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SPECIAL ARTICLE

Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update

Prepared by: REPROCESSING GUIDELINE TASK FORCE

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

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

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

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

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

SPAULDING CLASSIFICATION FOR MEDICAL DEVICES AND LEVEL OF DISINFECTION

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

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

PATHOGEN TRANSMISSION

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

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

Nonendoscopic transmission of infection

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

Endoscopic transmission of infection

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

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cases of previously unknown hepatitis and HIV. Whether the identified cases were related to prior endoscopy was not determined, however.[9,29] To date, there is no epidemiologic or microbiologic evidence linking the potential endoscopic exposures to the identified illnesses. Similar concerns for transmission via endoscopes used in otorhinolaryngology were not substantiated by genetic analysis of hepatitis C cases in 1 large study among veterans.[30] Nevertheless, this demonstrates that multiple endoscopic devices and accessories, in addition to the endoscope, may be subject to lapses in reprocessing and subsequently put patients at risk of exposure and possibly infection.

When the CDC Division of Healthcare Quality Promotion (formerly the Hospital Infection Program) reviewed its log of investigations between 1980 and 2002, no outbreaks of infection associated with GI endoscopy were found.[1,2] More recently, the CDC has investigated a number of outbreaks attributed to duodenoscope-related infections. Since 1990, healthcare facilities and manufacturers have been required to report to the FDA's Manufacturer and User-Facility Device Experience (MAUDE) database any information that reasonably suggests that a device (such as an endoscope, accessory, or automated endoscope washer–disinfector) has caused or contributed to a death, injury, or serious illness of a patient. Review of this open access, non–peer-reviewed database from 1990 to 2002 revealed 7 possible episodes of pathogen transmission during GI endoscopy. Between 2002 and 2010, the MAUDE database contained reference to infections suspected to have occurred after lapses in reprocessing, particularly those related to failure to use appropriate attachments to specialty channels or failure to clean all channels during reprocessing.[31] Recent scrutiny of press releases and other publicly available data from 2005 to 2012 suggests that the need for patient notification and screening because lapses in reprocessing continue to be a problem.[32] Subsequent to 2012, numerous MAUDE database submissions have cited transmission of infections after performance of ERCP (discussed below). Although there are no well-designed prospective studies on the incidence of pathogen transmission during GI endoscopy, and estimates of pathogen transmission based on case reports undoubtedly underestimate the true incidence of infection, available evidence suggests that this is a rare event.

Transmission of infection by duodenoscopes

Patient-to-patient transmission of carbapenem-resistant Enterobacteriaceae or other multidrug-resistant organisms by contaminated duodenoscopes during ERCP, despite appropriate and optimal reprocessing, has been reported by at least 8 major U.S. medical centers.[17-21] Similar outbreaks have been reported from Europe.[33,34] Altogether, 10 to 12 outbreaks and at least 60 clinical infections have been reported in the United States and 25 or more outbreaks resulting in over 250 infections and more than 20 deaths potentially related to duodenoscope transmission of infection have been reported worldwide in the past 3 years.[35,36,139] More than 1000 potentially exposed patients have been advised to undergo screening cultures, and at least 100 patients are believed to harbor silent carriage of the offending organisms. Transmission is attributed to persistent contamination at the elevator region and/or the elevator cable and has occurred with instrument designs from all major duodenoscope manufacturers.

GI ENDOSCOPE REPROCESSING

Flexible GI endoscopes should first be comprehensively cleaned and then subjected to at least HLD. This standard has been recommended by federal agencies such as the FDA[37] and CDC[38] and professional organizations such as the ASGE, the American College of Gastroenterology, the American Gastroenterology Association, the Society of Gastroenterology Nurses and Associates, the Association of PeriOperative Registered Nurses (AORN), and the Association for Professionals in Infection Control and Epidemiology.[39-44] These and other organizations have developed guidance documents that detail the sequence and specifics of each element of appropriate endoscope reprocessing.[39-47] These guidelines remain appropriate for the reprocessing of end-viewing flexible GI endoscopes when methodically practiced and competency of staff performing the reprocessing has been ensured. However, they have been supplemented by recent interim guidance from the FDA for reprocessing of side-viewing duodenoscopes.[48,49] Guidance for reprocessing of duodenoscopes will undoubtedly evolve further in coming years, so user facilities should comply with updated recommendations from manufacturers and the FDA as they become available.

In early 2015 the FDA emphasized the importance of training, oversight, and competency testing for reprocessing staff and close attention to optimal cleaning of the elevator mechanism on the leading end of duodenoscopes.[48] In May 2015 an FDA advisory panel emphasized the importance of ensuring availability of duodenoscopes for clinical care and expressed concern that existing reprocessing practices, even when performed appropriately, appeared to be insufficient for ensuring safety of side-viewing duodenoscopes.[50] In August 2015 the FDA went on to advise that together with "strict adherence to the duodenoscope manufacturer's reprocessing instructions" all centers using duodenoscopes should "closely evaluate whether they have the expertise, training and resources to implement one or more of several different options," including microbiologic culturing, ethylene oxide sterilization, use of a liquid chemical sterilant processing system, and repeated HLD.[49]

Compliance with reprocessing guidelines can still be improved. In a 2004 survey of Society of Gastroenterology

Nurses and Associates members at centers in the Mid-Atlantic States, compliance with published standards was inconsistent, and there was wide variation in compliance with both global principles and specific steps of manual cleaning, HLD, drying, and quality monitoring.[51] In 2009 the CDC piloted an infection control audit tool during inspection of 68 ambulatory surgical centers in 4 states to assess compliance with recommended practices.[10] Compliance with recommendations for reprocessing of endoscopic equipment was not uniform in 28% of 67 ambulatory surgery centers.

In October 2015 the FDA mandated all 3 duodenoscope manufacturers to prepare postmarket surveillance studies to evaluate whether, and how often, end users can appropriately complete existing cleaning and reprocessing instructions and how often they accomplish complete clearance of contaminating organisms when standard techniques are used.[52] Data from these studies will likely be available to inform practice in coming years. In the meantime, practice-based efforts should be aimed at improving compliance with accepted guidelines in all venues where endoscopy is performed.

To ensure ongoing awareness and optimal performance of reprocessing steps, all staff involved with the use, cleaning, and processing of flexible endoscopes should undergo documented brand and model-specific training at commencement of use and at least annually. A single, standard, work process within 1 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 or regulatory agencies or guidance from professional organizations is incorporated into unit policies and procedures.

Additionally, each endoscopy unit must have a comprehensive quality control program for reprocessing endoscopes, with a specific focus on duodenoscopes if they are used. This program should include specific written procedures for training staff involved with the processing of endoscopes, monitoring the actual cleaning and processing of endoscopes, and records of institutional compliance. In addition, documentation of all equipment tests, processes, and quality monitors used during endoscope reprocessing must be maintained, along with other staff training and processing records.

UNRESOLVED ISSUES REQUIRING FURTHER STUDY

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

The interval of storage after which endoscopes should be reprocessed before use, sometimes termed "hang time" or "shelf-life," has been the subject of limited investigations.[53-58] The available data suggest that contamination during appropriate storage for intervals of 7 to 21 days is negligible, unassociated with duration, occurs predominantly on the exterior of instruments, and involves only common skin organisms rather than significant pathogens. One study demonstrated limited contamination, predominantly by environmental nonpathogenic organisms, within 24 hours of reprocessing.[53] In a similar study, limited contamination by nonpathogenic organisms was noted on exterior surfaces and valve ports of endoscopes but none from fluid flushed through the biopsy channels after 5 days of storage.[54] A subsequent study serially sampled endoscopes during clean storage for 14 days.[55] Positive cultures were identified during the first 5 days of sampling but not thereafter. In a duplicate second phase, no surveillance cultures were positive, and in a third phase of testing after 7 days of storage, only a single culture was positive for *Staphylococcus epidermidis*, a low virulence skin organism. A recent study that performed a total of 96 cultures in 10 endoscopes at 0, 7, 14, and 21 days identified nonpathogenic organisms in 29 cultures, without relationship to time frame, and only 4 potential pathogens in low titers, also without relationship to time frame, location, or type of endoscope.[56] Another study cultured 4 colonoscopes after 3 and 5 days and 1, 2, 3, 4, 6, and 8 weeks of shelf time.[57] No medically significant growth was detected. Fewer than 2 colony-forming units of medically insignificant bacteria were identified in only 2 samples, at days 14 and 42. Hence, although reuse within 21 and perhaps even 56 days appears to be safe,[59] the data are insufficient to provide a maximal outer duration for use of appropriately cleaned, reprocessed, dried, and stored flexible endoscopes.

In the absence of more robust data, reprocessing within this interval *before use* may be advisable for instruments used in selected settings, such as procedures with anticipated entry to otherwise sterile regions, including the biliary tree, pancreas, or peritoneal space. This means reprocessing before reuse, not reprocessing of stored endoscopes after fixed intervals without scheduled reuse. With the evolving data, yet in the interest of utmost caution, the Society of Gastroenterology Nurses and Associates currently espouses a maximal storage interval without reprocessing of 7 days,[40] the Association for Professionals in Infection Control and Epidemiology is silent on reprocessing intervals,[44] and AORN recommends that a multidisciplinary team in each healthcare facility should conduct a risk assessment to determine the maximum storage time for an endoscope before it needs to be processed for use on the next patient.[43]

The importance of commercial endoscope storage cabinets using forced irrigation of endoscope channels with

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warmed or filtered air during storage for keeping endoscopes free of contamination remains incompletely defined. Several studies of proprietary cabinets suggest reduced culture loads in either clean or inoculated endoscopes after storage, although the use of alcohol flushes and adequacy of drying before storage were minimally defined.[60-62]

The optimal frequencies for replacement of (1) clean water bottles and tubing for insufflation of air and lens wash water and (2) waste vacuum canisters and suction tubing have not been determined. Concern is related in 1 instance to the potential for backflow from a soiled endoscope against the direction of forced fluid and air passage into the clean air/water source and in the other instance from a contaminated tubing and collection chamber against a vacuum into clean instruments used for subsequent patients. No data exist pertaining to the safety or potential risk of per procedure versus per day exchange of these attachments, and most guidelines do not address either issue. The FDA has released nonbinding draft guidelines regarding the reprocessing of backflow valves to prevent contamination of more distal tubing and devices in close proximity to the patient.[63] They stipulate that the most distal device or tubing nearest to the source of contamination and the accompanying exposed anti-backflow valves require replacement or reprocessing before reuse. Hence, for endoscope air/water (lens wash) channels, this means the air/water valve needs to be replaced per procedure but the water bottle feeding this channel can be changed daily. One-way valves for inline high-volume water flushing require replacement on a daily basis. Suction valves require replacement per procedure. However, given that suction valves allow 2-way flow when open, the interval for exchange of vacuum tubing and waste canisters remains incompletely addressed by the draft guideline. AORN recommends that water and irrigation bottles should be high-level disinfected or sterilized at least daily.[43] Some accreditation organizations survey for exchange of waste vacuum canisters and tubing for each procedure. Both issues warrant study.

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 reprocessing guidelines of several international organizations, including the Gastroenterological Society of Australia and the guideline of the combined European Society of Gastrointestinal Endoscopy and the European Society of Gastroenterology and Endoscopy Nurses and Associates committee.[64-66] Available data suggest that detection of nonenvironmental pathogens common to the GI tract in reprocessed instruments should serve as an indicator of contaminated or faulty reprocessing equipment, inadequate solutions, or failed human processes.[67-69] Practical use of endoscope cultures, however, 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 due to environmental contamination.

The CDC has provided guidance on performance of surveillance cultures for quality assurance,[70] although the nonvalidated methods provided were developed for source investigation of disease outbreaks rather than for surveillance purposes. Out of concern that recipients of negative cultures will misinterpret them as evidence of sterility, the American Society for Microbiology has advised against performance of endoscope cultures by hospital clinical diagnostic labs. They advise that endoscope cultures for either surveillance or outbreak investigations should be submitted to reference labs licensed to perform environmental cultures.[71] In May 2015 the FDA's Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee discussed the CDC's interim guidance for surveillance for bacterial contamination of duodenoscopes after reprocessing and concluded "the guidance is not sufficient in the current form to be implemented by healthcare facilities as a best practice." Furthermore, the panel expressed their belief that "more data and validation testing is needed before a surveillance program should be implemented by healthcare facilities."[50]

Endoscope cultures have also been used for routine *per procedure* confirmation of reprocessing adequacy for duodenoscopes. One major U.S. medical center resolved an ongoing outbreak of transmission related to duodenoscopes by using routine cultures after reprocessing of every instrument. In this so-called culture and quarantine approach, all instruments are sampled after HLD and then stored for 48 hours pending return of culture results demonstrating absence of pathogenic organisms before reuse.[72] It remains to be determined whether such an approach is practically or financially feasible for all centers performing procedures using duodenoscopes.

Uniform standards and guidance for sampling and culture technique or for use of alternate indicators of adequate cleaning are lacking. The Gastroenterological Society of Australia standards provide guidance for interpretation of varied culture results.[69] As noted, the recently distributed CDC methodology was designed for outbreak investigation and is not validated for quality surveillance of reprocessing adequacy or for confirmation of sterility.

Alternative indicators of adequate reprocessing have been proposed[73-75] but remain investigational and have not been widely applied in clinical practice.[76] Most widely studied is the use of testing for adenosine triphosphate residue as a potential marker of cleaning adequacy before exposure to HLD.[77] Although adenosine triphosphate testing methodology and threshold values are not standardized and adenosine triphosphate test results do not closely correlate with terminal HLD

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outcome, they do appear to correlate with clearance of bioburden by precleaning and manual cleaning steps. This test of bioburden therefore, may be useful for training, competency testing, and spot surveillance of the cleaning steps before HLD. Further research into methodology and utility of surveillance cultures or sampling is encouraged.

Relatively new technologies for automated washing and HLD with limited or no prior manual washing or brushing have been cleared by the FDA in recent years.[3] The demonstration of efficacy and FDA clearance for these technologies were based on laboratory testing and limited clinical use, supported by sophisticated research techniques. Independent, company-sponsored studies also demonstrated significant clearance of protein and other bioburden.[78] For duodenoscopes, the FDA currently advises that "the AER cleaning cycle only be used as a supplement to thorough manual cleaning according to the duodenoscope manufacturer's instructions."[79] These technologies, and those to come, warrant further well-designed, peer-reviewed studies using commercially available machines in clinical settings.

Endoscope durability and longevity are incompletely understood. Data from high-volume units suggest common intervals between major and minor repairs, but there are only limited published reports questioning material durability and the potential for reduced function or reduced ability to attain HLD after some interval of years or number of procedures. One study correlated greater surface adhesion of bacteria with simulated repetitive use equivalent to a number of years of high-volume use.[80] Two recent reports of duodenoscope contamination were related to unexpected wear and/or vendor-identified need for repairs, even in fully functional instruments that passed local user assessment of function.[33,72] Because instruments from low-volume endoscopy units may be retained for many years and those from busy departments are often sold on secondary markets, where they remain in use both in the United States and in other regions of the world, the manufacturers and resellers are encouraged to study and communicate data on these issues to guide the healthcare industry. Questions about the durability of endoscopes remain.

The optimal methods for cleaning and disinfection, or sterilization, of duodenoscopes remain incompletely defined. The spread of antibiotic-resistant organisms has served as an indicator alerting us to the now recognized risk of transmission of infection between patients by duodenoscopes that have been subjected to appropriate "optimal" cleaning and HLD. Indeed, the FDA Advisory Panel concluded that "duodenoscopes and AERs (automated endoscope reprocessors) do not provide a reasonable assurance of safety and effectiveness."[50] Although some panelists held that HLD is adequate when done properly, most believed that duodenoscopes should be reclassified as critical devices in the Spaulding Classification, thus shifting expectations toward sterilization. A variety of interim screening and reprocessing measures has been proposed and advised by the FDA to enhance the safety of duodenoscope reuse at this time,[35,46,81] and updated validation studies for duodenoscope reprocessing have recently been submitted to the FDA by all 3 endoscope manufacturers.[82] Nevertheless, no modality that is efficacious, efficient, and cost-effective has emerged for duodenoscope *sterilization* today. At present, the only low-temperature sterilization technique available is prolonged exposure to ethylene oxide. This technology, however, is costly, inefficient, associated with potential toxicity to personnel, cannot sterilize residual gross soil, warrants concern about endoscope durability, and is not widely available. Furthermore, ethylene oxide is not FDA-approved for reprocessing endoscopes. Clearly, other new or validated low-temperature reprocessing technologies and/or endoscope designs are needed. These challenges raise a number of questions that require more study to fully answer.

RECOMMENDATIONS

Professional organizations vary in recommended practices. This document is intended to complement independent guidelines by emphasizing those areas where a broad range of professionals have reached consensus based on the available evidence. When evidence is lacking, expert opinion, independent guidelines, or standards for accreditation may differ, as cited in the prior discussion and in some of the specific recommendations. Appendix A presents a description of categories describing the strength of the recommendations provided here and the evidence supporting the recommendations.

Users should always refer to FDA labeling and manufacturers' instructions for device-specific reprocessing guidance. Accrediting bodies will typically survey for performance in accordance with this guidance. In rare cases, FDA labeling claims and/or manufacturers' guidance may lag behind evolving data or rely on extreme assumptions or thresholds of safety that are not pertinent to safe, yet efficient, healthcare. If alternative practices are demonstrated to be optimal by several well-designed scientific studies and they are endorsed by multiple professional societies, they can be considered for use by an organization.[11] For instance, the FDA cleared labels for HLD with greater than 2% glutaraldehyde at 25°C advised contact times ranging from 20 to 90 minutes depending on the product. Multiple scientific studies and professional organizations support the efficacy of greater than 2% glutaraldehyde at 20 minutes at 20°C.[38]

Note that this guideline focuses on HLD of flexible GI endoscopes but does not attempt to thoroughly address sterilization of these instruments for extraluminal applications such as natural orifice translumenal endoscopic

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surgery or intraoperative endoscopy through open or laparoscopic access. It also does not address reprocessing of affiliated devices or flexible, rigid, or semirigid endoscopes used in other procedures, such as cystoscopy or bronchoscopy. Neither HLD nor extreme application of HLD processes can achieve the needs of sterile environments (eg, terminal sterilization of a wrapped instrument).[3] The terminology of HLD and the available agents for reprocessing have evolved since the first publication of this guideline. The FDA has acknowledged that flexible endoscopes cannot be sterilized with the available high-level disinfectants,[83] hence the longstanding FDA term "high-level disinfectant/sterilant" should no longer imply the ability to sterilize endoscopes with similar techniques. Here we use the term "high-level disinfectant," which should not be confused with lesser disinfectants used for environmental cleaning.

1. All healthcare personnel in the endoscopy suite should be trained in and comply with standard infection prevention and control recommendations (eg, standard precautions), including those to protect both patients and healthcare workers. Category IA[38]
2. Precleaning should be performed at the point of use, before bioburden has an opportunity to dry, and before comprehensive decontamination. Point of use precleaning should remove visible debris by wiping the exterior of the endoscope with appropriate detergent solution and aspiration of a large volume of detergent solution through the air/water and biopsy channels. Category 1B[38-40,43]
3. After point-of-use precleaning, transport the soiled endoscope to the reprocessing area for subsequent steps in high-level decontamination before remaining soil has an opportunity to dry. During transportation, soiled endoscopes should be contained in a manner to prevent exposure of staff, patients, or the environment to potentially infectious organisms. An open container can suffice for transport to immediately adjacent reprocessing rooms, but fully enclosed and labeled containers or bags should be used for transportation through corridors used for other patients, staff, or visitors to reprocessing areas. AORN provides additional guidance on this issue. Category II[43]
4. Perform pressure/leak testing after each use and before formal reprocessing, according to manufacturer guidelines. Category IB[39,40,43]
5. 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. Manual cleaning should occur within the manufacturer's recommended time frame. When cleaning is delayed beyond this interval, the manufacturer's directions for delayed processing should be followed. Strict compliance with manufacturer's guidance must be maintained, particularly for endoscopes with movable mechanisms such as the distal tip elevator present on duodenoscopes and linear US endoscopes. 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 manufacturer's instructions. Flush and brush all accessible channels to remove all organic (eg, blood or tissue) and other residues. Repeatedly actuate the valves during cleaning to facilitate access to all surfaces. Clean the external surfaces and components of the endoscope using a soft cloth, a sponge, or brushes. Category IB[15,38-40,43,84,85]
6. Use brushes appropriate for the size of the endoscope channel, parts, connectors, and orifices (eg, bristles should contact all surfaces) for cleaning. All brushes should be appropriately sized for the part of the endoscope being brushed and should be approved for this use by the endoscope manufacturer. Cleaning items should be disposable or thoroughly cleaned and disinfected between uses. Category II
7. Discard enzymatic detergents after each use, because these products are not microbicidal and will not retard microbial growth. Category IB[38,40,43,86]
8. Reusable endoscopic accessories (eg, biopsy forceps or other cutting instruments) that break the mucosal barrier should be mechanically cleaned as described above and then sterilized between each patient use (HLD is not appropriate). Reprocessing of single-use items should not be performed except according to FDA guidance. Category IA[23,38,39,43,44,46,65,87,88,90]
9. Ultrasonic cleaning of reusable endoscopic accessories and endoscope components may be used to remove soil and organic material from hard-to-clean areas. Category II[38,65]
10. Endoscopes (and accessories) that come in contact with mucous membranes are classified as semicritical items and should receive at least HLD after each patient use. Category IA[15,39,40,43,44,65,84]
11. There are new high-level disinfectants and agent-specific machines in the marketplace. Information regarding these technologies should be obtained from the FDA website and independent peer-reviewed publications. Use a high-level disinfectant and compatible reprocessing machine cleared by the FDA for their respective HLD claims (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm437347.htm). Category IA
12. The exposure time and temperature for disinfecting semicritical patient care equipment varies among the FDA-cleared high-level disinfectants. Follow the FDA-cleared label claims for HLD. Category IA[13,38,39,87,88,92-106]

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13. Select a liquid disinfectant or sterilization technology that is compatible with the endoscope. The use of specific high-level disinfectants or sterilization technologies on an endoscope should be avoided if the endoscope manufacturer warns against use because of functional damage (with or without cosmetic damage). Category IB[107,108]
14. The selection and use of disinfectants in the healthcare field is dynamic, and products may become available that were not in existence when this guideline was written. As newer disinfectants become available, persons or committees responsible for selecting disinfectants for GI endoscope reprocessing should be guided by FDA clearance of these products and by information in the scientific literature. Category II[86,87]
15. Completely immerse the endoscope and its components in the HLD solution and ensure that all channels are perfused. Nonimmersible GI endoscopes should not be used. Category IB[38-40,44,46,88,109-111]
16. HLD can be performed in an automated endoscope reprocessor (AER) or using manual processes. Use of an AER is advisable and should be adopted when feasible. When an AER is used, ensure that the endoscope and endoscope components can be effectively reprocessed in the AER (eg, the elevator wire channel of duodenoscopes is not effectively disinfected by most AERs, and this step should be performed manually). Users should obtain and review FDA-cleared model-specific reprocessing protocols from both the endoscope and the AER manufacturers and check for compatibility. Category IB[38-40,43,46,106,108,112,113]
17. If an AER is used, place the endoscope and endoscope components in the reprocessor and attach all channel connectors according to the AER and endoscope manufacturers' instructions to ensure exposure of all internal surfaces with the high-level disinfectant solution. Only approved connectors should be used. Category IB[38,40,43,106-108]
18. If an AER cycle is interrupted, HLD or sterilization cannot be ensured; therefore, the cycle should be repeated. Category II[40,43]
19. Because design flaws have compromised the effectiveness of AERs and can also involve endoscopes, the infection prevention staff should routinely review and document their attention to FDA advisories, manufacturer alerts, and the scientific literature for reports of endoscope and AER deficiencies that may lead to infection. Category II[107,114-117]
20. 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. Flush the channels with 70% to 90% ethyl or isopropyl alcohol and dry using filtered forced air. The final drying steps greatly reduce the risk of remaining pathogens and the possibility of recontamination of the endoscope by waterborne microorganisms. Some organizations stipulate use of "instrument air," which is further characterized relative to humidity, vapors, and so on. Category IA[40-42,44,88,112,118-122]
21. Visually inspect both endoscopes and reusable accessories frequently in the course of their use and reprocessing, including before, during, and after use as well as during and after cleaning and before HLD. Manual cleaning of complex endoscope components, such as elevators, requires optimal lighting and may be facilitated by magnification. Damaged endoscopes and accessories should be removed from use for repair or disposal. Category II[43]
22. When storing the endoscope, hang it in a vertical position to facilitate drying (with caps, valves, and other detachable components removed as per manufacturer instructions). Category II[38,40,43,44,46,88,123]
23. Endoscopes should be stored in a manner that will protect them from contamination. In the absence of data linking infection outbreaks to transport or storage and given the limited data on this issue, equipment and practices for storage and equipment for transport should be addressed at the facility level in conjunction with the infection prevention department or consultants. Category II[38,40,43,44,46,90]
24. Beyond the reprocessing steps discussed in these recommendations, no validated methods for additional duodenoscope reprocessing currently exist. However, units should review and consider the feasibility and appropriateness for their practice of using 1 or more of the additional modalities *suggested* by the FDA for duodenoscopes: intermittent or per procedure culture surveillance of reprocessing outcomes, sterilization with ethylene oxide gas, repeat application of standard HLD, or use of a liquid chemical germicide. Category II[36,49,80]
25. Although reuse of endoscopes within 21 days[56,59] of HLD appears to be safe, the data are insufficient to proffer a maximal outer duration for use of appropriately cleaned, reprocessed, dried, and stored flexible endoscopes. This interval remains poorly defined and warrants further study. As noted in the discussion above, some organizations advise shorter intervals. NR[43,44,53-57]
26. Use HLD or sterilize the water bottle (used for cleaning the lens and irrigation during the procedure) and its connecting tube at least daily. Sterile water should be used to fill the water bottle. Category IB[38,43,44,124-128]
27. Maintain a log for each procedure indicating the patient's name and medical record number (if available), the procedure and serial number or other identifier of the endoscope (and AER, if used), the date and type of the procedure, along with the name of the person performing the cleaning and HLD/sterilization process to assist in 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. Category II[38,40,44]

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28. Perform routine testing of the liquid HLD to ensure at least the minimum effective concentration of the active ingredient. Check the solution at the beginning of each day of use (or more frequently in accordance with manufacturer's guidelines) and document the results. If the chemical indicator shows that the concentration is less than the minimal effective concentration, the solution should be discarded. Category IA[38-40,43,44,88,96,129]
29. Discard the liquid HLD at the end of its reuse life (which may be single use), regardless of the minimal effective concentration. If additional liquid HLD is added to an AER (or basin, if manually disinfected), the reuse life should be determined by the first use/activation of the original solution (ie, the practice of "topping off" of a liquid HLD pool does not extend its reuse life). Category IB[40,51,88]
30. Facilities where endoscopes are used and disinfected should be designed to provide a safe environment for healthcare workers and patients. Eyewash stations should be available to reprocessing staff using caustic chemicals. Eyewash stations should not be placed on sinks used for washing or soaking soiled endoscopes. Air exchange equipment (eg, ventilation system and exhaust hoods) should be used to minimize the exposure of all persons to potentially toxic vapors (eg, glutaraldehyde). The vapor concentration of the chemical disinfectant used should not exceed allowable limits (eg, those of the American Conference of Governmental Industrial Hygienists and the Occupational Safety and Health Administration). Although organic vapor respirators appropriate for chemical exposures can provide respiratory protection (eg, in the event of spills), they are not intended for routine use and are not a substitute for adequate ventilation, vapor recovery systems, and work practice controls. Category IB and IC[38-40,44,47,130-132]
31. Reprocessing facilities should be designed with attention to the optimal flow of personnel, endoscopes, and devices to avoid contamination between entering dirty instruments and reprocessed clean instruments. Reprocessing of endoscopes (other than immediate precleaning) should not be performed in patient care areas because of risk of patient exposure to contaminated surfaces and devices. Category IC and II[47,133]
32. Personnel assigned to reprocess endoscopes should receive device-specific reprocessing instructions (ie, endoscope and/or AER manufacturer, as needed) to ensure proper cleaning and HLD or sterilization. Competency testing of personnel that reprocess endoscopes should be performed and documented on a regular basis (eg, commencement of use, at least annually, any time a breach is identified, when a major technique or new endoscope or reprocessing equipment is introduced, and in the context of local quality control efforts). Training and competency testing should include recognition of excessive wear or damage to instruments. Temporary personnel should not be allowed to reprocess endoscopes until competency has been established. Category IA[38-40,44]
33. All personnel using chemicals should be educated about the biologic and chemical hazards present while performing procedures that use disinfectants and should have competency documented with regard to use of the specific HLD or sterilization agents used in their practice setting. Category IC
34. Personal protective equipment (eg, gloves, gowns, eyewear, and respiratory protection devices) should be readily available and should be used, as appropriate, to protect workers from exposure to chemicals, blood, or other potentially infectious material. Category IC[38,43,133-137]
35. Healthcare facilities should ensure that users can readily identify whether and when an endoscope has been reprocessed. Category II[43]
36. The use of routine environmental microbiologic testing of endoscopes for quality assurance has not been established but warrants further study. NR[38]
37. If environmental microbiologic testing is performed, standard microbiologic techniques per CDC guidance should be used. Category II[38,138]
38. Reprocessing of nonendoscopic devices, accessories, and attachments should adhere to manufacturers' recommendations. Category IC and II
39. Standard infection prevention practices for aseptic administration of medications, including injectable agents and sedation and analgesia, should be used. Category IC[139]
40. In the event of an outbreak caused by a suspected infectious or chemical etiology, environmental sampling should be performed according to standard outbreak investigation protocols. Category 1A[36,38,44,58,140]
41. Endoscopy-related infections should be reported to all of the following:
    a. Persons responsible for infection control at the institution, with notification of the referring physician and potentially affected patients as appropriate.
    b. The appropriate public health agency (state or local health department as required by state law or regulation).
    c. The FDA (www.fda.gov/medwatch). Medical Device Reports submitted through "Medwatch" can be reviewed on the FDA's MAUDE database.[44]
    d. The manufacturer(s) of the endoscope, disinfectant/sterilant, and AER (if used). Category IB and IC[38,39,44]

SUMMARY AND ENDORSING ORGANIZATIONS

Flexible GI endoscopy is a valuable diagnostic and therapeutic tool for the care of patients with GI and

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

The original 2003 and 2011 position statements were endorsed by the collaborating organizations listed below. This 2016 update was initially drafted by a subcommittee of the Quality Assurance in Endoscopy Committee of the ASGE. Thereafter, significant input from those societies involved in previous versions of the document was incorporated, and it was redistributed for consideration of endorsement. 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, the Society for Healthcare Epidemiology of America, the Joint Commission on Accreditation of Healthcare Organizations, the American College of Gastroenterology, the American Gastroenterological Association, the American Society of Colon and Rectal Surgeons, the Society of American Gastrointestinal Endoscopic Surgeons, the Society of Gastroenterology Nurses and Associates, the Association of Perioperative Registered Nurses, the Association for Professionals in Infection Control and Epidemiology, and the 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 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 Association for the Study of Liver Disease, American College of Gastroenterology, American Gastroenterological Association, Association for Professionals in Infection Control and Epidemiology, American Society of Colon and Rectal Surgeons, Society for Healthcare Epidemiology of America, Society of American Gastrointestinal and Endoscopic Surgeons, Society of Gastroenterology Nurses and Associates

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Abbreviations: AER, automated endoscope reprocessor; AORN, Association of PeriOperative Registered Nurses; ASGE, American Society for Gastrointestinal Endoscopy; CDC, Centers for Disease Control and Prevention; FDA, U.S. Food and Drug Administration; HLD, high-level disinfection; MAUDE, Manufacturer and User-Facility Device Experience.

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APPENDIX A

The CDC system for categorizing recommendations is as follows:

Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.

Category IB. Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale.

Category IC. Required by state or federal regulations. Because of state differences, readers should not assume that the absence of an IC recommendation implies the absence of state regulations.

Category II. Recommended for implementation and supported by suggestive clinical or epidemiologic studies or theoretical rationale.

No recommendation (NR). Unresolved issue. Practices for which insufficient evidence or no consensus regarding efficacy exists.

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