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Cleaning and Disinfecting Gastrointestinal Endoscopy Equipment

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INTRODUCTION

The field of gastrointestinal (GI) endoscopy has expanded dramatically as new procedures, instruments, and accessories have been introduced into the medical community; more than 20 million GI endoscopies are performed annually in the United States.^{1,2} Although GI endoscopes are used as a diagnostic and therapeutic tool for a broad spectrum of GI disorders, more health care–associated infectious outbreaks and patient exposures have been linked to contaminated endoscopes than to any other reusable medical device.^{3–6} Failure to adhere to established reprocessing guidelines or the use of defective reprocessing equipment accounts for the majority of these cases.^{7–13} In addition, complex endoscopes such as the duodenoscope and linear echoendoscope with elevator mechanisms can transmit bacterial infections even when reprocessing protocols are reportedly followed in accordance with manufacturer and societal guidelines.^{14–16}

The topic of endoscope reprocessing 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 slow evolution with a high safety profile may have engendered some complacency on the part of endoscopists, to the point that many endoscopists are only vaguely aware of what goes on “behind the curtain” of the endoscope reprocessing room. Instruments are used on patients, taken away by GI nurses or other health care personnel, reprocessed, and returned ready for patient use.

As the complexity of reprocessing and recognition of its importance become a concern to the medical community and our patients, endoscopists must become more educated on these issues and thereby able to participate in informed discussions with their patients. This chapter presents a pragmatic approach to proper reprocessing of endoscopic equipment, with guidance for prevention and management of infection transmission, and includes newer sterilization and disinfection technologies.

PRINCIPLES OF REPROCESSING

Cleaning

Cleaning refers to removal of visible soiling, blood, protein substances, and other adherent foreign debris from surfaces, crevices, and lumens of instruments.¹⁷ It is usually accomplished with mechanical action using water, detergents, and enzymatic products. Meticulous physical cleaning must always precede disinfection and sterilization procedures, because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes.¹⁸ Mechanical cleaning alone reduces microbial counts by approximately 10^3 to 10^6 (three to six logs), equivalent to a 99.9% to 99.9999% reduction in microbial burden.^{19–26}

Sterilization

Sterilization is defined as the destruction or inactivation of all microorganisms. The process is operationally defined as a 12-log reduction of bacterial endospores.²⁷ Not all sterilization processes

Abstract

Outbreaks of infection transmission due to contaminated flexible endoscopes have focused the attention of health care personnel, senior management, device manufacturers, and regulators on the need to improve the approach used to offer this valuable service. This chapter presents the principles of flexible endoscope reprocessing along with a pragmatic approach to the judicious selection and proper reprocessing of endoscopic equipment, as well as guidance for prevention and management of infection transmission inclusive of newer sterilization (e.g., hydrogen peroxide vapor) and disinfection (e.g., improved hydrogen peroxide) technologies. It also provides an outline of the Quality Systems approach that is applicable to flexible endoscope reprocessing and the need for ongoing staff competency and audits of endoscope cleaning, disinfection, and storage practices. Furthermore, the most current regulatory, expert organization, and manufacturer's recommendations are reviewed.

Keywords

flexible endoscope reprocessing
Carbapenem-resistant Enterobacteriaceae
key reprocessing considerations
channel-purge drying cabinet
biofilm
flexible endoscope quality systems
reprocessing personnel
rapid cleaning monitoring tests

are alike, however. Steam is the most extensively utilized process and is routinely monitored by the use of biologic indicators (e.g., spore test strips) to show that sterilization has been achieved. When liquid chemical germicides (LCGs) are used to eradicate all microorganisms, they can be called chemical sterilants; however, the US Food and Drug Administration (FDA) and other authorities have stated that these processes do not convey the same level of assurance as other sterilization methods.^{28–30} Other commonly used sterilization processes include low-temperature gas such as ethylene oxide (ETO), liquid chemicals, and hydrogen peroxide gas plasma.³¹

Disinfection

Disinfection is defined broadly as the destruction of microorganisms, except bacterial spores, on inanimate objects (e.g., medical devices such as endoscopes). Three levels of disinfection are achievable depending on the amount and kind of microbial killing involved. These levels of disinfection are as follows:

1. High-level disinfection (HLD): the destruction of all viruses, vegetative bacteria, fungi, mycobacterium, and some, but not all, bacterial spores.^{32,33} For LCGs, HLD is operationally defined as the ability to kill 10^6 mycobacteria (a six-log reduction). The efficacy of HLD is dependent on several factors and includes the type and level of microbial contamination; effective precleaning of the endoscope; presence of biofilm; physical properties of the object; concentration, temperature, pH, and exposure time to the germicide; and drying after rinsing to avoid diluting the disinfectant.³²
2. Intermediate-level disinfection: the destruction of all mycobacteria, vegetative bacteria, fungal spores, and some nonlipid viruses, but not bacterial spores.
3. Low-level disinfection: a process that can kill most bacteria (except mycobacteria or bacterial spores), most viruses (except some nonlipid viruses), and some fungi.

Although this categorization for disinfection levels generally remains valid, there are examples of disinfection issues with prions, viruses, mycobacteria, and protozoa that challenge these definitions.³⁴

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). The 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](#).

Spaulding Classification

More than 40 years ago, Earle H. Spaulding developed a rational approach to disinfection and sterilization of medical equipment based on the risk of infection involved with the use of these instruments.^{35,36} The classification scheme defined these categories of medical devices and their associated level of disinfection as follows:

1. Critical: critical devices or instruments come into contact with sterile tissue or the vascular system. These devices confer a high risk for infection if they are contaminated. This category includes biopsy forceps, sphincterotomes, surgical instruments, and implants, when used in sterile anatomic locations. Reprocessing of these instruments requires sterilization.

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 (ed): *Disinfection, sterilization, and preservation*, ed 4. Philadelphia, 1991, Lea & Febiger, pp 1097–1106.

2. Semicritical: semicritical devices contact intact mucous membranes and do not ordinarily penetrate sterile tissue. These instruments include endoscopes, bronchoscopes, transesophageal echocardiography probes, and anesthesia equipment. Reprocessing of these instruments requires a minimum of HLD.
3. Noncritical: noncritical devices contact intact skin (e.g., stethoscopes or blood pressure cuffs). These items should be cleaned by low-level disinfection.

DISINFECTION AND GI ENDOSCOPY

Endoscopes

GI endoscopes are considered semicritical devices, and the resultant minimal standard for reprocessing is HLD. This standard is endorsed by governmental agencies including the Joint Commission (JC), the Centers for Disease Control and Prevention (CDC),³⁷ and the FDA.³⁸ It is also endorsed by gastroenterology societies such as the American Society for Gastrointestinal Endoscopy (ASGE), American College of Gastroenterology (ACG), and American Gastroenterological Association (AGA), as well as medical organizations, including the Association of Perioperative Registered Nurses (AORN), Society of Gastroenterology Nurses and Associates (SGNA), Association for Professionals in Infection Control and Epidemiology (APIC), and American Society for Testing and Materials (ASTM).^{39–42} HLD of endoscopes eliminates all viable microorganisms, but not necessarily all

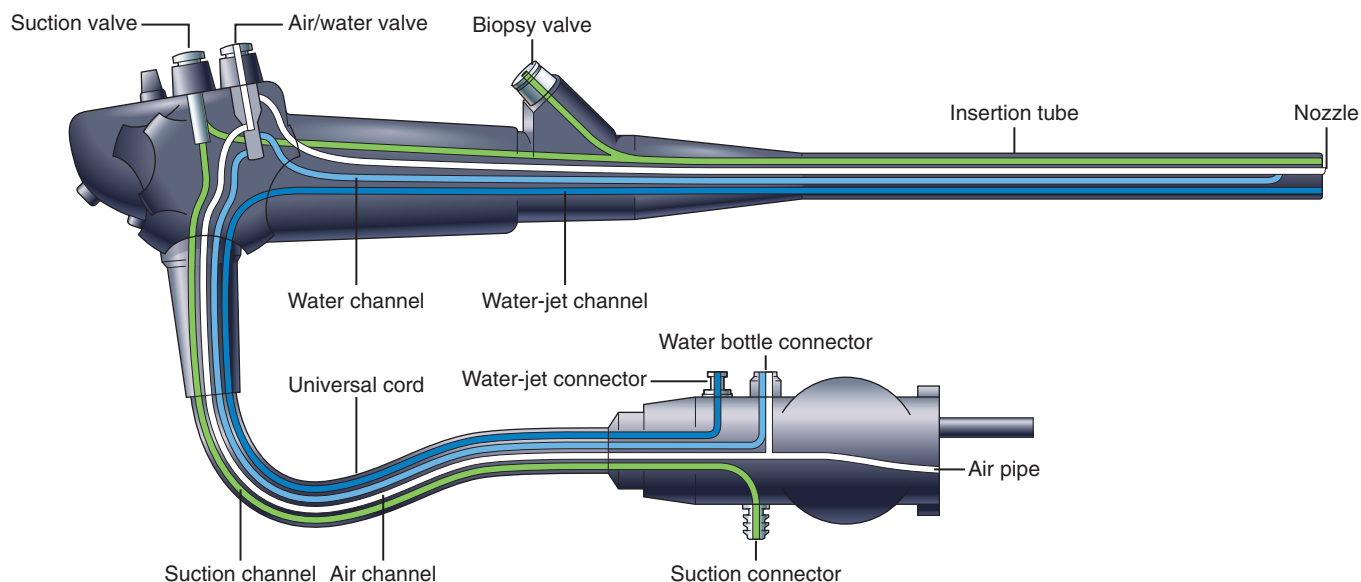


FIG 4.1 Schematic of internal channels of an endoscope. (Adapted from Olympus America. Copyright Olympus America Inc., 2003.)

bacterial spores.⁴³ Although spores are more resistant to HLD than other bacteria and viruses, they are likely to be killed when endoscopes undergo thorough manual cleaning. In addition, survival of small numbers of bacterial spores with HLD is considered acceptable because the intact mucosa of the GI tract is resistant to bacterial spore infection.

Endoscope sterilization, as opposed to HLD, is not required for “standard” GI endoscopy, as a reprocessing endpoint of sterilization has not been demonstrated to further reduce the risk of infectious pathogen transmission from endoscopes.⁴⁴ Sterilization of endoscopes is indicated when they are used as “critical” medical devices, such as intraoperative endoscopy when there is potential for contamination of an open surgical field.^{45,46} In addition, individual institutional policies may dictate sterilization of duodenoscopes and linear endoscopic ultrasound instruments due to elevator mechanisms that have been difficult to clean and eradicate all bacterial contaminants with HLD alone (see the later section on [Duodenoscope-Related Infections](#)).

Despite the complex internal design (Fig. 4.1) of endoscopes, HLD is not difficult to achieve with rigorous adherence to currently accepted reprocessing guidelines.⁴⁷ Endoscope features that challenge the reprocessing procedures include:

- Complex endoscope design with several long, narrow internal channels and bends that make it difficult to remove all organic debris and microorganisms (e.g., elevator channel and elevator lever cavity of duodenoscopes).
- A large variety of endoscope vendors and models require different cleaning procedures and devices and materials.
- Occult damage (e.g., scratches, crevices) to the endoscope can sequester microorganisms and promote biofilm formation.

Accessories

All valves, caps, connectors, and flushing tubes need to be adequately cleaned, rinsed, and disinfected or sterilized at the same time the patient-used endoscope is being reprocessed.⁴⁸ The water bottle used to provide intraprocedural flush solution and its connecting tubing should be sterilized or receive high-level

disinfection at least once daily. The water bottle should be filled with sterile water.^{49–52} Because accessory items often do not have unique identification numbers, it is critical to ensure they are dedicated to and stored with the endoscope that they are used with. This is necessary to ensure that if there is an outbreak, it is possible to identify which accessory components were used. This may require the use of disposable accessory holders or holders such as mesh bags that are also reprocessed along with the accessories.

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.^{49,50} These accessories may be available as disposable “single-use” or “reusable” instruments. Reuse of devices labeled *single-use only* remains controversial but has been commonly employed in many practices, primarily for economic benefits.^{44,53–56} The FDA⁵⁷ considers reprocessing a used single-use device into a ready-for-patient-use device as “manufacturing,” and as a result, hospitals or third-party reprocessing^{58,59} companies that reprocess these devices are required to follow the same regulations as the original equipment manufacturers (i.e., obtain 510[k] and premarket approval application; submit adverse event reports; demonstrate sterility and integrity of the reprocessed devices; and implement detailed quality assurance monitoring protocols). This includes the development of standards and policies to determine the maximum number of uses for the devices and the training of staff in the reprocessing procedures.^{59–62} The regulatory burden imposed by these requirements essentially eliminated the practice of the reprocessing of single-use devices by most hospitals.

Automated Endoscope Reprocessors (AERs)

AERs were developed to replace some of the manual disinfection processes and standardize several important reprocessing steps, thereby eliminating the possibility of human error and minimizing exposure of reprocessing department personnel to chemical

sterilants.^{63–70} AERs continuously bathe the exterior surface of the endoscope and circulate the LCG under pressure through the endoscope channels. The AER manufacturer identifies each endoscope (brand and model) that is compatible with the AER and specifies limitations of reprocessing models of endoscopes and accessories. Variations in AERs may require customization of the facility design to accommodate requirements for ventilation; water pressure, temperature, and filtration; plumbing; power delivery; and space. All models of AERs have disinfection and rinse cycles. In addition, the AERs may also have one or more of the following automated capabilities:^{32,68,71}

1. Some AERs utilize and discard small quantities of LCG per HLD cycle, whereas others have a reservoir of LCG that is reused over multiple cycles. The latter design results in gradual dilution of the LCG and requires intermittent testing to verify maintenance of the minimum effective concentration (MEC). Product-specific test strips need to be used regularly to monitor these solutions,⁴⁸ which should be discarded whenever they fall below the MEC or when the use-life expires, whichever comes first.
2. The temperature and cycle length can be altered to ensure HLD or sterilization based on the LCG and type of endoscope.
3. The AER should ensure circulation of LCGs through all endoscope channels at an equal pressure with flow sensors for automated detection of channel obstruction.
4. The AER should be self-disinfecting.
5. Vapor recovery systems are available.
6. Low intensity ultrasound waves are an option.
7. Variable number of endoscopes per cycle.
8. Some AERs flush the endoscope channels with forced air or with 70% to 80% ethyl or isopropyl alcohol followed by forced air to aid in drying the endoscope channels, thereby eliminating residual water, which reduces microbial growth during storage.
9. The AER should incorporate a self-contained or external water filtration system.

LCGs and AERs must meet specified performance levels for HLD to receive FDA clearance. This is defined as a reduction in residual organic loads and a 6-log₁₀ killing of resistant indicator organisms (typically *Mycobacterium bovis*). All AERs marketed in the United States meet these criteria. The ASGE has published a summary of vendor-specific AERs and their compatible LCGs.⁶⁵ The FDA has approved labeling some AERs as washer-disinfectors due to the introduction of automated, brushless washing of endoscope channels prior to the disinfection cycle. Utilization of this AER washing cycle provides an extra margin of safety by providing redundancy of cleaning; however, the existing multisociety guideline⁴⁵ and other international standards emphasize that manual cleaning is still necessary when a washer-disinfectant is used to assure the overall efficacy of HLD.^{65,72}

One AER (Steris System 1E [SS1E]; Steris Corp, Mentor, OH) has received FDA approval for liquid chemical sterilization, as opposed to HLD, for heat-sensitive devices that cannot be sterilized by traditional means.⁷³ This system uses filtered, ultraviolet-treated water that enters the AER and mixes with a peracetic acid-based formulation that is subsequently heated to 46°C to 55°C for liquid chemical sterilization.⁷⁴ This system is designed for “point of use” sterilization, as sterile storage is not possible. For flexible endoscopes processed through the SS1E, there is still a requirement for an alcohol rinse and drying prior to placing the endoscope into a storage cabinet.

The FDA also requested that AER manufacturers conduct additional validation testing to evaluate AER reprocessing

effectiveness with regard to the recess around the duodenoscope’s elevator lever area.⁷⁵ An FDA communiqué released in February 2016 indicated that validation testing on three AER models (Advantage Plus [Medivators; Minneapolis, MN], DSD Edge [Medivators], and System IE [Steris Corp]) was complete and adequate.⁷⁵ In November 2015, the FDA issued a recall under consent decree for all Custom Ultrasonics (Ivyland, PA) AERs because of the company’s inability to validate that their AERs were able to adequately wash and disinfect duodenoscopes to mitigate the risk of patient infection.⁷⁶ In a subsequent safety communication, the FDA recommended that health care facilities should not use Custom Ultrasonics System 83 Plus AERs for reprocessing duodenoscopes and should transition to alternative methods for duodenoscope reprocessing.⁷⁷

Liquid Chemical Germicides and Sterilization Technologies

LCGs have inherent limitations; however, they are universally used to reprocess flexible endoscopes and accessories due to their relative convenience, safety, and rapid action. LCGs used as HLDs should ideally have the following properties: broad antimicrobial spectrum, rapid onset of action, activity in the presence of organic material, lack of toxicity for patients and endoscopy personnel, long reuse life, low cost, odorless, ability to monitor concentration, and nondamaging to the endoscope or the environment.^{18,32} HLD solutions can act as sterilants if an increased exposure time is used^{28,48,78}; however, the exposure time required to achieve sterilization with most LCG solutions is far longer than is practical, and therefore these formulations are only used for HLD.^{48,79}

The efficacy of chemical disinfectants and sterilants is dependent on their physical properties including concentration and temperature; the length of exposure of the endoscope to the chemical solutions; the type and amount of microbial debris on the endoscope; and the mechanical components of the endoscope such as channels and crevices. Because the chemicals are toxic to humans and the environment, proper handling, thorough rinsing, and appropriate disposal are essential for human safety.⁷¹ When selecting a HLD product, institutional requirements need to be taken into consideration with important variables including the number of endoscopes processed per day, training requirements, turnaround time, cost information, and regulatory issues regarding safe use of the HLD products. Health care workers who use HLDs need to be familiar with and have readily accessible, product/brand-specific Material Safety Data Sheets (MSDS) and keep current with regulatory changes and new product developments.¹⁸ Users should consult with manufacturers of endoscopes and AERs for compatibility before selecting an LCG. The most commonly used FDA approved LCGs for disinfection of flexible endoscopes include glutaraldehyde, ortho-phthalaldehyde (OPA), peracetic acid, and hydrogen peroxide (Table 4.1)^{71,80,81} based chemicals in varying combinations and concentrations. Some formulations contain combinations of microbicidal agents, including glutaraldehyde and phenol/phenate, peracetic acid and hydrogen peroxide, and glutaraldehyde and isopropyl alcohol. The FDA periodically updates a list of approved HLD solutions along with some of their attributes, such as contact time and temperature required for HLD.⁸²

Sterilization of endoscopes is indicated on occasions when they are used as critical medical devices during open surgical procedures. The risk for contamination of the operative field exists when a nonsterile endoscope enters the abdomen through

TABLE 4.1 High-Level Disinfectants Currently Used for Endoscope Reprocessing

Agent/Action	Contact Time	Advantages	Disadvantages
<p>Glutaraldehyde Biocidal activity results from its alkylation of sulfhydryl, hydroxyl, carboxyl, and amino groups of microorganisms, which alters RNA, DNA, and protein synthesis</p>	<p>Minimum of 45 minutes at 25°C is indicated by the manufacturers (a minimum of 20 minutes at room temperature (20°C) is adequate according to expert opinion and published guidelines)</p>	<ul style="list-style-type: none"> • Long history of use in health care settings • Excellent biocidal activity • Relatively inexpensive • Not corrosive to endoscopes • Not classified as a human carcinogen • Can be used for manual or AER systems • Some products achieve high-level disinfection with a shorter exposure time but require a higher temperature (e.g., Rapicide, Medivators, Minneapolis, MN) (US FDA, 2009) 	<ul style="list-style-type: none"> • Fixes proteins which allows for biofilm formation; therefore, it is critical that medical devices are thoroughly cleaned prior to exposure. • Should not be used for reprocessing in patients with prion infection • Reusable for 14 to 28 days (depending on formulation) • MEC testing necessary • Vapors are sensitizing and work areas need to be properly ventilated and air quality monitored but less than glutaraldehyde. AER mitigates this issue. • Exposure may cause skin irritation or mucous membrane irritation (eye, nose, mouth), or pulmonary symptoms (epistaxis, asthma, rhinitis) • Exposure may cause colitis if the endoscope is not thoroughly rinsed • Relatively slow mycobacterial activity • Requires inactivation or special disposal protocol
<p>Orthophthalaldehyde (OPA) Similar to glutaraldehyde interacts with amino acids, proteins, and microorganisms. However, OPA is a less potent cross-linking agent. This is compensated for by the lipophilic aromatic nature of OPA that is likely to assist its uptake through the outer layers of mycobacteria and gram-negative bacteria. OPA appears to kill spores by blocking the spore germination process.</p>	<p>Minimum of 10 minutes at room temperature (20°C); minimum of 5 minutes at 25°C (when used with an AER)</p>	<ul style="list-style-type: none"> • Fast acting • Excellent microbicidal activity and superior mycobactericidal activity compared to glutaraldehyde • Odor not significant • No air quality monitoring required • Excellent materials compatibility • Does not coagulate blood or fix tissues to surfaces • Does not require exposure monitoring • No carcinogen classification • Stable in wide range pH 3–9 • In AERs, it lasts longer before reaching MEC limit (~80 cycles) compared to glutaraldehyde (~40 cycles). Reusable for 14 days 	<ul style="list-style-type: none"> • An aldehyde that cross-links proteins similar to glutaraldehyde but much less active as fixative • Not used for reprocessing in patients with prion infection • Stains skin, mucous membranes, clothing and environmental surfaces • More expensive than glutaraldehyde • Slow sporicidal activity • May not be compatible with all AERs • Potential irritant of eyes, skin, nose and pulmonary tree • May require neutralization prior to disposal • Concentrate limited use to one specific AER, and contraindicated for manual reprocessing
<p>7.5% Hydrogen Peroxide Produces destructive hydroxyl free radicals that can attack membrane lipids, DNA, and other essential cell components</p>	<p>15 to 30 minutes at 21°C (depending upon formulation)</p>	<ul style="list-style-type: none"> • No activation required • May enhance removal of organic matter and organisms • Active against a wide range of microorganisms • No disposal issues • No odor or irritation issues • Does not coagulate blood or fix tissues to surfaces • Inactivates cryptosporidium 	<ul style="list-style-type: none"> • Material compatibility concerns (brass, zinc, copper, and nickel/silver plating) both cosmetic and functional • Severely irritating and corrosive to eyes, skin and gastrointestinal tract if inadequately rinsed • Excessive exposure could cause irreversible tissue damage to the eyes, including blindness, inhalation of hydrogen peroxide vapors can be severely irritating to the nose, throat, and lungs
<p>Peracetic Acid Similar to other oxidizing agents it denatures proteins, disrupts cell wall permeability, and oxidizes sulfhydryl and sulfur bonds in proteins, enzymes, and other metabolites</p>	<p>5 minutes as 30°C or 12 minutes at 50°C to 56°C depending on formulation</p>	<ul style="list-style-type: none"> • Rapid sterilization cycle time (30–45 minutes) • Low-temperature (50°–55°C) liquid immersion sterilization • Has a significantly greater efficacy at higher temperatures (e.g., a 6-log reduction of spores at 50°C in less than 2 minutes) • Rapidly sporicidal • Environmentally friendly byproducts (acetic acid, O₂, H₂O) and leaves no residue • No adverse health effects when used under normal operating conditions • Compatible with many materials and instruments • Does not coagulate blood or fix tissues to protein • Does not allow biofilm creation and has the ability to remove glutaraldehyde hardened bioburden from biopsy channels • Has not caused resistant organisms 	<ul style="list-style-type: none"> • Potential material incompatibility (e.g., aluminum anodized coating becomes dull) • Can corrode copper, brass, bronze, plain steel and galvanized iron • Oxidizing ability may expose the leaks in internal channels of scopes previously disinfected with glutaraldehyde • Considered unstable, particularly when diluted • More expensive (endoscope repairs, operating costs, purchase costs) • Serious eye and skin damage (concentrated solution) with contact • Concentrates are used only in specific AER

AER, automated endoscope reprocessor; FDA, Food and Drug Administration; MEC, minimum effective concentration.

TABLE 4.2 Sterilization Technologies Used for Flexible Endoscope Reprocessing⁸⁸⁻⁹²

Agent/Action	Contact Time	Advantages	Disadvantages
Steam		<ul style="list-style-type: none"> • Nontoxic to environment, staff, and patients • Rapid cycle time • Minimally affected by organic/inorganic soiling • Penetrates device lumens and medical packing • Rapidly microbicidal 	<ul style="list-style-type: none"> • Deleterious for heat-sensitive instruments so only applicable for use with specially constructed flexible endoscopes as per MIFU • May leave instruments wet and susceptible to rust • Potential for burns
Ethylene oxide (ETO)	30 minutes to 1 hour exposure depending on model of ETO sterilizer (100% ETO sterilizer versus those that use a carrier gas)	<ul style="list-style-type: none"> • Penetrates device lumens • Compatible with most medical materials and endoscope manufacturers • Simple to operate and monitor • Sterile storage in ETO sterilization case 	<ul style="list-style-type: none"> • Requires 8–12 hours aeration time to remove ETO residue • Only 20% of United States hospitals have ETO on-site • Long turn-around time • No microbicidal efficacy data proving SAL 10⁻⁶ achieved • Studies question microbicidal activity in presence of organic matter and salt • ETO is toxic, a carcinogen, flammable • May damage endoscope • Requires special exposure monitoring • Requires special exhaust “scrubbers” to remove traces of ETO prior to release in environment • Requires specific ETO case to ensure adequate ETO penetration
Vaporized hydrogen peroxide	~50 minutes	<ul style="list-style-type: none"> • Safe for environment and no fumes • Leaves no toxic residue • No aeration necessary • Compatible with most devices including heat sensitive (temperatures <50°C) 	<ul style="list-style-type: none"> • Restrictions of endoscopes based on poor penetration into long and narrow lumens • Limited materials and comparative microbicidal efficacy data (not proven SAL 10⁻⁶ achieved)
Peracetic acid (liquid chemical sterilant)	~30–45 minutes	<ul style="list-style-type: none"> • Low temperature (50°–55°C) • Environmental friendly byproducts • Sterilant flows through endoscope which facilitates salt, protein and microbe removal 	<ul style="list-style-type: none"> • Used for immersible instruments only • One scope per cycle • Potential for contact eye and skin injury • Some material incompatibility (aluminum anodized coating) • Sterile storage is not possible

MIFU; manufacturers' instructions for use; SAL; sterility assurance level.

an incision, as occurs with selected methods of intraoperative enteroscopy or postsurgical anatomy endoscopic retrograde cholangiopancreatography (ERCP).^{84,85}

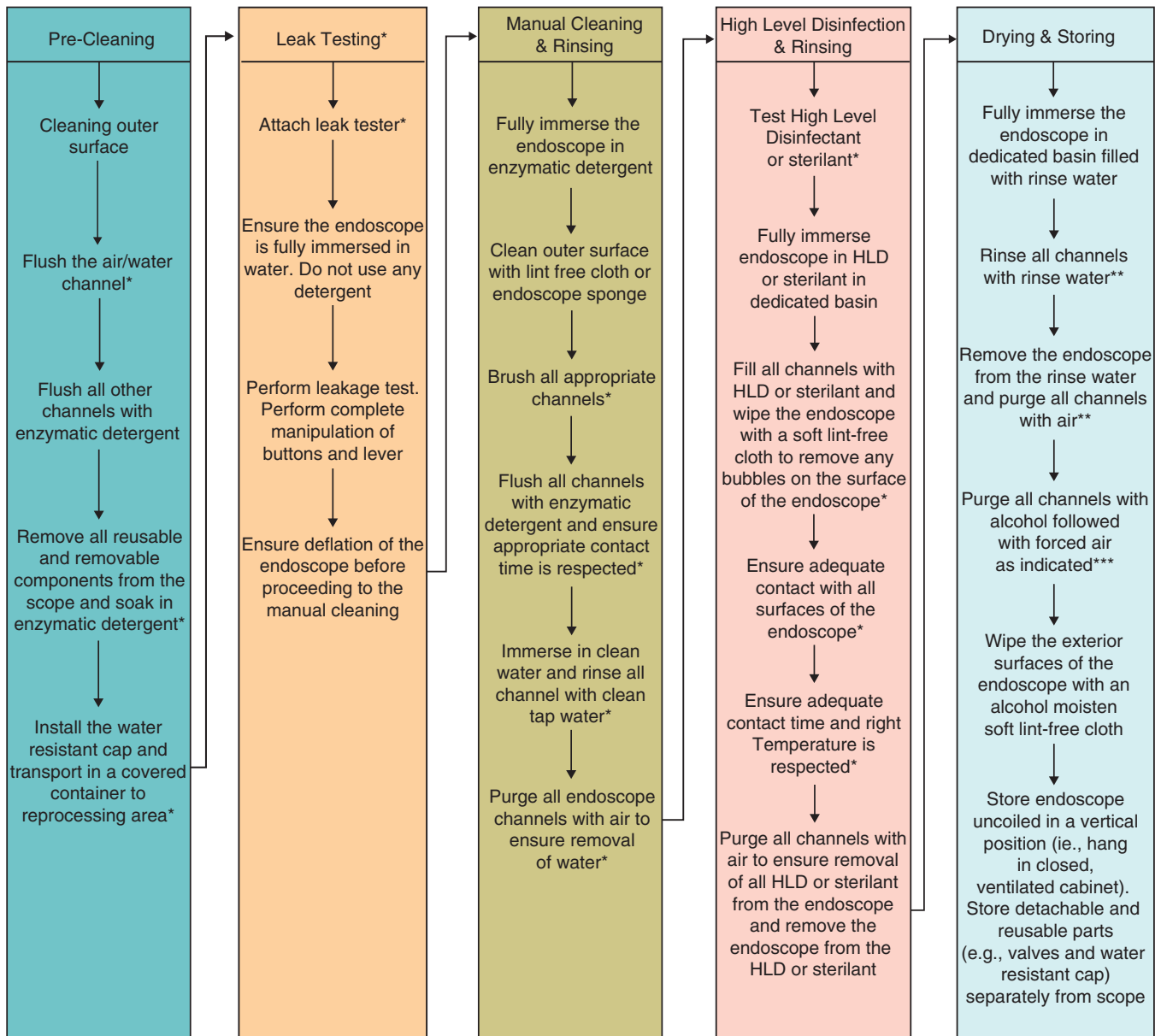
Endoscopes, when sterilized, require low-temperature methods because they are heat labile and therefore, unlike most other medical or surgical devices, they cannot undergo steam sterilization. ETO is the most commonly employed low-temperature sterilization process and a valuable method of sterilizing flexible endoscopes. However, a lengthy aeration time is required following ETO sterilization to allow desorption of all residual toxic gas from the endoscope. Additional steps must be taken, such as the application of a venting valve or the removal of the water-resistant cap to ensure proper perfusion with the gas and to prevent damage to the endoscope due to excessive pressure build-up. In addition, there are potential hazards to staff, patients, and the environment related to ETO toxicities (Table 4.2).⁸⁶ The International Agency for Research on Cancer has classified ETO as a known (group 1) human carcinogen. Within the past two decades, several new, low-temperature (< 60°C) sterilization systems have been developed, including hydrogen peroxide gas plasma, vaporized hydrogen peroxide, peracetic acid immersion, and ozone^{87–92} (see Table 4.2).

GI ENDOSCOPE REPROCESSING

Over the years there has been a continuous expansion of the diagnostic and surgical techniques being performed utilizing

ever more complex GI flexible endoscopes. The combination of ultrasonic capability with flexible endoscopes has opened up a new tool to use for the diagnosis and staging of cancers. However, along with these improvements that enhance diagnostic capabilities comes the increasing complexity of the endoscope channels. These complexities include double instrument channels with connector bridges, ultrasound probe channels, auxiliary channels, and elevator lever wire channels (sealed and unsealed). These complexities in endoscopes have far-reaching impacts in terms of reprocessing of reusable flexible endoscopes. This has been painfully highlighted by the recent outbreaks of antibiotic resistant bacteria associated with fully reprocessed endoscopes that remain contaminated^{15,28,93–104} and act as fomites that transmit bacteria to a high percentage of subsequent patients who are exposed to the contaminated endoscope (see later section on **Infection Control Issues** for more detailed information on infection transmission). Such outbreaks have focused attention on the cleaning and disinfection of flexible endoscopes. There has been a paradigm change in that it is now recognized that reprocessing of GI flexible endoscopes is an extremely complex process that requires a quality systems approach, which includes specific training for reprocessing personnel, adequate monitoring of various stages in the reprocessing cycle, and ongoing documentation of staff competency.^{48,95,105–114}

Human factors play a critical role in compliance with reprocessing of GI endoscopes.¹¹⁵ Ofstead et al (2010) demonstrated that compliance with all the reprocessing steps occurred for only



* As per manufacturer of the product

** As prescribed by the manufacturer or the High Level disinfectant AND in accordance to the manufacturer of the endoscope

*** Alcohol rinse and drying is not needed if scope is used immediately on another patient, unless the final rinse was with unfiltered tap water

FIG 4.2 Overview of the reprocessing steps for GI endoscopes. (From Public Health Agency of Canada [PHAC]: Infection Prevention and Control Guideline for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy. 2010, p 34. <http://www.phac-aspc.gc.ca>. [Figure 3, p 34; <http://www.phac-aspc.gc.ca/nois-sinp/guide/endo/index-eng.php>])

1.7% of flexible endoscopes reprocessed when cleaning steps were performed manually and disinfection was automated, compared to 75.4% compliance when both cleaning and disinfection were automated.¹⁵ Fig. 4.2 outlines the basic steps in reprocessing of a GI flexible endoscope. Until recently, the only aspect of this process that was monitored was to test the MEC of the high-level disinfectant to ensure it contained a sufficient concentration of the active ingredient. It is easy to see from the outline provided in Fig. 4.2 how steps could be overlooked. Often staff are not aware of additional channels in new models of

endoscopes and are not trained on specific cleaning requirements. The use of different sizes and types of channel brushes for the various different channel sizes, the fact that some channels cannot be brushed, and the multitude of different types of cleaning brushes available makes duodenoscopy reprocessing a confusing process prone to human error.

Regulatory Changes

Major changes in GI endoscope reprocessing over the past five years have occurred and include new regulatory requirements,

device-reprocessing guidelines, and endoscope manufacturers' instructions for use. The key “domino” in this chain of changes was the 2015 FDA Guide to Manufacturers of Reusable Medical Devices (FDA, March 2015) that required manufacturers to validate that their cleaning instructions were effective and could achieve predetermined benchmarks. Cleaning validation for medical device reprocessing was not previously required; the focus was on validation of the disinfection or sterilization protocols recommended by manufacturers for their medical devices. When transmission of carbapenem-resistant *Enterobacteriaceae* (CRE) associated with contaminated duodenoscopes was recognized and first investigated and reported in the United States,¹⁴ it was unclear why reprocessing of duodenoscopes was failing. However, it was clear that transmission rates from contaminated duodenoscopes were high (up to 45%) and that, in addition to causing infections, patients often became colonized with CRE and remained colonized long after the exposure to the CRE contaminated duodenoscope. Some health care facilities continued to report CRE transmission and suggested that the manufacturers' instructions for use (MIFUs) for endoscope reprocessing were inadequate^{15,103,116} and that was why endoscope contamination was ongoing. Although there had been recent design changes by the three main duodenoscope manufacturers whereby the elevator wire channel was sealed, the transmission of CRE was reported for duodenoscopes with both sealed and unsealed elevator wire channels.^{14,15,103} However, one thing was clear; it was very difficult to adequately clean the lever cavity in duodenoscopes, and visible patient debris under the elevator lever was detected in one published outbreak.⁹⁵ This has prompted new validated cleaning instructions for the lever cavity of duodenoscopes.¹¹⁷ The CRE outbreaks linked to contaminated duodenoscopes prompted the FDA to convene an advisory panel meeting in May 2015, and on August 4, 2015, the FDA issued a Safety Communication¹¹⁰ with the recommendations from the advisory panel meeting that included:

1. Establishing and implementing a comprehensive quality control program for endoscopy reprocessing to ensure meticulous adherence to MIFUs for duodenoscope reprocessing, adequate training of reprocessing personnel, and audits to ensure ongoing compliance.
2. Supplemental measures to be considered by sites offering ERCP procedures, including:
 - Microbiological culture with quarantine of contaminated endoscopes until culture results become available;
 - Meticulous cleaning and HLD followed by one of:
 - ETO sterilization,
 - Liquid chemical sterilization, or
 - Repeat HLD.

The FDA safety alert was followed by a CDC Health Advisory in September 2015, that indicated an immediate need for sites utilizing duodenoscopes to undertake audits of the reprocessing protocol, as well as staff training and longitudinal audits to document ongoing staff competency.

These events and actions have led to a “paradigm shift” regarding the reprocessing of flexible endoscopes,¹¹³ whereby the need for a total quality systems approach has been recognized. It is no longer adequate to accept that endoscope cleaning is being done properly just because the MIFUs are available to staff; rather, there needs to be evidence of monitoring and ongoing audits of cleaning compliance for all staff who reprocess endoscopes. In addition, the need to ensure the endoscopes are truly dry during storage to prevent biofilm formation has been

identified.^{97,98,108,110,113,118–121} If biofilm forms, the ability of disinfectants to reliably kill microorganisms within biofilm is dramatically reduced.^{118,122}

EFFICACY OF REPROCESSING

Overview of Quality Systems Approach

Although most published reports of infectious outbreaks related to flexible endoscopes have involved duodenoscopes, other endoscopes including colonoscopes, gastroscopes, bronchoscopes, cystoscopes, and ureteroscopes (see later sections on [Reprocessing Errors and Outbreak Management](#) and [Infection Control Issues](#)), have been shown to be contaminated and involved in infectious outbreaks. As such, every site offering flexible endoscopy procedures should ensure they have an established quality system for reprocessing these complex devices as recommended by the FDA¹¹⁰ and CDC.¹²³ [Table 4.3](#) provides an overview of what components are needed for such a system. As recommended by the CDC,¹²³ the first step that all health care facilities should undertake is to perform an audit by reviewing their current endoscopy services to ensure they meet all aspects of a quality system approach. This requires input from administration, risk management, endoscopy staff, and infection prevention and control to ensure that all components are adequately assessed and the appropriate policies and procedures documented and implemented.

[Table 4.4](#) provides an overview of the key steps in reprocessing and outlines where mistakes are frequently made, as well as the impact of such mistakes. It is important that audits done for endoscope reprocessing are observational and based on a specific checklist of critical components, as well as data to substantiate processes (e.g., time data to show contact time with detergent during cleaning, as well as transport times to determine how frequently it exceeds 1 hour). [Table 4.4](#) is a useful aid to review during initial training of staff, as well as during discussion of audit data on a yearly basis.

Cleaning Monitoring (Rapid Testing of Organic Residuals and Adenosine Triphosphate [ATP])

The need to monitor the adequacy of cleaning⁴⁸ is a critical step in the Total Quality System approach (see [Table 4.3](#)) to endoscope reprocessing. Appropriate benchmarks for cleaning markers have been established.^{48,54,109,118,121,124–126} There are a number of rapid cleaning tests (RCT) available for monitoring organic residuals such as hemoglobin, carbohydrate, and protein, as well as those that monitor ATP residuals. There are published data for some of these rapid test methods,^{112,125–132} but when selecting a rapid cleaning monitor, it is important to request that the rapid test manufacturer provide their validation data. Review of the pros and cons of the testing method based on the validation data provided by the manufacturer is an important step when selecting the RCT. Examples of the considerations for selecting the RCT are shown in [Table 4.5](#). Once the RCT has been selected, a way to document the RCT results is needed (e.g., a record sheet that identifies the scope tested, the person doing the testing, date and time of testing, result of testing, and the result of retesting for those scopes that fail the RCT and require recleaning).

Regardless of the method selected, the site should do initial testing for ALL endoscopes to determine the current baseline status. This should be performed on the next patient use of each endoscope after completion of manual cleaning and rinsing. If the initial RCT fails for the majority of the endoscopes, this

TABLE 4.3 Overview of Quality System Requirements for Endoscopy Reprocessing Program

Area	Specifics
1. Records: There must be documentation of all reprocessing components to ensure there is a way to link which endoscopes (and corresponding accessories) were used on which patient.	<ul style="list-style-type: none"> • Document which endoscope was used in the patient's medical record • Document in the reprocessing area which personnel cleaned each endoscope, which patient the endoscope was used on, the date/time it was cleaned, and which AER (automated endoscope reprocessor) was used to disinfect the endoscope (or which sterilizer was used).
2. Manufacturers' instructions for use (MIFU) for all endoscopes and reprocessing equipment	<ul style="list-style-type: none"> • Ensure the MIFU for reprocessing is available in the reprocessing area • Create a site-specific set of instructions that are based on the MIFU but indicate specific detergent, brushes, etc. that are used for reprocessing of each make/model of endoscope used at that site • If pump-assisted flushing is used during manual cleaning, ensure instructions for use are available • For manual cleaning, a succinct visual "aide" consisting of a summary of the process posted above the reprocessing sink, counters, etc., is useful.
3. Personnel <ul style="list-style-type: none"> • Qualifications • Training 	<ul style="list-style-type: none"> • Personnel should have appropriate qualifications (e.g., certificate in medical device reprocessing and/or course in endoscope reprocessing) • Formal training MUST be provided for all reprocessing staff for each specific endoscope used in the facility. This training must include risk to reprocessing personnel, measures to reduce the risk of exposure to infectious material, appropriate use of personal protective equipment (PPE), need for meticulous attention to every step in reprocessing, risk to patients of infections if reprocessing is done improperly. Training should include review of written instructions, demonstration of proper technique, observation of trainee for a defined number of endoscopes reprocessed, and sign-off regarding competency. • Personnel files should document all qualifications and all training for each staff person. • Ongoing competency assessment should be done every year and documented for all reprocessing personnel.
4. Reprocessing facilities	<ul style="list-style-type: none"> • Physically separate from patient service areas, treatment rooms and clean storage • Adequate sink size for flexible endoscopes • Adequate counter space for handling endoscopes • One-way work flow (dirty to clean) • Cleanable work surfaces • Adequate utilities, drains, air quality • Eye wash • Availability of appropriate PPE for staff • Appropriate equipment for automation of high-level disinfection (HLD) (e.g., AER) or sterilization process • Adequate endoscope storage facilities with restricted access
5. Reprocessing of endoscopes (see Table 4.2 for additional information)	<ul style="list-style-type: none"> • Traceability of each endoscope and reusable accessories used • Documentation of all monitoring performed for cleaning and minimum effective concentration (MEC) testing • Timely reprocessing • Routine cleaning and decontamination protocol for AER, flushing pump, sinks, connector tubing, endoscope storage cabinets • Policy on disposable and reusable ancillary items (e.g., water bottles, connector tubing, etc.)
6. Quality assurance program	<ul style="list-style-type: none"> • Preventative maintenance (PM) program for endoscopes, AERs, flushing pump with repair history records • Record keeping of preventative maintenance on all equipment • Regular audits to ensure ongoing adequacy of all stages of the program
7. Management/oversight	<ul style="list-style-type: none"> • Involvement of Infection Prevention and Control (IPAC) and workplace safety in all components of the endoscopy reprocessing is crucial • A structured management scheme with regular review of the endoscopy program that includes reprocessing considerations. • There should be regular review and reporting of monitoring data at appropriate management meetings to identify any potential issues

indicates that there may already be build-up biofilm (BBF) in the scopes being used. Remedial action would be needed for the endoscopes, which may include a longer soak time in detergent followed by extended brushing and flushing (as per scope manufacturer's input). If the endoscope fails the RCT after the remedial action, then it should be sent to the manufacturer for further remedial action (e.g., change of channels, etc.).

Surveillance Cultures

Another stage where monitoring of the endoscope can be done is post-HLD. A Rapid Post-Disinfection Test (RPDT) that could be completed just prior to the next patient use of the scope to confirm that the endoscope does not contain viable microorganisms would be ideal. However, there is little published data for

TABLE 4.4 Overview of the Issues Related to Reprocessing of Flexible Endoscopes

	Key Purpose	Reprocessing Steps	Common Errors	Impact
STEP 1: Bedside Clean	<p>Critical to wipe exterior and flush ALL channels to dislodge patient debris while still fresh and not dried.</p> <p>The bedside clean reduces the load of organic material and microbes for the full manual cleaning step.</p>	<p>Patient Procedure Room: Detergent or water solution (as per endoscope manufacturer's instructions) is used to:</p> <ul style="list-style-type: none"> Wipe exterior using sponge or lint-free cloth Suction or flush ALL channels (Note: this may require use of specific endoscope flushing adaptors as per MIFU) Place all accessory components in detergent or water to keep moist during transport. 	<ol style="list-style-type: none"> Forget to wipe exterior or forget to suction or flush some channels after patient procedure. 	<ol style="list-style-type: none"> Dried patient-material is harder to remove during full cleaning. Increases risk of inadequate cleaning and accumulation of organic material Higher level of contamination in cleaning sink; increased risk of transmission of microbes to reprocessing personnel
TRANSPORT	<p>An appropriate container is needed for transport of patient-used endoscopes to prevent drying of patient-material and protect endoscope from physical damage during transit</p> <p>Target ≤ 1 hour from time of bedside clean to commencement of full manual clean.</p>	<ol style="list-style-type: none"> Place endoscope and all accessory components in a sealed, leak-proof rigid container for transport. Keep moist during transport. Ensure patient-used endoscopes can be readily differentiated from patient-ready fully reprocessed endoscopes (e.g., specific labels on exterior of the transport container and/or the endoscope) Transport endoscope to reprocessing area promptly (i.e., ≤ 1 hour) 	<ol style="list-style-type: none"> Container not labeled to indicate that the endoscope inside is uncleaned and biohazardous Transported in plastic bag instead of rigid container Excessive time in transit (e.g., > 1 hour) 	<ol style="list-style-type: none"> Contaminated endoscope is mistaken for a processed endoscope and used on another patient. If transport container is not rigid there may be damage to endoscope during transport. Excessive transport time leads to replication of microbes initiating biofilm formation
STEP 2: Leak Test	<p>Ensure detection of any leaks that might allow water to enter inner scope cavity and damage light source and cause corrosion of internal components. Ensure a leaking endoscope is not used on patients as their secretions may enter damaged area and be protected from HLD and provide a reservoir for subsequent transmission to other patients.</p>	<p>Reprocessing Room Maintain "Dirty to Clean" workflow Pressurize the endoscope: Leak test: Manual: dry or submerged in water Automated: dry or submerged in water Observe for AT LEAST 30 seconds and manipulate the control levers to articulate the distal tip in all directions Check for bubbles if submerged in water OR: Check for a pressure drop if using the dry method of leak testing</p>	<ol style="list-style-type: none"> Water for leak test contains detergent Inadequate amount of time taken to check for bubbles No articulation of the control levers Failure to detect small leaks Failure to decontaminate endoscope that has failed leak test before shipping for repair 	<ol style="list-style-type: none"> Bubbles from leaks cannot be adequately observed when detergent bubbles are present Small bubbles may go undetected and result in water damage to scope Small leaks in bending section not detected without articulation to stretch the sheath. Risk of patient secretions containing infectious organisms getting into the damaged area and being transmitted to subsequent patients causing infection or colonization. Risk of transmitting infectious agents to biomedical technicians performing repair. Contamination of shipping container.
STEP 3: Manual Clean & Rinse	<p>Remove as much patient-derived organic material as well as microbes. This is critical to ensure the subsequent disinfection or sterilization process works effectively and can provide an adequate margin of safety.</p>	<p>Reprocessing Room</p> <ol style="list-style-type: none"> Disassemble reusable components such as valves, caps, flushing connectors etc. and process along with endoscope. Ensure endoscope is totally immersed in detergent solution. Ideally suction detergent through all channels and discard this material (not in the cleaning basin). Brush all openings including suction cylinder, air/water cylinder, instrument port, and outlets on umbilical end. Adequate contact time with detergent (as per detergent manufacturer's instructions) to loosen debris. Rinse away detergent using tap water. 	<ol style="list-style-type: none"> Reusable components not properly cleaned. Performing brushing while endoscope is not immersed. No suction step before brushing so all patient material from channel brushed and flushed into the detergent solution. Inadequate brushing of channels due to improper brush size or confusion regarding which brush to use. Inadequate contact time with detergent. Many detergents are protein solutions that need to be removed before the disinfection/sterilization step. 	<ol style="list-style-type: none"> Increased risk of accumulation of organic material and biofilm forming. Increased risk to personnel and environment due to aerosols of infectious debris. Contamination of detergent solution with high levels of patient secretions increases the risk of high levels of organic material and microbes on exterior and in channels. Inadequate brushing leads to improper cleaning and risk of excessive organic and microbial load for HLD. Detergent contact inadequate results in improper cleaning and leads to accumulation of organic material and microbes. If detergent is not adequately rinsed away this could lead to accumulation of protein and failure of HLD.

Continued

TABLE 4.4 Overview of the Issues Related to Reprocessing of Flexible Endoscopes—cont'd

	Key Purpose	Reprocessing Steps	Common Errors	Impact
Optional Step: Monitor manual cleaning	Monitoring of the manual cleaning ensures that the endoscope does NOT go on to HLD if it has not been properly manually cleaned. ST91 recommends that all scopes be tested for adequate cleaning at least once per week and preferably daily. This process of monitoring endoscope cleaning provides evidence of a Quality System as the cleaning adequacy is documented. It also serves as an ongoing way to monitor staff compliance with cleaning as part of annual competency assessment.	<p>Reprocessing Room</p> <ol style="list-style-type: none"> Once manual cleaning has been completed collect a sample from the channel(s) of the endoscope. Minimally a sample from the instrument port to the distal end should be collected and tested. Follow the MIFU for the rapid cleaning monitor. If the test result is below the manufacturer's cut-off for adequate cleaning, then the scope can be transferred to the AER for HLD (or manual HLD done) or sent for sterilization. If the test result is above the MIFU cut-off, then the endoscope needs to be fully re-cleaned and tested after the second manual clean. <p>NOTE: For duodenoscopes there should also be a sample from the elevator lever recess.</p> <ol style="list-style-type: none"> If the endoscope fails the rapid cleaning test after three rounds of cleaning it should be sent to the endoscope manufacturer for evaluation. 	<ol style="list-style-type: none"> Breach of any of the manual cleaning steps shown in Fig. 4.1 can lead to patient-derived material remaining in the endoscope that is sent for HLD or sterilization. HLD or sterilization processes fix the organic residues to the channel surface leading to build-up biofilm formation (BBF). 	<ol style="list-style-type: none"> Accumulation of BBF in the endoscope increases the risk of microbes in the BBF matrix surviving HLD and possibly being transmitted to subsequent patients.
STEP 4: Disinfection or Sterilization	HLD and sterilization are intended to kill any remaining microbes left after the cleaning step. HLD and sterilization can achieve 6 and 12 Log ₁₀ microbial reductions, respectively. All reusable accessory items must also be exposed to HLD or sterilization along with the endoscope they are dedicated to.	<p>Reprocessing Room</p> <ol style="list-style-type: none"> Ideally an automated endoscope reprocessor (AER) should be used for HLD or sterilization. Manual HLD instructions are available from manufacturers but the manual process is fraught with concerns including ensuring adequate vapor control to prevent staff exposure to toxic fumes, adequate channel perfusion when using manual syringe to inject HLD, dilution of HLD from water remaining in channels after manual cleaning, etc. When using an AER, it is necessary to change the sub-micron filter inside the AER as per MIFU. Fully reprocessed endoscopes and accessory components need to be handled using clean gloves to ensure skin organisms from bare hands are not transmitted to the endoscope post-HLD. 	<ol style="list-style-type: none"> Inadequate HLD contact due to poor manual perfusion of channels (e.g., bubbles or inadequate immersion). Breach in sub-micron filter inside AER leads to contaminated rinse water. Handling of endoscope post-HLD with un-gloved hands 	<ol style="list-style-type: none"> Increased risk of microbes surviving the HLD process due to inadequate contact with HLD. Microbes on the endoscope when put into storage can facilitate biofilm formation. Microbes on hands transferred to disinfected endoscope can survive and subsequently be transmitted to next patient that the endoscope is used for. Microbes transferred to endoscope from hands also increase the risk of biofilm formation if there is sufficient moisture.

STEP 5: Alcohol flush and forced air dry

Flush all channels with alcohol and then flush with forced air. This is intended to ensure that the channels are totally dry during storage. This step can be omitted if a channel-purge storage cabinet is used (as per cabinet manufacturer's instructions). Clean gloves should be used when handling the endoscope post-HLD during the drying process.

Reprocessing Room

1. Through drying of endoscope exterior and ALL channels is critical prior to storage. This can be done using appropriately filtered forced air. If a "channel-purge" storage cabinet is used the manual drying only needs to be done briefly to remove excess water prior to placing the endoscope in the cabinet (ongoing air purging once the endoscope is placed in the cabinet is preferred to ensure dryness is maintained as additional wet endoscopes are sequentially placed into the storage cabinet).
There are also small air-flushing pumps that can be used to ensure channel drying prior to placing the endoscope in a regular storage cabinet. Ensure adequate time is used for air-flushing to ensure scope is totally dry before being placed in a regular storage cabinet.
2. Ensure fully reprocessed endoscopes are somehow labeled or identified so they can be easily differentiated from patient-used endoscopes that are contaminated.

1. The volume of alcohol flushed and the time for manual forced air drying is not specified in MIFU and is often sub-optimal when performed manually.
2. Contaminated endoscope may be mistaken for a fully reprocessed endoscope and accidentally used on a patient.

1. Inadequate drying during storage is one of the key factors that leads to biofilm formation. Once formed, the biofilm protects microbes from being adequately killed by HLD or sterilization and increases the risk of organisms being transmitted to patients exposed to this contaminated endoscope.
2. Use of a contaminated endoscope can lead to transmission of infectious agents that result in colonization or infection.

STEP 6: Storage

Limited access to the clean storage room ensures the endoscopes remain microorganism free and are safe to use on the next patient. Storage for 5 to 7 days is safe providing the endoscope is stored totally dry. A method of tracking the duration of individual storage time for each endoscope is recommended so that it can be reprocessed once the 5- to 7-day storage is exceeded. Reusable valves should be dedicated to and stored alongside (but not inserted into the valve cylinders of the endoscope during storage) the endoscope they are used on. This facilitates adequate tracking of the valves associated with the endoscope if an outbreak occurs.

Clean Storage Room

1. Place the endoscope into the storage cabinet following MIFU. If storage cabinet is not capable of purging air through the channels – the endoscope should be hung vertically during storage. For channel-purge storage cabinets the endoscope can be stored vertically or horizontally as per MIFU. Some models alarm when scope has been stored in cabinet longer than 5 to 7 days.
2. If storage exceeds 5 to 7 days the endoscope needs to be reprocessed.
3. Store the valves and other reusable accessories in a mesh bag or disposable valve holder that is hung on the endoscope to ensure these items are dedicated to a specific endoscope.

1. Endoscope storage exceeds 5 to 7 days.
2. Staff handling the endoscopes with un-gloved hands
3. Valves are inserted into the valve cylinders during storage instead of being held in a separate mesh bag/disposable holder that is hung alongside the endoscope

1. Excessively long storage may lead to fungal or other types of overgrowth or contamination.
2. Contamination of endoscope may lead to microbial replication and biofilm formation if moisture is also present.
3. Valves inserted into the valve cylinders can lead to moisture retention that facilitates microbial replication and can lead to biofilm formation.

TABLE 4.5 Overview of Rapid Cleaning Test Methods for Monitoring Manual Cleaning of Flexible Endoscopes

RCT Method	Substrate Detected	Pros	Cons	Refs
1. ATP There are many manufacturers of RCT for ATP (e.g., 3M, St. Paul, MN; Ruhof, Mineola, NY; Healthmark, Fraser, MI; etc.)	ATP from residual patient secretions and from microbes*	<ul style="list-style-type: none"> • Rapid (< 2 mins to do test) once sample is collected • There is a sponge device to collect channel sample (faster channel sampling method than fluid flush method) • RCT for surface and liquid testing available (i.e., can test exterior of endoscope as well as fluid used to sample channels) • Numeric measure of relative light units (RLU) provides cut-off that is less subjective. 	<ul style="list-style-type: none"> • Cost (This is affected by the testing frequency selected by the site) • Insensitive for detection of viable bacteria (needs ~3 Log₁₀/mL of bacteria to generate 1 RLU) • Inability to link manufacturer's cut-off for acceptable cleaning to clinical outcomes (i.e., risk of infections or colonization) 	125, 128–133, 135
2. Organic Residuals There are many manufacturers of RCT for organic residuals (e.g., HealthMark, Ruhoff, STERIS [Mentor, OH], etc.)	Residual patient-derived organic material such as protein, hemoglobin, carbohydrate (RCT may test one or multiples of these organic markers).	<ul style="list-style-type: none"> • Rapid (< 2 mins to do test) once sample is collected • Simplistic “dip & read” color change of test strip indicator pads, or test using swab for surface or channel sample, then insert swab into test reagent and assess color change. 	<ul style="list-style-type: none"> • Inability to link manufacturer's published cut-off for acceptable cleaning to clinical outcomes (i.e., risk of infections or colonization) 	124, 127, 134, 136

*Note: ATP is present in high levels in human cells and secretions whereas in microorganisms the level of ATP per cell is very low. Testing ATP post-cleaning is NOT a measure of how high the level of viable bacteria are, but rather it is an assessment as to whether manual cleaning has removed sufficient patient-derived material to be considered adequately cleaned.

ATP, adenosine triphosphate; RCT, rapid cleaning test.

the two RPDT tests that are currently available (Table 4.6). In the absence of validated rapid test methods, culture is the only well-studied method for detection of microbial contamination of flexible endoscopes postdisinfection/-sterilization. However, there are a number of considerations when culture is used. There have been a variety of published studies on culture results from endoscopes, but there is little data on the recovery efficiency of the various endoscope extraction methods that have been used.¹³⁷ If a patient-ready endoscope is extracted by flushing the channel with bacterial culture media or other harvesting fluids containing various proteins or buffers containing salt, then the endoscope requires recleaning and disinfection prior to being used on a patient. If sterile, high-quality water (i.e., reverse osmosis or deionized water) is used to flush endoscope channels, the endoscope can be dried and then still be safely used on the next patient.

REPROCESSING PERSONNEL

Training

Personnel who reprocess flexible endoscopes must have thorough initial training regarding the reprocessing of all makes and models of endoscopes that they will be responsible for reprocessing (see Tables 4.3 and 4.4). The training process should be documented and new staff not allowed to reprocess endoscopes on their own until they have demonstrated, under supervision, that they are competent to perform reprocessing independently. The use of rapid cleaning monitor (RCM) tests for each endoscope reprocessed during training is an excellent way to document the adequacy of the trainee's ability to perform the cleaning process. Reprocessing errors are a common underlying problem for many of the reported outbreaks.^{95,97,98,123} The “human factors” study done by Ofstead et al (2010)¹¹⁵ showed that inadequate cleaning of channels related to the lack of adequate channel brushing (43% of scopes) and inadequate drying (45% of scopes) prior to storage of endoscopes were the two most common breaches in

endoscope reprocessing. As outlined by recent guidelines,^{48,107,108,123} initial training and ongoing competency assessment are critical to ensuring that staff can effectively reprocess flexible endoscopes.

Ongoing Competency Assessment

The compliance of reprocessing personnel with endoscope reprocessing protocols should be reviewed at least annually to document ongoing competency.⁴⁸ It is clear from some outbreaks that despite having adequate written protocols, staff may create breaches by not following some steps in the protocol.^{95,98,115} As such, observational audits are a useful approach to determining if staff are fully compliant in following the site protocol. If ongoing cleaning monitoring is performed, the results of these tests can be included as part of documentation of ongoing competency.

TRANSMISSION OF PATHOGENS

Transmission of exogenous pathogens (i.e., not derived from the patient) can be categorized as “nonendoscopic,” which is related to care of intravenous lines and administration of medications and anesthesia, or “endoscopic,” which is related to transmission by the endoscope, water bottles, and its accessories. Outbreaks of infection have been traced to process failures, including endoscopes that are damaged or difficult to clean; AER design problems or failures such as breakdowns in AER water filtration systems; and lack of adherence to reprocessing guidelines for endoscopes and accessories. There are also data that demonstrate that all the steps associated with manual endoscope reprocessing are rarely performed and some essential steps, such as brushing all endoscope channels and adequate drying prior to storage, are frequently deficient.¹¹⁵

These deficient reprocessing practices can be summarized as follows:^{32,96,115}

1. Inadequate or absent mechanical cleaning of the endoscope and channels before disinfection.

TABLE 4.6 Overview of Post-Disinfection Test Methods for Monitoring Microbial Contamination of Flexible Endoscopes

RCT Method	Substrate Detected	Pros	Cons	Refs
Rapid Endoscope Testing Methods Post-Disinfection				
1. NOW test (Commercially available; Healthmark, Fraser, MI)	Enzyme activity from any residual viable Gram negative bacteria	<ul style="list-style-type: none"> • Low limit of detection for Gram negative bacteria (10 CFU) • Test result available the morning after samples collected, before scope is used on patients • Targets key organisms of concern (i.e., Gram negatives) 	<ul style="list-style-type: none"> • Test takes 18 hrs incubation so not available for scopes used multiple times the same day • Test is dependent on efficiency of sample collection; there may be false-negatives if low levels of bacteria are not extracted by fluid flushing sample collection method • Cannot detect Gram positive organisms of concern (e.g., <i>S. aureus</i>, <i>Enterococcus</i>, etc.) • Cannot determine if the Gram-negative bacteria are antibiotic resistant or not. 	No published data
2. Polymerase chain reaction (PCR) Research PCR protocols	Residual genetic material from microbes	<ul style="list-style-type: none"> • Sensitive for detection of microbial genetic material • Quantitative detection is possible 	<ul style="list-style-type: none"> • May detect genetic material from dead microbes so need to ensure the PCR test is designed to only detect genetic material in intact microbes. • Currently there are no commercial methods for rapid PCR testing. • Limit of detection not fully established • Cannot determine if the bacteria detected are antibiotic-resistant or not. 	138
Traditional Culture Method				
3. Culture CDC endoscope culture protocol can be used. (Note: FDA is developing an alternative to the CDC culture protocol that is based on optimal extraction methods and optimal culture protocols.)	Detects viable microorganisms (bacteria, yeast and fungi)	<ul style="list-style-type: none"> • Detects viable organisms of high concern including Gram negatives and Gram positives. • Allows assessment of whether the bacteria detected are multi-antibiotic resistant • For outbreak investigation allows for genetic typing methods (e.g., PFGE) to help identify a point-source outbreak 	<ul style="list-style-type: none"> • Requires 48 to 72 hrs before results of culture are reported. • During outbreak investigation, quarantine of the endoscope pending culture results is necessary. • For routine surveillance (i.e., not an outbreak investigation) the endoscope is often not quarantined and may be used on multiple patients before culture results are available. Sites need to have a response plan in place regarding notification if culture shows organisms of concern on an endoscope that has been used on multiple patients (i.e., notify the patient, the doctor or both?) 	14, 15, 94, 97, 98–104, 107, 121, 135, 137–142

CDC, Centers for Disease Control; CFU, colony forming units; FDA, Food and Drug Administration; PFGE; pulsed-field gel electrophoresis.

2. Delay in reprocessing.
3. An inadequate disinfectant was used or used improperly at an incorrect concentration, temperature, or exposure period.
4. Flawed or malfunctioning AER units or use of incorrect connectors.^{20,101,142}
5. Failure to disinfect or sterilize the irrigation bottle of the endoscope regularly.^{143,144}
6. Endoscopic accessory instruments were not sterilized.
7. The endoscope and all channels were not dried adequately before storage.
8. Unrecognized problems with water supply.

Nonendoscopic Pathogen Transmission

Outbreaks of hepatitis B and C viruses have occurred due to failure to follow fundamental principles of aseptic technique and safe injection practices.^{145,146} These included improper handling of intravenous sedation tubing, reuse of syringes and needles, and use of single-dose or single-use medical vials on multiple patients.^{146–149}

The CDC guidelines for safe injection practices include the following recommendations:¹⁵⁰

- Use aseptic technique when preparing and administering medications and fluids.
- A sterile, single-use, disposable needle and syringe should be used for each injection on a single patient.
- Do not administer medications from single-dose vials or use IV solutions as a common source of supply for multiple patients.
- Do not keep multidose vials in the immediate patient treatment area.
- Do not reuse a syringe to access or administer medications from a vial that may be used on multiple patients, even if the needle is changed.
- In times of critical need, medications from unopened single-dose/single-use vials can be subdivided for multiple patients. However, this should only be performed by qualified health care personnel in accordance with standards in the United States Pharmacopeia chapter on Pharmaceutical Compounding.

Endoscopic Transmission of Pathogens

More health care–associated outbreaks and patient exposures have been linked to contaminated endoscopes than to any other reusable medical device.^{32,102} Nevertheless, endoscopy-related transmission of infection is very low and was originally estimated to have an incidence of approximately 1 infection per 1.8 million procedures.^{3,17} This is very likely an underestimate, as many endoscopy-related infections go unrecognized because of inadequate or nonexistent surveillance programs, the absence of clinical symptoms in many patients who are colonized, a long lag time between colonization and clinical infection, and the fact that the pathogens transmitted by endoscopy are often normal enteric flora.¹⁵¹ Endoscope-related transmission of bacterial infection has been rare since the adoption of the current multisociety reprocessing guidelines.^{45,151} However, recent outbreaks have occurred with duodenoscopes even when the manufacturers and societal guidelines were reportedly followed correctly (see later section on [Duodenoscopy-Related Infections](#)).¹⁵²

The primary concern raised by infectious outbreaks is that current reprocessing guidelines are not adequate to ensure patient safety when undergoing endoscopic procedures. Endoscopes can harbor between 10^9 and 10^{12} enteric organisms at the completion of some patient procedures. This bioburden is reduced by cleaning (i.e., bedside precleaning followed by manual cleaning) by a factor of 2 to 6 \log_{10} and the HLD step is expected to provide a 6 \log_{10} reduction of any microbes remaining after cleaning.^{124,153} Therefore the margin of safety associated with cleaning and HLD of GI endoscopes is low, and any deviation from proper reprocessing could lead to failure to eliminate contamination, with a possibility of subsequent patient-to-patient transmission.

Biofilms can contribute to reprocessing failure and endoscope-related infectious outbreaks.¹⁵⁴ Biofilms form in endoscope channels, in AERs, and within municipal and hospital water supplies as multilayered bacteria within exopolysaccharide. These biofilms protect the bacteria against physical (e.g., brushing, fluid flow) and chemical (e.g., disinfectant) forces, making the microorganisms more difficult to remove or completely kill by HLD.^{151,155} There is evidence that accumulation of fixed material within endoscope channels occurs over repeated usage. Biofilms that develop in endoscopes and AERs may not be detectable by surveillance culture, as cleaning and disinfection may have destroyed bacteria within the superficial layers but not those within the deeper layers. Prompt, meticulous, manual cleaning to remove biologic material and strict adherence to reprocessing protocols is the optimal approach to reduce biofilm formation/accumulation.^{155–158} Better biofilm removal protocols are needed to address this issue.

What Pathogens Are of Concern?

Pathogens of concern to the GI endoscopy community and general public include *Clostridium difficile*, *Helicobacter pylori*, *Escherichia coli*, norovirus, human immunodeficiency virus (HIV), hepatitis C virus (HCV), hepatitis B virus (HBV), and multidrug resistant organisms (MDROs) such as *M. tuberculosis*, vancomycin-resistant enterococcus (VRE), methicillin-resistant *Staphylococcus aureus* (MRSA), and CRE. All these established pathogens are susceptible to currently available chemical disinfectants and sterilants.^{17,32}

Low Concern Organisms (LCO) versus High Concern Organisms (HCO)

Surveillance cultures of endoscopes are assessed for two general categories of microbial growth, LCO and HCO. HCO should

not be detected after HLD as these organisms commonly result in a clinically significant infection including gram-negative bacteria (e.g., *Escherichia coli*, *Klebsiella spp.*, *Shigella spp.*, *Salmonella spp.*, *Pseudomonas aeruginosa*, other *Enterobacteriaceae*) as well as *Staphylococcus aureus*, and *Enterococcus spp.*¹⁵⁹ LCO are less often associated with disease; these bacteria typically include coagulase-negative staphylococci, micrococci, diptheroids, and *Bacillus spp.* The levels of LCO on a surveillance endoscope culture can vary depending on the reprocessing, handling, and culturing practices in a facility. Typically, fewer than 10 colony forming units (CFU) of LCO does not require intervention as this most likely represents collection process contamination rather than a significant problem with the disinfection or cleaning process.¹⁵⁹ Interpretation of culture results with 10 or greater CFU of LCO should be considered in the context of typical culture results at the facility.¹¹¹

Any endoscope found to be contaminated with a HCO or unacceptable CFU of LCO should cause concern and lead to repeat endoscope reprocessing followed by post-reprocessing cultures. The endoscope should be quarantined until it has been demonstrated to be free of HCO and has an acceptable level of LCO. Positive cultures should also prompt a review of the endoscopy unit reprocessing procedures to ensure adherence to the manufacturer's reprocessing instructions and to ensure proper culture methodology. If a reprocessing breach is identified, appropriate facility personnel should be notified and corrective actions should be immediately implemented. When bacteria are persistently recovered by surveillance cultures, refer to the manufacturer's instructions^{111,159} for evaluating the endoscope for mechanical defects and consider having the endoscope evaluated by the manufacturer. In addition, when ineffective reprocessing is suspected based on surveillance cultures, it might be helpful to review positive cultures among affected patients to determine whether transmission of relevant pathogens could have occurred.^{111,159}

Bacterial Infections

The vast majority of exogenously acquired endoscope-related infections have been caused by bacterial transmission. The bacteria involved have been true pathogens, which always have the potential to cause infection (e.g., *Salmonella spp.*), or opportunistic pathogens that cause infection if the microbial load is sufficient and/or host-factors are permissive (e.g., *Pseudomonas aeruginosa*). In the hierarchy of relative resistance to HLD, vegetative bacteria such as *Pseudomonas spp.* and *Salmonella spp.* are the most susceptible to disinfectants, whereas the mycobacteria are less susceptible and bacterial spores (e.g., *Bacillus subtilis* and *Clostridium difficile*) are the most difficult to eliminate (see [Box 4.1](#)). Nevertheless, as previously stated, all bacteria with the exception of a few bacterial spores are highly sensitive and eliminated by HLD. *Salmonella* is a serious primary pathogen, and *Pseudomonas* is ubiquitous in many water sources, and although both these pathogens have been associated most frequently with endoscopic transmission, they are both sensitive to multiple agents, including glutaraldehyde, and other HLDs. Transmission of bacterial pathogens from flexible endoscopes has been rare since the adoption of the current 2011 multisociety reprocessing guideline,^{45,160} with the exception of duodenoscopy-related infections (discussed later).

The most commonly reported infectious agents transmitted during GI endoscopy have been *Pseudomonas aeruginosa* (45 cases)^{161–163} and *Salmonella spp.* (84 cases).¹⁷ Isolated reports of

endoscopic transmission of other enteric bacteria include *Klebsiella* spp.,¹⁶⁴ *Enterobacter* spp.,¹⁶⁵ *Serratia* spp.,¹⁶⁶ and *Staphylococcus aureus*.¹⁶⁴ The few reports of endoscopic transmission of *Helicobacter pylori* were related to inadequate reprocessing of endoscopes and biopsy forceps.^{167–169} Current reprocessing guidelines are shown to inactivate *Clostridium difficile* spores,¹⁷⁰ and no cases of endoscopic transmission of this infection or mycobacteria have been reported. In summary, there have not been any observed GI endoscopy-related transmission of bacterial pathogens since introduction of the currently accepted reprocessing standards with the exception of duodenoscopy-related outbreaks (discussed later).

Viral Infections

Much greater anxiety is associated with the possibility of transmission of viral infections. This anxiety is surprising because the viruses of greatest concern (HBV, HCV, and HIV) are among the easiest microorganisms destroyed with standard reprocessing.¹⁷¹ Transmission of viral pathogens by GI endoscopy procedures is rare because these microorganisms are obligate intracellular microorganisms that cannot replicate outside living tissue. Thus, even when a flexible endoscope is contaminated with viral pathogens, the burden of virus cannot increase, as they are not capable of ex vivo replication. Enveloped viruses (e.g., HIV, HBV, HCV) die readily once dried and are more readily killed by HLD compared to nonenveloped viruses (e.g., enteroviruses, rotavirus), which can survive in dry conditions.

There has been concern about the possibility of HIV transmission by flexible GI endoscopy; however, no cases have been reported to date.^{171–173} There is only one well-documented case of HBV transmission by GI endoscopy that occurred in the setting of inadequate endoscope reprocessing.¹⁷⁴ However, transmission of HBV is very rare or does not occur when accepted reprocessing guidelines are followed.¹⁷⁵

Fungi

The presence of fungi is associated with prolonged storage of flexible endoscopes. Although transmission of *Trichosporon beigelii* and *Trichosporon asahii* occurred in the 1980s,^{176,177} there are no documented cases of fungal infections by GI endoscopy when updated reprocessing guidelines are followed.

Parasites

A single publication in the 1970s reported circumstantial evidence of *Strongyloides stercoralis* transfer to four patients from a contaminated upper endoscope. No subsequent reports of parasite transmission by GI endoscopes have been identified.¹⁷⁸

Prions

Creutzfeldt Jacob Disease (CJD) and variant CJD (vCJD) are degenerative neurologic disorders transmitted by proteinaceous infectious agents called prions. All prions remain infectious for years in a dried state, and resist all routine sterilization and disinfection procedures commonly used by health care facilities.^{17,178–181} CJD is confined to the central nervous system (CNS) and is transmitted by exposure to infectious tissues from the brain, pituitary, or eye, whereas 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.^{17,179–182} The CDC and other infection control experts conclude that current guidelines for cleaning and disinfecting medical devices need not

be changed to protect our patients from CJD, citing no reported cases of CJD transmission by endoscopy and the lack of exposure to high-risk CNS tissue during endoscopic procedures.^{17,183}

vCJD is a rare but fatal condition caused by the consumption of beef contaminated with a bovine spongiform encephalopathy agent. It differs from CJD in that the mutated prion protein can be found in lymphoid tissue throughout the body, including the gut and tonsils.^{182,184} Only three cases of vCJD have been reported in the United States, and all three patients contracted the disease elsewhere.¹⁸⁴ As vCJD is resistant to conventional disinfectants and sterilants, endoscopy should be avoided, if at all possible, in patients known to harbor this agent.^{17,184} Endoscopes used in individuals with definite, probable, or possible vCJD should be destroyed after use or quarantined to be reused exclusively on that same individual if required.^{182,184}

Duodenoscopy-Related Infections

Between 2012 and 2015, duodenoscopes resulted in 25 international outbreaks (at least eight in the United States) of antibiotic-resistant infections with CRE and other MDROs that sickened a reported 250 patients and resulted in 20 deaths.^{16,97,103,138,185–187} In addition, transmission resulting in a long-term carrier state has been recognized as a risk of exposure to contaminated duodenoscopes. Long-term carriage has important clinical implications due to the development of a delayed infectious complication weeks to months later or patient-to-patient transmission of pathogens when these carriers are subsequently admitted to health care or chronic care facilities.

Investigative cultures identified persistent contamination of duodenoscopes as the cause for patient infections with MDROs in most of the outbreaks.^{185,188} Furthermore, these duodenoscopy-associated infections occurred even though the sites reported strict adherence to reprocessing procedures according to manufacturer's instructions and professional guidelines.^{14,16,97,142,189} It is likely that MDROs are acting as a marker for ineffective reprocessing due to the complex design of duodenoscopes that have difficulty reaching crevices and channels involving the elevator mechanism where persistent colonization was identified.^{186,190} Duodenoscopes that persistently yield positive cultures likely harbor biofilms that cannot be eradicated with standard reprocessing.¹⁵⁵

In October 2015 the FDA and the CDC released an official health advisory alerting health care facilities to review their reprocessing procedures.^{191–202} In response to the problems with duodenoscopy reprocessing, the FDA requested all three duodenoscopy manufacturers to revise and validate their reprocessing instructions with provisions for additional duodenoscopy reprocessing measures.¹⁹¹ This led to the modification of manufacturers' reprocessing protocols with a larger emphasis on precleaning and manual cleaning before HLD.^{117,192–194} One duodenoscopy manufacturer (Olympus; Center Valley, PA) subsequently modified the design of the closed elevator channel to create a tighter seal.^{195,196}

In addition, the FDA has recommended that health care facilities performing ERCP consider employing supplemental measures for duodenoscopy reprocessing when facilities have the resources to do so.¹¹⁰ Most sites where outbreaks have occurred have chosen per procedure ETO sterilization after HLD as its primary reprocessing method, and in all reported instances, ETO has prevented further MDRO transmission.^{110,185} However, one site reported failure to eliminate MDRO contamination of a duodenoscopy after HLD and ETO.¹¹⁶ Alternative reprocessing

methods employed have included double HLD after each procedure^{110,185} or HLD with duodenoscope quarantine until negative culture results are obtained.¹⁵ Another supplemental option for reprocessing endorsed by the FDA includes the use of a liquid chemical sterilant processing system.^{110,197} Surveillance microbiological culturing should be considered in addition to these supplemental reprocessing measures. This involves sampling the duodenoscope channels and the distal end of the scope to identify any bacterial contamination that may be present on the scope after reprocessing.^{159,198} It must be recognized that the sensitivity of surveillance culturing of the elevator channel, the elevator lever cavity, or other scope channels is unknown. Until there are evidence-based guidelines, individual hospitals should choose from these different options based on available information and feasibility for their medical practice. However, at a minimum, there should be an audit of all facilities offering duodenoscope procedures to ensure the site has a quality system in place and is compliant with current MIFUs and guidelines.

REPROCESSING ERRORS AND OUTBREAK MANAGEMENT

Breaches of disinfection guidelines and device failures (e.g., endoscopes or AERs) are common in health care settings, resulting in potential patient injury or infection transmission.³¹ The identification of such a problem may stem from the result of microbiologic surveillance cultures, an infectious outbreak within an institution or isolation of a pathogen from individuals having a recent endoscopic procedure, identification of a break in reprocessing protocol, or a visibly faulty device. Endoscopy facilities should have written policies on the roles and responsibilities within the organization to identify, report, and analyze these failures.⁸¹

Investigation of a Reprocessing Problem or Device Failure

The investigation of a breach in reprocessing or resultant outbreak should be undertaken using a standardized approach. It should focus on the identification of factor(s) that led to the exposure and protect patients from potential adverse events. The investigation should not be punitive and not attempt to assign blame to any particular individual. Rutala et al (2007)¹⁹⁹ described a process for exposure investigation, and the ASGE has published guidelines for patient assessment and notification when there is a suspected failure in the disinfection or sterilization protocol.²⁰⁰ These can be summarized as follows:^{199,200}

1. Confirm that the reprocessing failure occurred and assess the duration of exposure (e.g., review sterilization methods and AER records of biological parameters).
2. Quarantine any endoscopes or associated accessories that malfunctioned or are at risk for inadequate reprocessing.
3. Do not use the devices in question, such as the endoscope or AER, until proper functioning is confirmed.
4. Prepare a list of potentially exposed patients, dates of exposure, and inadequately reprocessed or malfunctioning devices used.
5. Reporting:
 - Inform facility leadership: breaches in patient safety with serious potential infection risks should be reported to facility leadership, including infection control, risk management, public relations, legal department, and selectively to local/state public health agencies, the FDA, CDC, and the manufacturers of the involved equipment.^{200,203} This

will help with the investigation and lead to an expeditious correction of any deficiencies that are identified.

- A user facility is not required to report a device malfunction, but it can voluntarily advise the FDA of such product problems using the voluntary MedWatch Form FDA 3500 under FDA's Safety Information and Adverse Event Reporting Program.²⁰¹ However, if a device failure leads to a death or serious injury, the FDA and the manufacturer must be contacted, as outlined in facility policies, by the designated individual or department at the facility.²⁰² The FDA encourages health care professionals, patients, caregivers, and consumers to submit voluntary reports of significant adverse events or product problems with medical products to MedWatch (<https://www.accessdata.fda.gov/scripts/medwatch/>), the FDA's Safety Information and Adverse Event Reporting Program
 - Manufacturers are required to report to the FDA when they learn that any of their devices may have caused or contributed to a death or serious injury or when they become aware that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.^{201,202}
6. Patient notification and counseling:^{200,203} in instances where a breach in the reprocessing protocol or damaged equipment poses a risk to patients for adverse events, it becomes the institution's ethical obligation to notify patients in a timely manner. Notification may be accomplished by a direct meeting, telephone call, and letter sent by registered mail. The content should include an assessment of the risk, possible adverse events that may occur, symptoms and signs of the adverse event, time range for the adverse event, risk to other contacts, possible prophylactic therapy (including benefits and risks), and recommended medical follow-up. Prompt notification allows patients to take precautions to minimize the risk of transmitting infection to others and allows 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. On the other hand, adverse publicity associated with the reporting of a reprocessing error might lead patients to avoid potentially life-saving endoscopic procedures because of an unwarranted fear of infection. Personal counseling should be offered to all patients. The risk of infection should be discussed and placed in context to minimize patient anxiety. Patients should be advised against donating blood and tissue products and engaging in sexual contact without barrier protection until all serologic testing is complete. A toll-free helpline should be established to provide information to all patients at risk.
 7. Develop a long-term follow-up plan (e.g., long-term surveillance, changes in current policies and procedures) and prepare an after action report.

Infection Control Issues

There are risks related to infection transmission to personnel who handle patient-used endoscopes as well as to patients. Sites offering endoscopy procedures need to ensure the risk to personnel and patients is minimized.

Transporting Instruments

Flexible GI endoscopes are expensive and easily damaged. Unlike surgical instruments where the microbial load is less than 100

bacteria for 75% of instruments,^{139,204} the load of microorganisms in channels of flexible endoscopes can be as high as 10^{10} bacteria¹²⁴ per instrument channel (e.g., for colonoscopes). During transport from the procedure room to the reprocessing area,⁴⁸ flexible GI endoscopes require a rigid, sealed container that is appropriately labeled as biohazardous. This protects the endoscope from accidental damage and also ensures that any patient-derived secretions and microorganisms are adequately contained and cannot drip out and contaminate the environment. All reusable accessory items (valves, flushing adaptors, cleaning valves, etc.) should be transported along with the associated endoscope. During transport, the endoscope and all accessory items should be kept moist to prevent drying of patient-derived material. If endoscopes are transported to a central reprocessing facility, evaluation of the time of transport should be conducted to determine the frequency of excessive transit times.

Personal Protection

There are risks to reprocessing personnel being exposed to patient-derived infectious materials. Endoscopes contacting the GI tract can have very high levels of infectious organisms (including bacteria, viruses, fungi, etc.) in channels or on the endoscope surface. To mitigate these risks, reprocessing personnel need to be trained regarding standard precautions, personal protective equipment (PPE), hand hygiene, disposal of sharps, and dealing with chemical and/or infectious material spills.

Standard precautions are required when reprocessing any patient-used medical device. This means that staff treat all patient-used endoscopes as potentially infectious regardless of the underlying known illnesses that patients might have (e.g., *Clostridium difficile* infection, VRE colonization, human papilloma virus infection, candidiasis, etc.). Any handling of GI endoscopes should be done with due consideration to the potential to transmit infectious microorganisms to reprocessing personnel. Staff must be trained in appropriate PPE and reprocessing considerations aimed at reducing the generation of aerosols.

It is critical that appropriate PPE be available^{48,107,108} and include a gown (preferably a water-resistant gown), gloves (appropriate to the task), and a face shield/mask. Reprocessing personnel must be adequately trained in the proper donning and doffing of all PPE. Gowns, gloves, and a full-face shield (or combined face shield/mask) are required for cleaning of flexible endoscopes. The reprocessing staff needs to be trained in the appropriate use of protective gloves, as well as hand hygiene after removing gloves. Utility gloves used for cleaning of endoscopes should never be used at other stages in endoscope reprocessing (i.e., they are dedicated to the cleaning sinks). Disposable examination gloves must be available for handling cleaned endoscopes during connection to the AER. Fresh disposable gloves are needed for removing and handling fully reprocessed endoscopes from the AER and during manual channel drying and placing the endoscope into the clean storage cabinet. Fresh disposable gloves should also be used whenever an endoscope is removed from the clean storage cabinet. The use of gloves helps protect both the reprocessing personnel from contamination with patient-derived microorganisms and the fully reprocessed endoscope from contamination with skin-derived microorganisms from reprocessing personnel. Staff should always perform hand hygiene immediately after removing any type of glove. Handwashing sinks with appropriate soap, as well as waterless hand hygiene agent dispensers, must be available in the reprocessing area.

The workflow should proceed from “dirtiest to cleanest” in the reprocessing area, and there should be physical separation of “dirty” reprocessing areas and “clean” areas.^{48,107,108} This requires appropriate removal of PPE and hand hygiene when leaving the dirty reprocessing area to enter any of the clean areas.

Staff should take every precaution to reduce the generation of aerosols during reprocessing of GI endoscopes. This includes total immersion of the endoscope during cleaning.^{48,108} This ensures that any patient material removed from the channels during cleaning is contained within the detergent cleaning solution. Care is needed to ensure all brushing steps are done underneath the water surface to reduce aerosols. Holding the control head above water to insert the channel brush and then pulling the brush out of the channel while the control head is above the water generates significant aerosols of the contaminated detergent solution. In addition, during the air-flushing process after cleaning is completed, a piece of gauze should be placed over the distal end of the endoscope channel prior to placing it in an AER to prevent creation of aerosols when flushing out residual rinse water. A final, often overlooked step, is rinsing and decontamination of the sink after EACH endoscope is cleaned. This ensures that the sink does not accumulate microbial contamination over time and act as a reservoir within the reprocessing area to contaminate reprocessing personnel or other endoscopes. If flushing pumps are used as part of the manual cleaning step, they also require routine (usually daily) decontamination as per MIFU to ensure they do not become a reservoir of microbes that develop biofilm and subsequently contaminate endoscopes that they are used on.

Any single-use disposable sharps used in the procedure room should be disposed of in appropriate sharps containers in the procedure room. There should be **no** single-use disposable sharps transported to the reprocessing area. If there are reusable sharps (e.g., biopsy forceps) used for patient procedures, these should be appropriately transported to the reprocessing area in a labeled, rigid, sealed container that ensures separation from the endoscope. This reduces the risk that the biopsy forceps (or other sharp accessory device) could damage the endoscope during transit. Reprocessing of reusable sharps requires specific MIFU and adequate staff training to reduce the risk of sharps injuries to reprocessing personnel. Single-use, disposable accessories are preferred to eliminate the risks associated with reprocessing of reusable sharps.

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