Standard of Infection Prevention in the Gastroenterology Setting
Acknowledgements

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Preface
These standards are presented by the Society of Gastroenterology Nurses and Associates, Inc. (SGNA) to be used for all settings where gastrointestinal endoscopy is practiced. These standards have been developed to complement the SGNA Standard of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes.

Definitions
Automated endoscope reprocessor (AER) refers to machines designed for the purpose of cleaning and/or disinfecting or sterilizing flexible endoscopes and accessories”.

Bioburden refers to the microbiological load (i.e., number of viable organisms inside an object or on a surface) or organic material on a surface or object prior to decontamination or sterilization. Also known as "bioload" or "microbial load" (Rutala et al., 2008).

Cleaning refers to the physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use (US Food and Drug Administration [USFDA], 2015d). Cleaning must precede disinfection or sterilization.

Competency refers to an expected level of performance that integrates knowledge, skills, abilities, and judgment (American Nurses Association [ANA], 2015).

Culture of Safety refers to the attitude, beliefs, perceptions, and values that employees share in relation to safety in the workplace. It is the sum of what an organization does in the pursuit of safety (Joint Commission, 2017a).

Decontamination refers to the use of physical or chemical means to remove, inactivate, or destroy pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal (US Department of Labor [USDOL, 2012).

Disinfection refers to a process that destroys pathogens and other microorganisms by physical or chemical means. Disinfection processes do not ensure the same margin of safety associated with sterilization processes (USFDA, 2015c).

Exposure Control Plan refers to a written plan that outlines how employees will be protected from bloodborne pathogens.

Hand Hygiene refers to the act of cleaning hands with water or liquids and includes the use of water, soaps, antiseptics, or other substances, including alcohol-based hand rubs (Association of Professionals in Infection Control [APIC], 2015).

Occupational Exposure refers to reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of the employee's duties (USDOL, 2012).
**Personal Protective Equipment (PPE)** refers to specialized clothing or equipment worn by an employee for protection against a hazard (American Society of Gastrointestinal Endoscopists [ASGE], 2018; USFDA, 2015a; USDOL, 2012).

**Reprocessing** refers to the validated process used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization (USFDA, 2015c). In relation to endoscopy, it includes all the steps from pre-cleaning to proper storage.

**Safety Data Sheet (SDS)** refers to a descriptive sheet that accompanies a chemical or chemical mixture and provides information regarding the identity of the material; physical hazards, such as flammability; and acute and chronic health hazards associated with contact or exposure to the compound.

**Standard Precautions** refers to the minimum infection prevention measures that apply to all patient care, regardless of the suspected or confirmed infection status of the patient, in any setting where health care is delivered (CDC, 2007).

**Sterile** refers to the state of being free from viable microorganisms (Association for the Advancement in Medical Instrumentation [AAMI], 2015; Rutala et al., 2008).

**Sterilization** refers to a validated process resulting in the complete elimination or destruction of all forms of microbial life, including bacterial spores.

**Terminal cleaning** involves both cleaning and disinfection of surfaces to remove soil and biofilm and to kill microorganisms (Calderwood et al., 2018).

**Training** refers to the action of teaching a person a particular skill or type of behavior.
**Introduction**
Prevention of infection and pathogen transmission in the endoscopy setting is contingent upon compliance with infection control principles, strict adherence to manufacturers’ reprocessing guidelines, and development of a culture of safety. A culture of safety encourages open and safe communication; promotes personal accountability; fosters education, training, and competency; and includes a quality program in place for process improvement, such as SGNA’s Infection Prevention Champions program.

**Spaulding Classification**
The Spaulding Classification of medical devices is universally used to determine what type of disinfection or sterilization is appropriate for medical devices based on their use (Petersen et al., 2017; Rutala & Weber, 2016b). Three categories of medical devices and their associated level of disinfection are recognized: critical, semi-critical, and non-critical. Critical devices are those that break the mucus membrane and/or come into contact with sterile tissue or the vascular system (e.g., reusable biopsy forceps). Semi-critical devices (e.g., endoscopes) come in contact with mucous membranes or non-intact skin and should receive high level disinfection or sterilization. Noncritical devices are those that come into contact with intact skin (e.g., blood pressure cuffs and stethoscopes) and can be cleaned with soap and water or a low level disinfectant.

There are discussions regarding the modification of the Spaulding Classification. Gastrointestinal endoscopes are designated as semi-critical devices but may be classified as critical devices depending on the procedure or design of the endoscope (Petersen et al., 2017; Kovaleva, 2016; USFDA, 2015b). There is literature suggesting that duodenoscopes should be considered critical devices and require sterilization (Rutala & Weber, 2016b). As reprocessing of duodenoscopes continues to evolve, users must comply with updated recommendations from the manufacturers and the USFDA. Further discussions and research on this subject may lead to re-classification of other complex endoscope designs (e.g., convex linear array ultrasound scopes with elevator mechanisms) where sterilization may be recommended in the future.

**Infection Prevention Measures**
Every patient must be considered a potential source of infection. The chain of infection contains several factors for transmission, including viable microorganisms present, sufficient pathogens to pose an infection, a susceptible host, and a portal for the pathogen to enter (APIC, 2015).

Infection prevention measures that can disrupt the chain of infection include:
- Cleaning, disinfection, and sterilization of medical equipment;
- Correct use of Personal Protective Equipment;
- Hand hygiene;
- Engineering controls (e.g., ventilation, room design, water supply);
- Cleaning and disinfection of environmental surfaces;
- Administrative control and support;
- Training and continuing education;
- Written standardized operating procedures; and
- Documentation (Beilenhoff et al., 2008).
Endoscopy personnel may facilitate transmission of infection from patient to patient if they fail to carefully adhere to general infection prevention principles (ASGE, 2018; CDC, 2017b).

**Standard Precautions**

Standard precautions assume all patients and body fluids are potentially infectious. Two components of these precautions include hand hygiene and Personal Protective Equipment (PPE). Both are explained in further detail in this document.

1. **Hand hygiene**

   Hand hygiene is the single most effective measure to prevent the spread of bacteria (CDC, 2002; World Health Organization [WHO], 2009). Hand hygiene is the cornerstone in reducing health care associated infections and preventing occupational acquired infections and improving patient outcomes (APIC, 2015).

   To disrupt the transmission of microorganisms to patients, health care providers should practice hand hygiene at key points:
   - Before patient contact;
   - Before clean/aseptic procedures;
   - After body fluids exposure risks (even if gloves are worn);
   - After contact with a patient; and
   - After contact with a patient’s surroundings (WHO, 2009).

   Staff must understand the indications for washing hands with soap and water and when alcohol-based hand rubs are acceptable.

   Alcohol-based hand rubs have excellent in vitro germicidal activity against Gram-positive and Gram-negative vegetative bacteria (including multidrug-resistant pathogens such as MRSA and VRE), Mycobacterium tuberculosis, and a variety of fungi.

   Alcohol-based hand rubs have the following immediate advantages (WHO, 2009):
   - Elimination of the majority of germs (including viruses);
   - Short time required for action (20 to 30 seconds);
   - Availability of the product at the point of care;
   - Better skin tolerability; and
   - No need for any particular infrastructure (clean water supply network, washbasin, soap, hand towel).

   Although alcohol-based hand rubs are flammable, the risk of fires associated with such products is very low. Follow manufacturers’ guidelines for use.

   Following the widespread use of alcohol-based hand rubs as the gold standard for hand hygiene in health care, concern has been raised about their lack of efficacy against spore-forming pathogens, in particular *Clostridium difficile* (Bolan, 2016). They have virtually no activity against bacterial spores or protozoan oocysts, and reduced activity against some non-enveloped (non-lipophilic) viruses (WHO, 2009).
Hands need to be washed with soap and water when they are visibly dirty or soiled with blood or other body fluids and when exposure to potential spore-forming organisms, such as *C. difficile*, is strongly suspected. Hand hygiene using soap and water takes approximately 40 to 60 seconds. Avoid using hot water because repeated exposure to hot water may increase the risk of dermatitis.

Wearing gloves is not enough to prevent the transmission of pathogens in health care settings. Glove use does not replace the need to perform regular and frequent hand hygiene. Hand hygiene must always be performed before donning gloves and after removal because gloves may have microscopic defects and contamination may occur during the process of removing the gloves (WHO, 2009).

Hand hygiene equipment such as sinks, soap dispensers, paper towel dispensers, and alcohol-based foam dispensers should be conveniently located to permit good hand hygiene practices. The strategic placement of hand hygiene equipment leads to increased compliance of hand hygiene by staff members.

Performance indicators for measuring the compliance of health care workers and hand hygiene may include:
- Monitoring and recording adherence of hand hygiene by direct observation and timely coaching;
- Monitoring the volume of alcohol-based hand rub used in a dispenser; and
- Monitoring adherence to policies related to wearing of artificial nails and the length of nails (CDC, 2002).

Special considerations related to hand hygiene include but are not limited to the following:

a. **Fingernails**
   Fingernails can harbor pathogens that can then be transmitted by health care workers to patients. It is recommended that staff with direct contact to high-risk patients avoid false nails and that staff with natural nails trim them to ¼ inch long. Studies have shown that nail polish does not increase the number of bacteria but that chipped nail polish may support the growth of larger numbers of organisms (CDC, 2002; AAMI, 2015). Fingernail disease, such as onychomycosis, must be treated promptly because it can decrease the efficiency of hand hygiene (Longtin et al., 2011).

b. **Jewelry**
   The removal of jewelry allows for more effective hand hygiene (AAMI, 2015; Pyrek, 2015). Studies have demonstrated that the skin underneath rings is more heavily colonized than comparable areas of skin on fingers without rings (CDC, 2002).

c. **Contact Dermatitis and the Use of Hand Lotion**
   Healthy and intact skin is a prerequisite for effective hand hygiene. Contact dermatitis results largely from the frequent hand washing required to reduce the spread of pathogens and prevent infection. Compromised skin is vulnerable to the pathogens prevalent in the gastroenterology setting. The pain caused by contact dermatitis may
discourage health care workers from practicing proper hand hygiene, putting themselves and their patients at risk (Bolan, 2016). Hand lotions and creams can prevent and decrease skin dryness that happens from cleaning hands. Only facility-approved hand lotions must be used because they will not interfere with hand sanitizing products used when performing hand hygiene.

2. **Personal Protective Equipment (PPE)**

PPE is defined as specialized clothing or equipment that prevents blood or other potentially infectious material from passing through to clothing, onto skin, or into eyes or mouth when worn by an employee as protection against hazard or spread of infection (USFDA, 2015a; USDOL, 2012).

PPE must be selected based on the potential for exposure during a particular task performed in the GI setting and may include:
- Gloves to protect hands;
- Impervious gowns to protect skin and/or clothing;
- Masks to protect mouth/nose;
- Respirators to protect respiratory tract from airborne infectious agents;
- Goggles/eye shields to protect eyes (eyeglasses do not substitute for goggles/eyeshield);
- Face shields to protect face, mouth, nose, and eyes; and
- Head and shoe covers.

Effective use of PPE includes proper removal and disposal of contaminated PPE to prevent exposure to infection among both the GI staff and others (USFDA, 2015a). Staff members must demonstrate competency in donning and removing the PPEs, and they must remove and appropriately discard all used PPE at the point of use. Hand hygiene is the final step after removing and disposing of PPEs (CDC, 2007).

**Bloodborne Pathogens**

Bloodborne pathogens are infectious microorganisms that can cause disease in humans. These pathogens include Hepatitis B, Hepatitis C, and HIV. Health care workers are at risk for exposure to bloodborne pathogens (USDOL, 2012).

Employers must implement an exposure control plan that outlines employee protection measures (USDOL, 2012). The exposure control plan must include the following actions:
- Proper use of protective clothing and equipment;
- Provision and documentation of training to protect employees;
- Offer of Hepatitis B vaccination;
- Implementation of controls such as safer medical devices (e.g., needleless system, sharps containers); and
- Annual updates to the exposure control plan.

When an exposure to bloodborne pathogens occurs, the health care facility must have the appropriate resources available to contain and/or mitigate the contamination. Blood and other potentially infectious materials should be promptly cleaned up. Contaminated items should be discarded in compliance with federal regulations, using protective gloves and other PPE.
appropriate for this task. There should be processes in place to address the handling of specimens, contaminated wastes, and linen (ASGE, 2018).

**Safe Injection Practices to Prevent Transmission of Infections**
The investigation of four large outbreaks of hepatitis B virus (HBV) and (hepatitis C virus) HCV among patients in various types of health care facilities in the United States identified a need to define and reinforce safe injection practices. The primary breaches in infection control practice that contributed to these outbreaks included the reinsertion of used needles into a multiple-dose vial or solution container (e.g., saline bag), the use of a single needle/syringe to administer intravenous medication to multiple patients, and the preparation of medications in the same workspace where used needle/syringes were dismantled also may have been a contributing factor (CDC, 2015b).

These and other outbreaks of viral hepatitis could have been prevented by adherence to basic principles of aseptic technique for the preparation and administration of parenteral medications. The CDC (2016) outlines several safe injection practices that must be followed:

- Never reuse single dose vials.
- Never administer medications from single-dose vials or IV bags to multiple patients.
- Never administer medication from the same syringe to multiple patients, even if the needle is changed.
- Medication containers are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient.
- Single dose vials are preferred. However, if multi-dose vials are used, store the vials in a dedicated area and away from the patient care area. Multi-dose vials must be dated when opened and discarded according to institutional policies.
- Cleanse the rubber septum of medication vials with 70% alcohol, even if cap was in place, and allow the alcohol to dry before inserting a needle or blunt cannula into the vial.

Puncture-resistant containers for biohazardous materials and sharps should be located near the point of use. These puncture-resistant containers must have one-way openings and mechanisms to prevent overfilling. The protocol for removing and replacing full sharps disposal containers is a critical component of a disposal safety program (Perry et al., 2012).

Outbreaks related to unsafe injection practices indicate that some health care personnel are unaware of, do not understand, or do not adhere to basic principles of infection prevention and aseptic technique. Therefore, to ensure that all health care workers understand and adhere to recommended practices, principles of infection prevention and aseptic technique need to be reinforced in training programs and incorporated into institutional polices that are monitored for adherence to promote a culture of safety.

**Endoscopy Environment, Cleaning, and Disinfection**
Consider the entire endoscopy setting when establishing infection prevention guidelines. The physical environment must be maintained in such a way to facilitate proper infection prevention. The development of policies and protocols should include manufacturers’
Endoscopy scheduling, staffing, and workflow needs to be strategically managed so that there is adequate time and resources to thoroughly adhere to all infection prevention protocols, including room turnover and reprocessing activities. Managers and facility leaders need to be particularly cognizant of the time and resources necessary for proper infection prevention practices, including timely reprocessing of endoscopes in accordance with manufacturers’ instructions for use.

**Environment of Care Considerations**

Endoscopy units must provide an environment that protects both patients and staff from injury or infection. Several key points to consider when evaluating the endoscopy environment include:

- The endoscopy unit should have enough space to accommodate people, activities, and growth. Examination rooms and reprocessing areas need to be large enough so that staff may freely move to avoid cross-contamination between dirty and clean areas. Procedure room space will depend on the planned activity, with more complex cases generally taking place in larger rooms to accommodate more equipment, supplies, storage, and staff. When planning new endoscopy units, anticipate a future increase in the demand for endoscopic screening programs, as well as an increase in advanced procedures that utilize extra equipment (Caldwell et al., 2014; Petersen & Ott, 2008; Nelson et al., 2013).

- The reprocessing area should be physically separate from the patient procedure rooms (AAMI, 2015; Alvarado & Reichelderfer, 2000). The area must be specifically designed and dedicated to address reprocessing activities of decontamination and disinfection (Beilenhoff et al., 2008; Facilities Guidelines Institute [FGI], 2014; Joint Commission, 2014). The area should be restricted to authorized personnel. The physical space should be an appropriate size in relation to the volume of equipment reprocessed and the reprocessing equipment specifications. Space should be adequate to allow for the manual cleaning and rinsing of devices during decontamination. The work area identified should be sufficient so that “dirty” areas are physically separate from “clean” areas. The reprocessing work flow should be from dirty to clean to avoid cross-contamination (Petersen & Ott, 2008). There should be utility areas located outside of the reprocessing area; these areas should be clearly labeled as “clean” and “soiled”.

- Air handling in the endoscopy unit should conform to current CDC guidelines (Alvarado & Reichelderfer, 2000). Temperature and humidity should be regulated according to local and facility requirements. There should be negative air pressure in the reprocessing room and a minimum of 10 exchanges per hour, with at least two being fresh, outside air (The American Institute of Architects Academy of Architecture for Health [AIA], 2001; FGI, 2014; Joint Commission, 2014). Exhaust should be vented directly outside. Chemical vapors should not exceed allowable limits (Petersen et al., 2017). It is also important that staff understand the concepts of negative airflow; where negative airflow is required and how to ensure negative airflow is properly working.
- Reprocessing areas should have dedicated plumbing and drains. The room must have more than one sink and separate handwashing facilities. Sinks should be deep enough to allow complete immersion of the endoscope to minimize aerosolization and wide enough to avoid tight coiling of the endoscope (also consider endoscope manufacturer coiling parameters). Consider water filling and draining capacities to ensure optimal operational parameters. There should be ergonomic considerations to prevent undue physical strain on personnel.

- Eye wash stations for immediate emergency use must be available in the GI setting no greater than 10 seconds from the location of chemical use or storage (AORN, 2015; AAMI, 2015). Eye wash stations should not be near, or over, the decontamination sink so that flushing of the eyes is never performed over a contaminated area (CDC, 2017a). The eye wash station must be activated weekly and documented to ensure proper use during a potential chemical exposure. Refer to the eye wash manufacturer’s guidelines for proper maintenance of the device. Further, if eye wash stations are not flushed on a regular basis, the water in the pipes has the potential to harbor pathogens, including Legionella, Pseudomonas, amoebae, and fungi which may be transmitted (Kanamori, Weber, & Rutala, 2016).

- Endoscopes should also hang freely so that they are not damaged or contaminated by physical impact. Endoscopes should be stored in accordance with the endoscope and storage cabinet manufacturers’ instructions for use (IFU). Store reprocessed endoscopes in a cabinet that is of sufficient height, width, and depth to allow flexible endoscopes to hang vertically without coiling and without touching the bottom of the cabinet, or designed-and intended by the manufacturer for horizontal storage of flexible endoscopes (CDC, 2017a). The route from the reprocessor machine to the storage cabinet should not cross through the soiled processing area.

- Sterile supplies and medications should be stored at least 8-10 inches from the floor and in such a manner to prevent splash contamination during environmental cleaning. To avoid water damage, supplies should not be stored under sinks (Calderwood et al., 2014) or near sinks in order to prevent splash contamination of the supplies. Bottom shelving for supplies must be solid or have an impervious liner to prevent contamination during environmental cleaning. Supplies need to be rotated and checked regularly for expiration. Liquids should be placed on the bottom to prevent leaking on other supplies.

- Due to the nature of biohazardous materials and chemicals in the endoscopy unit, SGNA recommends facilities have policies in place prohibiting eating or drinking in designated areas (USDOL, 2017).

- Facilities must have a written policy to handle hazardous chemical spills (Joint Commission, 2017b). Endoscopy staff needs to be trained and have documented competencies on chemicals used and have quick access to Safety Data Sheets (Steege et al., 2014).
Cleaning and Disinfection Guidelines

Facilities are responsible for developing written policies or protocols outlining the responsibilities of endoscopy staff for routine and non-routine cleaning and/or disinfection of the environment. A well-established infection prevention plan, including housekeeping, should involve staff from infection prevention, environmental services, and the endoscopy department to establish the appropriate frequency, cleaning, disinfection, and maintenance of the unit (Quinn et al., 2015). Transmission of microorganisms on environmental surfaces can lead to hospital-acquired infections (Siani & Mallard, 2015). Any health care setting is at risk for infection transmission because patients seen in these settings may present with communicable diseases or other conditions. Consider the following when developing policies and protocols:

1. All staff should follow appropriate use of PPE when performing any cleaning or disinfection.
2. Supervisors or designees should be responsible for ensuring that staff follow proper cleaning procedures.
3. Endoscopy staff must demonstrate knowledge of the proper preparation and use including but not limited to the concentration, temperature, and contact time for chemicals used for cleaning and disinfection.
4. There should be a terminal cleaning plan in place and should include the cleaning of all surfaces in the procedure room to remove all soil and biofilm, followed by disinfection (Calderwood et al., 2018). Consult your facility policies for terminal cleaning requirements.
5. Frequently touched or contaminated surfaces – including door handles, light switches, endoscopy keyboards, video monitors, consoles, and endoscopic equipment – should be cleaned and disinfected frequently, including at the beginning of the day, between cases, and during terminal cleaning (Calderwood et al., 2014).
6. “Orphan equipment” such as infrequently used point-of-care devices, computers on wheels, portable monitors, or items that may be vulnerable to being missed must be regularly cleaned and disinfected according to manufacturers’ recommendations (Carling & Huang, 2013).
7. Cell phones, tablets, other personal communication and/or hand-held electronic devices, and their accessories are highly susceptible to contamination by microorganisms, some potentially pathogenic. Reducing the numbers of microorganisms present on the devices may protect patients from the risk of health care associated infections (HAIs) (AORN, 2015; Pyrek, 2015). There are challenges in cleaning mobile communication devices. The current literature suggests that using wipes moistened with alcohol or bleach are effective in reducing levels of pathogenic bacterial load on mobile communication devices and that wipes moistened with saline or water may be similarly effective because of mechanical removal. However, several studies have demonstrated that most health care personnel do not regularly clean their phones (Ganapathy Shathivelk, P.C., Velvzhi, G., Sucilathangam, G. & Revathy, C., 2017). The health care team must also perform hand hygiene before and after use of these devices to minimize transmission of the pathogens.
8. Staff attire in the GI setting and its role in cross-transmission remains poorly established, and SGNA supports additional research in this area. The gastroenterology setting is not a sterile environment, and facilities need to consider if it is necessary to provide hospital-laundered scrubs (Calderwood et al., 2014). There are limited studies to support
the need for gastroenterology staff to change their clothing once they arrive at work. Some studies support that controlled laundry of garments reduces the risk of transferring microorganisms from the health care facility to home (Calderwood et al., 2014; Pyrek, 2015). If staff launder their scrubs at home, a hot water cycle followed by a cycle in the dryer has been associated with the elimination of both pathogenic Gram-positive and Gram-negative bacteria (Bearman et al., 2014).

There is research addressing the role of transmission of bacteria on the staff’s lab coats. Bacterial survival ability increases on inanimate surfaces including lab coat fabrics such as cotton and polystyrene (Hamid et al., 2016). The areas of the lab coat that demonstrate larger numbers of bacteria include the sleeves or pocket (Bearman et al., 2014).

9. Point-of-care blood glucose monitoring devices have been associated with outbreaks of HBV. These devices involve the use of fingerstick devices and opportunities exist for the transmission of bloodborne pathogens (Dolan et al., 2016). To prevent exposure to bloodborne pathogens while using the blood glucose monitoring devices, avoid handling test strip containers with soiled gloves. If a new test strip is needed, discard soiled gloves and perform hand hygiene before obtaining a new test strip. Clean and disinfect the blood glucose monitoring device after each patient use, using manufacturer recommendations. Clean any visible blood and dirt from meters before disinfecting with facility-approved disinfectants.

10. Storage shelves, drawers, bins, and cabinets must be cleaned on a regular basis.

11. Establish responsibility (i.e., endoscopy staff or environmental management) for regular cleaning of all surfaces and equipment.

12. Floors and walls in the endoscopy unit need to be cleaned on a regular basis (determined by facility) and when spills/splashes occur or when visibly soiled (Rutala et al., 2008).

13. At the beginning of the day, endoscopy staff needs to verify that all patient care areas in the GI setting have been properly cleaned (Calderwood et al., 2014).

14. Non-critical patient care equipment – including reusable blood pressure cuffs, stethoscopes, hospital beds – are disinfected after each use, using an EPA-registered hospital disinfectant, following the label’s safety precautions and directions, with attention to contact time (Rutala & Weber, 2016a). Disinfection of non-critical patient care surfaces should be completed between each patient and when visibly soiled. When available, use disposable equipment on patients with contact precautions.

Special Considerations
The GI staff may encounter patients with Clostridium difficile, tuberculosis, vancomycin-resistant Enterococci (VRE), carbapenem-resistant Enterobacteriaceae (CRE), and other infections that require specific methods to prevent or decrease the spread of infection. Examples of these methods include:

- Perform rigorous cleaning of the environment with an EPA-registered hospital disinfectant that has been approved for the elimination of C. difficile spores (ASGE, 2018; Rutala et al., 2008). Restrict room access following procedures with suspected or known airborne transmitted illness (e.g. tuberculosis) (AORN, 2015).

- Enhance environmental cleaning for surfaces following care of patients with known pathogens (e.g. VRE, CRE, C. difficile) (Anderson et al., 2017).
Patients may present with various parasitic or vermin infestations such as head lice, scabies, or bed bugs. Preventing the spread of infestations and being aware of trends and guidelines should be a primary concern. Personnel should be proactive, familiar with facility policies and guidelines, and work with infection prevention specialists to address possible scenarios.

The same infection prevention principles in the endoscopy unit must be followed outside of the endoscopy unit, especially in cases where patients may be in isolation or in a high-risk area such as the operating room.

**General Considerations for Endoscope Handling**

Endoscopy units need to have clearly established processes for endoscope handling and transport from the endoscope cabinet to the procedure room, and then transporting the endoscope to the decontamination area following the procedure. Endoscopy staff need to not only follow established processes for endoscope handling in a systematic manner, but they also need to understand the principles of infection prevention that guide their actions. These considerations include the following:

- Verify that the room is clean prior to bringing a clean endoscope and patient into the procedure room.
- If the endoscope in the storage cabinet is not dry, the endoscope must be reprocessed prior to use. Similarly, if visible stains or dried residue are found on the scope insertion tube or distal tip (e.g., by distal channel openings and lenses), reprocess the scope again before use.
- Gloves should be worn during all phases of endoscope handling: when removing the clean endoscope from storage and transporting to a procedure room, when removing endoscopes from AERs, and when taking the clean endoscope into storage (Calderwood et al., 2014).
- Before beginning a procedure, verify that all the equipment, including the endoscope, is clean and in working order based upon manufacturers’ instructions describing inspection before use.
- At the end of the procedure, before leaving the procedure room, pre-clean the endoscope, following manufacturer’s instructions.
- Establish a system to communicate the time of pre-cleaning to the reprocessing staff in order for them to prioritize and ensure that the endoscope is reprocessed within the manufacturer’s indicated timeframe. If the endoscope is not reprocessed in a timeframe recommended by the manufacturer, follow delayed reprocessing instructions (CDC, 2017a).
- Transport the pre-cleaned endoscope to the reprocessing area in a puncture-resistant, hospital-approved container, with an OSHA-approved biohazard label to indicate a contaminated endoscope (USDOL, 2012; Spruce, 2016). If reusable containers are used for endoscope transport, have a system in place to assure that the containers are cleaned after each use and in accordance with the reusable container’s instruction for use.

**Reprocessing Endoscopes**

Endoscopes are semi-critical medical equipment and should receive high-level disinfection or sterilization. Many factors can affect the safety and cleanliness of endoscopes. This may include the design and maintenance of endoscopes, failure to fully adhere to manufacturers’
instructions for reprocessing, lack of a standard process to evaluate cleaning efficacy, efficacy of AERs, and poor water quality. All of these factors play a role in microbial transmission (Koveleva et al., 2013).

In order to guide them in all phases of reprocessing, staff must have all manufacturers’ reprocessing instructions readily available at the point of use (USFDA, 2015d). Reprocessing steps must be followed stringently, and the environment must be well-maintained (Noronha & Brosnak, 2014).

For more specific information endoscope reprocessing, refer to the SGNA Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes.

**Reprocessing Accessories**

Endoscopic accessories may be reusable. The USFDA requires that the manufacturers of reusable devices provide validated instructions for cleaning and high-level disinfection or sterilization (Petersen et al., 2017). Accessories classified as critical devices (i.e., those that break the mucus membrane and/or come into contact with sterile tissue or the vascular system) require sterilization. SGNA suggests consideration be made for using disposable medical devices to support safety and infection prevention.

**Quality Assurance of Endoscope Reprocessing**

Infection prevention in endoscope reprocessing is crucial to ensuring safety of patients and staff in the endoscopy setting. Infections have been linked to inadequate reprocessing and human error (Wendorf et al., 2015; CDC, 2017a). Lack of knowledge or unfamiliarity with endoscope channels, accessories, and specific steps required for reprocessing has been linked to a risk of infection transmission (Petersen et al., 2017).

**Ensuring Safety**

AERs should also state clearly which endoscopes they can reprocess (Alfa, 2016). In addition, AER manufacturers should provide device-specific reprocessing instructions based upon validation studies. The USFDA released recommendations in 2009 that encouraged endoscope manufacturers to work with other manufacturers to help ensure that endoscopes, endoscope accessories, and AERs are compatible and that all connections fit properly. End users must resolve any inconsistencies in the instructions between endoscope and AER manufacturers (Petersen et al., 2017; USFDA, 2009). Manufacturers should also communicate any reprocessing updates promptly (USFDA, 2009).

Personnel must complete endoscope reprocessing in a timely and efficacious manner (Edmiston & Spencer, 2014). Moisture promotes biofilm development (Kovaleva et al., 2013). If biofilm develops, HLD may not be effective in killing and/or inactivating microorganisms (Roberts, 2013). Strict adherence to the reprocessing protocol is essential for infection prevention. Review and update reprocessing protocols according to manufacturers’ instructions for use, institutional policy, and regulatory agencies. Consult with an infection prevention advisor when modifications to the reprocessing protocol are required.

Ensuring consistent endoscope reprocessing should be a multidisciplinary effort involving infection prevention personnel, clinical staff, and Environment of Care (EC) professionals.
Designate and assign an individual in the endoscopy setting to monitor compliance with the reprocessing protocol. Managers and supervisors must be familiar with the principles and practices of reprocessing and remain current on manufacturers’ instructions if they are to train and monitor staff. Endoscopy units should participate in regular, focused audits of infection prevention protocols, including reprocessing of endoscopes (CDC, 2017a; Joint Commission, 2014). The multidisciplinary team should be engaged to conduct product evaluation and risk assessment when the adoption of new technologies is being considered, or when manufacturer instructions, guidance documents and facility policy require harmonization (AAMI, 2013).

**Confirming the Process**

All settings where gastroenterology endoscopy procedures are performed need to have a system for tracking endoscopes and reusable endoscopic accessories through the entire cleaning and disinfection process. For complete traceability, document each phase of the process, including pre-cleaning, along with the staff involved at each stage of endoscope handling (CDC, 2017a; Petersen et al., 2017).

“Visibly clean” is a method routinely used to assess the adequacy of manual cleaning (AAMI, 2015; Rutala et al., 2008). This may involve the use of a magnifying glass to inspect for gross soil. Visual inspection is insufficient to determine cleaning adequacy in narrow and internal channels of a scope and cannot detect microorganisms or bioburden (Alfa et al., 2014). The use of a borescope may be helpful to assess damage and moisture in the endoscope’s internal channels. Rapid cleaning verification tools are available. These tools can provide documentation on cleaning efficacy but do not reflect microbial activity. If a facility chooses to use rapid cleaning verification tools, testing of endoscope lumen or elevator channel should be done immediately after manual cleaning so that any improperly cleaned devices are re-cleaned prior to HLD. Culturing can serve as a quality control measure of the adequacy of duodenoscope reprocessing (CDC, 2015a; USFDA, 2018a, 2018b). Facilities should consider the regular use of these processes to verify ongoing cleaning adequacy (Alfa, 2013) and to assess reprocessing efficacy (USFDA, 2018a, 2018b).

Endoscopes and reusable accessories should be visually inspected during all stages of handling (Petersen et al., 2017). Damaged endoscopes and accessories should be removed from service for repair or disposal, as this may affect their function and interfere with adequate reprocessing (Petersen et al., 2017; USFDA, 2009). Follow manufacturer’s instructions when sending endoscopes out for repair to comply with special reprocessing or shipping considerations (CDC, 2017a; Lee et al., 2015). All maintenance schedules and services as outlined by the manufacturer should be performed for endoscopes and AERs (CDC, 2017a). A system should be in place to track repairs and maintenance of endoscopes, loaner endoscopes, or other reusable endoscopic equipment (Chapman, 2010). A plan for the replacement of endoscopes and other reusable equipment is also essential.

If there are any doubts related to improper cleaning, disinfection, or contamination, the equipment should be taken out of service (e.g., endoscope, AER, accessories, flushing pump, etc.) until corrective actions have been taken and satisfactory results have been achieved. Corrective actions such as repairs or improved training should be initiated to correct deficiencies in reprocessing. Any item that may not have been appropriately disinfected or
sterilized must be reprocessed (Petersen et al., 2011; Beilenhoff et al., 2008; USFDA, 2009; Rutala & Weber, 2007).

Once there is confirmation that an endoscope has been properly reprocessed, it is suggested that a system exist for identifying scopes that are clean and ready to use (Rutala & Weber, 2016c; CDC, 2017a). Endoscopes can be stored for 7 days if they have been effectively reprocessed and are stored in a way that keeps them completely dry and free from contamination (Schmelzer, Daniels, and Hough, 2015). SGNA supports a 7-day storage interval for reprocessed endoscopes but only if they were reprocessed and stored according to professional guidelines and manufacturer instructions.

**Quality Assurance**
Infection Prevention is the cornerstone of the gastrointestinal endoscopy unit’s quality assurance program. Quality assurance is dependent on promoting a culture of safety, where all members of the gastroenterology endoscopy team are engaged in preventing, detecting, and minimizing hazards and error without attaching blame to individuals (Agency for Healthcare Research and Quality [AHRQ], 2017). A culture of safety cannot fully exist without a Just Culture.

A Just Culture is part of an overall safety culture where the focus is on identifying errors and potential errors. The endoscopy team is taught to recognize and report safety risks in an effort to improve processes. Breaches in infection prevention are intended to trigger fact-finding and systems improvement instead of blame (AHRQ, 2017). Engaged team members have an important role in establishing and maintaining a culture of safety (Joint Commission, 2017a).

**Infection Prevention Champions**
When staff members are personally invested in infection prevention and uphold high performance standards, they can influence their peers to do the same. Unit-based safety teams have been associated with improvements in safety culture measurements and have been linked to lower error rates (AHRQ, 2017). Facilities are encouraged to consider the SGNA Infection Prevention Champions Program, a safety initiative aimed at further strengthening staff’s commitment to infection prevention on their units. Unit-designated SGNA Infection Prevention Champions carry out the mission and vision of the program, educating self and staff on infection prevention topics, maintaining high quality control, and addressing performance improvement needs (SGNA, 2017). Facilities receive resources, support, and recognition to strengthen their infection prevention program. Evidence suggests that having an infection prevention champion can lead to sustained improvement in the area of infection prevention (Calderwood et al., 2018; SGNA, 2017).

**Competency**
It is important for endoscopy staff to consistently demonstrate accountability and responsibility in their practice regarding infection prevention. Managers and supervisors set clear expectations in proper infection prevention measures, provide the necessary resources, facilitate ongoing training, and monitor staff competence. Orientation programs and ongoing education must be structured and designed for infection prevention and patient safety. Temporary staff
must not be allowed to reprocess equipment in a manual or automated system until competency has been established (Petersen et al., 2011). All health care workers must be educated on appropriate infection prevention measures in the gastroenterology setting. Core components of an education program should cover the following topics:

- Hand hygiene
- Standard precautions;
- Personal protective equipment;
- OSHA rules on occupational exposure to blood-borne pathogens;
- Reprocessing procedures for endoscopes and accessory equipment;
- Proper set-up, disassembly, and reprocessing of endoscopes;
- Mechanisms of disease transmission;
- Maintenance of a safe work environment;
- Safe use and handling of high-level disinfectants and sterilants;
- Ensure proper disposable of single use devices/components;
- Environmental and terminal cleaning; and
- Safe medication handling.

**Response to Failure in Infection Prevention**

Breakdown in infection prevention processes, breaches during the reprocessing continuum, and endoscopy equipment or device failures all have the potential to place patients at risk for injuries, including potential infection. Infections related to endoscopic procedures should be reported to infection prevention, appropriate health agencies as required, the USFDA, and the manufacturer of the equipment, reprocessing supply item, or accessory in question (Rutala et al., 2008; Petersen et al., 2017). Endoscopy managers or supervisors need to ensure that staff are familiar with facility policies and assume personal accountability to report these failures and potential risks. Policies should address response to failure with an emphasis on supporting processes that aid in identifying and minimizing potential risks. Endoscope tracking is just one example of how an organization uses a process to follow the endoscope through a cycle of use. Each step can be traced and replicated in the event of breakdown. Tracking includes the ability to determine when specific endoscopes were used for specific patients, loaned to other units or facilities, reprocessed, or repaired. Tracking is also essential for responding to device or product recalls (CDC, 2017a).

**Summary**

Every patient must be considered a potential source of infection. Endoscopy personnel have the responsibility and ability to decrease that potential by adhering to infection prevention principles. Ensuring a culture of safety and infection prevention in the endoscopy setting requires a multi-factorial approach that encourages open and safe communication, accountability, education, training, competency, and quality process improvement. Following these principles will guide an endoscopy unit to create best practices and maintain a safe environment for all patients and personnel.

SGNA supports further research and evidence-based practice in the area of infection prevention in the gastroenterology setting.
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**Recommended Reading**


