



Multisociety guideline on reprocessing flexible GI endoscopes and accessories

Lukejohn W. Day, MD,¹ V. Raman Muthusamy, MD, MAS,² James Collins, BS, RN, CNOR,³
Vladimir M. Kushnir, MD,⁴ Mandeep S. Sawhney, MD, MS,⁵ Nirav C. Thosani, MD,⁶ Sachin Wani, MD⁷

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Gastrointestinal (GI) endoscopy is highly effective for the prevention, diagnosis, and treatment of many digestive diseases.¹ Endoscopes used in endoscopy are complex, diverse, and essential devices that require meticulous cleaning and reprocessing in strict accordance with manufacturer guidelines before being reused on patients. Multiple risks are associated with endoscopic procedures; one such risk includes patients developing an exogenous infection (ie, pathogen introduced through a contaminated device).² Exogenous infections in endoscopy are attributed to a myriad of causes. In general, pathogen transmission related to standard end-viewing endoscopes are associated with a failure to follow established cleaning and disinfection/sterilization guidelines for endoscopes, accessories, or associated equipment or with the use of defective equipment.³⁻⁵ On the other hand, exogenous infections have occurred in patients undergoing specialized procedures using duodenoscopes, despite following established reprocessing protocols⁶⁻¹⁰; such observations and findings have raised questions about the optimal methods for the cleaning and disinfection of these unique devices. At the same time, in recent years, concerns have been raised that many of these infectious risks to patients may be underestimated as a result of

under-reporting or non-recognition. Consequently, this information highlights the need for clear, evidence-based reprocessing guidelines.

Gaps and variation in implementing infection prevention practices are common in endoscopy units across the United States,¹¹ and compliance with reprocessing guidelines is inconsistent. Such variation emphasizes the need for standards and updates to infection control guidelines as it relates to GI endoscopes. Several guidelines have covered the topics of safety in endoscopy units,¹² antibiotic prophylaxis before endoscopy,¹³ and standards for minimizing nonendoscopic infections and developing an infection control program in endoscopy units²; together, these guidelines aid in improving infection control practices within endoscopy units. Given the rising concerns of endoscope-related infections, it is imperative to evaluate the current literature and standards for endoscope reprocessing. This guideline contains expanded details related to the critical reprocessing steps of cleaning and drying and incorporates recent evidence as it pertains to improving the reprocessing of GI endoscopes.

SPAULDING CLASSIFICATION FOR MEDICAL DEVICES AND LEVEL OF DISINFECTION

The classification system first proposed by Dr E. H. Spaulding in 1957 divides medical devices into categories based on the risk of infection involved with their use.¹⁴

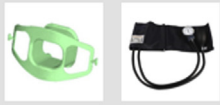
Patient Contact	Device Classification	Examples	Reprocessing
Intact skin	Non-critical		Low-level disinfection; Intermediate-level disinfection
Mucous membranes; Non-intact skin	Semi-critical		High-level disinfection
Sterile areas of the body; Vascular system	Critical		Sterilization

Figure 1. Spaulding classification system for medical devices.

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 medical devices. Three categories of medical devices and their associated level of disinfection are recognized (Fig. 1):

1. **Critical:** A device that enters the vascular system or sterile tissue. These devices should be sterilized, defined as the destruction of all microbial life. Examples of critical devices include endoscopes used in sterile settings such as laparoscopic endoscopy, endoscopic devices used for performing invasive procedures such as endoscopic retrograde cholangiopancreatography (ERCP) and interventional endoscopic ultrasound (EUS), and equipment used for obtaining biopsy specimens and performing polypectomies and sphincterotomies.
2. **Semi-critical:** A device that comes into contact with intact mucous membranes or nonintact skin and does not penetrate sterile tissue. These devices should be sterilized, but high-level disinfection (HLD) is acceptable if sterilization is not feasible.
3. **Non-critical:** Devices that do not ordinarily touch the patient or touch only intact skin. Devices such as stethoscopes, blood pressure cuffs, or mouth guards are classified as non-critical. These items may be subjected to low-level disinfection/manual cleaning.

A number of modalities are recommended to achieve each level of disinfection used in the Spaulding classification. These modalities include:

- **Sterilization:** Process by which all forms of viable organisms are eliminated or destroyed from a medical device.¹⁵

- **High-level disinfection:** Elimination of all vegetative microorganisms, mycobacteria, small or nonlipid viruses, medium or lipid viruses, fungal spores, and some, but not all, bacterial spores and prions may remain.¹⁵ In the Spaulding classification system, semi-critical items should be subject to HLD at a minimum.
- **Intermediate-level disinfection:** Eradicates vegetative microorganisms, including *Mycobacterium tuberculosis*, all fungi, and inactivates most viruses but does not kill bacterial spores. Some semi-critical and non-critical devices may undergo intermediate-level disinfection.
- **Low-level disinfection:** Eradicates some viruses, most vegetative bacteria, and some fungi; it may not remove resistant pathogens such as bacterial spores or tubercle bacilli.^{15,16}
- **Cleaning:** Process of eliminating residual organic material and bacterial burden on the interior and exterior of a medical device.¹⁶

There have been calls for revision of the Spaulding classification. At the time the Spaulding classification system was developed some pathogens had not been identified, whereas others have developed resistance to disinfection methods over time.¹⁷ Disinfection studies of specific pathogens, such as prions and some viruses and bacteria, have questioned the current definitions of high-, intermediate-, and low-level disinfection and, as a result, have raised concerns about the current Spaulding classification paradigm.¹⁷ Rather than abandoning the classification system, test methods should be used to confirm the various levels of disinfection needed to include newer or resistant pathogens. Several authors suggest that the Spaulding classification for critical devices should be expanded to include those devices that “directly or secondarily enter sterile tissue.”^{18,19} By this definition, some endoscopes (eg, duodenoscopes and echoendoscopes)

TABLE 1. Clinical questions addressed in the multisociety guideline on the reprocessing of flexible GI endoscopes and accessories using GRADE and non-GRADE methodologies

GRADE	Non-GRADE
1. Is there a benefit of repeat high-level disinfection (ie, 1 cycle of manual cleaning and 2 cycles of endoscope reprocessing using an automated endoscope reprocessor) compared with single high-level disinfection in the reprocessing of endoscopes? 2. Is there a benefit of ethylene oxide sterilization compared with single high-level disinfection in the reprocessing of GI endoscopes? 3. What is the maximum storage time for a GI endoscope during which it will remain clean and patient ready after it has undergone reprocessing? 4. What is the efficacy of microbiologic surveillance in detecting bacterial contamination in fully reprocessed endoscopes?	1. What training and competencies are required for staff to perform endoscope reprocessing? 2. What steps should be complied with in the precleaning/point of use treatment of endoscopes? 3. What is the optimal endoscopy unit layout and flow for the reprocessing of endoscopes? 4. What role does leak testing play in the reprocessing of endoscopes? 5. What key elements should be complied with during the manual cleaning phase of reprocessing? 6. What is the role of both exterior and interior inspection of endoscopes during the reprocessing process? 7. Are there optimal parameters for the drying of endoscopes? 8. Is there a benefit to using ethyl or isopropyl alcohol in the drying of endoscopes? 9. After the reprocessing of an endoscope, what is the best method for storing an endoscope when it is not in use? 10. What is the optimal way an endoscope should be positioned within a storage cabinet? 11. Do endoscope accessories need to be stored with an individual endoscope? 12. What is the frequency for replacing the tubing used for insufflation of air, irrigation water, suction tubing, and waste vacuum canisters? 13. Do water bottles used during endoscopy need to be filled with sterile water? 14. In patients undergoing endoscopy, does the use of simethicone (either in the water bottle or through the endoscope working channel) affect the reprocessing of endoscopes? 15. What factors should be considered in the reprocessing of endoscope accessories and devices? 16. What policies and procedures should endoscopy units follow in terms of endoscope maintenance? 17. What guidelines should endoscopy units follow when loaner endoscopes are used? 18. What are the essential elements of an endoscopy unit infection control leadership team?

GRADE, Grading of Recommendations Assessment, Development and Evaluation.

would be classified as critical devices and require sterilization. Given that the environment in which endoscopes are introduced and used is not sterile (and thus each time that the endoscope enters the digestive tract sterility is immediately broken), reclassification of endoscopes within Spaulding is not advocated.

AIMS AND OBJECTIVES

The objective of this guideline is to provide evidence-based recommendations for the reprocessing of flexible GI endoscopes based on rigorous review and synthesis of the contemporary literature, using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework. A full description of the methodology used to develop this guideline can be found in [Appendix 1](#) (available online at www.giejournal.org). The GRADE framework is a comprehensive and transparent system for rating the quality of evidence and strength of

recommendations. Four clinical questions were addressed using the GRADE methodology.* Eighteen additional reprocessing issues, which are not amenable to the GRADE methodology, were examined using a comprehensive literature review to provide an evidence-based guide examining the necessary elements in flexible endoscope reprocessing using HLD ([Table 1](#)). Details on the reprocessing of flexible GI endoscopes, training/competency of endoscopy unit reprocessing personnel, maintenance of endoscopes, and endoscopy unit leadership are included in this guideline, whereas other areas critical to reprocessing (ie, endoscopy unit layout and reprocessing of accessories) are outlined in [Appendix 2](#) (available online at www.giejournal.org). [Table 2](#) enumerates the entire multisociety guideline recommendations on the reprocessing of flexible GI endoscopes and accessories.

*an asterisk indicates those clinical questions that are addressed using GRADE methodology.

TABLE 2. Multisociety guideline recommendations on the reprocessing of flexible GI endoscopes and accessories

Staff training and competency of endoscope reprocessing skills
- Endoscopy unit has a written environmental disinfection and endoscope reprocessing policy and staff are oriented to it (Strong recommendation, Low quality of evidence). - All healthcare personnel in the endoscopy unit are trained in and comply with standard infection prevention and control recommendations (eg, universal precautions), including those to protect both patients and healthcare workers (Strong recommendation, Low quality of evidence). - Personnel assigned to reprocess endoscopes receive model-specific reprocessing instructions and training (ie, endoscope manufacturer, as needed) to promote proper cleaning and high-level disinfection (HLD)/sterilization and to maintain proper documentation of all reprocessing steps. Staff should receive these instructions, training, and have competency documented before being assigned to perform HLD or sterilization of those devices (Strong recommendation, Low quality of evidence). - Competency evaluation of personnel that reprocess endoscopes is performed and documented on a schedule defined by the organization (eg, commencement of employment, at least annually, anytime a breach is identified, when a major technique or new endoscope or reprocessing accessory is introduced, and in the context of local quality control efforts). Temporary personnel should not be allowed to reprocess endoscopes until competency has been established and verified (Strong recommendation, Moderate quality of evidence).
Endoscopy unit layout
- Reprocessing facilities are designed with attention to the optimal flow of personnel, endoscopes, and devices to avoid contamination between entering soiled instruments and reprocessed instruments (Strong recommendation, Low quality of evidence). - Reprocessing of endoscopes (other than immediate precleaning/point of use treatment) are not performed in patient care areas because of risk of patient exposure to contaminated surfaces and devices (Strong recommendation, Low quality of evidence). - There are separate areas for manual cleaning and disinfecting equipment and drying and storage of clean endoscopes (Strong recommendation, Low quality of evidence). - Facilities where endoscopes are used and disinfected are designed to provide a safe environment for healthcare workers and patients (Strong recommendation, Moderate quality of evidence). - Eyewash stations are available to reprocessing staff using caustic chemicals (Strong recommendation, Low quality of evidence). - Eyewash stations are placed near sinks used for washing or soaking soiled endoscopes (Strong recommendation, Low quality of evidence). - Air exchange equipment (eg, ventilation system and exhaust hoods) are used to minimize the exposure of all persons to potentially toxic vapors. 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) (Strong recommendation, Moderate quality of evidence).
GI endoscope reprocessing
Precleaning
- Perform precleaning/point of use treatment immediately after a procedure is completed, before bioburden has an opportunity to dry, and before comprehensive decontamination (Strong recommendation, Low quality of evidence). - Wipe the exterior of the endoscope with a detergent solution described in the manufacturers' instructions for use (IFU) (Strong recommendation, Low quality of evidence). - Aspirate detergent through all channels (eg, air/water and biopsy channels) until the aspirant is clear (Strong recommendation, Low quality of evidence). - Perform precleaning/point of use treatment of specific areas of duodenoscopes (eg, elevator channel, recess) and specialty care endoscopes (eg, balloon attachment groove in echoendoscopes) per manufacturer instructions (Strong recommendation, Low quality of evidence). - Immediately transport the soiled endoscope to the reprocessing area for subsequent steps in HLD before the endoscope and remaining soil have an opportunity to dry (Strong recommendation, Low quality of evidence). - Use fully enclosed, puncture resistant, leak-proof, and labeled containers for transportation of soiled endoscopes to prevent exposure of staff, patients, and the environment to potentially infectious organisms during transport (Strong recommendation, Low quality of evidence). - Perform pressure/leak testing according to the endoscopy manufacturers' IFU. Pressure/leak testing should occur after bedside precleaning/point of use treatment and before manual cleaning (Strong recommendation, Moderate quality of evidence).
Manual cleaning
- Before manual or automated HLD, meticulously clean the entire endoscope, including valves, channels, connectors, and all detachable parts, using only model-specific cleaning devices (such as brushes) designed for the endoscope model being cleaned (Strong recommendation, Low quality of evidence). - Manual cleaning occurs within the manufacturers' recommended time frame, usually within 60 minutes after the endoscope is released from the procedure. When cleaning is delayed beyond this interval, the manufacturers' IFU for delayed processing are followed (Strong recommendation, Low quality of evidence). - Disconnect and disassemble endoscope components (eg, air/water and suction valves) and completely immerse the endoscope and components in an appropriate detergent that is compatible with the endoscope, according to the manufacturers' IFU (Strong recommendation, Low quality of evidence). - Use reprocessing labeling to identify channels that are accessible to flushing and those that are accessible to both flushing and brushing. Flush and brush all accessible channels to remove all organic (eg, blood or tissue) and other residues. At a minimum, per the manufacturers' recommendations in the IFU, repeatedly actuate the reusable elevators of duodenoscopes and linear echoendoscopes to facilitate access for cleaning the recess behind the elevator (Strong recommendation, Low quality of evidence). - Clean the external surfaces and components of the endoscope using a soft cloth, sponge, or brushes, as described in the endoscope manufacturers' IFU (Strong recommendation, Low quality of evidence).

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TABLE 2. Continued

• Use brushes appropriate for the size of the endoscope channel, parts, connectors, and orifices (eg, bristles should contact all surfaces) for cleaning. All brushes are appropriately sized for the part of the endoscope being brushed and should be approved for this use by the endoscope manufacturer (Strong recommendation, Low quality of evidence). • Use cleaning tools that are disposable or thoroughly clean and disinfect them between uses according to the manufacturers' IFU (Strong recommendation, Low quality of evidence). • Discard enzymatic detergents after each use and any time the solution is outside the prescribed dilution concentration or temperature range (Strong recommendation, Low quality of evidence). • Using lighted magnification, visually inspect both endoscopes and reusable accessories frequently in the course of their use and reprocessing. This inspection may include before, during, and after use (Strong recommendation, Low quality of evidence). • Exterior endoscope inspection should be done after each manual cleaning cycle and before HLD or sterilization (Strong recommendation, Low quality of evidence).
High-level disinfection
• HLD should be performed in an automated endoscope reprocessor (AER) (Strong recommendation, Moderate quality of evidence). • Use a high-level disinfectant and a compatible U.S. Food and Drug Administration (FDA)-cleared AER (Strong recommendation, Low quality of evidence). • Follow the FDA-cleared label claims for exposure time and temperature for disinfecting semi-critical patient care equipment (Strong recommendation, Moderate quality of evidence). • Select a liquid disinfectant or sterilization technology that is compatible with the endoscope, per the recommendations of the endoscope and/or the HLD/sterilizer manufacturers validated recommendations (Strong recommendation, Low quality of evidence). • Ensure that the endoscope and endoscope components can be effectively reprocessed in the AER (eg, the elevator wire channel of duodenoscopes may not be effectively disinfected by some AERs, and this step should be performed manually). Users should obtain and review FDA-cleared model-specific reprocessing instructions for use from both the endoscope and the AER manufacturers and check for compatibility (Strong recommendation, Low quality of evidence). • Place the endoscope and endoscope components in the AER 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. Only approved connectors should be used (Strong recommendation, Low quality of evidence). • A full AER cycle should be repeated if the cycle is interrupted (Strong recommendation, Low quality of evidence). • Maintain a log for each procedure indicating the patient's name and medical record number, the procedure and the serial number or other identifiers of the endoscope (and AER), the date and type of the procedure, and the name of the person performing the cleaning and HLD/sterilization process to assist in the event of an outbreak investigation. Logs for transmission identification and reporting should include identifiers and use of specific loaner endoscopes that may be added to local inventories on a temporary basis (Strong recommendation, Low quality of evidence). • If manual HLD is performed (ie, the AER is undergoing repairs), then ◦ Completely immerse the endoscope and its components in the high-level disinfectant solution and ensure that all channels are perfused (Strong recommendation, Low quality of evidence). ◦ Perform minimum effective concentration testing of the liquid high-level disinfectant as recommended in the HLD manufacturers' IFU. Check the solution at the beginning of each day of use (or more frequently in accordance with manufacturers' guidelines) and record the results. If the chemical indicator shows that the concentration is less than the recommended minimum effective concentration, then the solution should be discarded (Strong recommendation, Low quality of evidence). ◦ Discard the liquid high-level disinfectant at the end of its reuse life (which may be single use), regardless of the minimal recommended concentration. If an 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 (Strong recommendation, Low quality of evidence). • Healthcare facilities should verify that users can readily identify whether and when an endoscope has been reprocessed (eg, logs, radiofrequency identification, reprocessing tags) (Strong recommendation, Moderate quality of evidence). • Ongoing cleaning and routine maintenance of AERs should be conducted according to the manufacturers' IFU and all repairs should be recorded as part of the organization's quality assurance program (Strong recommendation, Low quality of evidence). • Documentation of all equipment tests, processes, and quality monitors used during endoscope reprocessing are maintained as well as other staff training and processing records in accordance with institutional guidelines (Strong recommendation, Low quality of evidence). • In a nonoutbreak setting, repeat HLD has no additional benefit compared with single HLD in reducing bacterial contamination rates for duodenoscopes. Insufficient and limited data exist for all other endoscope design models (Conditional recommendation, Moderate quality of evidence). • In nonoutbreak settings, limited data suggest that ethylene oxide sterilization does not reduce bacterial contamination rates in duodenoscopes compared with single HLD (Conditional recommendation, Moderate quality of evidence). • The use of ethylene oxide sterilization on duodenoscopes during infectious outbreaks has been associated with terminating these outbreaks and such a modality should be considered in selected settings and patient populations (Conditional recommendation, Low quality of evidence). • Insufficient and limited data exist for all other endoscope design models in comparing sterilization to single HLD. Routine use of ethylene sterilization for all endoscopes is not recommended (Conditional recommendation, Moderate quality of evidence).
Drying
• After HLD, rinse the endoscope and flush the channels with sterile or filtered water to remove the disinfectant solution. Discard the rinse water after each use/cycle. Most AERs are programmed to perform a terminal rinse after automated HLD (Strong recommendation, Low quality of evidence). • Endoscopes should undergo drying after the completion of all reprocessing steps as described in the endoscope manufacturers' IFU (Strong recommendation, Low quality of evidence).

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TABLE 2. Continued

• The exterior of the endoscope should be completely dried using a clean, lint-free cloth (Strong recommendation, Low quality of evidence). • Drying of endoscope channels (or areas that are inaccessible to drying with a cloth) should be performed with forced, pressure-regulated filtered air (Strong recommendation, Moderate quality of evidence). • Drying the interior of an endoscope should use a sufficiently prolonged flow of medical air through all accessible channels, ideally simultaneously and for at least 10 minutes, for greatest efficiency (Strong recommendation, Moderate quality of evidence). • Endoscopes should be completely dried after reprocessing and before use (Strong recommendation, Moderate quality of evidence). • Follow manufacturers' IFU on using ethyl or isopropyl alcohol for drying endoscopes (Strong recommendation, Moderate quality of evidence).
Storage
• Endoscopes should be stored in secure cabinets per manufacturer instructions (Strong recommendation, Low quality of evidence). • Endoscope cabinets may be specialized drying or conventional cabinets (Strong recommendation, Low quality of evidence). • Individuals should perform hand hygiene and wear clean gloves during all phases of handling endoscopes (Strong recommendation, Low quality of evidence). • Endoscope cabinets are stored in a secure room (Strong recommendation, Low quality of evidence). • Endoscopes can be placed either in a vertical or horizontal position depending on the validated design of the endoscope cabinet and per endoscope manufacturers' instructions (Strong recommendation, Moderate quality of evidence). • If placed in a vertical position, the endoscope should not be coiled or positioned in a manner that promotes acute angulations and should not touch the bottom of the cabinet (Strong recommendation, Low quality of evidence). • All endoscope accessories (ie, caps, valves, and other detachable components) are removed as per manufacturer instructions but do not need to be stored with a specific endoscope (Strong recommendation, Low quality of evidence). • Data are insufficient to proffer a maximal outer duration for the use of appropriately cleaned, reprocessed, dried, and stored flexible endoscopes. Endoscopy units can evaluate the available literature, perform an assessment as to the benefits and risks around the optimal storage time for endoscopes, and develop a policy and procedure specific to their unit on endoscope storage time (Conditional recommendation, Moderate quality of evidence). • The use of routine environmental microbiologic testing of endoscopes for quality assurance has not been established but is currently the most recognized technique to detect bacterial contamination of reprocessed endoscopes. If microbiologic testing of fully reprocessed and dried endoscopes is considered and performed, then standard microbiologic techniques per FDA and Centers for Disease Control and Prevention guidance should be used (Conditional recommendation, Moderate quality of evidence).
Endoscope accessories and associated equipment
• A backflow-prevention valve used in the irrigation/flushing system requires replacement/reprocessing per procedure, whereas the irrigation tubing can be replaced on a daily basis (Strong recommendation, Low quality of evidence). • The interval for exchange of vacuum tubing and waste canisters remains incompletely understood but, at a minimum, should be changed daily (Strong recommendation, Low quality of evidence). • Water bottles (used for cleaning the lens of the endoscope and irrigation during the procedure) undergo daily HLD or sterilization (or are replaced daily) per manufacturers' IFU (Strong recommendation, Low quality of evidence). • Use sterile water for those endoscopic procedures with intended traversal of mucosa (eg, peroral endoscopic myotomy procedures, endoscopic necrosectomy, interventional EUS) (Strong recommendation, Low quality of evidence). • Endoscopy unit follows manufacturers' IFU on the type of water to be used in the water bottle for an endoscopic procedure. In the absence of a manufacturer recommendation/guidance, the endoscopy unit performs an independent risk assessment for use of sterile vs clean tap water for standard endoscopic procedures (eg, EGD and colonoscopy) in which mucosal penetration would be unusual/not anticipated (Strong recommendation, Low quality of evidence). • Endoscopy unit follows manufacturers' IFU on the addition of simethicone in water bottles and irrigation devices including cleaning and disinfection of endoscopes after simethicone has been used (Strong recommendation, Moderate quality of evidence). • Reusable endoscopic accessories (eg, biopsy forceps or other cutting instruments) that break the mucosal barrier are mechanically cleaned and then sterilized between each patient use (Strong recommendation, Low quality of evidence). • Reprocessing of single-use items is not performed unless the facility can comply with FDA guidance for reprocessing single-use devices (Strong recommendation, Low quality of evidence). • Reprocessing of nonendoscopic devices, accessories, and attachments complies with manufacturers' recommendations (Strong recommendation, Low quality of evidence).
Maintenance of endoscopes
• Endoscopy unit complies with the manufacturers' IFU regarding endoscope maintenance and repair (Strong recommendation, Low quality of evidence). • Endoscopy unit has policies tracking the repairs and maintenance of equipment, including loaner devices (Strong recommendation, Low quality of evidence). • When equipment is sent out for service/repair, the equipment undergoes reprocessing as directed by the receiving facility before sending the endoscope for service/repair (Strong recommendation, Low quality of evidence). • On return of equipment from repair facilities, the equipment is reprocessed according to the device manufacturers' IFU before being placed back into service (Strong recommendation, Low quality of evidence). • Interdisciplinary team communication (eg, reprocessing personnel, clinicians who use the devices) should be established and implemented when equipment is down for repair (Strong recommendation, Low quality of evidence). • Detailed operating and reprocessing instructions accompany loaned devices (Strong recommendation, Low quality of evidence).
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TABLE 2. Continued

• Loaned endoscopes are delivered in advance of the procedure with time for them to be reprocessed before first use on patients (Strong recommendation, Low quality of evidence). • If the end-user and/or reprocessing staff are unfamiliar with the operation or reprocessing of the loaner equipment, detailed instructions and in-services are completed by the company issuing the loaner (Strong recommendation, Low quality of evidence). • Loaner equipment is compatible with existing reprocessing equipment and cleaning/disinfectant solutions (Strong recommendation, Low quality of evidence). • Loaner equipment is visually inspected for defects, tested for functionality, and reprocessed on receipt and placement into service. Loaner equipment condition and reprocessing are recorded according to facility protocols. Other information recorded includes the name of the company issuing the loaner; make, model, and serial number of the loaner equipment; dates the loaner was entered into service and returned to the lender; and patients in whom the device was used (Strong recommendation, Low quality of evidence). • A mechanism is in place for traceability of loaned endoscope(s) (Strong recommendation, Low quality of evidence). • All known prior culture data should be provided with the loaned endoscope. If the loaned endoscope is found to be culture positive, then the manufacturer should be notified (Strong recommendation, Moderate quality of evidence).
Endoscopy unit infection control leadership
• Endoscopy units should have a qualified, interdisciplinary, and diverse leadership team that meets regularly (Strong recommendation, Moderate quality of evidence). • Endoscopy unit leadership team includes a designated, qualified individual who directs infection prevention plans and addresses infection outbreaks, should they occur (Strong recommendation, Moderate quality of evidence). • In the event of an outbreak (ie, defined by the institution's infection control program) caused by a suspected infectious or chemical etiology, environmental sampling should be performed according to standard outbreak investigation protocols that comply with proper methodology and validated testing (Strong recommendation, Moderate quality of evidence). • Endoscopy-related infections should be reported to the following (Strong recommendation, Low quality of evidence): ◦ Patient who underwent the procedure. ◦ Persons responsible for infection control at the institution, with notification of referring physician(s) and potentially affected patients as appropriate. ◦ Appropriate public health agency (state or local health department as required by state law or regulation). ◦ The FDA (www.fda.gov/medwatch). Medical Device Reports submitted through Medwatch can be reviewed on the FDA's Manufacturer and User Facility Device Experience database. ◦ The manufacturer(s) of the endoscope, disinfectant/sterilant and AER (if used).

STAFF TRAINING AND COMPETENCY OF ENDOSCOPE REPROCESSING SKILLS

What training and competencies are required for staff to perform endoscope reprocessing?

Recommend.

- Endoscopy units have a written environmental disinfection and endoscope reprocessing policy and staff are oriented to it (Strong recommendation, Low quality of evidence).
- All healthcare personnel in the endoscopy unit are trained in and comply with standard infection prevention and control recommendations (eg, universal precautions), including those to protect both patients and healthcare workers (Strong recommendation, Low quality of evidence).
- Personnel assigned to reprocess endoscopes receive model-specific reprocessing instructions and training (ie, endoscope manufacturer, as needed) to promote proper cleaning and HLD/sterilization and to maintain proper documentation of all reprocessing steps. Staff should receive these instructions, training, and have competency documented before being assigned to perform HLD or sterilization of those devices (Strong recommendation, Low quality of evidence).
- Competency evaluation of personnel that reprocesses endoscopes is performed and documented on a

schedule defined by the organization (eg, commencement of employment, at least annually; anytime a breach is identified; when a major technique or new endoscope or reprocessing accessory is introduced; and in the context of local quality control efforts). Temporary personnel should not be allowed to reprocess endoscopes until competency has been established and verified (Strong recommendation, Moderate quality of evidence).

To ensure ongoing awareness and optimal performance of reprocessing steps, all staff involved with the use, cleaning, and reprocessing of flexible endoscopes should receive the same training and competency evaluation (regardless of practice setting) and undergo documented brand- and model-specific training at the commencement of employment and at least annually.¹⁵ A single standard training process and workflow within an institution may be insufficient, given differences among manufacturers' instructions and varied instrument designs. Additional training, along with updated evaluation and documentation of competency, is required whenever a change in reprocessing guidance is received from the endoscope manufacturer, regulatory agencies, or guidance from professional organizations and such changes should be incorporated into endoscopy unit policies and procedures.^{2,15,16,20} Principles that should

be incorporated into endoscopy unit reprocessing training programs include the following: they are competency-based, training checklists are used, staff are routinely audited (eg, by direct observation) for compliance with all steps involved in the reprocessing of endoscopes, and staff feedback is sought.²¹ Finally, recommendations with regard to the use of personal protective equipment, required vaccinations for employees, using universal precautions, and minimizing transmission of infections to staff working in an endoscopy unit should be followed, as previously reported.²

GI ENDOSCOPE REPROCESSING

Compliance with published reprocessing standards is inconsistent, and adherence to reprocessing guidelines can be improved.²² Wide variation exists in observing both global principles and following the specific steps of manual cleaning, HLD, drying, quality monitoring, and infection control guidelines.^{11,23,24} Reprocessing audits in the setting of infectious outbreaks in endoscopy units reveal lapses in reprocessing steps such as incomplete drying, incorrect brushing and flushing of endoscope channels during manual cleaning, improper storage of endoscopes, use of contaminated bottles containing enzymatic solution during the precleaning/point of use treatment process, and poor maintenance of automated endoscope reprocessors (AERs) and handwashing sinks.^{9,25-31} Taken together, this body of literature illustrates that additional work and attention is needed to help reinforce and standardize our reprocessing and infection control guidelines.

What steps should be complied with in the precleaning/point of use treatment of endoscopes?

Recommend.

- Perform precleaning/point of use treatment immediately after a procedure is completed, before bioburden has an opportunity to dry, and before comprehensive decontamination (Strong recommendation, Low quality of evidence).
- Wipe the exterior of the endoscope with a detergent solution described in the manufacturers' instructions for use (IFU) (Strong recommendation, Low quality of evidence).
- Aspirate detergent through all channels (eg, air/water and biopsy channels) until the aspirant is clear (Strong recommendation, Low quality of evidence).
- Perform precleaning/point of use treatment of specific areas of duodenoscopes (eg, elevator channel, recess) and specialty care endoscopes (eg, balloon attachment groove in echoendoscopes) per manufacturer instructions (Strong recommendation, Low quality of evidence).

- Immediately transport the soiled endoscope to the reprocessing area for subsequent steps in HLD before the endoscope and remaining soil have an opportunity to dry (Strong recommendation, Low quality of evidence).
- Use fully enclosed, puncture resistant, leak-proof, and labeled containers for transportation of soiled endoscopes to prevent exposure of staff, patients, and the environment to potentially infectious organisms during transport (Strong recommendation, Low quality of evidence).

Endoscope reprocessing begins immediately after the endoscope is no longer needed for the procedure. Several steps must be completed before taking the endoscope to the reprocessing area. Precleaning/point of use treatment includes removing fluids and debris from both the external and internal surfaces of the endoscope.^{2,15,16,32,33} Precleaning/point of use treatment is the first step in preventing the development of biofilm within endoscopes. Biofilm results from bacteria attaching to a surface and producing extracellular polysaccharides, enabling organisms to become trapped³⁴ and resistant to degradation in future steps of reprocessing. Additionally, serial cycles of reprocessing yield "buildup biofilm" harboring layers of protective polysaccharides and mixed varieties of microorganisms that are even further resistant to both clearance and sampling.³⁵ Therefore, diligent and consistent precleaning/point of use treatment is an essential first step in reprocessing. After transporting the endoscope in a fully closed (ie, water and puncture resistant) and labeled (ie labeled as "Biohazard") container to the reprocessing area, several consecutive steps are performed before beginning HLD. After precleaning/point of use treatment, sequential steps to be performed are leak testing, manual cleaning and rinsing of the endoscope, and inspection.

What role does leak testing play in the reprocessing of endoscopes?

Recommend.

- Perform pressure/leak testing according to the endoscope manufacturers' IFU. Pressure/leak testing should occur after bedside precleaning/point of use treatment and before manual cleaning (Strong recommendation, Moderate quality of evidence).
- Punctured or torn areas on the exterior sheath or internal channels of endoscopes can lead to penetration of fluid and/or pathogens, leading to instrument damage or transmission of microorganisms.³⁶ Leak testing of endoscopes, when performed correctly, facilitates the detection of internal or external damage or defects. This process is performed before submerging the endoscope in cleaning fluids during manual cleaning. Multiple leak test modalities are available,^{16,37} and endoscopy units should follow the endoscope manufacturers' instructions on how to perform a leak test. Endoscopy units should follow the

equipment's instructions for routine maintenance and use of the leak testing equipment. Endoscopes that fail a leak test are removed from use in the endoscopy unit after being reprocessed in accordance with original equipment manufacturer IFU^{2,15,20,32,33,36-38} and communicated to the clinical team.

What key elements should be complied with during the manual cleaning phase of reprocessing?

Recommend.

- Before manual or automated HLD, meticulously clean the entire endoscope, including valves, channels, connectors, and all detachable parts using only model-specific cleaning devices (such as brushes) designed for the endoscope model being cleaned (Strong recommendation, Low quality of evidence).
- Manual cleaning occurs within the manufacturers' recommended time frame, usually within 60 minutes after the endoscope is released from the procedure. When cleaning is delayed beyond this interval, the manufacturers' IFU for delayed processing are followed (Strong recommendation, Low quality of evidence).
- Disconnect and disassemble endoscope components (eg, air/water and suction valves) and completely immerse the endoscope and components in an appropriate detergent that is compatible with the endoscope, according to the manufacturers' IFU (Strong recommendation, Low quality of evidence).
- Use reprocessing labeling to identify channels that are accessible to flushing and those that are accessible to both flushing and brushing. Flush and brush all accessible channels to remove all organic (eg, blood or tissue) and other residues. At a minimum, per the manufacturers' recommendations in the IFU, repeatedly actuate the reusable elevators of duodenoscopes and linear echoendoscopes to facilitate access for cleaning the recess behind the elevator (Strong recommendation, Low quality of evidence).
- Clean the external surfaces and components of the endoscope using a soft cloth, sponge, or brushes, as described in the endoscope manufacturers' IFU (Strong recommendation, Low quality of evidence).
- Use brushes appropriate for the size of the endoscope channel, parts, connectors, and orifices (eg, bristles should contact all surfaces) for cleaning. All brushes are appropriately sized for the part of the endoscope being brushed and should be approved for this use by the endoscope manufacturer (Strong recommendation, Low quality of evidence).
- Use cleaning tools that are disposable or thoroughly clean and disinfect them between uses according to the manufacturers' IFU (Strong recommendation, Low quality of evidence).
- Discard enzymatic detergents after each use and any time the solution is outside the prescribed dilution con-

centration or temperature range (Strong recommendation, Low quality of evidence).

After a successful leak test the endoscope undergoes manual cleaning.^{2,15,20,32,33,36-38} Manual cleaning occurs within the manufacturers' recommended time frame, ideally immediately after an endoscope has been used. When cleaning is delayed beyond this interval (eg, after-hours emergent endoscopy procedures), the manufacturers' directions for delayed processing should be followed. The manual cleaning process involves immersing the endoscope in a detergent; cleaning the entire exterior surface of the endoscope, including valves, channels, and connectors; and flushing and brushing the endoscope channels. Additional steps may be required for specialized endoscopes. Specifically, further cleaning may be required for the reusable elevator channels of duodenoscopes and the balloon attachment groove in echoendoscopes. Brushing the forceps elevator and elevator recess on duodenoscopes and rinsing both these areas in a detergent solution multiple times are such additional steps that may be required during manual cleaning. Successful and systematic manual cleaning reduces the potential of bio-film formation on endoscopes and significantly decreases the number of pathogens by 99.9%.³⁹

What is the role of both exterior and interior inspection of endoscopes during the reprocessing process?

Recommend.

- Using lighted magnification, visually inspect both endoscopes and reusable accessories frequently in the course of their use and reprocessing. This inspection may include before, during, and after use (Strong recommendation, Low quality of evidence).
- Exterior endoscope inspection should be done after each manual cleaning cycle and before HLD or sterilization (Strong recommendation, Low quality of evidence).

Suggest.

- Manual cleaning of complex endoscope components, such as elevators and recess grooves, requires optimal lighting, which can be facilitated by magnification (Conditional recommendation, Low quality of evidence).
- No recommendation can be made for the routine use of borescopes during any step of the reprocessing process. Borescopes may play a role in the auditing of reprocessing steps in the training and assessment of staff competency (Conditional recommendation, Moderate quality of evidence).

The exterior of the endoscope and associated accessories should be visually inspected after manual cleaning for cleanliness and damage; if any remaining debris is present, then the endoscope/accessory should undergo repeat manual cleaning.^{2,16,32,37} Conversely, recent debate has emerged around the role of visually inspecting the internal channels of endoscopes. The use of borescopes (ie, a slender optical tool used to inspect

the inside of a structure) after reprocessing has detected abnormalities within endoscope internal channels, including damage (ranging from minor scratches to buckling) (86%-100%), debris (22%-96%), and water droplets/fluid (8%-95%).^{31,40-42} The clinical significance of these findings is unclear. Some changes noted by a borescope may represent normal functionally insignificant wear and tear. Additionally, no qualitative or quantitative microbiologic testing was performed on observed abnormalities noted in endoscope internal channels and no immediate or long-term follow-up was provided on patients undergoing endoscopy who were included in studies involving borescopes. Furthermore, there is wide variation in visual interpretations noted among borescope users and a lack of standardization regarding the interpretation and short- and long-term management of borescopic findings. Some guidelines propose their use as an adjunctive tool during an investigation of functional channel problems but not on a fixed or per-procedure schedule.^{16,32} Additional larger and more rigorous studies of this new tool are needed to further elucidate how it can be useful during reprocessing.

Disinfection of flexible GI endoscopes

Recommend.

- HLD should be performed in an AER (Strong recommendation, Moderate quality of evidence).
 - Use a high-level disinfectant and a compatible FDA-cleared AER (Strong recommendation, Low quality of evidence).
 - Follow the FDA-cleared label claims for exposure time and temperature for disinfecting semi-critical patient care equipment (Strong recommendation, Moderate quality of evidence).
 - Select a liquid disinfectant or sterilization technology that is compatible with the endoscope, per the recommendations of the endoscope and/or the high-level disinfectant/sterilizer manufacturers' validated recommendations (Strong recommendation, Low quality of evidence).
 - Ensure that the endoscope and endoscope components can be effectively reprocessed in the AER (eg, the elevator wire channel of duodenoscopes may not be effectively disinfected by some AERs, and this step should be performed manually). Users should obtain and review FDA-cleared model-specific reprocessing IFU from both the endoscope and the AER manufacturers and check for compatibility (Strong recommendation, Low quality of evidence).
 - Place the endoscope and endoscope components in the AER 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. Only approved connectors should be used (Strong recommendation, Low quality of evidence).
 - A full AER cycle should be repeated if the cycle is interrupted (Strong recommendation, Low quality of evidence).
 - Maintain a log for each procedure indicating the patient's name and medical record number, the procedure and the serial number or other identifiers of the endoscope (and AER), the date and type of the procedure, and the name of the person performing the cleaning and HLD/sterilization process to assist in the event of an outbreak investigation. Logs for transmission identification and reporting should include identifiers and use of specific loaner endoscopes that may be added to local inventories on a temporary basis (Strong recommendation, Low quality of evidence).
 - If manual HLD is performed (ie, the AER is undergoing repairs), then
 - Completely immerse the endoscope and its components in the high-level disinfectant solution and ensure that all channels are perfused (Strong recommendation, Low quality of evidence).
 - Perform minimum effective concentration testing of the liquid high-level disinfectant as recommended in the HLD manufacturers' IFU. Check the solution at the beginning of each day of use (or more frequently in accordance with manufacturers' guidelines) and record the results. If the chemical indicator shows that the concentration is less than the recommended minimum effective concentration, then the solution should be discarded (Strong recommendation, Low quality of evidence).
 - Discard the liquid high-level disinfectant at the end of its reuse life (which may be single use), regardless of the minimal recommended concentration. If an 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 (Strong recommendation, Low quality of evidence).
 - Healthcare facilities should verify that users can readily identify whether and when an endoscope has been reprocessed (eg, logs, radiofrequency identification, reprocessing tags) (Strong recommendation, Moderate quality of evidence).
 - Ongoing cleaning and routine maintenance of AERs should be conducted according to the manufacturers' IFU, and all repairs should be recorded as part of the organization's quality assurance program (Strong recommendation, Low quality of evidence).
 - Documentation of all equipment tests, processes, and quality monitors used during endoscope reprocessing are maintained, as well as other staff training and processing records in accordance with institutional guidelines (Strong recommendation, Low quality of evidence).
- Flexible GI endoscopes should be comprehensively cleaned and subjected to at least HLD. This standard has been recommended by federal agencies such as the FDA⁴³ and the

CDC¹⁵ and by U.S. professional organizations, including the American Society for Gastrointestinal Endoscopy, the American College of Gastroenterology, the American Gastroenterology Association, Society of Gastrointestinal Nurses and Associates, the Association of Perioperative Registered Nurses, and the Association for Professionals in Infection Control and Epidemiology.^{2,16,20,32} These and other organizations have developed guidance documents that detail the sequence and specifics of each element of appropriate endoscope reprocessing.^{2,15,16,20,32,33,37,38,44}

No infectious transmission of pathogens has been linked to standard (ie, end-viewing) endoscopes when all reprocessing steps are followed thoroughly according to the endoscope reprocessing instructions manual or quick reference guides. On the other hand, outbreaks have been linked to duodenoscopes^{6-8,10} in spite of appropriate compliance with reprocessing guidelines. This has prompted the FDA to take several steps in recent years. First, the FDA has advised that together with strict compliance with duodenoscope manufacturers' reprocessing instructions all endoscopy units using duodenoscopes should implement 1 or more of several supplemental options including microbiologic culturing, ethylene oxide (EtO) sterilization, use of a liquid chemical sterilant processing system, or repeat HLD.⁴⁵ Second, the FDA ordered duodenoscope manufacturers to conduct human factors validation testing of duodenoscope reprocessing instructions. These studies illustrated that user reprocessing manuals are cumbersome and challenging to follow, and opportunities exist to improve them. Third, postmarketing surveillance microbiologic studies have indicated higher than expected duodenoscope contamination rates after reprocessing. For example, .3% to 4.4% of duodenoscopes are contaminated with low/moderate concern organisms, whereas the contamination rate of duodenoscopes with high concern organisms is 4.1% to 6.1%.⁴⁶ Preliminary data indicate a number of factors may contribute to contamination, including the complexity of the distal end of duodenoscopes, inaccessible channels, prolonged storage in noncontrolled environments, human factors, damaged areas, and waterborne pathogens from rinsing water.⁴⁷ However, a paucity of data exists regarding the effectiveness of the recommended FDA supplemental measures despite the fact that nearly 90% of U.S. endoscopy units implemented 1 or more of them.⁴⁸

Is there a benefit of repeat HLD (ie, 1 cycle of manual cleaning and 2 cycles of HLD using an AER) compared with single HLD in the reprocessing of endoscopes?*

Recommend.

- In a nonoutbreak setting, repeat HLD has no additional benefit compared with single HLD in reducing bacterial contamination rates for duodenoscopes. Insufficient and limited data exist for all other endoscope design models (Conditional recommendation, Moderate quality of evidence).

To date, 2 randomized controlled trials comparing repeat HLD and single HLD have been conducted in endoscopy units during nonoutbreak settings. In a single-center study, Snyder et al⁴⁹ compared rates of culture positivity for ≥ 1 multidrug-resistant organism from the elevator mechanism or working channel of duodenoscopes after (1) standard cleaning and HLD versus (2) standard cleaning/HLD followed by repeat HLD versus (3) standard cleaning/HLD followed by EtO sterilization. The study was terminated early because of the futility of evaluating the primary outcome; no duodenoscope was positive for multidrug-resistant organisms, and bacterial growth >0 and ≥ 10 colony-forming units was not statistically different among the 3 reprocessing arms of the study. In a second larger study, Bartles et al⁵⁰ compared cleaning plus repeat HLD versus single HLD among 45 duodenoscopes and linear echoendoscopes (2925 patient encounters) across 4 hospitals in Washington state within a 6-month time period. With a nearly 100% compliance rate, repeat HLD did not improve contamination rates or reduce culture positivity rates compared with single HLD. Most positive cultures were from elevator channels, and only 8 high concern pathogens, all from elevator channels, were observed. Collectively, these 2 studies demonstrate no significant reduction in endoscope bacterial contamination after repeat cycles of HLD (odds ratio [OR], .92; 95% confidence interval [CI], .72-1.18) (Fig. 2). Thus, it does not appear that repeat HLD compared with single HLD confers an additional benefit for reducing bacterial contamination rates in duodenoscopes during a noninfectious outbreak setting.

Another process that has been explored for reducing infectious risks from endoscopes is the repetition of all reprocessing steps (ie, repeat manual cleaning followed by repeat HLD in an AER). One study examining duodenoscopes⁵¹ demonstrated a 1-log reduction in culture positivity of endoscopes using repeated manual washing and HLD. Additionally, in a single-arm noncomparative study, Rex et al⁵² showed a low rate of positive cultures for known pathogens (.3%) and for organisms of low pathogenic potential (4.9%) and no transmission of infections from duodenoscopes when following this protocol. Although repeat reprocessing, including both repeat manual cleaning and HLD, can further minimize culture positivity on endoscopes, this process does not entirely eliminate contamination, and future studies directly comparing this process with single HLD and sterilization methods are needed.

Is there a benefit of EtO sterilization compared with single HLD in the reprocessing of endoscopes?*

Recommend.

- In nonoutbreak settings, limited data suggest that EtO sterilization does not reduce bacterial contamination rates in duodenoscopes compared with single HLD

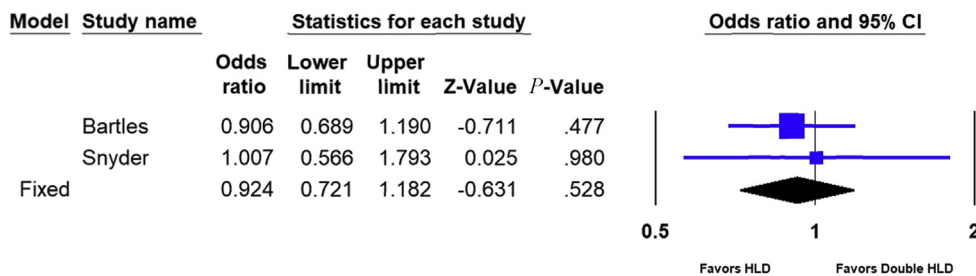


Figure 2. Comparing the reprocessing of endoscopes using repeat high-level disinfection (HLD) (ie, 1 cycle of manual cleaning and 2 cycles of HLD using an automated endoscope reprocessor) versus single HLD in terms of reducing endoscope bacterial contamination. *CI*, Confidence interval.

(Conditional recommendation, Moderate quality of evidence).

- The use of EtO sterilization on duodenoscopes during infectious outbreaks has been associated with terminating these outbreaks and such a modality should be considered in selected settings and patient populations (Conditional recommendation, Low quality of evidence).
- Insufficient and limited data exist for all other endoscope design models in comparing sterilization with single HLD. Routine use of EtO sterilization for all endoscopes is not recommended (Conditional recommendation, Moderate quality of evidence).

Very limited outcome data are available that illustrates EtO sterilization for flexible endoscopes results in better patient outcomes. To date, only 1 study has compared EtO sterilization with other endoscope reprocessing methods. In the prospective, randomized trial of 3 reprocessing sequences cited above, Snyder et al⁴⁹ showed no statistically significant difference among the single HLD, repeat HLD, and EtO sterilization study arms, yet numerically the contamination rates with nonpathogenic organisms in the EtO sterilization arm were higher. This may have been because of endoscope handling during the culture sampling process or because of damage as a result of undergoing the EtO sterilization process. Although limited, these data suggest that EtO sterilization may not be superior to single HLD for duodenoscope reprocessing with respect to reducing endoscope contamination rates.

EtO sterilization of duodenoscopes can be an effective tool in some clinical situations, specifically when there are infectious outbreaks observed among patients who have undergone ERCP. A systematic review by Muscarella⁵³ examined all reported carbapenem-resistant Enterobacteriaceae- and multidrug-resistant organisms-related infections in the United States and Europe attributed to duodenoscope exposure and assessed the adequacy of reprocessing in these outbreaks. Factors such as endoscope design, lapses in reprocessing guidelines, damage to the endoscope, or a lack of servicing, maintenance, and repair of the endoscope were hypothesized to be contributors to these outbreaks.⁵³ In this review, 6 of 17 studies

implemented EtO sterilization as an intervention during infectious outbreaks; in at least 3 and possibly 6 studies this intervention yielded an absence of culture positivity from duodenoscopes at all sites, thereby stopping the outbreaks.^{6,7,54-57} Similar data exist for EtO sterilization ceasing outbreaks attributed to bronchoscopes.^{58,59} Therefore, the implementation of EtO sterilization appears to be an effective tool for terminating carbapenem-resistant Enterobacteriaceae and multidrug-resistant organism outbreaks associated with duodenoscopes. However, sterilization technology is costly, inefficient, and associated with potential toxicity to reprocessing personnel and surrounding communities; additionally, there are concerns about endoscope performance and durability, and such technology is not widely available. Given these limitations, it may be more feasible to selectively use sterilization of duodenoscopes that have been used in high-risk patients, such as those who are colonized with carbapenem-resistant Enterobacteriaceae/multidrug-resistant organisms or at risk for developing such infections after an ERCP.

Are there optimal parameters for the drying of endoscopes?

Recommend.

- After HLD, rinse the endoscope and flush the channels with sterile or filtered water to remove the disinfectant solution. Discard the rinse water after each use/cycle. Most AERs are programmed to perform a terminal rinse after automated HLD (Strong recommendation, Low quality of evidence).
- Endoscopes should undergo drying after the completion of all reprocessing steps as described in the endoscope manufacturers' IFU (Strong recommendation, Low quality of evidence).
- The exterior of the endoscope should be completely dried using a clean, lint-free cloth (Strong recommendation, Low quality of evidence).
- Drying of endoscope channels (or areas that are inaccessible to drying with a cloth) should be performed with forced, pressure-regulated filtered air (Strong recommendation, Moderate quality of evidence).

- Drying the interior of an endoscope should use a sufficiently prolonged flow of medical air through all accessible channels, ideally simultaneously and for at least 10 minutes, for greatest efficiency (Strong recommendation, Moderate quality of evidence).
- Endoscopes should be completely dried after reprocessing and before use (Strong recommendation, Moderate quality of evidence).

Incomplete drying of endoscopes is linked to multiple outbreaks of waterborne organisms,^{4,60-63} with a reported endoscope contamination rate of 80% if endoscopes are improperly dried.⁶⁴ There is wide variation among endoscopy units with respect to drying of endoscopes; in particular, nearly 10% report not drying endoscopes after reprocessing and less than half use forced air drying.⁴⁸ First, the exterior of the endoscope should be entirely dried using a clean, lint-free cloth. Next, high-efficiency particulate air-filtered medical or instrument air is applied to all endoscope channels. Solely relying on vertical hanging without prior or concurrent flushing of channels with filtered air is an ineffective method for endoscope drying.^{41,65,66} Also, manual drying with a forced air pistol directed into several areas at varying time points provides inadequate drying.^{31,65} Multiple modalities exist for delivering continuous forced filtered air into endoscope channels for drying purposes. Such modalities include the use of a prolonged air purge cycle at the end of HLD by an AER and prolonged direct air delivery into all channels using a tabletop flushing apparatus, “automated” flushing devices, and a variety of air purge storage cabinets. Prolonged, simultaneous airflow through all endoscope channels using a dedicated endoscope-drying apparatus, device,⁶⁵ or storage cabinet^{31,65-68} offers effective drying of the endoscope as measured by either borescopic visual inspection of the working channel or moisture detection papers. Last, longer intervals of continuous air instillation, using either specific drying devices for a minimum of 10 minutes⁶⁵ or endoscope storage cabinets for a minimum of 1 hour,⁶⁶ are sufficient for the drying of the internal working channels.

Debate exists on the extent to whether an endoscope needs to be dried before it can be used after it has been reprocessed. In this area there is tremendous variability in terms of reprocessing guideline recommendations. On one hand, several European guidelines recommend only removal of major water residue from the endoscope channels and outer surfaces if it is to be used immediately or within a short period of time (ie, within 3 hours).^{33,69,70} Conversely, several reprocessing guidelines within the United States recommend complete drying of the endoscope after every reprocessing cycle.^{16,32,37} Given that rapid bacterial growth is facilitated by moisture, incomplete drying of endoscopes may increase the risk of infection. Also, because there is often the uncertainty of when an endoscope will be reused, all endoscopes should be completely dried after reprocessing and before use.

Is there benefit to using ethyl or isopropyl alcohol in the drying of endoscopes?

Recommend.

- Follow manufacturers’ IFU on using ethyl or isopropyl alcohol for drying endoscopes (Strong recommendation, Moderate quality of evidence).

A common preliminary step used in the drying of endoscopes is the application of 70% to 90% ethyl or isopropyl alcohol through endoscope working channels. This is often accomplished as a terminal cycle in many AERs just before a brief air purge. Alcohol offers 2 benefits: (1) purging and promotion of evaporation of residual water within endoscope channels, thereby reducing the potential for bioburden buildup, and (2) the intrinsic antimicrobial properties of alcohol.¹⁶ Despite these potential benefits, data on the use of alcohol flushes during the drying of endoscopes are scarce. One small case report in the United States demonstrated that switching to suctioning 70% alcohol through a duodenoscope working channel followed by compressed air during the drying phase helped to contain an outbreak of *Pseudomonas aeruginosa*.⁶⁰ Extrapolating from the pulmonary literature suggests that using alcohol for drying purposes significantly reduces bronchoscope contamination rates.⁷¹ However, alcohol also has protein fixation properties that could lead to the retention of organisms within the endoscope.³³ At the present time, there are no data that strongly support or refute the use of alcohol flushes for the drying of endoscopes.

After the reprocessing of an endoscope, what is the best method for storing an endoscope when it is not in use?

Recommend.

- Endoscopes should be stored in secure cabinets per manufacturer instructions (Strong recommendation, Low quality of evidence).
- Endoscope cabinets may be specialized drying or conventional cabinets (Strong recommendation, Low quality of evidence).
- Individuals should perform hand hygiene and wear clean gloves during all phases of handling endoscopes (Strong recommendation, Low quality of evidence).
- Endoscope cabinets are stored in a secure room (Strong recommendation, Low quality of evidence).

Suggest.

- Endoscope cabinets should not be placed in procedure rooms (Conditional recommendation, Low quality of evidence).

Proper endoscope storage ensures that moisture does not collect on or within the endoscope.^{68,72} Endoscopes should be stored per manufacturer instructions in a secure location within a manufacturer-approved storage cabinet. Multiple endoscope storage cabinet designs exist, ranging from conventional vertical cabinets with filtered

passive air flow to those that offer continuous multi-channel forced air drying. Drying cabinets have connectors that force air through each endoscope channel, and as such endoscopes can be stored vertically or horizontally. Commercial endoscope storage cabinets using forced irrigation of endoscope channels with warm, filtered air during storage achieves complete drying of channels and reduces the proliferation of *P aeruginosa*,⁶⁶ but their importance for keeping endoscopes free of contamination remains incompletely defined.^{66-68,73} In contrast, in conventional cabinets endoscopes hang vertically, whereas active or passive ventilation with filtered air helps prevent moisture from forming on or within endoscopes. Passive cabinets without airflow directed into all channels are not sufficient for drying the endoscope from a wet state. Endoscope cabinets should be stored in a secure location that are near procedure rooms. Cabinet maintenance should be performed as directed by the manufacturer and should be routinely inspected for damage and cleaned on a routine basis (and when soiled) with an Environmental Protection Agency-registered hospital disinfectant.

What is the optimal way an endoscope should be positioned within a storage cabinet?

Recommend.

- Endoscopes can be placed either in a vertical or horizontal position depending on the validated design of the endoscope cabinet and per endoscope manufacturers' instructions (Strong recommendation, Moderate quality of evidence).
- If placed in a vertical position, the endoscope should not be coiled or positioned in a manner that promotes acute angulations and should not touch the bottom of the cabinet (Strong recommendation, Low quality of evidence).

Suggest.

- Avoid having hanging endoscopes touching one another (Conditional recommendation, Low quality of evidence). Endoscopes should be stored in a manner that will protect them from contamination; consequently, they can be stored vertically or horizontally based on cabinet design. If an endoscope is to be stored in a vertical position, then it should not be coiled or positioned in a manner that promotes acute angulations where water could pool or collect, and endoscopes should not touch the bottom of the cabinet.^{15,16,20,32,33,37,69} One factor that may impact the manner in which endoscopes are positioned is the drying modality used before storing them. Using automated drying (ie, using a drying device that applies continuous air through all channels for a set period of time) before placing an endoscope within a storage cabinet has shown no difference in the detection of fluid droplets within working channels of endoscopes stored vertically or horizontally.⁶⁵ This suggests that if an endoscope first undergoes automated drying, then vertical storage in a conventional cabinet may not be necessary. Last, although

no evidence exists to support the contention that contact between vertically hung endoscopes will yield cross-contamination, care should be taken to avoid having hanging endoscopes touching each other.

Do endoscope accessories need to be stored with an individual endoscope?

Recommend.

- All endoscope accessories (ie, caps, valves, and other detachable components) are removed as per manufacturer instructions but do not need to be stored with a specific endoscope (Strong recommendation, Low quality of evidence).

All accessories should be detached from the endoscope during storage. There is no evidence that co-locating accessories with an endoscope that has undergone HLD improves outcomes or aids in addressing infection control outbreaks when they occur in endoscopy units. Alternatively, there are some reusable devices (ie, removable valves and biopsy channel caps) that can withstand sterilization. If these reusable devices undergo sterilization, then co-localization or tracking/labeling of such devices is not necessary. Finally, 1 rationale for the use of disposable buttons/valves has been to avoid the need for co-location. Again, there is no evidence demonstrating that the use of disposable buttons/valves will reduce infections in patients who undergo endoscopy; furthermore, such a practice can be costly, have environmental consequences, and there are concerns about their ease of use. Given a lack of evidence, storage of endoscope accessories should follow the manufacturers' instructions.

What is the maximum storage time for a GI endoscope, during which it remains clean and patient ready, after it has undergone reprocessing?*

Recommend.

- Data are insufficient to proffer a maximal outer duration for the use of appropriately cleaned, reprocessed, dried, and stored flexible endoscopes. Endoscopy units can evaluate the available literature, perform an assessment regarding benefits and risks around the optimal storage time for endoscopes, and develop a policy and procedure specific to their unit on endoscope storage time (Conditional recommendation, Moderate quality of evidence).

The storage time after which endoscopes should be reprocessed before use, termed "hang-time" or "shelf-life," has been the subject of limited, small investigations.^{72,74-80} Eight studies have examined endoscope storage time evaluating microbial cultures in 1242 procedures. Among these studies there was tremendous variability in terms of endoscope storage time (range, 1-56 days), the timing of when the endoscope was cultured (range, 1-56 days), and which area(s) of the endoscope were cultured (varied among exterior surface, working

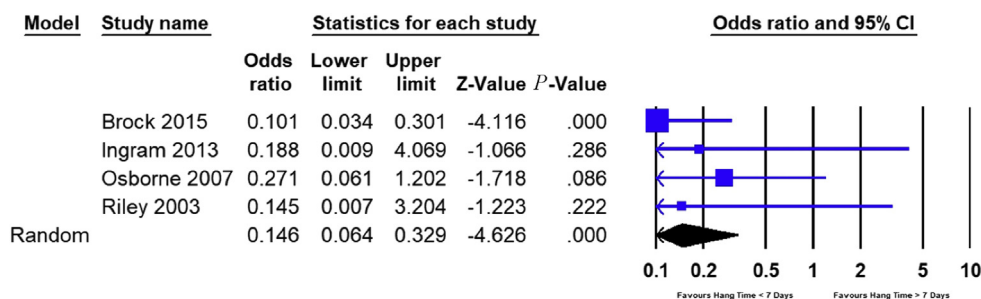


Figure 3. Endoscope storage time comparing <7 and ≥ 7 days with respect to endoscope bacterial contamination rates for any organism (ie, pathogenic and nonpathogenic organisms). *CI*, Confidence interval.

channel, air/water/suction channels of the endoscope). The most frequent pathogen isolated in these studies was nonpathogenic coagulase-negative *Staphylococcus*. Overall, endoscopes with a shorter storage time appeared to have lower rates of any bacterial contamination. Specifically, an endoscope storage time of under 7 days had a lower bacterial contamination rate for any pathogen compared with endoscopes with a storage time of ≥ 7 days (OR, .15; 95% CI, .06-.33) (Fig. 3).^{72,75,77,79} Furthermore, an endoscope storage time of under 7 days was also associated with a lower bacterial contamination rate for any pathogen compared with an endoscope storage time ≥ 14 days (OR, .43; 95% CI, .19-.99).^{72,80} Notably, when restricting the analyses to only bacterial contamination with pathogenic organisms, there was no difference between endoscope storage times of <7 days and ≥ 7 days (OR, .50; 95% CI, .13-1.97) (Fig. 4).^{74,77} Hence, although the reuse of endoscopes within 21 and perhaps even 56 days appears to be safe, the data are insufficient to provide a maximal outer duration for the use of appropriately cleaned, reprocessed, dried, and stored flexible endoscopes.

What is the efficacy of microbiologic surveillance in detecting bacterial contamination in fully reprocessed endoscopes?*

Recommend.

- The use of routine environmental microbiologic testing of endoscopes for quality assurance has not been established but is currently the most recognized technique to detect bacterial contamination of reprocessed endoscopes. If microbiologic testing of fully reprocessed and dried endoscopes is considered and performed, then standard microbiologic techniques per FDA and CDC guidance should be used (Conditional recommendation, Moderate quality of evidence).

Microbiologic testing of endoscopes after reprocessing, during storage, or before use has not been advised in current U.S. standards. However, surveillance culturing as a quality assurance measure is advised in the reprocessing guidelines of several international organizations.⁸¹ The detection of

nonenvironmental pathogens common to the GI tract in reprocessed instruments could serve as an indicator of contaminated or faulty reprocessing equipment, inadequate solutions, or failed human processes. Practical use of endoscope cultures is confounded by the delay in feedback when using standard microbiologic culture techniques and the rigor and expense required to yield reliable samples, given the frequent isolation of both pathogenic and nonpathogenic organisms because of environmental contamination. Studies assessing the culturing of endoscopes to validate the adequacy of HLD vary widely between the types of endoscopes cultured, frequency that cultures were obtained, culturing technique, number of samples obtained, and the definition of a positive culture (type of organism identified [pathogenic vs nonpathogenic/environmental], number of colony-forming units necessary). In addition, several sites with known outbreaks of duodenoscopy-transmitted infections were unable to culture the transmitted organism from the implicated duodenoscopes.⁵⁷ Although variability in duodenoscopy surveillance sampling and culturing protocols persists, the FDA, CDC, and American Society for Microbiology have recently provided detailed guidance on how this can be accomplished.⁸² Some U.S. endoscopy units have adopted a “culture and quarantine” process that yielded fewer culture-positive duodenoscopes and terminated the transmission of infections between patients during ERCP.^{51,83} Despite its limitations, the use of surveillance microbial cultures remains the most reliable indicator of residual contamination on reprocessed endoscopes, and this method of assessment of reprocessing adequacy has been used in FDA-ordered postmarket surveillance studies of reprocessing adequacy.⁸²

Several alternative indicators to assess adequate reprocessing have been proposed but have not been widely applied in clinical practice.⁸⁴⁻⁸⁷ Testing for adenosine triphosphate (ATP) residue as a potential marker of cleaning adequacy, before exposure to HLD, is 1 such indicator. Studies assessing ATP testing showed variation regarding commercial testing devices used, methodology, and threshold values for abnormal results. An ATP relative light

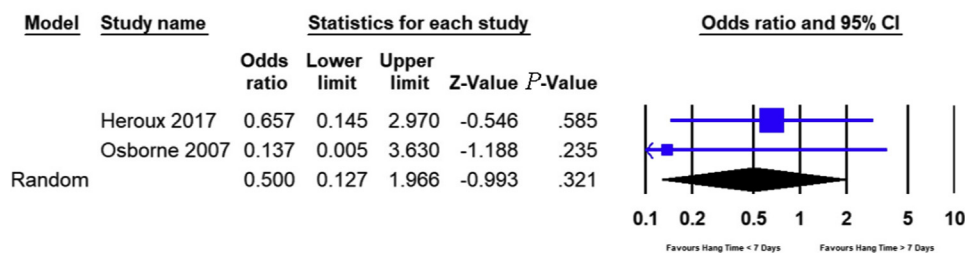


Figure 4. Endoscope storage time comparing <7 and ≥7 days with respect to endoscope bacterial contamination rates for pathogenic organisms. *CI*, Confidence interval.

unit of <200 (3M Clean Trace) has been shown to be associated with “clean” benchmarks of <6.4 mg/cm² protein, <2.2 mg/cm² hemoglobin, and <4-log¹⁰ colony-forming units/cm² bioburden in a simulated study of the manual cleaning of duodenoscopes⁸⁸; this threshold has been validated in a follow-up clinical study of colonoscopes and duodenoscopes.⁸⁹ Alternatively, other studies have suggested a lower relative light unit of <100 may be associated with adequate manual cleaning of colonoscopes.⁹⁰ In addition, the sensitivity and specificity of ATP testing performed after manual cleaning of duodenoscopes compared with terminal cultures was only 30% and 53%, respectively.⁹¹ A subsequent systematic review did not support the use of ATP as a substitute for bacterial culture in duodenoscope surveillance but suggested that it may be a useful tool to assess the adequacy of manual cleaning.⁹² Furthermore, the FDA has issued a communication advising against the use of ATP testing as a method of duodenoscope surveillance, because no sponsor has provided validation of test strips or has received FDA clearance for this indication.⁹³ Available data suggest that both terminal microbial surveillance cultures and ATP testing after manual cleaning have limitations in duodenoscope surveillance and assessing the adequacy of endoscope reprocessing. Thus, ATP assessment of bioburden may be useful for training, competency testing, and spot surveillance of the cleaning steps before and after HLD.⁹⁴⁻⁹⁶

MAINTENANCE OF ENDOSCOPES

What policies and procedures should endoscopy units follow in terms of endoscope maintenance?

Recommend.

- Endoscopy unit complies with the manufacturers’ IFU regarding endoscope maintenance and repair (Strong recommendation, Low quality of evidence).
- Endoscopy unit has policies tracking the repairs and maintenance of equipment, including loaner devices (Strong recommendation, Low quality of evidence).
- When equipment is sent out for service or repair, the equipment undergoes reprocessing as directed by the

receiving facility before sending the endoscope for service or repair (Strong recommendation, Low quality of evidence).

- On return of equipment from repair facilities, the equipment is reprocessed according to the device manufacturers’ IFU before being placed back into service (Strong recommendation, Low quality of evidence).
- Interdisciplinary team communication (eg, reprocessing personnel, clinicians who use the devices) should be established and implemented when equipment is down for repair (Strong recommendation, Low quality of evidence).

Despite careful handling of endoscopes, the instrumentation will eventually require servicing to remain in optimal working order. Using an endoscope or supporting equipment that is not properly functioning may compromise patient or operator safety and could result in more severe equipment damage. When an endoscope and/or endoscopic equipment demonstrates suboptimal performance or an overt defect has been discovered, the device(s) should be immediately removed from service and clearly tagged and identified as in need of servicing until cleared for use by clinical/bioengineering personnel. A repair and maintenance log should be used in conjunction with the endoscope inventory to assist facilities in tracking endoscope status and its location for repairs and preventative maintenance. An entry should be made every time equipment is sent out or returned. When equipment is sent out for servicing, an entry should be made into the maintenance log detailing equipment model and serial number, company providing service, date sent for servicing, and reason for sending the equipment for servicing.³⁶

What guidelines should endoscopy units follow when loaner endoscopes are used?

Recommend.

- Detailed operating and reprocessing instructions accompany loaned devices (Strong recommendation, Low quality of evidence).
- Loaned endoscopes are delivered in advance of the procedure with time for them to be reprocessed before first use on patients (Strong recommendation, Low quality of evidence).

- If the end-user and/or reprocessing staff are unfamiliar with the operation or reprocessing of the loaner equipment, detailed instructions and in-services are completed by the company issuing the loaner (Strong recommendation, Low quality of evidence).
- Loaner equipment is compatible with existing reprocessing equipment and cleaning and disinfectant solutions (Strong recommendation, Low quality of evidence).
- Loaner equipment is visually inspected for defects, tested for functionality, and reprocessed on receipt and placement into service. Loaner equipment condition and reprocessing are recorded according to facility protocols. Other information recorded includes the name of the company issuing the loaner; make, model, and serial number of the loaner equipment; dates the loaner was entered into service and returned to the lender; and patients in whom the device was used (Strong recommendation, Low quality of evidence).
- A mechanism is in place for traceability of loaned endoscope(s) (Strong recommendation, Low quality of evidence).
- All known prior culture data should be provided with the loaned endoscope. If the loaned endoscope is found to be culture positive, then the manufacturer should be notified (Strong recommendation, Moderate quality of evidence).

Situations arise where endoscopy units may use endoscopes that are not owned or leased by them (ie, loaned endoscopes). The endoscopy unit has both a legal and ethical responsibility to ensure that loaned endoscopes are safe to use on patients who undergo endoscopic procedures and that they are properly maintained while in the custody of the endoscopy unit. In some cases, endoscopy staff may be unfamiliar with the type and manufacturer of loaned endoscope, and thus staff should receive training with regard to the loaned endoscope with a focus on the reprocessing and maintenance of it. With regard to reprocessing of the loaned endoscope(s), the endoscopy unit should follow the manufacturers' IFU for reprocessing and the endoscopy unit's policies and procedures on reprocessing. Before the first use on patients, the loaned endoscope(s) must be reprocessed. Additionally, the loaned endoscope should be tracked for every case in which it is used to ensure traceability of patients for any infectious outbreaks and for recall purposes. When the facility's equipment is returned from servicing, the equipment should undergo an incoming inspection by clinical/bioengineering staff with a notation entered into the repair and maintenance log listing the model and serial number of the equipment, date the equipment is returned from servicing, visual inspection of the equipment for defects, functionality testing for operational readiness, and that the equipment has been reprocessed according to the facility's policy.

ENDOSCOPY UNIT INFECTION CONTROL LEADERSHIP

What are the essential elements of an endoscopy unit infection control leadership team?

Recommend.

- Endoscopy units should have a qualified, interdisciplinary, and diverse leadership team that meets regularly (Strong recommendation, Moderate quality of evidence).
- Endoscopy unit leadership team includes a designated, qualified individual who directs infection prevention plans and addresses infection outbreaks, should they occur (Strong recommendation, Moderate quality of evidence).
- In the event of an outbreak (ie, defined by the institution's infection control program) caused by a suspected infectious or chemical etiology, environmental sampling should be performed according to standard outbreak investigation protocols that comply with proper methodology and validated testing (Strong recommendation, Moderate quality of evidence).
- Endoscopy-related infections should be reported to the following (Strong recommendation, Low quality of evidence):
 - o Patient who underwent the procedure.
 - o Persons responsible for infection control at the institution, with notification of referring physician(s) and potentially affected patients as appropriate.
 - o Appropriate public health agency (state or local health department as required by state law or regulation).
 - o The FDA (www.fda.gov/medwatch). Medical Device Reports submitted through Medwatch can be reviewed on the FDA's Manufacturer and User Facility Device Experience database.
 - o The manufacturer(s) of the endoscope, disinfectant/sterilant, and/or AER (if used).

A high-quality and safe endoscopy unit needs to have a well-defined governance structure. Key objectives of the endoscopy unit leadership team are to develop policies and procedures that focus on infection control while at the same time directing performance improvement projects on enhancing and maintaining safe infection control standards. Clearly outlined administrative functions and responsibilities, accountability, development of policies and procedures, risk assessment, and managing and leading quality and safety improvement efforts have been defined and outlined as critical functions of an endoscopy unit leadership team.^{16,21,97}

The leadership team should be a diverse, multidisciplinary group that includes endoscopists, endoscopy nurses, and infection preventionists and possibly include endoscopy unit reprocessing personnel, risk management, key frontline endoscopy unit staff, and hospital/organizational leaders. At a minimum, an endoscopy unit must have a qualified individual who directs infection prevention plans.⁹⁸ An infection control champion develops

TABLE 3. Areas within flexible GI endoscope reprocessing that require further study and research

Staff training and competency of endoscope reprocessing skills
• What are the most effective educational modalities and tools for training reprocessing staff? • How does one ensure that an individual is competent to reprocess an endoscope? • How often do the skills of endoscope reprocessing personnel need to undergo competency assessments to maintain good compliance with all manufacturers' steps and effective log reduction of bioburden from manual cleaning and high-level disinfection? • How can automation, visual aids and technology facilitate total compliance with all recommended steps performed by the reprocessing personnel?
Endoscopy unit layout
• What is the optimal location of where endoscopes should be reprocessed, such as centralized sterile processing departments or decentralized areas where endoscopy unit staff perform reprocessing?
GI endoscope reprocessing
• What is the efficacy of repeating both manual cleaning and HLD compared with sterilization, only repeat HLD or HLD alone? • What wear and tear visualized on a borescope examination are permissible before the endoscope is returned to the manufacturer? • What role do borescopes play in auditing and assessing reprocessing staff? • What is the role of routine biomarker testing (ie, adenosine triphosphate testing) after the manual cleaning steps of endoscopes, particularly those with an elevator mechanism? • How should the postprocedure endoscope disinfection process be modified in the event of a procedure performed in a patient with known or suspected to harbor multidrug-resistant organisms? • If ethylene oxide sterilization of duodenoscopes is used in patients with known multidrug-resistant organisms, what repeat culturing of the duodenoscope is needed to confirm bacterial eradication? • Are there sufficient duodenoscopes and echoendoscopes available in the United States to allow for the extended turn-around time related to advanced reprocessing techniques such as ethylene oxide sterilization, culture and quarantine, or repeat HLD? What are the financial impacts on healthcare facilities from a capital standpoint if these techniques are used? • What is the accuracy of adenosine triphosphate to detect residual blood and protein in assessing the adequacy of endoscope reprocessing for quality assurance purposes? • What other markers (eg, total organic carbon) could serve as a surrogate for assessing endoscope reprocessing? • Do the use of alcohol flushes during the drying process aid in reducing contamination rates on endoscopes? • What is the maximum length of endoscope storage time that is permissible? • What is the efficacy and performance of liquid chemical sterilant processing systems compared with HLD automated endoscope reprocessor? • What time duration of applying forced medical air into endoscope channels is required to ensure that an endoscope is dried? • What degree of endoscope drying after HLD is required before patient use or endoscope storage? • What is the most effective method for confirming an endoscope is dry after HLD? • What are the optimal quality parameters that are needed for endoscope drying and storage? • What role could artificial intelligence or newer innovations play in improving the reprocessing process? • What is the efficacy and safety of disposable endoscopes (and disposable endoscope components) compared with standard endoscopes? What is the financial and environmental impact of using these newer technologies? • What other alternative methods can effectively and rapidly disinfect endoscopes? • What is the value and reliability of new AERs that incorporate other aspects of reprocessing, such as manual cleaning? • What devices that incorporate programmable features (eg, AERs, washers, sterilizers) should have lock-down mechanisms in place to prevent both user and manufacturer from deviating from the FDA-cleared instructions for use parameters for the device?
Endoscope accessories and associated equipment
• Do vacuum tubing and waste canisters used during endoscopy need to be changed on a per procedure basis or daily? • Is there an optimal and safe concentration of simethicone that can be used during endoscopy? • What is the clinical impact of simethicone on the adequacy of HLD and on the risk of transmission of infection? • Do enhanced reprocessing methods effectively remove simethicone residue?
Maintenance of endoscopes
• What is the correlation between endoscope durability and longevity and infection risk?
Endoscopy unit infection control leadership
• What methods should be used to identify a "physician champion" for the endoscopy unit infection control program? • What methods should be developed to implement a "culture of infection control" at all levels of patient care and delivery of services within an endoscopy unit? • What leadership skills and attitudes are required to address challenges and changes in the arena of endoscope reprocessing and endoscopy unit infection control?

educational materials on infection control practices for staff, facilitates change management on infection control topics, manages outbreaks of endoscopically transmitted infections should they occur, and ensures that improvements in the arena of infection control are sustained.^{99,100}

AREAS OF UNCERTAINTY

There are areas of uncertainty within endoscope infection control and reprocessing, especially in the arena of new technologies and innovations. Newer

endoscope technologies are on the horizon, which may help to minimize the infectious risk that endoscopes pose to patients. Similar to the transition to single-use accessories, there has been a movement toward the use of single-use, sterile endoscopes. There are a number of benefits of single-use endoscopes including eliminating the risk of cross-contamination and no required reprocessing. The FDA has cleared the use of sterile, single-use endoscopes for both colonoscopy¹⁰¹ and ERCP.¹⁰² Early data has shown some promising results with single-use endoscopes. For example, single-use duodenoscopes have performance ratings and completion times similar to reusable duodenoscopes when used in anatomic models, but single-use devices are associated with lower image quality.¹⁰³ In one clinical setting, single-use duodenoscopes were successfully used across a wide array of complex maneuvers, with few procedural adverse events and little crossover to reusable endoscopes.¹⁰² Despite these promising results, questions remain regarding the economic viability, environmental impact, ability to obtain similar performance outcomes across a wide array of operator experience, and patient reaction to single-use endoscopes. Along these lines, regulatory bodies have had a high degree of interest around disposable devices in endoscopy as evidenced by the FDA recently recommending that healthcare facilities transition to using duodenoscopes with either disposable components (including distal endcaps) or to fully disposable duodenoscopes when they become available in order to reduce the infectious risk to patients undergoing endoscopy.¹⁰⁴ Additional endoscope reprocessing research questions requiring further study are outlined in [Table 3](#).

ENDOSCOPE REPROCESSING AND CORONAVIRUS

Coronavirus disease 2019 (COVID-19) is caused by a novel member of the coronavirus family, severe acute respiratory syndrome–coronavirus 2 (SARS-CoV-2), and can lead to a spectrum of symptoms ranging from a mild viral illness to a severe acute respiratory syndrome. After initial reports of the illness from Wuhan, China in late December 2019, COVID-19 has progressed to a global pandemic. SARS-CoV-2 is transmitted by respiratory droplets and aerosols. Although infectious virus has not been consistently isolated from stool samples, reports have documented the presence of viral RNA in such samples.¹⁰⁵ As a result, several questions around the role of endoscope reprocessing, infection control, and endoscopy units during the COVID-19 pandemic have been raised.

Manual cleaning and HLD eliminates nearly all microorganisms from endoscopes during reprocessing.³⁹ The

viricidal nature of detergents used during reprocessing are effective at inactivating coronaviruses, including SARS-CoV-2.¹⁰⁶ Transmission of viral infections during endoscopy is rare and when identified has been attributed to noncompliance with reprocessing steps. Accordingly, there is no need for specific alterations in reprocessing protocols during the pandemic, and a multisociety document exists specifically addressing COVID-19–related issues and infection control within endoscopy units.¹⁰⁷

CONCLUSIONS

Flexible GI endoscopy is a valuable diagnostic and therapeutic tool for the care of patients with GI, pancreas, biliary, and hepatic disorders. Compliance with accepted guidelines for the reprocessing of GI endoscopes between patients is paramount to the safety and success of their use. When these guidelines are followed, pathogen transmission can be effectively and significantly minimized, thereby reducing harm to patients. However, recent infectious outbreaks attributed to endoscopes have heightened awareness around infection control practices within endoscopy units. The reprocessing of endoscopes and minimizing endoscopy-related infections require a team-based, multidisciplinary approach and comprises several interrelated and critical elements; this includes staff training and ongoing competency assessment, efficient endoscopy unit layout, maintenance of endoscopes, reprocessing of endoscope accessories, and a robust, diverse endoscopy unit leadership team. Consequently, ongoing compliance with accepted reprocessing standards is required and increased efforts, research, and resources should be directed toward improving compliance with established reprocessing guidelines.

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Abbreviations: AER, automated endoscope reprocessor; ATP, adenosine triphosphate; CDC, Centers for Disease Control and Prevention; COVID-19, coronavirus disease 2019; EtO, ethylene oxide; FDA, U.S. Food and Drug Administration; GRADE, Grading of Recommendations Assessment, Development and Evaluation; HLD, high-level disinfection; IFU, instructions for use; SARS-CoV-2, severe acute respiratory syndrome-coronavirus 2

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Current affiliations: Division of Gastroenterology and Hepatology, University of California San Francisco, San Francisco, California, USA (1), Department of Medicine, UCLA Health, Los Angeles, California, USA (2), Department of Digestive Diseases, Cleveland Clinic, Cleveland, Ohio, USA (3), Division of Gastroenterology, Washington University, St Louis, Missouri, USA (4), Division of Gastroenterology, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts, USA (5) Division of Gastroenterology, Hepatology and Nutrition, McGovern Medical School, UTHealth, Houston, Texas, USA (6), Division of Gastroenterology and Hepatology, University of Colorado Anschutz Medical Campus, Aurora, Colorado, USA (7).

APPENDIX 1

Methods

Overview

This guideline was prepared by a working group of the American Society for Gastrointestinal Endoscopy (ASGE) Quality Assurance in Endoscopy committee. It includes a systematic review of available literature for the reprocessing of flexible GI endoscopes. After evidence synthesis, recommendations were drafted by the full panel on April 20, 2019 and approved by the members of the Quality Assurance in Endoscopy and Standards of Practice committees as well as by the ASGE Governing Board in the fall of 2019.

Panel composition and conflict of interest management

The panel consisted of 2 content experts (R.M. and M.S.) and committee members with expertise in systematic reviews and meta-analysis (N.T.), committee chairs (L.W.D. and S.W.), and other committee members. All panel members were required to disclose potential financial and intellectual conflicts of interest, which were addressed according to ASGE policies (<https://www.asge.org/forms/conflict-of-interest-disclosure> and <https://www.asge.org/docs/default-source/about-asge/mission-and-governance/asge-conflict-of-interest-and-disclosure-policy.pdf>).

Formulation of clinical questions

For all clinical questions potentially relevant patient-important outcomes were identified a priori and rated from not important to critical through a consensus process. Relevant clinical outcomes included the overall rate of microbial contamination after flexible endoscopes had undergone various methods of reprocessing such as single HLD, repeat HLD, and ethylene oxide sterilization. Additionally, the rate of microbial contamination per various durations of endoscope storage time for flexible endoscopes and the role of microbiologic surveillance and testing in determining persistent microbial contamination after reprocessing were assessed.

Literature search and study selection criteria

Separate literature searches were conducted for overall rate of endoscope microbial contamination using various methods of reprocessing, rate of endoscope microbial contamination with various durations of endoscope storage times, and role of microbiologic testing in determining persistent microbial contamination of endoscopes after reprocessing. A medical librarian performed a comprehensive literature search from 1960 to March 31, 2018 in the following databases: Ovid MEDLINE(R) Epub Ahead of

Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily, Ovid MEDLINE and Versions(R); EMBASE (Elsevier); Wiley Cochrane Library. Combinations of text words and subject headings were used, including Endoscopes, Gastrointestinal and Equipment Contamination or Equipment Reuse or Sterilization or Simethicone or Luminescent Measurements or Biofilms or Adenosine Triphosphate or Quality Control. The search was limited to English language articles with animal studies excluded. No date limits were applied. All article types were included, except comments, editorials, letters, notes, case reports, and conference abstracts published before 2016. The literature search yielded 770 citations.

For each treatment modality a literature search for existing systematic reviews and meta-analyses was performed. If none was identified, a full systematic review and meta-analysis (when possible) was conducted using the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-analyses criteria. Citations were imported into EndNote (Thompson Reuters, Philadelphia, Pa, USA), and duplicates were removed. Studies were first screened by title and abstract and then by full text, and all conflicts were resolved by consensus.

Data extraction and statistical analysis

If data extraction was needed for a meta-analysis, data were extracted by 2 independent reviewers using Microsoft Excel (Microsoft Corporation, Redmond, Wash, USA). The primary estimate of effect was based on a priori identified outcomes of interest. For outcomes with limited or no available direct comparisons, indirect comparisons were used to estimate the magnitude and direction of effect. Heterogeneity was assessed using the I^2 and Q statistic. Significant heterogeneity was defined at $I^2 > 50\%$ and significant P value ($<.05$) on the Q statistic. Random-effects models were used if significant heterogeneity was detected. Otherwise, fixed-effects models were used. Studies were weighted based on their size. A priori sources of heterogeneity for each outcome were hypothesized and addressed in sensitivity analyses when applicable. Publication bias was assessed using funnel plots and the classic-fail-safe. Statistical analyses were performed using Comprehensive Meta Analysis V₃ (Biostat Inc, Englewood, NJ, USA).

Certainty in evidence (quality of evidence)

The certainty in the body of evidence (also known as quality of the evidence or confidence in the estimated effects) was assessed for each effect estimate of the outcomes of interest on the following domains: risk of bias, precision, consistency and magnitude of the estimates of effects, directness of the evidence, risk of publication bias, presence of dose–effect relationship, and an assessment of the effect of residual confounding.

Considerations in the development of recommendations

During an in-person meeting, the panel developed recommendations based on the following: the certainty in the evidence, the balance of benefits and harms of the compared management options, the assumptions about the values and preferences associated with the decision along with available data on resource utilization, and cost-effectiveness. The final wording of the non-Grading of Recommendations Assessment, Development and Evaluation recommendations (including direction and strength), remarks, and qualifications were decided by consensus using criteria highlighted in [Supplementary Table 1](#),¹⁰⁹ (available online at www.giejournal.org) and were approved by all members of the panel. The strength of individual recommendations is based on the aggregate quality of evidence and an assessment of the anticipated benefits and harms. Weaker recommendations are indicated by phrases such as “we suggest...,” whereas stronger recommendations are stated as “we recommend....” Recommendations for clinical questions addressed using Grading of Recommendations Assessment, Development and Evaluation methodology are labeled as either “strong” or “conditional” with a description of the quality of supporting evidence (very low, low, moderate, high). [Supplementary Table 2](#) (available online at www.giejournal.org) provides the suggested interpretation of strong and conditional recommendations by patients, clinicians, and healthcare policymakers.

APPENDIX 2

Endoscopy unit layout

What is the optimal endoscopy unit layout and flow for the reprocessing of endoscopes?

Recommend.

- Reprocessing facilities are designed with attention to the optimal flow of personnel, endoscopes, and devices to avoid contamination between entering soiled instruments and reprocessed instruments (Strong recommendation, Low quality of evidence).
- Reprocessing of endoscopes (other than immediate pre-cleaning/point of use treatment) are not performed in patient care areas because of risk of patient exposure to contaminated surfaces and devices (Strong recommendation, Low quality of evidence).
- There are separate areas for manual cleaning and disinfecting equipment and drying and storage of clean endo-

scopes (Strong recommendation, Low quality of evidence).

- Facilities where endoscopes are used and disinfected are designed to provide a safe environment for healthcare workers and patients (Strong recommendation, Moderate quality of evidence).
- Eyewash stations are available to reprocessing staff using caustic chemicals (Strong recommendation, Low quality of evidence).
- Eyewash stations are placed near sinks used for washing or soaking soiled endoscopes (Strong recommendation, Low quality of evidence).
- Air exchange equipment (eg, ventilation system and exhaust hoods) are used to minimize the exposure of all persons to potentially toxic vapors. The vapor concentration of the chemical disinfectant used should not exceed allowable limits^{37,108} (eg, those of the American Conference of Governmental Industrial Hygienists and the Occupational Safety and Health Administration) (Strong recommendation, Moderate quality of evidence).

Well-designed endoscopy units maximize efficiency, improve workflows, ensure safe working conditions, and enhance the patient and staff experience. Separate, dedicated rooms for manual cleaning (ie, decontamination or “dirty” room) and disinfection (ie, reprocessing or “clean” room) of endoscopes are required and should be in close proximity to one another. The sizes and required elements within these rooms comply with the American Institute of Architects and U.S. Department of Health Guidelines for Design and Construction of Hospital and Health Care Facilities¹¹⁰ and conform to specific federal, state, and local regulatory agencies and appropriate healthcare accreditation groups.^{111,112} Ensuring adequate space to efficiently and safely perform the tasks within each room (ie, sufficient lighting, appropriate ventilation, necessary plumbing, and electrical support) and having the needed equipment and accessories influence the layout of these rooms. Given the high volume and repetitive nature of reprocessing endoscopes, ergonomic designs should be taken into consideration and safety engineering practices used within these areas. The anticipated workload of the reprocessing area can impact equipment decisions; for example, a 1.5 to 2:1 ratio of automatic endoscope reproprocessors to procedure rooms has been advocated to ensure that an endoscopy unit is operating efficiently.¹¹³ After reprocessing is complete, endoscopes are stored in a separate, secure space. Last, the layout of the endoscopy unit should allow for either unidirectional or circular patient and staff flow, with the goal of minimizing the number of steps taken by individuals.^{113,114}

Endoscope accessories and associated equipment

What is the frequency for replacing the tubing used for insufflation of air, irrigation water, suction tubing, and waste vacuum canisters?

Recommend.

- A backflow-prevention valve used in the irrigation/flushing system requires replacement/reprocessing per procedure, whereas the irrigation tubing can be replaced on a daily basis (Strong recommendation, Low quality of evidence).
- The interval for exchange of vacuum tubing and waste canisters remains incompletely understood but, at a minimum, should be changed daily (Strong recommendation, Low quality of evidence).

No data exist pertaining to the safety or potential risk of per procedure versus per day exchange of many endoscope attachments (ie, valves, irrigation and suction tubing, and canisters), and most guidelines do not address this issue. The U.S. Food and Drug Administration has provided guidance regarding the reprocessing of backflow valves used in the irrigation system (eg, valve intended to prevent the proximal irrigation system from being contaminated by the backflow of fluids from the patient).¹¹⁵ These recommendations stipulate that the most distal device (eg, components of the irrigation system between the patient and the backflow-prevention valve, including the backflow-prevention valve) require replacement or reprocessing before reuse. On the other hand, proximal devices (eg, components of the irrigation system between the water bottle and the backflow-prevention valve, excluding the backflow-prevention valve) can be used for multiple patients in 1 day. This means the backflow-prevention valve needs to be replaced per procedure, but the water bottle feeding the irrigation tubing can be changed daily. However, because suction valves allow 2-way flow when open, the interval for exchange of vacuum tubing and waste canisters remains incompletely addressed but, at a minimum, should be changed daily.

Do water bottles used during endoscopy need to be filled with sterile water?

Recommend.

- Water bottles (used for cleaning the lens of the endoscope and irrigation during the procedure) undergo daily high-level disinfection or sterilization (or are replaced daily) per manufacturers' instructions for use (Strong recommendation, Low quality of evidence).
- Use sterile water for those endoscopic procedures with intended traversal of mucosa (eg, peroral endoscopic myotomy procedures, endoscopic necrosec-

tomy, interventional EUS) (Strong recommendation, Low quality of evidence).

- The endoscopy unit follows manufacturers' instructions for use on the type of water to be used in the water bottle for an endoscopic procedure. In the absence of a manufacturer recommendation/guidance, the endoscopy unit performs an independent risk assessment for use of sterile versus clean tap water for standard endoscopic procedures (eg, esophagogastroduodenoscopy (EGD) and colonoscopy) in which mucosal penetration would be unusual/not anticipated (Strong recommendation, Low quality of evidence).

Several questions arise around the use of water bottles during endoscopy. First, water bottles (used for cleaning the lens of the endoscope and irrigation during the procedure) should be either high-level disinfected/sterilized or replaced at least daily and according to manufacturers' instructions for use. In particular, GI endoscope manufacturers recommend sterile water should be used for endoscope lens cleaning and, in some cases, for irrigation.^{32,33,38} Second, there is controversy around the type of water that should be used in water bottles during endoscopy. There is no increased risk of bacterial growth within water bottles or associated clinical adverse events when either tap or sterile water is used.^{116,117} Additionally, some authors advocate that using tap water for endoscopic procedures performed in nonsterile areas of the GI tract may be appropriate; arguments for this approach note that patients undergoing endoscopy drink tap water both before and after the procedure with no adverse events, and pathogens that may be found in tap water do not necessarily cause disease outside of certain circumstances.¹¹⁸ This limited data suggest that tap water may be safe to use during endoscopy in some circumstances and is potentially cost-effective. Simultaneously, sterile water is appropriate to use in some clinical situations. For example, using sterile water in irrigation bottles is recommended for immunosuppressed patients undergoing procedures (eg, liver transplant patients) because such a practice leads to fewer waterborne healthcare-associated colonization/infections.^{119,120} At the same time, improved water quality has been correlated with prevention of the transmission of antibiotic-resistant bacteria. In summary, although tap water may be safe to use in water bottles during some endoscopic procedures, given the concern that in selected patients it may be harmful, sterile water should be considered as the primary water source used in water bottles during endoscopy, especially in situations where endoscopy is expected to be performed in nonsterile areas or where mucosa is expected to be traversed or penetrated.^{15,16,20,32,33,37,38}

In patients undergoing endoscopy, does the use of simethicone (either in the water bottle or through the endoscope working channel) affect the reprocessing of endoscopes?

Recommend.

- The endoscopy unit follows manufacturers' instructions for use on the addition of simethicone in water bottles and irrigation devices including cleaning and disinfection of endoscopes after simethicone has been used (Strong recommendation, Moderate quality of evidence).

Suggest.

- If simethicone is requested, then use the lowest concentration (ie, .5% or less) and smallest volume needed. Also, when simethicone is used during endoscopy it should be administered through the endoscope working channel (Conditional recommendation, Moderate quality of evidence).

Concerns have been raised about the use of simethicone and other defoaming agents during endoscopy. The addition of simethicone to water bottles or its administration through endoscope working channels is believed to reduce bubbles noted during endoscopy, which can improve mucosal visualization within the GI tract.^{121,122} However, data have emerged showing that simethicone droplets may persist in endoscope working channels despite adequate high-level disinfection¹²³ or within waterjets used during endoscopy¹²⁴; these findings have raised concerns about the infectious risk it may pose to patients. Two factors impact the persistence of simethicone within endoscope working channels: concentration of simethicone used and delivery method. Using a lower simethicone concentration (.5%) is no different from using sterile water alone. Not until higher concentrations of simethicone are used are any differences appreciated in terms of visualizing droplets within working channels, yet this observation disappears if endoscopes undergo dual reprocessing. Furthermore, the mode of simethicone delivery plays an important role. More liquid droplets are detected in endoscopes that have simethicone delivered via a water bottle/irrigation jet channel compared with having simethicone only flushed through the working channel.¹²⁵ As a result, a number of recommendations have been proposed by societies and endoscope manufacturers ranging from discouraging the use of any simethicone during endoscopy to using the lowest possible concentration when it is necessary during a procedure.

Reprocessing of endoscope accessories

What factors should be considered in the reprocessing of endoscope accessories and devices?

Recommend.

- Reusable endoscopic accessories (eg, biopsy forceps or other cutting instruments) that break the mucosal bar-

rier are mechanically cleaned and then sterilized between each patient use (Strong recommendation, Low quality of evidence).

- Reprocessing of single-use items is not performed unless the facility can comply with FDA guidance for reprocessing single-use devices (Strong recommendation, Low quality of evidence).
- Reprocessing of nonendoscopic devices, accessories, and attachments complies with manufacturers' recommendations (Strong recommendation, Low quality of evidence).

The use of accessories/devices within endoscopy units plays a vital role in the care of patients undergoing endoscopy and helps to aid in the diagnosis and treatment of many GI conditions. There has been a growing trend toward and recommendations for using single-use accessories/devices during endoscopy. Several advantages to this approach include helping to prevent cross-contamination to patients and staff, reducing staff injuries during reprocessing, and ensuring a functioning accessory/device with each use. When used, single-use endoscopic accessories/devices should be discarded immediately after a procedure and not be reprocessed.^{2,16,20,32,33,38,69} Some endoscopic accessories/devices are defined as reusable and should be reprocessed/sterilized per manufacturer instructions for use.

Endorsing organizations

The original 2003, 2011, and 2016 position statements were endorsed by the collaborating organizations listed below. This 2018/2019 update was initially drafted by a subcommittee of the Quality Assurance in Endoscopy Committee of American Society for Gastrointestinal Endoscopy and members of the Standards of Practice committee. Thereafter, significant input from the endorsing organizations was incorporated, and it was 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:

- 2003 Endorsing Organizations: American Society for Gastrointestinal Endoscopy, Society for Healthcare Epidemiology of America, 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, and Federated Ambulatory Surgery Association.
- 2011 Endorsing Organizations: American Society for Gastrointestinal Endoscopy, Society for Healthcare

Epidemiology of America, 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, Joint Commission, Society of American Gastrointestinal and Endoscopic Surgeons, Society of Gastroenterology Nurses and Associates.

- 2016 Endorsing Organizations: American Society for Gastrointestinal Endoscopy, American College of Gastroenterology, American Gastroenterological Association, American Society of Colon and Rectal Surgeons, Association of Professionals in Infection Control and Epidemiology, Society for Healthcare Epidemiology of America, Society of American Gastrointestinal and Endoscopic

Surgeons, Society of Gastroenterology Nurses and Associates.

Disclosure

Users should always refer to FDA-cleared labeling and manufacturers' instructions for device-specific reprocessing guidance. Accrediting bodies will typically survey for performance in accordance with this guidance. In rare cases, FDA-cleared labeling claims and/or manufacturers' guidance may be 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.¹²⁶

SUPPLEMENTARY TABLE 1. Grading of Recommendations Assessment, Development and Evaluation categories of quality of evidence

Categories	Meaning	Interpretation
High	We are confident that the true effect lies close to that of the estimate of the effect.	Further research is very unlikely to change our confidence in the estimate of the effect.
Moderate	We are moderately confident in the estimate of the effect; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.	Further research is likely to have an impact on our confidence in the estimate of the effect and may change the estimate.
Low	Our confidence in the estimate of the effect is limited; the true effect may be substantially different from the estimate of the effect.	Further research is very likely to have an impact on our confidence in the estimate of the effect and is likely to change the estimate.
Very low	We have very little confidence in the estimate of the effect; the true effect is likely to be substantially different from the estimate of the effect.	Any estimate of the effect is very uncertain.

SUPPLEMENTARY TABLE 2. Interpretation of definitions of the strength of recommendation using Grading of Recommendations Assessment, Development and Evaluation framework

Implications for	Strong recommendation	Conditional recommendation
Patients	Most individuals in this situation would want the recommended course of action, and only a small proportion would not.	Most individuals in this situation would want the suggested course of action, but many would not.
Clinicians	Most individuals should receive the intervention. Formal decision aids are not likely to be needed to help individual patients make decisions consistent with their values and preferences.	Recognize that different choices will be appropriate for individual patients and that you must help each patient arrive at a management decision consistent with his or her values and preferences. Decision aids may be useful in helping individuals to make decisions consistent with their values and preferences.
Policymakers	The recommendation can be adopted as policy in most situations. Compliance with this recommendation according to the guideline could be used as a quality criterion or performance indicator.	Policymaking will require substantial debate and involvement of various stakeholders.