Multisociety Guideline on Reprocessing Flexible GI Endoscopes: 2011

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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 reprocessing before being used on subsequent patients. The most commonly used methods for reprocessing endoscopes result in high-level disinfection. To date, all published occurrences of pathogen transmission related to GI endoscopy have been associated with failure to follow established cleaning and disinfection/sterilization guidelines or use of defective equipment. Despite the strong published data regarding the safety of endoscope reprocessing, concern over the potential for pathogen transmission during endoscopy has raised questions about the best methods for disinfection or sterilization of these devices between patient uses.

To this end, 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 that time, high-level disinfectants, automated reprocessing machines, endoscopes, and endoscopic accessories have all evolved.[3-6] However, the efficacy of decontamination and high-level disinfection is unchanged, and the principles guiding both remain valid.[7]

Additional outbreaks of infection related to suboptimal infection prevention practices during endoscopy or lapses in endoscope reprocessing have been well publicized. A cluster of hepatitis C cases was attributed to grossly inappropriate intravenous medication and sedation practices.[8] In numerous other instances, risk of infection transmission has been linked to less willful, but incorrect, reprocessing as a result of unfamiliarity with endoscope channels, accessories, and the specific steps required for reprocessing of attachments.[9] Recent on-site ambulatory surgery center surveys confirm widespread gaps in infection prevention practices.[10] Given the ongoing occurrences of endoscopy-associated infections attributed to lapses in infection prevention, an update of the multisociety guideline is warranted.

This document provides an update of the previous guideline, with additional discussion of new or evolving reprocessing issues and updated literature citations, where appropriate. Specific additions or changes include review of expanded details related to critical reprocessing steps (including cleaning and drying), reprocessing issues for various endoscope attachments such as flushing catheters, discussion of risks related to selected periprocedural practices including medication administration, and mention of newly recognized issues for which there are incomplete data with which to guide practice. They include endoscope shelf life or "hang time" (the interval of storage after which endoscopes should be reprocessed before use), the role of microbiological surveillance testing of endoscopes after reprocessing, and questions regarding endoscope durability and longevity from the standpoint of infection prevention.

SPAULDING CLASSIFICATION OF 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.[11] 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 of endo-scopic instruments that require sterilization are biopsy forceps and sphincterotomes.

- Semicritical: A device that comes in contact with intact mucous membranes and does not ordinarily penetrate sterile tissue. These devices (eg, endoscopes) should receive at least high-level disinfection, defined as the destruction of all vegetative microorganisms, mycobacteria, small or non-lipid 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.[12] Patient outcomes are not routinely tracked; however, reports of pathogen transmission resulting from these procedures are rare. In the largest review to date, comprising 265 scientific articles published between 1966 and 1992, 281 instances of pathogen transmission were attributed to GI endoscopy.[13,14] 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. When the ASGE Technology Assessment Committee reviewed the 28 cases in that series that had occurred since the adoption of specific guidelines for cleaning and disinfection between 1988 and 1992, it concluded that the incidence of pathogen transmission was approximately 1 in 1.8 million procedures.[15]

Since 1993, there have been very few additional reported occurrences of pathogen transmission during GI endoscopy, and essentially all have been associated with clear lapses in either infection prevention practices or reprocessing of the endoscope and accessories. Hence, transmission can be categorized as 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 accessories.

Nonendoscopic Transmission of Infection

The importance of good general infection prevention practices is highlighted by several outbreaks of hepatitis C virus including one at a New York endoscopy center related to improper handling of intravenous sedation tubing, multidose vials, and/or reuse of needles.[16] A similar, more recent cluster of 6 cases of hepatitis C occurred among patients at a Las Vegas endoscopy center.[8] These cases were caused by 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 more than 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

One instance of *Trichosporon* esophagitis was caused by failure to sterilize biopsy forceps among patients.[17] A Taiwanese case of *Acinetobacter* prosthetic valve endocarditis after polymicrobial bacteremia was, in the absence of other apparent sources, attributed to upper endoscopy performed 11 days earlier for esophagitis with associated esophageal ulceration.[18] The authors presumed that transmission occurred by hands of staff contaminated after direct contact with the hospital environment. Several occurrences of hepatitis C virus transmission have been associated with breaches in accepted endoscope reprocessing protocols.[19-21] Most recently, lapses in the 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, including several Veterans Administration hospitals.[9] The risk of *potential* transmission of infectious agents in these settings prompted widespread patient notification and screening, with the subsequent discovery of numerous cases of previously unknown hepatitis and HIV. Whether the identified cases were related to previous endoscopy remains undetermined.[9,22] To date, there is no epidemiologic or microbiological evidence linking the potential endoscopic exposure to the identified illnesses. Nevertheless, this demonstrates that multiple endoscopic devices and accessories, in addition to the endoscope, may be subject to lapses in reprocessing and subsequently put patients at risk of exposure and possibly infection.

When the U.S. Centers for Disease Control and Prevention (CDC) Division of Healthcare Quality Promotion (formerly the Hospital Infection Program) reviewed its log of investigations between 1980 and 2002, no outbreaks of infection associated with GI endoscopy were found.[1,2] Since 1990, health care facilities and manufacturers have been required to report to the FDA's MAUDE (Manufacturer and User-Facility Device Experience) database any information that reasonably suggests that a device (such as an endoscope, accessory, and automated endoscope washer–disinfector) has caused or contributed to a death, injury, or serious illness of a patient. Review of this open-access, non–peer-reviewed database from 1990 to 2002 revealed 7 possible occurrences of pathogen transmission during GI endoscopy. Since 2002, the MAUDE database contains reference to infections suspected to have occurred after lapses in reprocessing, particularly those related to failure to use appropriate attachments to specialty channels or failure to clean all channels during reprocessing.[23] Although there are no well-designed prospective studies on the incidence of pathogen transmission during GI endoscopy and estimates of pathogen transmission based on case reports may underestimate the true incidence of infec-

tion, available evidence suggests that this is an extremely rare event.

GI ENDOSCOPE REPROCESSING

Flexible GI endoscopes should first be completely cleaned and then subjected to at least high-level disinfection. This standard has been recommended by federal agencies such as the FDA[24] and CDC;[25] professional organizations such as ASGE, the American College of Gastroenterology, the American Gastroenterology Association, the Society of Gastroenterology Nurses and Associates (SGNA), the Association of periOperative Registered Nurses (AORN), and the Association for Professionals in Infection Control and Epidemiology.[26-31] These organizations have developed guidance documents that detail the sequence and specifics of each element of appropriate endoscope reprocessing.[25-31] There are no published studies of confirmed transmission of infection when these guidelines have been followed. However, compliance with reprocessing guidelines can be improved. In 1991, Gorse and Messner[32] surveyed 2030 members of SGNA and found that compliance with various aspects of existing guidelines ranged from 67% to 93%. That same year, a collaborative study by the FDA and 3 state health departments investigating endoscope reprocessing at 26 health care facilities reported that 24% of patient-ready endoscopes (GI endoscopes and bronchoscopes) were culture positive, and these were associated with "a number of fundamental errors in the disinfection process."[33,34] More concerning, in 1997, Jackson and Ball[35] surveyed 19 family practice and internal medicine offices performing flexible sigmoidoscopy and found that all were deficient in following reprocessing guidelines in at least one area. Although 2 subsequent studies suggested that compliance with reprocessing guidelines had improved,[36,37] a minority of endoscopy centers still did not conform completely to accepted guidelines. In a 2004 survey of SGNA members at centers in the Mid-Atlantic states, compliance with published standards was, again, inconsistent, and there was wide variation in adherence to both global principles and specific steps of manual cleaning, high-level disinfection, drying, and quality monitoring.[38] Most recently, in 2009, the CDC piloted an infection control audit tool during inspection of 68 ambulatory surgical centers in 4 states to assess adherence to recommended practices.[10] Adherence to recommendations for reprocessing of endoscopic equipment was not uniform in 28.4% of 67 ambulatory surgery centers. Future efforts should be aimed at improving compliance with accepted guidelines in all centers where endoscopy is performed.

UNRESOLVED ISSUES REQUIRING FURTHER STUDY

A variety of issues pertinent to reprocessing of flexible endoscopes remain unresolved based on currently available data. Some have received little comment in the existing literature and standards, whereas others have generated considerable discussion or even formal position statements. All warrant further study to clarify optimal practices.

The interval of storage after which endoscopes should be reprocessed before use, sometimes termed hang time or shelf life, has been the subject of limited investigations.[39-41] The available data suggest that contamination during appropriate storage for intervals of 7 to 14 days is negligible, is not associated with duration, occurs only on the exterior of instruments, and involves only common skin organisms rather than significant pathogens. One study demonstrated limited contamination, predominantly by environmental nonpathogenic organisms, within 24 hours of reprocessing.[39] In a similar study, limited contamination by nonpathogenic organisms was noted on exterior surfaces and valve ports of endoscopes, but none from fluid flushed through the biopsy channels after 5 days of storage.[40] A subsequent study sampled endoscopes serially during clean storage for 14 days. Positive cultures were identified during the first 5 days of sampling, but not thereafter. In a duplicate second phase, no surveillance cultures were positive, and in a third phase of testing after 7 days of storage, only a single culture was positive for *Staphylococcus epidermidis*, a low virulence skin organism.[41] Hence, although reuse within 10 to 14 days appears to be safe, the data are insufficient to provide a maximal duration for use of appropriately cleaned, reprocessed, dried, and stored flexible endoscopes. In the absence of full data, however, reprocessing during this interval before use may be advisable, particularly for (a) instruments used infrequently because of low volumes or specialty applications, (b) instruments used in patients at high-risk of infection such as those whose immune systems are suppressed by medications or disease, and (c) instruments used in procedures with anticipated entry to otherwise sterile regions such as the biliary tree, pancreas, and peritoneal space. In the interest of utmost caution, AORN and the Association for Professionals in Infection Control and Epidemiology espouse maximal storage intervals without reprocessing of 5[30] and 7[31] days, respectively.

The optimal frequencies for replacement of (a) clean water bottles and tubing for insufflation of air and lens wash water and (b) waste vacuum canisters and suction tubing have not been determined. In one instance, concern relates to the potential for backflow from a soiled endoscope against the direction of forced fluid and air passage into the clean air/water source and, in the other, from contaminated tubing and collection chamber against a vacuum into clean instruments used for subsequent patients. No data exist pertaining to the safety or potential risk of per-procedure versus per-day exchange of these attachments, and most guidelines do not address these 2 issues. In the interest of utmost caution, AORN espouses changing the clean air/water bottle and tubing for each patient,[30] and some accreditation organizations survey for exchange of waste vacuum canisters and tubing for each procedure. Both issues warrant study.

Microbiological surveillance testing of endoscopes after reprocessing, during storage, or before use has not been advised in current American standards. However, this quality assurance measure is advised in reprocessing guidelines of several international organizations, including the Gastroenterological Society of Australia and the guideline of the combined European Society of Gastrointestinal Endoscopy and the European Society of Gastroenterology and Endoscopy Nurses and Associates committee.[42-44] Available data suggest that detection of nonenvironmental pathogens common to the GI tract in reprocessed instruments should serve as an indicator of contaminated or faulty reprocessing equipment, inadequate solutions, or failed human processes.[45-47] The use of surveillance cultures is confounded by the delay in feedback when using standard microbiological culture techniques and the frequent isolation of nonpathogenic organisms caused by environmental contamination. Alternative indicators of adequate reprocessing have been proposed,[48] but they remain investigational and have not been widely applied in clinical practice. The Gastroenterological Society of Australia standards provide guidance for interpretation of varied culture results.[42] Nevertheless, uniform standards and guidance for sampling and culture technique or for use of alternate indicators of adequate cleaning[1,25] are lacking. Further research on the methodology and utility of surveillance cultures or sampling is encouraged.

Relatively new technologies for high-level disinfection are now available, including one cleared by the FDA for *automated washing* without brushing before high-level disinfection (EvoTech; Advanced Sterilization Products, Irvine, Calif).[3] The demonstration of efficacy and FDA clearance was based on laboratory testing and limited clinical use supported by sophisticated research techniques. Recent independent company–sponsored studies also demonstrate significant clearance of protein and other bioburden.[49] Another reprocessor and disinfectant combination was recently cleared with labeling for high-level disinfection after attenuated washing and brushing (OER-Pro; Olympus America, Center Valley, Pa). These technologies and those still to come warrant further well-designed, peer-reviewed studies by using commercially available machines in clinical settings.

Endoscope durability and longevity are incompletely understood. Data from high-volume units suggest common intervals between major and minor repairs, but there are no published data regarding material durability and the potential for reduced function or reduced ability to attain high-level disinfection after a certain number of years or procedures. Because instruments from low-volume endoscopy units may be retained for many years and those from busy departments are often sold on secondary markets, where they remain in use both in the United States and in other regions of the world, the manufacturers and resellers are encouraged to study and communicate data on these issues to guide the health care industry.

RECOMMENDATIONS

Professional organizations vary in recommended practices. This document is not intended to replace independent guidelines nor to confuse users of such guidelines, but to complement them by emphasizing those areas in which a broad range of professionals have reached consensus based on the available evidence. When evidence is lacking, expert opinion, independent guidelines, or standards for accreditation may differ, as cited in the previous discussion and in some of the specific recommendations. The Appendix presents description of categories of the strength of the recommendations provided here and the evidence supporting the recommendations.

Users should always refer to FDA labeling and manufacturers' instructions for device-specific reprocessing guidance. Accrediting bodies will typically survey for performance in accord with this guidance. In rare cases, FDA labeling claims and/or manufacturers' guidance may lag behind evolving data or rely on extreme assumptions or thresholds of safety that are not pertinent to safe, yet efficient, health care. If alternative practices are demonstrated to be optimal by several well-designed scientific studies and are endorsed by multiple professional societies, they can be considered for use by an organization.[25]

Note that this guideline focuses on high-level disinfection of flexible GI endoscopes, but does not attempt to thoroughly address sterilization of these instruments for extraluminal applications such as Natural Orifice Transluminal Endoscopic Surgery® or intraoperative endoscopy through open or laparoscopic access. It also does not address reprocessing of flexible, rigid, or semirigid endoscopes used in other procedures, such as cystoscopy and bronchoscopy. Neither high-level disinfection nor extreme application of high-level disinfection processes can achieve the needs of sterile environments, eg, terminal sterilization of a wrapped instrument.[3] The terminology of high-level disinfection and the available agents for reprocessing have evolved since the first publication of this guideline. The FDA has acknowledged that flexible endoscopes cannot be sterilized with the available high-level disinfectants,[50] hence, the long-standing FDA term high-level disinfectant/sterilant should no longer imply the ability to sterilize endoscopes with similar techniques. Here we use the term high-level disinfectant, which should not be confused with lesser disinfectants used for environmental cleaning.

1. All health care personnel in the endoscopy suite should be trained in and adhere to standard infection prevention and control recommendations (eg, standard precautions), including those to protect both patients and health care workers. **Category IA**[25]

2. Precleaning should be performed at the point of use, before bioburden has an opportunity to dry and before complete decontamination. Point-of-use precleaning

should remove visible debris by wiping the exterior of the endoscope with appropriate detergent solution and aspiration of a large volume of detergent solution through the air/water and biopsy channels. **Category IB**[25-27,29,30]

3. After point-of-use precleaning, transport the soiled endoscope to the reprocessing area for subsequent steps in high-level decontamination before remaining soil dries. During transportation, soiled endoscopes should be contained in a manner that prevents exposure of staff, patients, or the environment to the potentially infectious organisms. An open container can suffice for transport to immediately adjacent reprocessing rooms, but fully enclosed and labeled containers or bags should be used for transportation to distant reprocessing areas. **Category II**[30]

4. Perform pressure/leak testing after each use and before formal reprocessing, according to manufacturer guidelines. **Category IB**[25-27,30]

5. Before manual or automated high-level disinfection, meticulously clean the entire endoscope, including valves, channels, connectors, and all detachable parts. Disconnect and disassemble endoscope components (eg, air/water and suction valves) as far as possible and completely immerse the endoscope and components in an appropriate detergent that is compatible with the endoscope, according to the manufacturer's instructions. Flush and brush all accessible channels to remove all organic (eg, blood, tissue) and other residues. Repeatedly actuate the valves during cleaning to facilitate access to all surfaces. Clean the external surfaces and components of the endoscope by using a soft cloth, sponge, or brushes. **Category IB**[13,24-27,30,51,52]

6. Use brushes appropriate for the size of the endoscope channel, parts, connectors, and orifices (eg, bristles should contact all surfaces) for cleaning. Cleaning items should be disposable or thoroughly cleaned and disinfected/sterilized between uses. **Category II**[25,27,43,53]

7. Discard enzymatic detergents after each use because these products are not microbicidal and will not retard microbial growth. **Category IB**[25,27,54]

8. Reusable endoscopic accessories (eg, biopsy forceps, other cutting instruments) that break the mucosal barrier should be mechanically cleaned as described previously and then sterilized between each patient use (high-level disinfection is not appropriate). **Category IA**[13,19,25,26,30,31,43,53,55-57]

9. Ultrasonic cleaning of reusable endoscopic accessories and endoscope components may be used to remove soil and organic material from hard-to-clean areas. **Category II**[25,43]

10. Endoscopes (and accessories) that come in contact with mucous membranes are classified as semicritical items and should receive at least high-level disinfection after each patient use. **Category IA**[13,26,27,30,31,43,51,53]

11. There are new high-level disinfectants and agent-specific machines on the market. Information regarding these technologies should be obtained from the FDA Web site and independent peer-reviewed publications. Use a high-level disinfectant cleared by the FDA for high-level disinfection (www.fda.gov/cdrh/ode/germlab.html). **Category IA**[13,25-28,31,53,55,58]

12. The exposure time and temperature for disinfecting semicritical patient care equipment vary among the FDA-cleared high-level disinfectants. Follow the FDA-cleared label claim for high-level disinfection unless several well-designed experimental scientific studies, endorsed by professional societies, demonstrate that an alternative exposure time is effective for disinfecting semicritical items. The FDA label claim for high-level disinfection with greater than 2% glutaraldehyde at 25°C ranges from 20 to 90 minutes depending on the product. Multiple scientific studies and professional organizations support the efficacy of greater than 2% glutaraldehyde for 20 minutes at 20°C. **Category IA**[11,25,26,55,58-73]

13. Select a liquid disinfectant or sterilization technology that is compatible with the endoscope. The use of specific high-level disinfectants or sterilization technologies on an endoscope should be avoided if the endoscope manufacturer warns against their use because of functional damage (with or without cosmetic damage). **Category IB**[25,74,75]

14. The selection and use of disinfectants in the health care field is dynamic, and products may become available that were not in existence when this guideline was written. As newer disinfectants become available, persons or committees responsible for selecting disinfectants for GI endoscope reprocessing should be guided by FDA clearance of these products and by information in the scientific literature. **Category II**[25,55,58]

15. Completely immerse the endoscope and its components in the high-level disinfectant solution and ensure that all channels are perfused. Nonimmersible GI endoscopes should not be used. **Category IB**[25-27,30,31,53,55,76-78]

16. If an automated endoscope reprocessor (AER) is used, ensure that the endoscope and endoscope components can be effectively reprocessed with the AER (eg, the elevator wire channel of duodenoscopes is not effectively disinfected by most AERs and this step should be performed manually). Users should obtain and review model-specific reprocessing protocols from both the endoscope and the AER manufacturers and check for compatibility. **Category IB**[25-27,53,76-80]

17. If an AER is used, place the endoscope and endoscope components in the reprocessor and attach all channel connectors according to the AER and endoscope manufacturers' instructions to ensure exposure of all internal surfaces with the high-level disinfectant solution. **Category IB**[25,27,76-78]

18. If an AER cycle is interrupted, high-level disinfection or sterilization cannot be ensured; therefore, the cycle should be repeated. **Category II**[27]

19. Because design flaws have compromised the effectiveness of AERs and can also involve endoscopes, the in-

fection prevention staff should routinely review FDA advisories, manufacturer alerts, and the scientific literature for reports of endoscope and AER deficiencies that may lead to infection. **Category II**[77,81-84]

20. After high-level disinfection, rinse the endoscope and flush the channels with sterile, filtered, or tap water to remove the disinfectant solution. Discard the rinse water after each use/cycle. Flush the channels with 70% to 90% ethyl or isopropyl alcohol and dry by using forced air. The final drying steps greatly reduce the risk of remaining pathogens, as well as the possibility of recontamination of the endoscope by waterborne microorganisms. **Category IA**[25-27,31,55,82,85-89]

21. Visually inspect both endoscopes and reusable accessories frequently in the course of their use and reprocessing, including before, during, and after use, as well after cleaning and before high-level disinfection. Damaged endoscopes and accessories should be removed from use for repair or disposal. **Category II**[30]

22. When storing the endoscope, hang it in a vertical position to facilitate drying (with caps, valves, and other detachable components removed, per manufacturer's instructions). **Category II**[25,27,31,53,55,90]

23. Endoscopes should be stored in a manner that will protect them from contamination. **Category II**[25,27,31,53,55]

24. Although reuse of endoscopes within 10 to 14 days of high-level disinfection appears to be safe, the data are insufficient to provide a maximal duration for use of appropriately cleaned, reprocessed, dried, and stored flexible endoscopes. This interval remains poorly defined and warrants further study. As noted in the previous discussion, several organizations advise shorter intervals. **No recommendation**[30,31,39-41]

25. High-level disinfect or sterilize the water bottle (used for cleaning the lens and irrigation during the procedure) and its connecting tube at least daily. As noted in the previous discussion, some organizations espouse more frequent exchange of water bottles and tubing. Sterile water should be used to fill the water bottle. **Category IB**[25,30,31,91-95]

26. Maintain a log for each procedure indicating the patient's name and medical record number (if available), the procedure, and the serial number or other identifier of the endoscope (and AER, if used) to assist in an outbreak investigation. **Category II**[25,27,31]

27. Perform routine testing of the liquid high-level disinfectant to ensure at least the minimum effective concentration of the active ingredient. Check the solution at the beginning of each day of use (or more frequently) and document the results. If the chemical indicator shows that the concentration is less than the minimal effective concentration, the solution should be discarded. **Category IA**[25-27,29,31,55,66,96,97]

28. Discard the liquid high-level disinfectant at the end of its reuse life (which may be a single use), regardless of the minimal effective concentration. If additional liquid high-level disinfectant is added to an AER (or basin, if manually disinfected), the reuse life should be determined by the first use/activation of the original solution (ie, the practice of "topping off" of a liquid high-level disinfectant pool does not extend its reuse life). **Category IB**[27,55,98]

29. Facilities where endoscopes are used and disinfected should be designed to provide a safe environment for health care workers and patients. Air exchange equipment (eg, ventilation system and exhaust hoods) should be used to minimize the exposure of all persons to potentially toxic vapors (eg, glutaraldehyde). The vapor concentration of the chemical disinfectant used should not exceed allowable limits (eg, those of the American Conference of Governmental Industrial Hygienists and the Occupational Safety and Health Administration). Although organic vapor respirators appropriate for chemical exposures can provide respiratory protection (eg, in the event of spills), they are not intended for routine use and are not a substitute for adequate ventilation, vapor recovery systems, and work practice controls. **Categories IB and IC**[25-27,31,99-102]

30. Personnel assigned to reprocess endoscopes should receive device-specific reprocessing instructions (ie, endoscope and/or AER manufacturer, as needed) to ensure proper cleaning and high-level disinfection or sterilization. Competency testing of personnel that reprocess endoscopes should be performed and documented on a regular basis (eg, at the start of use, annually). Temporary personnel should not be allowed to reprocess endoscopes until competency has been established. **Category IA**[25-27,31]

31. All personnel using chemicals should be educated about the biological and chemical hazards present while performing procedures that use disinfectants. **Category IC**

32. Personal protective equipment (eg, gloves, gowns, eyewear, respiratory protection devices) should be readily available and should be used, as appropriate, to protect workers from exposure to chemicals, blood, or other potentially infectious material. **Category IC**[25,103-106]

33. Health care facilities should ensure that users can readily identify whether and when an endoscope has been reprocessed. **Category II**

34. The use of routine environmental microbiological testing of endoscopes for quality assurance has not been established but warrants further study. **No recommendation**[25]

35. If environmental microbiological testing is performed, standard microbiological techniques should be used. **Category II**[25,107]

36. Reprocessing of nonendoscopic devices, accessories, and attachments should adhere to manufacturers' recommendations. **Categories IC and II**

37. Standard infection prevention practices for aseptic administration of medications, including injectable agents and sedation and analgesia, should be used. **Category IC**[108]

38. In the event of an outbreak caused by a suspected infectious or chemical etiology, the environmental sam-

pling should be performed according to standard outbreak investigation. **Category IA**[25,31,109-111]

39. Endoscopy-related infections should be reported to all of the following: (a) persons responsible for infection control at the institution; (b) the appropriate public health agency (state or local health department as required by state law or regulation); (c) the FDA (www.fda.gov/medwatch); (d) the manufacturer(s) of the endoscope, disinfectant/sterilant, and AER (if used). **Categories IB and IC**[25,26,31,112]

SUMMARY AND ENDORSING ORGANIZATIONS

Flexible GI endoscopy is a valuable diagnostic and therapeutic tool for the care of patients with GI and pancreaticobiliary disorders. Compliance with accepted guidelines for the reprocessing of GI endoscopes between patients is critical to the safety and success of their use. When these guidelines are followed, pathogen transmission can be effectively prevented. Increased efforts and resources should be directed to improve compliance with these guidelines. Further research in the area of GI endoscope reprocessing should be encouraged.

The original 2003 position statement was endorsed by the collaborating organizations listed in the following. This 2011 update was initially drafted by the Quality Assurance in Endoscopy Committee of ASGE and the Guideline Committee of the Society for Healthcare Epidemiology of America. Thereafter, significant input from the endorsing organizations was incorporated and redistributed for consensus. It has received the endorsement of the following organizations, which are committed to assisting the FDA, equivalent international agencies, and manufacturers in addressing critical infection control issues in GI device reprocessing:

- American Society for Gastrointestinal Endoscopy
- Society for Healthcare Epidemiology
- American College of Gastroenterology
- American Gastroenterological Association
- American Society of Colon and Rectal Surgeons
- Accreditation Association for Ambulatory Health Care
- Association of periOperative Registered Nurses
- Association of Professionals in Infection Control and Epidemiology
- The Joint Commission
- Society of American Gastrointestinal and Endoscopic Surgeons
- Society of Gastroenterology Nurses and Associates

2003 ENDORSING ORGANIZATIONS

- American Society for Gastrointestinal Endoscopy
- Society for Healthcare Epidemiology of America
- The Joint Commission on Accreditation of Healthcare Organizations

- American College of Gastroenterology
- American Gastroenterological Association
- American Society of Colon and Rectal Surgeons
- Society of American Gastrointestinal Endoscopic Surgeons
- Society of Gastroenterology Nurses and Associates
- Association of Perioperative Registered Nurses
- Association for Professionals in Infection Control and Epidemiology
- Federated Ambulatory Surgery Association

APPENDIX

The CDC system for categorizing recommendations is as follows:

- **Category IA**: Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.
- **Category IB**: Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale.
- **Category IC**: Required by state or federal regulations. Because of state differences, readers should not assume that the absence of an IC recommendation implies the absence of state regulations.
- **Category II**: Recommended for implementation and supported by suggestive clinical or epidemiologic studies or theoretical rationale.
- **No recommendation**: Unresolved issue. Practices for which insufficient evidence or no consensus regarding efficacy exists.

Abbreviations: AER, automated endoscope reprocessor; ARON, Association of periOperative Registered Nurses; CDC,

Centers for Disease Control and Prevention; FDA, U.S. Food and Drug Administration; SGNA, Society of Gastroenterology Nurses and Associates.

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