GIE®

SPECIAL ARTICLE

Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update

Prepared by: REPROCESSING GUIDELINE TASK FORCE

Bret T. Petersen, MD, FASGE, Chair, Jonathan Cohen, MD, FASGE, Ralph David Hambrick, III, RN, Navtej Buttar, MD, David A. Greenwald, MD, FASGE, Jonathan M. Buscaglia, MD, FASGE, James Collins, RN, Glenn Eisen, MD, MPH, FASGE

This article was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE).

The beneficial role of GI endoscopy for the prevention, diagnosis, and treatment of many digestive diseases and cancer is well established. Like many sophisticated medical devices, the endoscope is a complex, reusable instrument that requires meticulous cleaning and reprocessing in strict accordance with manufacturer and professional organization guidance before being used on subsequent patients. To date, published episodes of pathogen transmission related to GI endoscopy using standard end-viewing instruments have been associated with failure to follow established cleaning and disinfection/sterilization guidelines or use of defective equipment. Recent reports pertaining to transmission among patients undergoing specialized procedures using side-viewing duodenoscopes with distal tip elevators have raised questions about the best methods for the cleaning and disinfection or sterilization of these devices between patient uses.

In 2003 the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Healthcare Epidemiology of America collaborated with multiple physician and nursing organizations, infection prevention and control organizations, federal and state agencies, and industry leaders to develop evidence-based guidelines for reprocessing GI endoscopes.[1,2] Since then, high-level disinfectants, automated reprocessing machines, low-temperature sterilization methods, endoscopes, and endoscopic accessories have evolved.[3-7]

Additional outbreaks of infections related to suboptimal infection prevention practices during endoscopy,[8,9] lapses in endoscope reprocessing, contamination or malfunction of automated reprocessing machines, and transmission during ERCP have been well publicized. A cluster of cases of hepatitis C virus infection was attributed to grossly inappropriate intravenous medication and sedation practices.[8,89] In other instances, risk of infection transmission has been linked to incorrect reprocessing as a result of unfamiliarity with endoscope channels, accessories, and the specific steps required for reprocessing of attachments.[9] On-site ambulatory surgery center surveys confirm that gaps in infection prevention practices are common.[10] Given the ongoing occurrences of endoscopy-associated infections attributed to lapses in infection prevention, an update of the 2003 multisociety guideline was published in 2011.[11,12,91] Now, after the recent experience with transmission by duodenoscopes despite appropriate reprocessing practices, an update to incorporate evolving information is again warranted.

This update of the 2011 multisociety guideline retains the expanded details related to critical reprocessing steps of cleaning and drying and incorporates recent guidance that is specific to those endoscope models with movable

0016-5107/$36.00
http://dx.doi.org/10.1016/j.gie.2016.10.002

elevators at the distal tip, such as duodenoscopes and linear US endoscopes. It also updates information on those issues for which there are incomplete data to guide practice. These issues include endoscope "shelf-life" or "hang time" (the interval of storage after which endoscopes should be reprocessed before use), the role of microbiologic surveillance testing of endoscopes after reprocessing, questions regarding endoscope durability and longevity from the standpoint of infection prevention, and the evolution of various enhanced reprocessing approaches for duodenoscopes.

SPAULDING CLASSIFICATION FOR MEDICAL DEVICES AND LEVEL OF DISINFECTION

The classification system first proposed by Dr E. H. Spaulding divides medical devices into categories based on the risk of infection involved with their use.[13] This classification system is widely accepted and is used by the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), epidemiologists, microbiologists, and professional medical organizations to help determine the degree of disinfection or sterilization required for various medical devices. Three categories of medical devices and their associated level of disinfection are recognized:

- Critical: A device that enters normally sterile tissue or the vascular system. Such devices should be sterilized, defined as the destruction of all microbial life. Examples include endoscopes used in sterile settings such as laparoscopic endoscopy and endoscopic accessories such as biopsy forceps and sphincterotomes.
- Semicritical: A device that comes into contact with intact mucous membranes and does not ordinarily penetrate sterile tissue. These devices (eg, GI endoscopes) should receive at least high-level disinfection (HLD), defined as the destruction of all vegetative microorganisms, mycobacteria, small or nonlipid viruses, medium or lipid viruses, fungal spores, and some, but not all, bacterial spores.
- Noncritical: Devices that do not ordinarily touch the patient or touch only intact skin, such as stethoscopes or patient carts. These items may be cleaned by low-level disinfection.

PATHOGEN TRANSMISSION

More than 20 million GI endoscopic procedures are performed annually in the United States.[14] Patient outcomes are not routinely tracked; however, reports of pathogen transmission resulting from these procedures are rare. In a large and now historical review comprising 265 scientific articles published between 1966 and 1992, 281 episodes of pathogen transmission were attributed to GI endoscopy.[15,16] In each instance, pathogen transmission was associated with a breach in currently accepted cleaning and disinfection guidelines, use of an unacceptable liquid chemical germicide for disinfection, improper drying, or defective equipment. In the subsequent 20 years, relatively few additional reports of pathogen transmission during GI endoscopy were published, and essentially all were associated with clear lapses in either infection prevention practices or reprocessing of the endoscope and accessories.

Most recently, reports in both the medical literature and general media have identified clusters of transmission of multidrug-resistant organisms during endoscopy with side-viewing duodenoscopes using mechanical elevators for device manipulation.[17-22] In contrast to prior episodes of transmission, these outbreaks occurred despite apparently appropriate cleaning and HLD. The details of these episodes highlight the challenges with consistent clearance of all organisms from the exposed, complex, moving parts and operating channels of duodenoscopes and the potential role of biofilms in hindering adequate reprocessing. Transmission episodes can generally be categorized as either "nonendoscopic" and related to care of intravenous lines and administration of anesthesia or other medications or "endoscopic" and related to transmission by the endoscope and/or accessories.

Nonendoscopic transmission of infection

The importance of good general infection prevention practices is highlighted by several outbreaks of hepatitis C, including 1 at a New York endoscopy center related to improper handling of intravenous sedation tubing, multidose vials, and/or reuse of needles.[23] A similar cluster of 6 cases of hepatitis C infection occurred among patients at a Las Vegas endoscopy center.[8] These cases were attributed to cross-contamination from syringes reused to draw additional doses of anesthetic from single-use vials, which were then used for multiple patients undergoing endoscopy. Surveillance testing was offered to over 40,000 patients of several affiliated endoscopy centers that used these unsafe practices, the results of which have not been formally published.

Endoscopic transmission of infection

Several episodes of transmission of hepatitis C virus have been associated with breaches in accepted endoscope reprocessing protocols.[24-26] Transmission of infection has also been attributed to failure to sterilize biopsy forceps between patients[27] and contamination of clean instruments by the hands of staff after direct contact with the hospital environment.[28] Most recently, lapses in use of appropriate tubing with attached 1-way valves and lapses in reprocessing of the tubing used to attach water pumps to endoscope irrigation channels have been recognized in numerous centers around the United States.[9] The risk for *potential* transmission of infectious agents in these settings prompted widespread patient notification and screening, with the subsequent discovery of numerous