Chapter **4**

Cleaning and Disinfecting Gastrointestinal Endoscopic Equipment

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Introduction

Articles in the lay press suggesting that endoscopes are inadequately reprocessed have raised undue fear regarding the potential for transmission of infection during endoscopy. When current guidelines for endoscope cleaning and disinfection are followed, this risk is virtually eliminated. This topic has largely been taken for granted by many endoscopists, however. Standardized cleaning and disinfection protocols have been available for some time, and, with few exceptions, changes have been gradual. This situation may have engendered some complacency on the part of endoscopists, to the point that many endoscopists were only vaguely aware of what went on "behind the curtain" of the endoscope reprocessing room; instruments were used on patients, taken away by gastrointestinal (GI) nurses or other health care personnel, reprocessed, and returned ready for patient use. As the amount of information available to patients increases via the Internet (often not based on scientific evidence), endoscopists must be able to discuss this subject confidently with their patients.

Since the first report of fiberoptic GI endoscopy in 1961,[1] the endoscope has undergone almost continuous evolution in design. Although most of these developments have been aimed at improving the diagnostic and therapeutic capability of GI endoscopy, the introduction of fully immersible endoscopes in 1983 greatly facilitated cleaning and disinfection of the internal channels of the endoscope.[2,3] The development of video imaging technology, which provided a tremendous increase in the quality and resolution of the endoscopic image, had few implications for endoscope reprocessing. However, some changes have come at the cost of increasing complexity

of design, presenting new challenges to cleaning and disinfection. The addition of an elevator lever to the duodenoscope allowed easier cannulation of the papilla during endoscopic retrograde cholangiopancreatography (ERCP), although the new exposed movable part at the distal tip of the instrument and the associated control-wire channel also added new reprocessing steps. A similar type of elevator is present on current endoscopic ultrasound (EUS) endoscopes, or echoendoscopes. Echoendoscopes also possess an additional channel to inflate a balloon at the tip (needed to create the acoustic interface) that must be cleaned and disinfected. The incorporation of a dedicated high-flow water irrigation channel (distinct from the standard air and water channels) in some models of endoscopes adds yet another channel that requires reprocessing (regardless of use) in addition to the external equipment that connect to this channel.

Current reprocessing guidelines are discussed in detail. These guidelines, although applicable to nearly all GI endoscopes, do not apply to sheathed endoscope systems. One endoscopic sheath system that is approved by the U.S. Food and Drug Administration (FDA) is commercially available.[4–8] In contrast to the popular misconception of an "endoscope condom," the sheath is actually a part of the endoscope insertion tube and contains several channels. Because this is a complete endoscope system, the sheaths are not compatible with other endoscopes. Although the sheath itself is disposable and does not need conventional cleaning and disinfection (i.e., a new sheath is used for each procedure), the control dials on the handpiece are not protected and do require reprocessing. These dials are removable and require conventional cleaning and disinfection or sterilization. There are two main

disadvantages of the system: (1) The only currently marketed sheathed endoscope for use in the GI tract is a flexible sigmoidoscope; (2) the imaging technology of the instrument uses fiberoptic rather than video-chip technology.[9] Readers should refer to the manufacturer's instructions for reprocessing this type of endoscope.

Principles of Disinfection

Definitions

Cleaning is a term that is both simple to understand and difficult to define precisely in terms of a measurable endpoint. The official definition of cleaning used by the FDA is "the removal, usually with detergent and water, of adherent visible soil, blood, protein substances, and other debris from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination."[10] Although this definition seems straightforward, there is as yet no uniform consensus on how this process is operationally defined or what the endpoint of the process should be. How hot should the water be, and what concentration of detergent should be used? How many times should the cleaning brush be passed down the endoscope channels? What does "visibly clean" mean, and how can this be applied to the internal channels of an endoscope that cannot be examined? Many experimental methods can be used to determine the efficacy of cleaning by the detection of residual protein, carbohydrate, blood, or viral or bacterial RNA or DNA,[11–16] although these are impractical for routine clinical use.

Despite the difficulty in precisely defining the process or the subsequent endpoint, there is ample evidence that endoscope cleaning (as currently performed) is an essential part of the disinfection process. Mechanical cleaning alone reduces microbial counts by approximately 10^3–10^6 (three to six logs), or a 99.9% to 99.9999% reduction.[17–24] Cleaning is an integral part of any endoscope reprocessing regimen because failure to clean endoscopes or their accessories adequately can defeat disinfection or sterilization processes.[25]

Antiseptics are chemicals intended to reduce or destroy microorganisms on living tissue (e.g., skin), as opposed to *disinfectants,* which are used on inanimate objects (e.g., medical devices such as endoscopes). *Disinfection* is defined broadly as the destruction of pathogenic and other types of microorganisms. There are three levels of disinfection, as follows:

1. *High-level disinfection:* The destruction of all mycobacteria, nonlipid or small viruses, fungi, vegetative bacteria, and lipid or medium viruses and most, although not necessarily high numbers of, spores.
2. *Intermediate-level disinfection:* The destruction of all mycobacteria, vegetative bacteria, and fungal spores and some nonlipid viruses but not bacterial spores.
3. *Low-level disinfection:* The destruction of most bacteria (except mycobacteria), most viruses (except some nonlipid viruses), and some fungal spores (and not bacterial spores).[10]

For liquid chemical germicides (LCGs), high-level disinfection is operationally defined as the ability to kill 10^6 mycobacteria

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Box 4.1 Descending Order of Resistance of Microorganisms to Liquid Chemical Germicides

Prions (transmissible spongiform encephalopathy agents)
    Creutzfeldt-Jakob (CJD)
    Variant Creutzfeldt-Jakob (vCJD)
Bacterial spores
    Bacillus subtilis
    Clostridium sporogenes
Mycobacteria
    Mycobacterium tuberculosis
Nonlipid or small viruses
    Poliovirus
    Coxsackievirus
    Rhinovirus
Fungi
    Trichophyton spp.
    Cryptococcus spp.
    Candida spp.
Vegetative bacteria
    Pseudomonas aeruginosa
    Salmonella choleraesuis
    Enterococci
Lipid or medium-sized viruses
    Herpes simplex virus (HSV)
    Cytomegalovirus (CMV)
    Coronavirus
    Hepatitis B virus (HBV)
    Hepatitis C virus (HCV)
    Human immunodeficiency virus (HIV)
    Ebola virus

Modified from Bond WW, Ott BJ, Franke KA, et al: Effective use of liquid chemical germicides on medical devices: instrument design problems. In Block SS, editor: Disinfection, sterilization, and preservation, *ed 4, Philadelphia, 1991, Lea & Febiger, pp 1097–1106.*

(a six-log reduction). The FDA defines a high-level disinfectant as a sterilant that is used for a shorter contact time.[26] This difference in the way the same chemical is used to achieve different levels of disinfection and sterilization is important for endoscopy because the contact times for sterilization with any given LCG are generally much longer (hours) than for high-level disinfection (minutes) and may be detrimental to the endoscope. The relative resistance of various microorganisms to LCGs is shown in **Box 4.1**.

Sterilization is the destruction or inactivation of all microorganisms, or the absence of all microbial life. As an endpoint, it is an absolute (sterile or not sterile). The process is operationally defined as a 12-log reduction of bacterial endospores.[27] Not all sterilization processes are alike, however. Steam and dry heat are the most extensively characterized processes; both are thermal methods that do not require the same physical contact as LCGs to achieve sterilization, and the processes are routinely monitored by the use of biologic indicators (e.g., spore test strips) to show that sterilization has been achieved. Although theoretically sterilization could be achieved with LCGs, the FDA and other authorities have stated that these processes do not convey the same sterility assurance as other sterilization methods.[26,28,29]
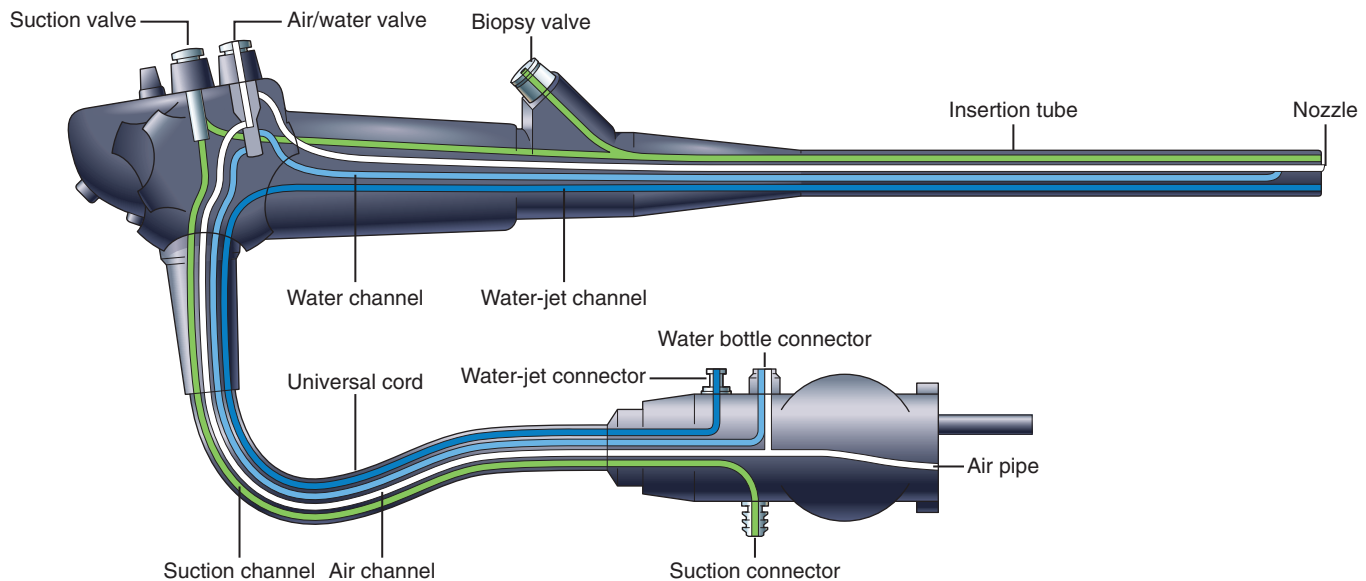
Fig. 4.1   Schematic of internal channels of an endoscope. *(Adapted from Olympus America. Copyright © Olympus America Inc., 2003.)*

The Spaulding classification system divides medical devices into categories based on the risk of infection involved with their use.[30,31] With some modifications, this classification scheme is widely accepted nationally and internationally and has been used by the FDA, the Centers for Disease Control and Prevention (CDC), epidemiologists, microbiologists, and professional medical organizations to determine the degree of disinfection or sterilization needed for various medical instruments. Three categories of medical devices and their associated level of disinfection are recognized, as follows:

1. *Critical:* Devices or instruments that are introduced into the human body and come into contact with normally sterile tissue or the vascular system. Because of the potential for infection if the device is contaminated with microorganisms, these devices require sterilization.
2. *Semicritical:* Devices that contact intact mucous membranes and do not ordinarily penetrate sterile tissue. They should receive at least high-level disinfection.
3. *Noncritical:* Devices that do not ordinarily touch the patient or touch only intact epithelium (e.g., stethoscopes or patient carts). These items may be cleaned by low-level disinfection.

Disinfection and Gastrointestinal Endoscopy

GI endoscopes are considered semicritical devices and should undergo at least high-level disinfection. This standard has been endorsed by the FDA[32]; the CDC[33]; and numerous professional medical organizations, including the American Society for Gastrointestinal Endoscopy (ASGE), the American College of Gastroenterology (ACG), the American Gastroenterology Association (AGA), the Society of Gastroenterology Nurses and Associates (SGNA), the Association of Perioperative Registered Nurses (AORN), the Association for Professionals in Infection Control and Epidemiology (APIC), and the American Society for Testing

and Materials (ASTM).[34–37] Because of design considerations, GI endoscopes can be a challenge to clean and disinfect. Endoscopes are heat-labile instruments and cannot be steam autoclaved. They possess several long, narrow internal channels with bends (**Fig. 4.1**) that require exposure to the LCG to achieve high-level disinfection. Generally, the air and water channels are too narrow to allow the passage of a cleaning brush (although the LCG is routinely circulated through this channel); however, one manufacturer has designed an endoscope with air and water channels that can be brushed.[38] Despite the complex internal design, high-level disinfection is not difficult to achieve with rigorous adherence to currently accepted guidelines. Most accessory instruments used during endoscopy either contact the bloodstream (e.g., biopsy forceps, snares, and sphincterotomes) or enter sterile tissue spaces (e.g., biliary tract) and are classified as critical devices. As such, these devices require sterilization.

Most accessories used during GI endoscopy are labeled by the FDA for single use (i.e., disposable) and are intended to be discarded at the end of the procedure. Because these items are sterilized by the manufacturer, reprocessing is not an issue. However, some accessories are designed to be resterilized and reused and are designated as such by FDA. In this case, cleaning and sterilization is performed by the user according to the manufacturer's instructions. The issue of sterilization of endoscopic accessories becomes considerably more complex when the reuse of single-use devices (SUDs) is considered. Although labeled for single use (disposable), many hospitals safely clean, resterilize, and reuse SUDs, resulting in decreased costs and reduced medical waste generation.[39–42] Despite the absence of evidence suggesting that this practice resulted in patient injury, the FDA issued a guidance document on August 14, 2000, that altered the agency's regulatory policy. The FDA considered the process of reprocessing (i.e., cleaning and sterilizing) a used SUD into a ready-for-patient-use device as "manufacturing," and as a result hospitals or third-party reprocessing companies that reprocessed SUDs were required to follow the same regulations as the original equipment manufacturers: premarket notification and approval requirements,

Table 4.1 **Pathogens Reportedly Transmitted during Gastrointestinal Endoscopy**		
Organism	**Probable Cases**	**Failure in Reprocessing Guideline**
Pseudomonas aeruginosa	227	Failure to clean/disinfect between patients Inadequate cleaning Inadequate disinfectant Failure to disinfect all channels (particularly elevator channel) Failure to disinfect/sterilize water bottle Failure to dry with 70% alcohol Faulty/contaminated AER ($n = 143$)
Salmonella spp.	48	Inadequate cleaning Inadequate disinfectant Failure to sterilize forceps
Helicobacter pylori	10	Forceps not cleaned or sterilized between patients Inadequate cleaning Inadequate disinfectant
Klebsiella pneumoniae	5	Failure to dry with 70% alcohol Failure to disinfect elevator channel
Hepatitis C virus	4	Inadequate disinfectant Inadequate exposure to LCG Failure to disinfect all channels with LCG Failure to sterilize forceps
Serratia marcescens	2	Inadequate disinfectant Failure to dry with 70% alcohol Failure to disinfect elevator channel
Enterobacter spp.	2	Inadequate cleaning Inadequate disinfectant
Hepatitis B virus	1	Inadequate cleaning Inadequate disinfectant Failure to disinfect all channels with LCG
Trichosporon spp.	1	Failure to sterilize forceps

AER, automatic endoscope reprocessor; LCG, liquid chemical germicide.
From Nelson DB: Infectious disease complications of GI endoscopy. Part II. Exogenous infections. Gastrointest Endosc *57:695–711, 2003, with permission from the American Society for Gastrointestinal Endoscopy.*

including 510(k) and premarket approval application (PMA); registration and listing; submission of adverse event reports; manufacturing and labeling requirements; tracking of devices; and correcting or removing from the market unsafe medical devices. Enforcement of these regulations was phased in over the subsequent 18 months (all aspects taking effect by February 14, 2002). The most onerous requirement was that a 510(k) or PMA was needed for each device that the institution intended to reprocess (both manufacturer and model-specific).[43] The regulatory burden imposed by these requirements essentially eliminated the practice of reprocessing of SUDs by most hospitals.

Risks of Inadequate Disinfection

Before discussing the specifics of current guidelines for endoscope cleaning and disinfection, it is helpful to understand how guidelines evolved over time in response to episodes of infection to minimize or eliminate vulnerabilities in the reprocessing procedure. Initially, endoscopes were simply washed with tap water and detergent, followed by exposure to alcohol.[44] In the 1970s, centers began using various "disinfectants" to reprocess endoscopes.[45–52] The germicides used were generally antiseptic agents. Many of the agents that were considered to be effective at that time (e.g., alcohols, phenolics, iodophors, quaternary ammonium compounds, and chlorhexidine) have

since been shown to be inadequate for high-level disinfection of GI endoscopes (**Table 4.1**).[53]

To standardize the cleaning and disinfection process, the ASGE, the AGA, and the ACG published joint guidelines on endoscope reprocessing in 1988. Key components of these guidelines were the emphasis on thorough manual cleaning of the instrument and all channels, high-level disinfection with an approved LCG (with a 10-minute exposure for glutaraldehyde specified at that time), a water rinse to remove residual sterilant, and a final drying step with forced air. The handles of nonimmersible endoscopes were to be cleaned with alcohol.[54] The British Society of Gastroenterology (BSG) published similar guidelines the same year, although notable differences included a recommended exposure time for glutaraldehyde of 4 minutes, the use of quaternary ammonium detergents as an acceptable second-line disinfectant, and only a brief mention of drying.[55] One of the authors of the BSG guidelines interpreted the guidelines as applying only to the insertion tube (which had direct patient contact) rather than to the entire endoscope (particularly the control handpiece, which was not high-level disinfected) and recommended that if the handpiece was "extensively contaminated," or if the next patient was known to be immunocompromised, only then was high-level disinfection of the entire instrument necessary. If the instrument was not submersible, cleaning with alcohol and chlorhexidine was "practical."[56]

More recent guidelines in the United States from multiple organizations have been uniformly consistent (all endorsing a 20-minute exposure to glutaraldehyde at room temperature).[34–36,57] The importance of close adherence to reprocessing guidelines becomes apparent in the subsequent section. The major difference with formal guidelines originating outside the United States has been the endorsement of a shorter glutaraldehyde exposure time of 10 minutes.[58–60] Actual facility practices in other countries can vary substantially, highlighting the difficulty in generalizing reports of infection to the experience in the United States.[61–65]

It is essential that a record be kept of the instrument used for each procedure so that in the event of a possible endoscope-related transmission the history of that instrument from the index case can be traced. This record is particularly important if a patient were subsequently found to have variant Creutzfeldt-Jakob disease (vCJD).

Specific Agents

The most commonly reported infectious agent transmitted during GI endoscopy is *Pseudomonas aeruginosa,* with 227 cases described in the medical literature (see Table 4.1).[25] *P. aeruginosa* is an opportunistic pathogen that is widely found in the environment, and the organism thrives in a moist environment.[66] Endoscopes and their ancillary equipment are a potential reservoir and may serve as a source of contamination. Early reports of *Pseudomonas* transmission during endoscopy (similar to reports of other organisms at that time) were generally related to inadequate cleaning or the use of inadequate disinfectants; however, later reports have centered around the following major areas: (1) flawed automatic endoscope reprocessor (AER) units (responsible for more than half of the reported cases), (2) failure to disinfect or sterilize the irrigation bottle of the endoscope regularly, (3) failure to recognize and disinfect the elevator channel of duodenoscopes, and (4) failure to dry the endoscope and all channels completely with a 70% alcohol solution followed by forced air.

There have been 48 cases of *Salmonella* species attributed to GI endoscopy.[25] In these reports, failure to clean the internal instrument channels mechanically was a uniform occurrence, and this was usually compounded by the use of an ineffective disinfectant. Because these cases were relatively early in the evolution of endoscope reprocessing (and preceded the guidelines standardizing these protocols), it is not surprising that there have been no reported cases of *Salmonella* transmission since 1987.

The 10 reported cases of endoscopic *Helicobacter pylori* transmission are almost as interesting as the initial confirmatory study by Marshall with self-inoculation. In one case, the author underwent endoscopy immediately after the instrument had been used in a patient known to harbor *H. pylori*. The endoscope was reprocessed by wiping the insertion tube with a paper towel soaked with benzethonium chloride and sucking the "disinfectant" through the instrument channels without cleaning. Perhaps predictably, the author developed acute *H. pylori* infection.[67] Another case was associated with endoscopic research dealing with *H. pylori* and was attributed to failure to clean and sterilize (or even disinfect) the endoscopic biopsy forceps between subjects (although reprocessing of the endoscope or other ancillary study equipment is not

mentioned).[68] The remaining cases were due to inadequate cleaning and the use of inadequate LCGs.

Much greater anxiety is associated with the possibility of transmission of viral infections. This anxiety is surprising because the viruses of greatest concern (i.e., hepatitis B virus [HBV], hepatitis C virus [HCV], and human immunodeficiency virus [HIV]) are among the easiest microorganisms to destroy with standard reprocessing. Before the advent of the reprocessing guidelines in 1988, there were three cases of HBV attributed to endoscopy. Two early reports suggested a temporal relationship between the use of an endoscope in an HBV-positive individual preceding the case and subsequent development of HBV infection, although in both cases no actual investigation was performed, and endoscope cleaning and disinfection were unacceptable by current standards.[69,70] In the third case, subtyping of HBV was used to confirm that transmission was likely. In this instance, the air and water channels were not exposed to glutaraldehyde.[71] Two more recent cases of HBV infection attributed to endoscopy are unlikely.[25,72,73]

There have been four cases of HCV transmission during GI endoscopy, all outside the United States. In three cases, a breach in currently accepted guidelines for endoscope reprocessing was reported.[74,75] In the fourth case, the transmission was believed to be due to contamination of multidose vials used for sedation (and associated with the *procedure* but not the endoscope itself).[76] This type of contamination was also the case in outbreaks of HCV at two endoscopy clinics in 2002 and 2007 in the United States. In the first case, the cause was initially attributed to deficient endoscope reprocessing practices by the lay press, but subsequent investigation by the New York State Department of Health determined that the cause was the improper reuse of needles and contamination of multidose vials.[77] A similar cause was found for the transmission of HCV in at least six patients at a Nevada endoscopy clinic.[78] These cases highlight the importance of general infection control practices, which are discussed later.

No cases of endoscopic transmission of HIV have been reported. Three studies have shown that glutaraldehyde disinfection of endoscopes contaminated with HIV completely eliminates the virus.[79–81]

There have been 317 putative episodes of transmission of infection reported in the medical literature. In the absence of defective equipment (notably the automated endoscope reprocessor), there has been a failure to follow currently accepted guidelines for cleaning and disinfection in each case.[25] These deficient practices can be summarized as follows:

1. Mechanical cleaning of the endoscope and channels before disinfection was inadequate or absent.
2. An inadequate or ineffective disinfectant was used.
3. An appropriate disinfectant was not used for an adequate exposure period.
4. Endoscopic accessory instruments were not sterilized.
5. The endoscope and all channels were not dried.

Liquid Chemical Germicides

The FDA defines a *high-level disinfectant* as a sterilant that is used under the same contact conditions except for a shorter contact time. LCGs were previously classified as sterilants by passing the Association of Official Analytical Chemists

Table 4.2 **Disinfectants**	
FDA-Cleared Sterilants and High-Level Disinfectants for High-Level Disinfection of Endoscopes	**Disinfectants Inadequate for High-Level Disinfection of Endoscopes (Examples)**
2.4%–3.5% glutaraldehyde	Phenolic solutions
	Hexachlorophene
3.4% glutaraldehyde/26% isopropanol	Iodophor solutions
	Povidone-iodine
1.12% glutaraldehyde/1.93% phenol/phenate	quaternary ammonium solutions
	Benzalkonium chloride
	Benzethonium chloride
	Cetrimide
0.55% *ortho*-phthalaldehyde	Chlorhexidine
0.60% *ortho*-phthalaldehyde	
5.75% *ortho*-phthalaldehyde (diluted)	
0.2% peracetic acid	Chlorhexidine/cetrimide
2.0% hydrogen peroxide	Alkyldiaminoethylglycine hydrochloride
7.5% hydrogen peroxide	
8.3% hydrogen peroxide/7.0% peracetic acid	Ethyl or isopropyl alcohol*
7.35% hydrogen peroxide/0.23% peracetic acid	
1.0% hydrogen peroxide/0.08% peracetic acid	
Hypochlorite/hypochlorous acid 650–675 ppm (active free chlorine)	
Hypochlorite/hypochlorous acid 400–450 ppm (active free chlorine)	

*When used for high-level disinfection; appropriate for terminal drying.
FDA, U.S. Food and Drug Administration.
From Nelson DB: Infectious disease complications of GI endoscopy. Part II. Exogenous infections. Gastrointest Endosc 57:695–711, 2003, with permission from the American Society for Gastrointestinal Endoscopy.

(AOAC) Sporicidal Test.[82] Older LCGs (e.g., ≥2% glutaraldehyde) were approved by the FDA for sterilization and high-level disinfection (although the prolonged exposure time required made this impractical). However, more recently approved LCGs, such as 0.55% *ortho*-phthalaldehyde (Cidex OPA) and hypochlorite 400–450 ppm (Sterilox), that passed the AOAC Sporicidal Test have not been given an indication for device sterilization (i.e., high-level disinfection only). The FDA has approved many LCGs for use as high-level disinfectants or sterilants in the reprocessing of endoscopes and other reusable medical devices (**Table 4.2**). These include 2.4% to 3.5% glutaraldehyde, 3.4% glutaraldehyde/26% isopropanol, 1.12% glutaraldehyde/1.93% phenol/phenate, 0.55% to 0.60% *ortho*-phthaldehyde, 0.2% peracetic acid, 2.0% and 7.5% hydrogen peroxide, 8.3% hydrogen peroxide/7.0% peracetic acid, 7.35% hydrogen peroxide/0.23% peracetic acid, 1.0%

hydrogen peroxide/0.08% peracetic acid, and hypochlorite/hypochlorous acid 400 ppm or greater active free chlorine.[82]

Many LCGs are labeled for multiple reprocessing cycles for a specific time period. However, as these sterilants are reused, dilution occurs, which can reduce their effectiveness. Product-specific test strips should be used regularly to monitor these solutions to insure that they are above their minimum effective concentration (MEC). Solutions should be discarded whenever they fall below the MEC or when the use-life expires, whichever comes first. Users should consult with manufacturers of endoscopes and AERs (if used) for compatibility before selecting an LCG. Two agents (0.2% peracetic acid, 5.75% *ortho*-phthalaldehyde) are used for a single disinfection cycle and are not reusable (i.e., single use—each cycle requires new LCG); the hypochlorite/hypochlorous acid solution is generated from electrolysis of a saline solution for each cycle.[83–85]

Automatic Endoscope Reprocessors

Historically, cleaning and high-level disinfection of endoscopes has been performed manually. The high-level disinfection step involved placing mechanically cleaned endoscopes into a basin or container of LCG (usually glutaraldehyde) that was also circulated through the internal channels of the instrument. Exposure of endoscopy personnel to some LCGs has been reported to cause respiratory, nasal, and skin problems, however.[86,87] AERs were designed to ensure that reprocessing is performed consistently and to replace some manual disinfection steps. In addition, AERs may minimize the exposure of endoscopy personnel to the LCG.[88] It is crucial, however, that users understand that endoscopes must be mechanically cleaned before reprocessing in an AER. Although several devices are labeled by the FDA as "washer-disinfectors," and one device has been approved to bypass the mechanical cleaning step, this has not been endorsed or sanctioned by any of the gastrointestinal societies that represent the end-users (mechanical cleaning is still recommended before the use of all AERs). It is also important to verify that the endoscope and the AER are compatible and use appropriate connectors.[89]

Cleaning and Disinfecting Endoscopes

A guideline for reprocessing GI endoscopes that has been endorsed by numerous gastroenterology, infection control, surgical, nursing, and hospital organizations contains detailed recommendations for this process.[90] A similar guideline (although broader in scope) by the Healthcare Infection Control Practices Advisory Committee (HICPAC) of the CDC has been finalized.[91] The pertinent steps to achieve high-level disinfection of endoscopes from these guidelines are summarized as follows:

1. Perform pressure/leak testing after each use according to the manufacturer's guidelines.
2. Disconnect and disassemble endoscope components (e.g., air/water and suction valves) as far as possible and completely immerse the endoscope and components in the enzymatic detergent.

3. Immediately after use, meticulously clean the entire endoscope, including valves, channels, connectors, and all detachable parts, with an enzymatic detergent compatible with the endoscope according to the manufacturer's instructions. Flush and brush all accessible channels to remove all organic (e.g., blood, tissue) and other residues. Repeatedly actuate the valves during cleaning to facilitate access to all surfaces. Clean the external surfaces and components of the endoscope using a soft cloth, sponge, or brushes.

4. Use brushes appropriate for the size of the endoscope channel, parts, connectors, and orifices (e.g., bristles should contact all surfaces) for cleaning. Cleaning items should be disposable or thoroughly cleaned and disinfected or sterilized between uses.

5. Discard enzymatic detergents after each use because these products are not microbicidal and do not retard microbial growth.

6. Use a high-level disinfectant or sterilant approved by the FDA for high-level disinfection (http://www.fda.gov/cdrh/ode/germlab.html).

7. Exposure time and temperature for disinfecting semicritical patient care equipment vary among the FDA-approved high-level disinfectants. Follow the FDA-approved label claim for high-level disinfection, unless several well-designed experimental scientific studies, endorsed by professional societies, show an alternative exposure time is effective for disinfecting semicritical items. The FDA label claim for high-level disinfection with greater than 2% glutaraldehyde at 25° C ranges from 20 to 90 minutes depending on the product. However, multiple scientific studies and professional organizations support the efficacy of greater than 2% glutaraldehyde for 20 minutes at 20° C.

8. Select a disinfectant or sterilant that is compatible with the endoscope. The use of specific high-level disinfectants or sterilants on an endoscope should be avoided if the endoscope manufacturer warns against use because of functional damage (with or without cosmetic damage).

9. Completely immerse the endoscope and endoscope components in the high-level disinfectant or sterilant and ensure all channels are perfused. Nonimmersible GI endoscopes should be phased out.

10. If an AER is used, ensure that the endoscope and endoscope components can be effectively reprocessed in the AER (e.g., the elevator wire channel of duodenoscopes is not effectively disinfected by most AERs, and this step must be performed manually). Users should obtain and review model-specific reprocessing protocols from both the endoscope and the AER manufacturers and check for compatibility.

11. If an AER is used, place the endoscope and endoscope components in the reprocessor and attach all channel connectors according to the instructions of the AER and endoscope manufacturers to ensure exposure of all internal surfaces to the high-level disinfectant or chemical sterilant.

12. If an AER cycle is interrupted, high-level disinfection or sterilization cannot be ensured and should be repeated.

13. After high-level disinfection, rinse the endoscope and flush the channels with sterile, filtered, or tap water to remove the disinfectant or sterilant. Discard the rinse water after each use or cycle. Flush the channels with 70% to 90% ethyl or isopropyl alcohol and dry using forced air. The final drying steps greatly reduce the possibility of recontamination of the endoscope by waterborne microorganisms.

14. 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).

15. Endoscopes should be stored in a manner that protects the endoscope from contamination.

16. Perform high-level disinfection or sterilization of 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.

17. Perform routine testing of the liquid sterilant or high-level disinfectant to ensure MEC of the active ingredient. Check the solution at the beginning of each day of use (or more frequently), and document the results. If the chemical indicator shows that the concentration is less than the MEC, the solution should be discarded.

18. Discard the liquid sterilant or high-level disinfectant at the end of its reuse life (which may be single use) regardless of the MEC. If additional liquid sterilant or high-level disinfectant is added to an AER (or basin, if manually disinfected), the reuse life should be determined by the first use or activation of the original solution (i.e., the practice of "topping off" of a liquid sterilant or high-level disinfectant pool does not extend the reuse life).

Although some authorities have advocated that cleaned and disinfected endoscopes that have been stored should undergo an additional cleaning and disinfection process before the beginning of an endoscopy schedule (i.e., first-case reprocessing), there are no data to support this as a routine practice. When GI endoscope cleaning and disinfection guidelines are strictly followed and endoscopes are stored appropriately, this additional procedure is unnecessary. Generally, however, if there is doubt about a cleaning and disinfection cycle, or the instrument is found to be wet after storage (or otherwise stored improperly), the endoscope should be reprocessed.

Disinfection Procedure Compliance

Adherence to established guidelines for the cleaning and disinfection of endoscopes is imperative. When these guidelines are followed, the risk of transmission of infection is virtually eliminated; however, this is not a reason for complacency because compliance with existing reprocessing guidelines is not uniform. In 1991, Gorse and Messner[92] surveyed 2030 SGNA members and found that compliance with existing guidelines was 67% in some areas. A collaborative study by the FDA and three state health departments published in 1992 investigated endoscope reprocessing at 26 health care facilities and found that 24% of patient-ready endoscopes were contaminated, and these were attributed to fundamental errors in the disinfection process.[93,94]

Although office endoscopy has been shown to be as safe as endoscopy practiced in more regulated settings (e.g., hospitals),[95] the absence of formal infection control programs and personnel may leave the office setting more vulnerable to compliance issues with regard to endoscope reprocessing. In one study of 19 family practice and internal medicine offices performing flexible sigmoidoscopy, all were found to deviate from accepted reprocessing guidelines in at least one area.[96] Although two more recent studies suggest that compliance with reprocessing guidelines has improved,[97,98] there is room for further improvement. The challenge facing practitioners in the field of GI endoscopy is to ensure that compliance with these guidelines is universal, regardless of the practitioner or setting.

Reprocessing Personnel

Only trained personnel who understand the importance of strict adherence to established protocols should perform endoscope reprocessing (as a corollary, untrained personnel should not reprocess endoscopes). This training should include device-specific reprocessing instructions (for both the endoscope and the reprocessing equipment) and education regarding the biologic and chemical hazards associated with the cleaning and disinfection of endoscopes with LCGs. These individuals should meet annual competency standards for endoscope reprocessing. In addition, all health care personnel in the endoscopy suite should be trained in and adhere to standard infection control recommendations (e.g., standard precautions), including recommendations to protect both patients and health care workers.[33] Personal protective equipment, such as gloves, gowns, eyewear, and respiratory protection devices, should be readily available. This equipment should be used, as appropriate, to protect reprocessing personnel from exposure to chemicals, blood, or other potentially infectious material.[99–102]

Novel Infectious Agents

Although Creutzfeldt-Jakob disease (CJD) and vCJD are rare, the impact of these diseases on endoscope reprocessing is addressed. CJD and vCJD are degenerative neurologic disorders transmitted by proteinaceous infectious agents called prions (although this is a simplification). Prions are unusually resistant to disinfection by conventional chemical high-level disinfectants or sterilants.[103,104] The incidence of CJD in the United States is extremely low, with approximately 250 cases per year, or 0.97 cases per 1 million persons per year.[105] Tissues and secretions that come into contact with the endoscope during procedures, such as saliva, gingival tissue, intestinal tissue, feces, and blood, are considered noninfectious by the World Health Organization.[103] A draft statement on CJD and medical device reprocessing from the CDC concluded that current guidelines for cleaning and disinfection of these instruments need not be changed.[35] Other infection control experts have concurred, citing the lack of exposure to high-risk tissue and the importance of mechanical cleaning in removing microbial contamination,[31,104]

The clinical relevance of the more recent finding of abnormal prion proteins in the olfactory (but not respiratory) epithelium of affected patients with regard to infection control or endoscope reprocessing is unclear.[106] To date, there have been no reported cases in the world literature of transmission of CJD (or any other transmissible spongiform encephalopathy) by endoscopy. vCJD is a more recently recognized and even more rare syndrome that is believed to be due to consumption of beef products containing the bovine spongiform encephalopathy (BSE) agent, possibly requiring a susceptible genotype by the individual.[107] The only case of the disease reported in the United States was found in a 22-year-old patient that had moved from the United Kingdom. Despite active surveillance since 1990, BSE has not been detected in the United States.[108] In contrast to CJD, the prions associated with vCJD can be detected in the lymphoid tissue of affected individuals (e.g., tonsil, appendix, and possibly ileum and rectum).[107,109–112] The prions in these tissues are present in lower concentrations and are approximately 50% less infective than central nervous system tissue when homogenized and injected intracerebrally in mice.[113] The infectivity of intact tissue that might be encountered at endoscopy and the risk of subsequent transmission to another individual via gut inoculation are unknown but would undoubtedly be lower.

Given the virtual absence of vCJD in the United States, rigorous adherence to current guidelines for the cleaning and disinfection of endoscopes would seem to be adequate. There is no evidence that changes to current endoscopic practices or endoscope reprocessing guidelines are warranted, but these should be responsive to new information as it evolves. The European Society for Gastrointestinal Endoscopy (ESGE) stated that because it is impossible to ensure that an instrument used in a patient with vCJD can be cleaned, that instrument should either be destroyed or quarantined for use in other vCJD patients only. The safest option is not to perform endoscopy on these patients or, if absolutely necessary, to use an old instrument and subsequently destroy it. A larger potential problem in Europe is the situation in which a patient who has undergone endoscopy is subsequently found to have vCJD. The instrument should be quarantined (or, ideally, destroyed). How to deal with the group of patients who had subsequently undergone endoscopy with that instrument is a complicated issue that would require input from the hospital administration and government infectious diseases authorities.

General Infection Control Practices

The importance of general infection control practices has been highlighted by the transmission of HCV to at least six individuals at a Nevada endoscopy clinic. The subsequent epidemiologic investigation revealed that the outbreak was due to unsafe injection practices, specifically the reuse of syringes and the use of single-use medical vials on multiple patients.[78] A review of nonhospital health care–associated HBV and HCV transmission outbreaks in the United States over the last decade showed that in each case, failure to follow fundamental principles of infection control and aseptic technique was the cause.[114] Although this problem is not unique to endoscopy, it is imperative that health care workers in endoscopy units understand and adhere to recommended infection control practices.

References

The complete reference list is available online at www.expertconsult.com.