SHEA Position Paper

Multi-society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes

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The beneficial role of gastrointestinal 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 episodes of pathogen transmission related to gastrointestinal 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, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Healthcare Epidemiology of America (SHEA) convened a conference at which representatives from physician and nursing organizations, infection control organizations, federal and state agencies, and industry leaders presented and discussed the latest information on this subject. A consensus panel on the second day reviewed the data presented at the conference to recommend evidence-based guidelines for reprocessing gastrointestinal endoscopes.

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.[1] This classification system is widely accepted and is used by the 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

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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 endoscopic instruments that require sterilization are biopsy forceps and papillotomes.
- Semicritical: A device that comes into 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 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 10 million gastrointestinal endoscopic procedures are performed annually in the United States. 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 episodes of pathogen transmission were attributed to gastrointestinal endoscopy.[2] 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, they concluded that the incidence of pathogen transmission was approximately 1 in 1.8 million procedures.[3]

Since 1993, there have been only five additional reported cases of pathogen transmission during gastrointestinal endoscopy, all occurring outside the United States. One instance of *Trichosporon* esophagitis was caused by failure to sterilize biopsy forceps between patients.[4] There have been four episodes of transmission of hepatitis C virus (HCV), and each has been associated with a breach in accepted endoscope reprocessing protocols or a lapse in general infection control practices (inappropriate use of multi-dose vials/bottles and/or reuse of syringes).[5-7] The importance of good general infection control practices is highlighted by a recent outbreak of HCV at a New York endoscopy center. Although it was initially attributed to endoscopic transmission in the lay press, investigation by the New York City Department of Health revealed the cause was not the endoscopy itself, but related to improper handling of intravenous sedation tubing or multidose vials and/or reuse of needles (letter on file, New York City Department of Health; unpublished data presented at conference). This aspect of standard infection control practice must also be addressed when future reports of pathogen transmission are published. When the 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 gastrointestinal endoscopy were found. Since 1990, healthcare facilities and manufacturers have been required to report to the FDA any information that reasonably suggests that a device (such as an endoscope, accessory, or automated endoscope washer–disinfector) has caused or contributed to a death, injury, or serious illness of a patient. Review of the FDA Manufacturer And User-Facility Device Experience (MAUDE) database from 1990 to 2002 revealed seven possible episodes of pathogen transmission during gastrointestinal endoscopy. Although there are no well-designed prospective studies on the incidence of pathogen transmission during gastrointestinal endoscopy, and estimates of pathogen transmission based on case reports may underestimate the true incidence of infection, available evidence suggests that this is an extremely rare event.

GASTROINTESTINAL ENDOSCOPE REPROCESSING

Flexible gastrointestinal endoscopes should first be cleaned and subjected to at least high-level disinfection. This standard has been recommended by federal agencies such as the FDA[8] and CDC[9]; professional organizations such as the ASGE, the American College of Gastroenterology, the American Gastroenterology Association, the Society of Gastroenterology Nurses and Associates, the Association of Perioperative Registered Nurses, and the Association for Professionals in Infection Control and Epidemiology; and the American Society for Testing and Materials.[10-13] Guidelines are available from these organizations that discuss, in a step-by-step fashion, the elements of appropriate endoscope reprocessing.[10-14] There are no published studies of transmission of infection when these guidelines have been followed.

However, compliance with reprocessing guidelines can be improved. In 1991, Gorse and Messner surveyed 2,030 members of the Society of Gastroenterology Nurses and Associates and found that compliance with various aspects of existing guidelines ranged from 67% to 93%.[15] That same year, a collaborative study by the FDA and three state health departments investigating endoscope reprocessing at 26 healthcare facilities reported that 24% of patient-ready endoscopes (gastrointestinal endoscopes and bronchoscopes) were culture positive, and these were associated with "a number of fundamental errors in the disinfection process."[16,17] More concerning, Jackson and Ball 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.[18] Although two more recent studies suggest that compliance with reprocessing guidelines has improved,[19,20] a minority of endoscopy centers still did not conform completely to accepted guidelines. Future efforts should be aimed at improving compliance with accepted guidelines in all venues where endoscopy is performed.

RECOMMENDATIONS (SEE THE APPENDIX FOR A DESCRIPTION OF CATEGORIES)

Professional organizations vary in recommended practices. The current document is not intended to replace these guidelines, but to complement them, emphasizing those areas in which a broad range of professionals have reached consensus based on the available evidence. Endoscopes employing disposable components (eg, protective barrier devices, sheaths, or valves) can provide an alternative to conventional liquid chemical disinfection. Users should refer to manufacturers' instructions for appropriate reprocessing.

1. All healthcare personnel in the endoscopy suite should be trained in and adhere to standard infection control recommendations (eg, standard precautions), including those to protect both patients and healthcare workers. *Category IA*[9]

2. Perform pressure/leak testing after each use according to manufacturer guidelines. *Category IB*[11-14,21]

3. Disconnect and disassemble endoscope components (eg, air/water and suction valves) as far as possible and completely immerse the endoscope and components in the enzymatic detergent. *Category 1B*[21-23]

4. Cleaning is essential prior to manual or automated disinfection. Meticulously clean the entire endoscope, including valves, channels, connectors, and all detachable parts with an enzymatic detergent compatible with the endoscope immediately after use, according to the manufacturer's instructions. Flush and brush all accessible channels to remove all organic (eg, blood or 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 using a soft cloth, a sponge, or brushes. *Category IA*[2,10-14,21,24-33]

5. 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*[14,21,28,33]

6. Discard enzymatic detergents after each use, as these products are not microbicidal and will not retard microbial growth. *Category IB*[12,14,21,23]

7. Reusable endoscopic accessories (eg, biopsy forceps or other cutting instruments) that break the mucosal barrier should be mechanically cleaned as described above and then sterilized between each patient use (high-level disinfection is not appropriate). *Category IA*[2,5,9-14,21,26,28,33,34]

8. 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*[21,33]

9. 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*[2,9-12,14,21,26,28,33,35]

10. Use a high-level disinfectant/sterilant cleared by the FDA for high-level disinfection/sterilization (www.fda.gov/cdrh/ode/germlab.html). *Category IA*[2,9,10-12,14,21,26,28,35,36]

11. The exposure time and temperature for disinfecting semicritical patient care equipment varies 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 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. However, multiple scientific studies and professional organizations support the efficacy of greater than 2% glutaraldehyde at 20 minutes at 20°C. *Category IA*[1,10,21,26,27,32,37-49]

12. Select a disinfectant/sterilant that is compatible with the endoscope. The use of specific high-level disinfectants/sterilants on an endoscope should be avoided if the endoscope manufacturer warns against use because of functional damage (with or without cosmetic damage). *Category IB*[21,50,51]

13. The selection and use of disinfectants in the healthcare 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 gastrointestinal endoscope reprocessing should be guided by products cleared by the FDA and information in the scientific literature. *Category II*[21,26,36]

14. Completely immerse the endoscope and its components in the high-level disinfectant/sterilant and ensure that all channels are perfused. Nonimmersible gastrointestinal endoscopes should be phased out immediately. *Category IB*[10,11,13,14,21,26,28,52-54]

15. If an automated endoscope washer–disinfector (AEWD) is used, ensure that the endoscope and endoscope components can be effectively reprocessed in the AEWD (eg, the elevator wire channel of duodenoscopes is not effectively disinfected by most AEWDs and this step must be performed manually). Users should obtain and review model-specific reprocessing protocols from both the endoscope and the AEWD manufacturers and check for compatibility. *Category IB*[10,12,14,21,28,52-56]

16. If an AEWD is used, place the endoscope and endoscope components in the reprocessor and attach all channel connectors according to the AEWD and endoscope manufacturers' instructions to ensure exposure of all internal surfaces with the high-level disinfectant/chemical sterilant. *Category IB*[14,21,52-54]

17. If an AEWD cycle is interrupted, high-level disinfection or sterilization cannot be ensured. *Category II*[14]

18. Because design flaws have compromised the effectiveness of AEWDs, the infection control staff should routinely review FDA advisories, manufacturer alerts, and the scientific literature for reports of AEWD deficiencies that may lead to infection. *Category II*[53,57-60]

19. After high-level disinfection, rinse the endoscope and flush the channels with sterile, filtered, or tap water to remove the disinfectant/sterilant. Discard the rinse water after each use/cycle. Flush the channels with 70% to 90%

ethyl or isopropyl alcohol and dry using forced air. The final drying steps greatly reduce the possibility of recontamination of the endoscope by waterborne microorganisms. *Category IA*[10-13,21,26,30,58,61-63]

20. When storing the endoscope, hang it in a vertical position to facilitate drying (with caps, valves, and other detachable components removed as per manufacturer instructions). *Category II*[11,12,14,21,26,28,64]

21. Endoscopes should be stored in a manner that will protect them from contamination. *Category II*[11,14,21,26,28]

22. 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. Sterile water should be used to fill the water bottle. *Category IB*[11,21,65-68]

23. Maintain a log indicating for each procedure the patient's name and medical record number (if available), the procedure, the endoscopist, and the serial number or other identifier of the endoscope (and AEWD, if used) to assist in an outbreak investigation. *Category II*[11,14,21]

24. Perform routine testing of the liquid sterilant/high-level disinfectant to ensure minimal 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*[10-12,14,21,26,35,42]

25. Discard the liquid sterilant/high-level disinfectant at the end of its reuse life (which may be single-use), regardless of the minimal effective concentration. If additional liquid sterilant/high-level disinfectant is added to an AEWD (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 sterilant/high-level disinfectant pool does not extend its reuse life). *Category IB*[14,26,69]

26. Facilities where endoscopes are used and disinfected should be designed to provide a safe environment for healthcare 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 sterilant 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. *Category IB and IC*[10,11,14,21,70-73]

27. Personnel assigned to reprocess endoscopes should receive device-specific reprocessing instructions (ie, endoscope and/or AEWD manufacturer, as needed) to ensure proper cleaning and high-level disinfection or sterilization. Competency testing of personnel reprocessing endoscopes should be done on a regular basis (eg, commencement of employment, annually). Temporary personnel should not be allowed to reprocess endoscopes until competency has been established. *Category IA*[10-12,14,21]

28. All personnel using chemicals should be educated about the biological and chemical hazards present while performing procedures that use disinfectants. *Category IC*[21,74]

29. Personal protective equipment (eg, gloves, gowns, eyewear, and 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*[21,74-76]

30. Healthcare facilities should develop protocols to ensure that users can readily identify whether an endoscope is contaminated or is ready for patient use. *Category II*

31. The use of routine environmental microbiologic testing of endoscopes for quality assurance has not been established. *No recommendation*.[21]

32. If environmental microbiologic testing is performed, standard microbiologic techniques should be used. *Category II*[21,77]

33. In the setting of an outbreak caused by a suspected infectious or chemical etiology, the environmental sampling should be performed according to standard outbreak investigation. *Category 1A*[11,21,78]

34. Endoscopy-related infections should be reported to:

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 CDC.

e) The manufacturer(s) of the endoscope, disinfectant/sterilant, and AEWD (if used) *Category IB and IC*[10,11,21,79]

SUMMARY

Flexible gastrointestinal endoscopy is a valuable diagnostic and therapeutic tool for the care of patients with gastrointestinal and pancreaticobiliary disorders. Compliance with accepted guidelines for the reprocessing of gastrointestinal 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 gastrointestinal endoscope reprocessing should be encouraged. The organizations that endorsed this guideline are committed to assisting the FDA and manufacturers in addressing critical infection control issues in gastrointestinal device reprocessing.

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APPENDIX

The Centers for Disease Control and Prevention 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.