–472.
10. Spach DH, Silverstein FE, Stamm WE. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. *Ann Intern Med* 1993;118:117–128.
11. Seoane-Vazquez E, Rodriguez-Monguio R, Visaria J, Carlson A. Endoscopy-related infections and toxic reactions: an international comparison. *Endoscopy* 2007;39:742–746.
12. Seoane-Vazquez E, Rodriguez-Monguio R. Endoscopy-related infection: relic of the past? *Curr Opin Infect Dis* 2008;21:362–366.
13. Rey J-F. Endoscopic disinfection: a worldwide problem. *J Clin Gastroenterol* 1999;28:291–297.
14. Cowen AE. The clinical risks of infection associated with endoscopy. *Can J Gastroenterol* 2001;15:321–331.
15. Weber DJ, Rutala WA. Lessons learned from outbreaks associated with bronchoscopy. *Infect Control Hosp Epidemiol* 2001;22: 403–408.
16. Weber DJ, Rutala WA. Lessons learned from outbreaks and pseudo-outbreaks associated with bronchoscopy. *Infect Control Hosp Epidemiol* 2012;33:230–234.
17. Honeybourne D, Neuman CS. An audit of bronchoscopy practices in the United Kingdom: a survey of adherence to national guidelines. *Thorax* 1997;52:709–713.
18. Petersen BT, Chennat J, Cohen J, et al. Multisociety guideline on reprocessing flexible GI endoscopes: 2011. *Infect Control Hosp Epidemiol* 2011;32:527–537.
19. Greenwald D. Reducing infection risk in colonoscopy. *Gastrointest Endosc Clin N Am* 2010;20:603–614.
20. Centers for Disease Control and Prevention. Injection safety: information for providers. http://www.cdc.gov/injectionsafety/providers.html. Accessed March 10, 2012.
21. Rutala WA, Weber DJ. How to assess risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. *Infect Control Hosp Epidemiol* 2007;28:146–155.
22. Centers for Disease Control and Prevention. United States life tables, 2007. *Natl Vital Stat Rep* 2011;59(9):1–60.
23. National Safety Council. Injury facts, 2011. http://www.nsc.org/news_resources/injury_and_death_statistics/Pages/TheOddsofDyingFrom.aspx. Accessed March 10, 2012.
24. Centers for Disease Control and Prevention. Viral hepatitis statistics and surveillance. http://www.cdc.gov/hepatitis/Statistics/index.htm. Accessed March 10, 2012.
25. Centers for Disease Control and Prevention. HIV in the United States. http://www.cdc.gov/hiv/resources/factsheets/us.htm. Accessed March 10, 2012.
26. Shimokura G, Chai F, Weber DJ, et al. Patient-care practices associated with an increased prevalence of hepatitis C virus infection among chronic hemodialysis patients. *Infect Control Hosp Epidemiol* 2011;32:415–424.