



ASGE guideline for infection control during GI endoscopy

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

The Quality Assurance in Endoscopy Committee of the American Society for Gastrointestinal Endoscopy (ASGE) updated and revised this document, which was originally prepared by The Standards of Practice Committee of the ASGE and was published in 2008.¹ In preparing this guideline, a search of the medical literature was performed by using PubMed, supplemented by accessing the related-articles feature of PubMed. Additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When little or no data existed from well-designed prospective trials, emphasis was given to results from large series and reports from recognized experts. Guidelines for appropriate use of endoscopy are based on a critical review of the available data and expert consensus at the time the guidelines are drafted. Further controlled clinical studies may be needed to clarify aspects of this guideline. This guideline may be revised as necessary to account for changes in technology, new data, or other aspects of clinical practice.

This guideline is intended to be an educational tool to provide information that may assist endoscopists in delivering care to patients. This guideline is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment. Clinical decisions in any particular case involve a complex analysis of the patient's condition and available courses of action. Therefore, clinical considerations may lead an endoscopist to take a course of action that varies from these guidelines.

Millions of GI endoscopies are performed annually throughout the United States, and it is reassuring that documented instances of infectious adverse events remain rare.² Several recent reports of infections with multidrug-resistant organisms (MDRO) associated with duodenoscopy use suggest that prior assumptions regarding endoscopy-related infection rates may be an underestimate, particularly for ERCP. These outbreaks of infection have led to a reassessment of current infection control practices. Endoscopy-related transmission of infections may occur if microorganisms are spread from patient to patient by contaminated equipment or if microorganisms are spread from the gut lumen during endoscopy through the bloodstream to susceptible organs, adjacent tissues, or prostheses. Non-endoscopic transmission of infections within endoscopy units also can occur if microorganisms are transmitted from patients to endoscopy personnel.

The purpose of this document is to disseminate information and promote understanding of endoscopy-related transmission of infection in order to minimize its risk of occurrence. Circumstances in which an endoscopy-related infection might occur are discussed, as are measures to prevent such infection, including endoscope reprocessing and reprocessing failure, general infection control, protection of endoscopy personnel, and the importance of leadership.

OVERVIEW OF ENDOSCOPIC TRANSMISSION OF INFECTION

Over the course of an endoscopic examination, the external surface and internal channels of flexible endoscopes are exposed to body fluids and contaminants. Disinfection of these reusable instruments pose special challenges. Flexible endoscopes are heat labile devices and as such are not suitable for steam sterilization. Therefore, reprocessing is achieved by mechanical and detergent cleaning, followed by high-level disinfection (HLD), rinsing, and drying.

Stringent guidelines for the reprocessing of flexible endoscopes were developed by the ASGE and the Society for Healthcare Epidemiology of America, who convened with representatives from physician, nursing, and infection control organizations, industry leaders, and federal and state agencies. This conference resulted in the 2003 publication of the Multisociety Guideline for Reprocessing of Flexible GI Endoscopes,³ which was updated in 2011⁴ and in 2016.⁵ Historically, in the absence of defective equipment, reported cases of transmission of infection have resulted from failure to adhere to these guidelines. Since 2012, multiple U.S. and international medical centers have reported patient-to-patient transmission of MDROs such as carbapenem-resistant *Enterobacteriaceae* (CRE), without identifiable, overt breaches of reprocessing protocol.⁶ Transmission of these organisms has been linked to the elevator channel endoscopes (duodenoscopes, linear array EUS scopes) and primarily attributed to persistent contamination of the elevator mechanism, the elevator cable, and the cable channel itself.

Bacterial infections

When clinically significant bacterial infections are transmitted endoscopically, they are often recognized because their incubation periods are often short, and patients usually develop overt clinical symptoms. However, cases of transmission may be missed if the illness is subclinical or if symptoms are attributed to other factors associated with the procedure (issues related to the interventions performed or to sedation) or to other patient-specific conditions or events. Overall, although accurate data on infection transmission rates are difficult to obtain because of the lack of a proper mechanism for reporting and calculation of transmission rates, a summary of the available data, in the context of these reporting limitations, is provided below.

A total of 84 cases of endoscopy-related transmission of *Salmonella* species between patients were reported between 1974 and 1987,⁷⁻¹⁵ but none have been reported since that time. Overall, there have been rare reports of endoscopic transmission of *Pseudomonas* species.^{16,17} As recently as 2011, 4 patients who underwent upper endoscopy were found to be infected with multidrug-resistant *Pseudomonas*. Several potential causes for the transmission were identified, including insufficient initial cleaning, shortening of immersion and brushing times, insufficient channel flushing, and inadequate drying before storage.¹⁸ In addition to inadequate reprocessing of the endoscope itself, the propensity for organism growth in moisture-rich environments is a common factor in facilitating transmission. In some instances, an unsterilized irrigation water bottle attached to the endoscope was identified as a source of infection.^{19,20} A lack of cleaning and drying of the air-water and/or the elevator channels of duodenoscopes also was implicated in some cases of transmission of

Pseudomonas infection.²¹⁻²⁴ Failure of automated endoscope washer-dryers has been implicated in several cases.^{22,25,26} Recently, a strain of *Pseudomonas* with reduced susceptibility to glutaraldehyde was reported.²⁷

A few reports of endoscopic transmission of *Helicobacter pylori* were attributed to inadequate reprocessing of endoscopes and biopsy forceps.^{28,29} Up to 61% of endoscopes became contaminated after use in patients infected with *H pylori*,³⁰ but conventional cleaning and disinfection of the instruments are highly effective in eliminating *H pylori*. Before widespread application of standardized reprocessing guidelines, there were isolated reports of endoscopic transmission of other enteric bacteria, including *Klebsiella*,³¹ *Enterobacter*,¹⁷ *Serratia*,³² and *Staphylococcus*.³¹

There have been no reports of transmission of mycobacteria by GI endoscopy. Current reprocessing guidelines were shown to be adequate in eradicating mycobacteria, and to date there are no reports of transmission of mycobacteria by GI endoscopy.³³ Similarly, reprocessing under the current guidelines was shown to inactivate biofilm and the spores of *Clostridium difficile* and other bacteria,^{34,35} and no cases of transmission of *C difficile* have been reported.

As mentioned previously, transmission of MDROs, including CRE, via duodenoscopes, has been reported.^{24,36-38} Unlike prior outbreaks of endoscope-transmitted infections, no recognized breaches of standard reprocessing protocol have been identified in outbreaks of duodenoscope-associated CRE to date. These transmissions seem to be related to difficult-to-clean or even sealed portions of these specific endoscopes, particularly the areas around the elevator regions of duodenoscopes.

Chronic viral infections

Documentation of transmission of viral infections by endoscopy is more challenging, because these infections have a longer incubation period, and patients may be asymptomatic or minimally symptomatic. Thus, linking transmission of these infections to a previously performed procedure may be difficult. Still, existing data suggest that risk of viral transmission via endoscopy is extremely low to non-existent.

Hepatitis C. There are rare reports of transmission of hepatitis C in situations where lapses in HLD of endoscopes occurred. Older case reports and epidemiologic studies suggested an association between endoscopy and hepatitis C virus (HCV) seropositivity. However, interpretation of these reports is difficult because of a reliance on self-reporting of risk factors for HCV and other inherent biases. In fact, the documented cases of HCV were all related to non-endoscopic transmission rather than direct endoscopy-related transmission. Bronowicki et al³⁹ documented transmission of hepatitis C from an infected patient to 2 subsequent patients who underwent colonoscopy with the same instrument. Transmission was

originally attributed to 2 breaches in endoscope reprocessing: failure to clean the working channel of the endoscope manually before disinfection and failure to sterilize the biopsy forceps between patients. However, inadequate aseptic techniques practiced at this center also raise the possibility of transmission of the virus via contaminated intravenous tubing, syringes, or multi-dose vials rather than the endoscope itself.^{40,41} In another example, a single-center report showed that 8 of 87 (9.2%) HCV-negative patients seroconverted after propofol vials designed for single use were reused on multiple patients undergoing endoscopic procedures.⁴²

There is evidence, however, that when currently accepted reprocessing guidelines are followed, transmission of HCV is extremely rare to non-existent. A multi-center prospective cohort study followed 8260 HCV-seronegative patients undergoing endoscopy.⁴³ All centers reported compliance with internationally accepted guidelines for cleaning and disinfection of endoscopes. All 8260 patients, including 912 patients who underwent an endoscopy with an instrument previously used on HCV carriers, remained seronegative at follow-up testing performed 6 months after their endoscopic procedures. Four seroconversions occurred over the study period in a control group of 38,280 blood donors, which indicated a background seroconversion rate of 0.042 per 1000 patient-years.

Similar results were reported in a prospective cohort study of 859 patients, with a high prevalence of hepatitis C of 71%.⁴⁴ Endoscopes were cleaned and disinfected in accordance with guidelines published by the ASGE and the Society of Gastroenterology Nurses and Associates. Of the 149 patients who were seronegative and for whom follow-up serology could be obtained, 4 subsequently developed antibodies to HCV. Two were found to have had HCV RNA in blood samples obtained before an endoscopy, which indicated that they were infected before undergoing endoscopy. Of the remaining 2 patients who developed anti-HCV antibodies after an endoscopy, neither had HCV RNA detected on follow-up testing at 3 and 6 months after the procedure, which suggested false-positive serologic tests. Thus, endoscopy did not result in transmission of hepatitis C in any of these patients, despite the extremely high exposure risk in this cohort.

Hepatitis B. A handful of isolated case reports suggest that transmission of hepatitis B via endoscopy is possible.⁴⁵⁻⁴⁷ However, transmission of hepatitis B appears to be very rare, even when inadequate cleaning and disinfection occurs, and there are no reported cases of transmission when currently accepted guidelines are followed.

In 5 prospective studies, 120 patients who had undergone endoscopy with an instrument previously used in a patient infected with hepatitis B were followed.⁴⁸⁻⁵² No hepatitis B virus (HBV)-seronegative patients developed clinical or serologic evidence of hepatitis B over a 6-month follow-up. In 4 additional prospective studies, a

total of 722 patients who were HBV seronegative were observed for up to 12 months after an endoscopy.⁵³⁻⁵⁶ The background prevalence rates of hepatitis B surface antigen positivity in these populations were up to 9.6%. In total, only 3 of the 722 patients seroconverted. None of the seroconversions were attributed to the endoscopy because none of these patients had undergone an endoscopy with an instrument previously used on a patient who was infected. In addition, the seroconversion rate was lower than that for a control population not undergoing endoscopy. In a recent prospective cohort study from a center in which ASGE reprocessing guidelines were followed, none of 30 seronegative patients undergoing endoscopy with instruments previously used in patients who were hepatitis B surface antigen-positive subsequently seroconverted.⁴⁴ Finally, a recent Canadian study of patients who underwent endoscopy in a unit with identified infection control lapses over a 9-year period confirmed the negligible risk of HBV infection after endoscopy. In this study, 5042 of 6728 (75%) living patients completed blood-borne pathogen testing after endoscopy, and there was no increased risk for infection among those who underwent a procedure within 7 days of a known HBV or HCV case.⁵⁷

Taken together, these data indicate that when currently accepted guidelines for cleaning and disinfection of endoscopes are followed, transmission of hepatitis B after endoscopic procedures does not occur or is very rare.

HIV. There are no reports of transmission of HIV by endoscopy. Manual cleaning of the endoscope with detergent eradicates >99.0% of the virus from the instrument, and subsequent disinfection with glutaraldehyde has been shown to eliminate the virus from endoscopes.^{4,58-60}

Miscellaneous microbial transmission

Parasites. A single report documented transmission of *Strongyloides* to 4 patients from a contaminated instrument.⁶¹ There are no other reports of transmission of parasites by endoscopy.

Fungi. There are no documented cases of transmission of fungal infections by GI endoscopy.

Prions. Creutzfeldt-Jacob disease (CJD) is a neurologic disease that is transmitted by proteinaceous agents called prions. GI endoscopy does not result in contact of the endoscope or accessories with prion-infected tissues, and, therefore, there is no theoretical need for any special processing of endoscopes used on patients with CJD.⁶² There are no reports of transmission of CJD by endoscopy.

Variant CJD (vCJD) is a related condition caused by the consumption of beef contaminated by the bovine spongiform encephalopathy agent. Approximately 125 cases have been reported worldwide, with a single case reported in the United States. vCJD differs from CJD in that the mutated prion protein can be found in lymphoid tissue throughout the body, including the tonsils and the gut. The mutated prions are resistant to conventional

disinfectants and sterilants. We, therefore, recommend that an endoscopy be avoided, if at all possible, in patients with known vCJD.⁶³ When an endoscopy must be performed in a patient with known vCJD, we recommend use of an instrument dedicated for patients with vCJD or one that is approaching the end of its life and that can be destroyed after use. Given the absence of any further reported cases of vCJD in the United States, no changes to general reprocessing guidelines are warranted at this time.

Use of endoscopes in animal models

There is a paucity of data regarding risk of transmission of infection via endoscopes used in animal models. The Centers for Disease Control and Prevention (CDC) recommends that “when medical or surgical instruments, especially those invasive instruments that are difficult to clean [eg, endoscopes], are used on animals, these instruments should be reserved for future use only on animals.”⁶⁴ Some endoscope manufacturers recommend that endoscopes that have been used on animal models should be reprocessed in dedicated automated endoscope reprocessors separate from those used for human endoscopes.

REPROCESSING OF ENDOSCOPES

The single best protection against patient-to-patient transmission of microorganisms by endoscopy is careful compliance with reprocessing guidelines and manufacturers’ U.S. Food and Drug Administration (FDA)–approved instructions for use.⁵ This section defines and discusses key concepts in endoscope reprocessing. More in-depth discussion is left to the Multisociety Guideline for Reprocessing of Flexible GI Endoscopes 2016 update.⁵

Definitions

Cleaning. This is defined as the physical removal of organic material and/or soil, generally by using water with detergents. This process is designed to remove organisms rather than kill them.

Disinfection. Disinfection eradicates most microorganisms and is commonly performed by using liquid chemical germicides. There are 3 levels of disinfection depending on the degree of microbial elimination involved:⁶⁵ (1) High: This includes pasteurization, use of glutaraldehyde or another agent confirmed to achieve HLD. HLD destroys vegetative microorganisms, mycobacteria, fungi, small or nonlipid viruses, and medium or lipid viruses, but not necessarily large numbers of bacterial spores. Chemical germicides registered as “sterilants” may be used for sterilization or for HLD, depending on such factors as dilution, contact time, and frequency of reuse. The specifics of such factors may vary with each product and are included on approved labeling.⁶⁵ (2) Intermediate:

This uses hospital-grade disinfectant and a U.S. Environmental Protection Agency–approved tuberculocidal cleaner and/or disinfectant and is indicated for any item that touches mucous membrane or skin that is not intact (eg, thermometers). (3) Low: This level of disinfection will inactivate most vegetative bacteria, some fungi, and some viruses, but it does not reliably inactivate resistant microorganisms.

Sterilization

Sterilization eliminates all microbials, including bacterial spores. It is most commonly achieved with heat or ethylene oxide gas.

Spaulding classification

The Spaulding classification categorizes medical devices based on the risk of infection involved with use. The categories of medical devices and their associated levels of disinfection are as follows:

Critical-use items. Critical use items enter sterile tissue or vascular spaces and hence carry significant risk for infection if contaminated. These items include needles, surgical instruments, biopsy forceps, and urinary catheters. Processing for reuse of these items requires sterilization.

Semi-critical–use items. These items, such as endoscopes, come in contact with mucous membranes and do not ordinarily penetrate sterile tissue. Processing for reuse requires HLD.

Noncritical items. These items 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.

REPROCESSING METHODS

Endoscope reprocessing is a multistage process that includes manual cleaning, HLD (or sterilization in some cases), rinsing, drying, and storage. The ASGE Multisociety Guideline on the Reprocessing of Flexible GI Endoscopes: 2016 update should be referred to for additional information on the multistage process outlined below.⁵

Manual cleaning

The first, and one of the most important, steps in the prevention of transmission of infection by endoscopy, is manual cleaning of the endoscope with detergent solution and brushes.^{66,67} Only model-specific cleaning devices, designed for the endoscope model being cleaned, should be used.⁵ This should be performed as soon as possible on removal of the endoscope from the patient to prevent drying of material on the surface of the endoscope and within the channels. Manual cleaning minimizes the chances of bacterial biofilm developing within the endoscope channels. The efficacy of cleaning and disinfection is dependent on appropriate training of

personnel and compliance with manufacturers' recommendations. Endoscopes equipped with an elevator channel merit special attention during both manual cleaning and disinfection in order to ensure effective reprocessing of the instrument. This includes both duodenoscopes used in ERCPs and linear-array echoendoscopes used for certain EUS procedures. Manual cleaning of the complex endoscope components, such as elevators, requires optimal lighting and may be facilitated with magnification.⁵

HLD

HLD is the standard of care recommended by governmental agencies and all pertinent professional organizations for the processing of flexible GI endoscopes.^{2,4,68,69} HLD is operationally defined by the FDA as a 6-log reduction of *Mycobacteria*⁷⁰ and is achievable by using a variety of FDA-approved liquid chemical germicide solutions with a manual process or an automated endoscope reprocessor.^{71,72}

Sterilization

Traditionally, sterilization of endoscopes and accessories has been indicated for the rare occasions when they are to be used as critical medical devices, when there is a potential for contamination of an open surgical field.⁶⁵ Sterilization can be achieved by using a variety of methods, including ethylene oxide gas treatment, and it can be achieved with appropriately long exposure to liquid chemical germicides.^{72,73} Because of the complexity of the instrument channel design, sterilization of flexible endoscopes is difficult to accomplish.^{74,75} In addition, endoscope durability and function are potentially compromised with repeated cycles of sterilization.⁷⁶ Users report that endoscopes experience a shortened use life because of material degradation issues when processed repeatedly in ethylene oxide.⁷⁷ Because of these factors as well as a lack of data for demonstrable benefits to the further reduction in endoscope bacterial spore counts achieved by sterilization instead of HLD, sterilization with ethylene oxide is not recommended over HLD for standard GI endoscopes.⁷⁴ However, an FDA-cleared liquid chemical sterilant processing system has been approved to provide sterilization of cleaned, immersible, reusable, and heat-sensitive critical and semi-critical medical devices.⁷⁷

Reusable biopsy forceps, snares, sphincterotomes, and other accessories designed to breach the GI mucosal surface all require sterilization.⁷⁰ Reusable accessories have the potential for cost savings because they can be used over several procedures; however, repeated sterilization may damage the devices.^{78,79}

Although the use of tap water in the irrigation bottle can be safe, with no difference in rates of bacterial cultures compared with sterile water and no associations with clinical infections with use of either tap or sterile water,⁸⁰⁻⁸² it

is recommended that sterile water be used in irrigation bottles when endoscopy is performed in special populations such as liver transplant patients, because of uncertainty regarding the presence of potential water-borne pathogens in tap water.⁸³

Duodenoscopes

Because of recent duodenoscope-associated MDRO and CRE infections and known difficulties in adequately cleaning the elevator channel, the FDA has advised consideration of further measures for reprocessing of duodenoscopes including use of double reprocessing cycles, uniform or intermittent surveillance with use of a "culture and hold" policy in which the endoscope is cultured after HLD and withdrawn from use until the results prove negative for persistent contamination, or sterilization by treatment with ethylene oxide gas or a liquid chemical sterilant.⁸⁴ If not used uniformly, the aforementioned measures can be used when endoscopes that have been used in patients with known MDRO or CRE infections are reprocessed. A facility's decision to use any of these measures is based on available resources as well as local prevalence and estimated risks of duodenoscope-related transmission of infection. All endoscopy centers should closely evaluate whether they have the expertise, training, and resources to implement 1 or more of the FDA suggested supplemental measures to enhance duodenoscope reprocessing.⁵

Linear array echoendoscopes

There is limited data regarding risk of transmission of CRE via linear array echoendoscopes.⁸⁵ Some centers, out of an abundance of caution, have begun processing linear echoendoscopes in a manner similar to that used for duodenoscopes, given that both devices contain elevators.⁸⁶ However, other than anecdotal reports, there are no published studies of these devices being associated with patient-to-patient transmission of MDROs.

Rinsing, drying, and storage

A critical part of the cleaning and disinfecting process involves proper rinsing and drying of the endoscope channels. During rinsing, large volumes of water are flushed through all channels to accomplish complete evacuation of liquid chemical germicides. Water used for rinsing endoscopes after HLD varies in different institutions and is either potable tap water, bacteria-free water, sterile, or sterile-filtered water.^{87,88} However, none of these water types is necessarily free of bacteria, despite their label claims, and the potential for contamination of disinfected endoscopes, and, therefore, for nosocomial infection, still exists.^{5,88,89} Microbiologic monitoring of rinse water is not recommended by the CDC, although this remains a controversial issue,^{5,90-93} with some countries encouraging the practice.⁹⁴ Endoscopes that are sterilized with ethylene oxide must have the channels and materials purged by

prolonged evacuation in a strongly negative pressure or vacuum environment, in order to remove any potential toxic residue from the ethylene oxide gas. In addition, before endoscopes undergo gas sterilization, all moisture must be eliminated from the endoscope channels to avoid the creation of ethylene glycol (antifreeze) during ethylene oxide sterilization.

Thorough drying of the endoscope after rinsing minimizes proliferation of microorganisms during storage, because any residual rinse water that remains in endoscope channels may provide an environment for the microorganisms to colonize and multiply.^{5,95} After the endoscope is rinsed with water, a 70% alcohol flush promotes drying and inhibits the growth of organisms in stored instruments.⁹⁶ After the instruments are dried, they should be stored in an upright hanging position as per manufacturers' recommendations. There are incomplete data, however, on the importance of commercially sold endoscope storage cabinets, including forced-air irrigation of endoscope channels during storage for keeping endoscopes free of contamination.⁹⁷

There is little information regarding how long endoscopes placed in storage may remain unused before reprocessing is required. Two studies indicate that once endoscopes are appropriately reprocessed, dried, and stored, it is not necessary to reprocess them again if used within 5 to 7 days.^{98,99} Other data demonstrate that the use of endoscopes within 21 days of HLD appears to be safe.^{5,100} This interval remains poorly defined and requires further study.

Reprocessing failure

Reprocessing failures typically arise because of equipment (automated endoscope reprocessor) or product (HLD) failure or because of human error.¹⁰¹ Because the efficacy of manual cleaning and HLD is operator-dependent, assignment of staff responsible for endoscope reprocessing, extensive training of the reprocessing personnel, process validation, and quality assurance cannot be overemphasized. Staff competency should be assessed, at the very least, on an annual basis.

Although the risk of transmission of infection through endoscopy is extremely low, institutions have an ethical obligation to inform affected patients in a timely manner when a significant breach in reprocessing is discovered or an endoscope-associated infection is suspected. Prompt notification and counseling may minimize patient anxiety, allow patients to take precautions to minimize the risk of transmitting infection to others, and allow for early serologic testing. This may help distinguish chronic infections from those potentially acquired at the time of endoscopy and to permit earlier initiation of treatment for newly acquired infections.

In the event of reprocessing failure or outbreak caused by a suspected infectious or chemical etiology, environmental sampling should be performed according to standard

outbreak investigation protocols.^{102,103} Based on these protocols,^{102,103} we provide the following recommendations for the management of cases of reprocessing failure: (1) When a breach of the HLD protocol is discovered, it should be reported to the institution's designated infection control personnel, local and/or state public health agencies, the FDA, the CDC, and the manufacturers of the involved equipment (eg, endoscope, disinfectant and/or sterilant, and automated endoscope reprocessor).^{102,103} (2) Patients at risk should be notified directly, in a timely manner, of the breach and of the estimated risk of infection. Successful notification or attempts at notification should be documented. (3) Early serologic testing is imperative to distinguish prior infections from those potentially acquired as a result of the breach in the HLD protocol. For cases in which testing is delayed, it may be difficult to exclude the endoscopic procedure as a potential source of the infection. (4) Patients should be advised against donating blood and tissue products and engaging in sexual contact without barrier protection until all serologic testing is complete. (5) Personal counseling should be offered to all patients. The risk of infection should be discussed and placed in context, to minimize patient anxiety. In addition, the possibility that the patient has a prior chronic viral infection should be discussed, along with the role of testing in distinguishing pre-existing from newly acquired infections. (6) Patients should be asked whether they developed new symptoms suggestive of transmission of enteric bacteria or viruses after the endoscopic procedure. Prior vaccination history for hepatitis A and B should be documented. If patients have undergone prior hepatitis B vaccination, post-vaccination titers should be documented if they were measured. An attempt should be made to identify risk factors for hepatitis B, hepatitis C, and HIV. If patients have previously undergone testing for these infections, the results should be documented. (7) Baseline serologic testing for hepatitis B, hepatitis C, and HIV should be performed after reprocessing failure. Patients should be informed about their baseline serology results in a timely manner. (8) Performance of repeat testing, which may include serology and RNA tests, should be considered. The timing and the choice of tests will be influenced by the period of time that has elapsed between patient exposure and initial testing, by the presence or absence of patient symptoms, and by the advice of the institution's infectious diseases specialist. Institutions may consider obtaining follow-up testing at 6 weeks, 3 months, and 6 months after the procedure. In some situations, additional follow-up testing may be advisable at 1 year after exposure.

GENERAL INFECTION CONTROL

Establishing and maintaining general infection control guidelines within an endoscopy unit are essential for creating a high-quality and safe environment for patients and personnel. However, significant practice variation

with regard to infection control has been reported in endoscopy units across the United States. Gaps in both infection control and safety have been noted in over a fifth of U.S. ambulatory endoscopy units, with notable lapses reported for hand hygiene, personal protective equipment, injection safety, medication handling, and equipment processing.¹⁰⁴ Such variation highlights the need for continued and sustained efforts by endoscopy units to ensure that infection control guidelines are maintained and enforced.

Transmission of infection from patient to patient

Two modes of patient-to-patient transmission of infection have been outlined⁵ and are classified as non-endoscopic and endoscopic modes of transmission. Both modes have been clearly linked to patients developing infections after an endoscopic procedure and in most cases were the result of a lack of personnel carefully complying with general infection control policies and procedures. Examples of non-endoscopic transmission of infectious organisms include improper handling of intravenous sedation tubing, use of multi-dose vials and/or reuse of needles by endoscopy unit personnel when caring for patients. Both transmission modes put patients at risk of exposure to possible development of an infection and in most cases can be significantly minimized by good infection control practices.

Transmission of infection from patients to endoscopy unit personnel

There are several reports of documented transmission of infection from patients to health care personnel working in endoscopy units. Potential modes of transmission may include needle stick injury,^{105,106} blood splashes to the conjunctiva,¹⁰⁷ inhalation of aerosolized microorganisms,¹⁰⁸ and transfer from direct handling of patients. Furthermore, endoscopy unit staff are at higher risk for some types of infections in comparison to other health care workers or the general population. For example, there is a higher prevalence of *H pylori* infection in endoscopy personnel, with an increased prevalence observed with increasing years of practice.¹⁰⁹⁻¹¹² Appropriate use of personal protective equipment and good hand hygiene should minimize most of these infection risks. Moreover, endoscopy units need to have policies and procedures in place for when personnel have a potential exposure to an infectious organism while at the workplace.¹¹³

Management of endoscopy unit personnel exposed to infectious agents

There are nearly 600,000 annual percutaneous injuries experienced by U.S. health care workers,¹¹⁴ with over 5 million health care workers at risk.¹¹⁵ The risk of developing an infection after such an exposure is low for

endoscopy unit personnel with respect to diseases such as HIV,¹¹⁶ HCV,¹¹⁷ and HBV.¹¹⁸ In the event of inadvertent exposure of endoscopy unit personnel to potentially infectious agents, institutional guidelines should be followed. The Occupational Safety and Health Act (OSHA), the U.S. Public Health Service, and the CDC have published recommendations for management after exposure,^{119,120} including the following: (1) when prophylaxis is indicated after exposure, (2) the need for consulting experts in the management of such exposures, (3) monitoring for compliance with after-exposure prophylaxis as well as for adverse events and for seroconversion.

Protection of personnel

OSHA 1991, updated in 2001, established guidelines for health care facilities whereby employers are responsible for providing a safe and healthful work environment.^{121,122} Areas in which health care personnel encounter blood and other body fluids, such as an endoscopy unit, places them at the greatest risk of being exposed to blood-borne infections. In order to minimize such risks, the OSHA Blood-Borne Pathogens Standard (OSHA ST 29 CFR part 1910.1030) was established and requires employers to evaluate each employee task and provide training to protect employees from exposure to harmful substances. The OSHA Blood-Borne Pathogens Standard established the following requirements for health care facilities: (1) development of an exposure control plan that defines anticipated exposure risks for each employee task and outlines risk-reduction approaches, (2) exposure control plan updated annually, (3) implement the use of universal precautions, (4) identify and use engineering controls (defined as physical changes to the work area or process that effectively minimize a worker's exposure to hazards) to minimize exposure to blood-borne pathogens, (5) identify and ensure the use of work practice controls, (6) provide personal protective equipment for personnel, (7) make available after-exposure evaluation and follow-up to any occupationally exposed worker who experiences an exposure incident, (8) use labels and signs to communicate hazards, (9) provide information and training to workers, (10) maintain worker medical and training records.

Finally, it is further recommended that all of the above requirements be directed by a qualified individual, documented in writing and accessible to all personnel, include policies and procedures to support them, and that there be a process for ongoing assessment of compliance and competency with regard to them.¹¹³

Standard precautions

Standard precautions are defined as the basic level of infection control precautions, which are to be used, as a minimum, in the care of all patients. The goal of standard precautions is to reduce the risk of transmission of

blood-borne and other pathogens from both recognized and unrecognized sources.

The CDC recommends standard precautions for the care of all patients, regardless of their diagnosis or presumed infection status. Standard precautions apply to (1) blood, (2) all body fluids, secretions, and excretions (except sweat), (3) non-intact skin; and (4) mucous membranes. Because a patient's infectious status is often unknown at the time of an endoscopy, it is prudent to apply standard precautions for blood and body fluids when interacting with all patients. Standard precautions include:^{4,123} (1) hand hygiene, (2) personal protective equipment, (3) safe medication administration practices, (4) safe handling of potentially contaminated equipment or surfaces in the patient environment.

Precautions at the institutional level

A variety of measures are needed for optimal infection control among employees, both before and during the period of employment. OSHA mandates that all employees should be immunized against HBV,¹²⁴ although the risk of HBV infection to endoscopy unit personnel is small.¹²⁵ Other agencies and medical societies have gone further and recommended that health care personnel should have documented immunity or be immunized against a number of other vaccine-preventable diseases. Such vaccinations include annual influenza immunizations, measles/mumps/rubella, varicella (if the individual has not had chickenpox in the past), tetanus/diphtheria/pertussis, and meningococcus.^{123,124} Additionally, a majority of states have immunization laws for health care workers with which institutions must comply. Last, an effective and readily accessible employee health service may play a critical role in the management of after-exposure prophylaxis.¹²⁵

Precautions in the endoscopy unit

A number of essential precautions should be observed in the endoscopy unit in order to minimize infectious risks to both personnel and patients. Hands should be washed before and after each patient interaction, whether or not gloves are worn. The use of soap and water is required when hands are visibly soiled or an employee has an encounter with a patient with a suspected and/or known infectious cause of diarrhea. In all other cases, alcohol-based agents are acceptable.^{102,126} In endoscopy units, the prevention of *C difficile* transmission should be considered when endoscopy is performed on patients with diarrhea or known *C difficile* infection. Handwashing with soap and water should be undertaken for mechanical removal of spores from employee hands. Similarly, the use of gloves by health care workers during this type of patient encounter is required, because it has been shown to decrease the incidence of *C difficile*-associated diarrhea and the point prevalence of asymptomatic *C difficile* carriage in inpatients.¹²⁷

Patients with respiratory diseases that can be spread via an airborne route (eg, tuberculosis) may place endoscopy unit personnel at an increased risk of contracting the disease. Special precautions should be undertaken for patients who fall into this category and require endoscopy. Endoscopic procedures should be performed in a negative-pressure room, such that the direction of the air flow is from the outside adjacent space into the procedure room. Additionally, the use of personal respiratory protection is indicated for persons entering these rooms and for staff who lack immunity to airborne viral diseases (eg, measles, varicella zoster virus, influenza). Finally, the procedure room should be cleaned per standard protocol as described below.¹²⁸

Maintenance of a clean and sanitary environment for patients and personnel must be ensured. After the endoscopic procedure, exposed surfaces should be thoroughly cleaned of visible contaminants and then disinfected with an Environmental Protection Agency-registered hospital disinfectant.^{65,129} Rigorous cleaning of the endoscopy unit with a bleach-containing disinfectant for environmental disinfection is needed when patients with, or suspected of having, *C difficile* or norovirus undergo an endoscopic procedure. Also, isolation precautions that are otherwise indicated in patients who are potentially infected should be maintained when patients are transported to endoscopy units. For some patients, convenience or isolation requirements may require performance of an endoscopy at the bedside, rather than in the endoscopy unit. Finally, each endoscopy unit should have a plan in place for the cleaning and disinfecting of the procedural space at the end of the day.⁴

Safe medication administration practices and the safe use of needles in the endoscopy unit must be followed. Needles should be discarded in sharps containers without recapping to avoid inadvertent needle sticks. Endoscopy units and institutions should adopt needleless systems for administration of parenteral drugs whenever feasible. Clear and detailed recommendations for safe injection practices have been outlined in several recent guidelines.^{102,113,130,131} In particular, it should be emphasized that single-dose vials should be used, all medications should be labeled, reuse of syringes to enter a medication vial or solution should be prohibited, and the same syringe should not be used to administer medications to multiple patients.

It should be noted that infection control and the architectural layout of the endoscopy unit are intertwined. Endoscopy unit infection control policies should address procedure room work areas, reprocessing rooms, the separation of soiled and clean tasks and the flow of soiled and clean equipment through the unit, and the handling of specimens, tissues, soiled linens, and contaminated wastes should conform to both state and national regulatory guidelines.¹³² The physical design of the endoscopy unit and rooms significantly influences whether these infection control issues can be adequately and efficiently addressed.^{133,134}

Personal protective equipment

Personal protective equipment is defined as specialized clothing or equipment that does not permit blood or other potentially infectious material to pass through clothes or into skin, eyes, or mouth when worn by an employee for protection against a hazard. OSHA requires that employers provide all generally available protective attire, that they instruct employees in their use, and that they ensure their use by the employee.¹³² The ASGE Technology Assessment Committee and ASGE Ensuring Safety in the Gastrointestinal Endoscopy Unit Task Force provided a thorough discussion of personal protective equipment, their rationale, and the applicable regulations about their use.^{113,135} Although there are no endoscopy-specific mandates, institution-wide policies must define appropriate protective wear for the reasonably anticipated exposure of a given task and in most cases is dictated by whether personnel are at risk for a low or high risk exposure.¹³³ Gowns, gloves, masks, and eyewear should be worn in all settings in which contact with blood-borne pathogens or other potentially infectious materials might be anticipated. Of note, personal protective equipment should never be reused and must be removed when the wearer leaves a procedure room.

Terminal cleaning

The endoscopy unit should have a written plan addressing the terminal cleaning of all procedure rooms, including methods and chemical agents for cleaning and disinfecting the procedure space at the end of the scheduled procedure day.¹¹³ Terminal cleaning should be performed after known cases of *C. difficile* and potentially other organisms as determined by the local institution.

The terminal cleaning process should include cleaning of all surfaces in the procedure room sufficient to remove all soil and biofilm, followed by proper disinfection. This requires use of 2 distinct agents because chemical disinfectants are not effective at cleaning, and cleaning agents are not effective at disinfecting surfaces. Agents for terminal cleaning should have efficacy in spore removal, which may differ from requirements for agents used in sterile operating rooms.

Before the first procedure of the day, staff should verify that all procedure and recovery areas have been properly cleansed. A training and competency assessment program should be in place for staff who are involved in terminal cleaning to ensure proper and safe handling and use of the chemicals.

LEADERSHIP

Although it is essential for all staff to participate in enforcing and maintaining infection control, it is critical to have a leadership and governance structure in place to develop policies and procedures around infection control as well as to lead and potentially direct quality improvement

TABLE 1.

<p>The Centers for Disease Control and Prevention system for categorizing recommendations is as follows:</p> <p>Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.</p> <p>Category IB. Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale.</p> <p>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.</p> <p>Category II. Recommended for implementation and supported by suggestive clinical or epidemiologic studies or theoretical rationale.</p> <p>No recommendation. Unresolved issue. Practices for which insufficient evidence or no consensus regarding efficacy exists.</p>
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projects in this area. It is necessary for endoscopy units to have defined and inclusive leadership, with a focus on meeting and satisfying regulatory requirements with regard to safety and infection control.¹³⁶ This leadership team should be diverse and include both physician and nursing representation. Furthermore, at a minimum, endoscopy units are required to have a qualified person who directs infection prevention plans.¹³⁷ The role of this individual is to serve as an infection control champion and to implement infection control best practices and technology, lead change management among staff, and be responsible for developing educational materials on infection control practices for staff. Evidence suggests that having a defined and engaged infection control champion in an organization can lead to significant and sustained improvements in the area of infection control.^{138,139}

SUMMARY

1. Transmission of infection as a result of GI endoscopes is extremely rare, and most reported cases are attributable to lapses in currently accepted endoscope reprocessing protocols or to defective equipment.
2. Endoscopes should undergo HLD as recommended by governmental agencies and all pertinent professional organizations for the reprocessing of GI endoscopes (Table 1, Category IB and IC).
3. Attention should be focused on preventing transmission of highly resistant organisms by duodenoscopes, in particular, on ensuring cleaning and HLD of the elevator mechanism and elevator wire channel (Category IB).
4. Extensive training of staff involved in endoscope reprocessing is mandatory for quality assurance and for effective infection control, and documentation of this training is required (Category IC).
5. The efficacy of manual cleaning and HLD is operator dependent, thus assignment of personnel responsible for endoscope reprocessing, extensive training of

- reprocessing personnel, process validation, and quality assurance is vital, and staff competency should be assessed at the very least on an annual basis (Category IB and IC).
6. In the event of reprocessing failure, the institution's designated infection control personnel, local and/or state public health agencies, the FDA, the CDC, and the manufacturers of the involved equipment should be notified immediately (Category IC).
 7. General infection control principles should be complied with in the endoscopy unit (Category IA and IC).
 8. Use of standard precautions reduces the transmission of infection from patients to endoscopy personnel (Category IA and IC).
 9. Endoscopy units must have a qualified individual who directs their infection prevention plans (Category II).

DISCLOSURE

All authors disclosed no financial relationships relevant to this publication.

Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; CDC, Centers for Disease Control and Prevention; CJD, Creutzfeldt-Jacob disease; CRE, carbapenem-resistant Enterobacteriaceae; FDA, U.S. Food and Drug Administration; HBV, hepatitis B virus; HCV, hepatitis C virus; HLD, high-level disinfection; MDRO, multidrug-resistant organism; OSHA, Occupational Safety and Health Act; vCJD, variant Creutzfeldt-Jacob disease.

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