

Standard of Infection Prevention in the Gastroenterology Setting



Society of Gastroenterology Nurses and Associates, Inc.

Acknowledgements

Copyright © 2015 Society of Gastroenterology Nurses and Associates, Inc. (SGNA).

This document was prepared and written by the members of SGNA Practice Committee and adopted by the SGNA Board of Directors in 2015. It is published as a service to SGNA members.

SGNA Practice Committee 2015-16

Ann Herrin, BSN RN CGRN, Chair
Midolie Loyola MSN RN CGRN, Co-chair
Susan Bocian MSN BSN RN
Angela Diskey MSN RN CGRN
Cynthia M. Friis, MEd BSN RN-BC
LeaRae Herron-Rice MSM BSN RN CGRN
Michelle R. Juan, MSN RN CGRN
Marilee Schmelzer, PhD RN
Susan Selking BSN RN CGRN

Society of Gastroenterology Nurses and Associates, Inc.
330 North Wabash, Suite 2000
Chicago, Illinois 60611
Tel: (800) 245-SGNA or (312) 321-5165
Fax: (312) 673-6694
Online: www.SGNA.org
Email: SGNA@smithbucklin.com

Disclaimer

The Society of Gastroenterology Nurses and Associates, Inc. presents this guideline for use in developing institutional policies, procedures, and/or protocols. Information contained in this guideline is based on current published data and current practice at the time of publication. The Society of Gastroenterology Nurses and Associates, Inc. assumes no responsibility for the practices or recommendations of any member or other practitioner, or for the policies and practices of any practice setting. Nurses and associates function within the limits of state licensure, state nurse practice act, and/or institutional policy.

Table of Contents

Preface.....	4
Definitions.....	4
Introduction.....	5
Spaulding classification.....	5
Infection Prevention Measures.....	5
Standard Precautions.....	6
- Hand Hygiene.....	6
- Personal Protective Equipment.....	7
Bloodborne Pathogens.....	8
Communication Devices in the GI Lab.....	8
Staff Attire in the GI Setting	8
Environment.....	8
Special Considerations.....	10
Reprocessing.....	10
Quality Assurance of Endoscope Reprocessing.....	12
- Ensuring Safety.....	12
- Confirming the Process.....	13
Quality Assurance Measures.....	14
Culture of Safety.....	15
Infection Prevention Champions.....	15
Staff Competency.....	15
Competency Programs.....	16
Response to Failure in Infection Prevention.....	17
Summary.....	17
References.....	18

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 disinfecting endoscopes and accessories.

Bioburden refers 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, Weber & the Healthcare Infection Control Practices Advisory Committee, 2008).

Cleaning refers to removal of all soil and organic material. Cleaning must precede disinfection or sterilization.

Competency refers to an expected level of performance that integrates knowledge, skills, abilities, and judgment (American Nurses Association, 2013).

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 (Occupational Safety and Health Administration [OSHA], 2012).

Disinfection refers to the thermal or chemical destruction of pathogenic and other types of microorganisms (Rutala et al., 2008).

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).

Material Safety Data Sheet (MSDS) 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.

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 (OSHA, 2012).

Personal Protective Equipment (PPE) refers to specialized clothing or equipment worn by an employee for protection against a hazard (American Society of Gastrointestinal Endoscopy [ASGE], 2008; Food and Drug Administration [FDA], 2015; OSHA, 2012).

Reprocessing refers to the validated process of cleaning and then disinfecting or sterilizing endoscopes and accessories. In relation to endoscopy, it includes all the steps from pre-cleaning to drying.

Sterile refers to the state of being free from viable microorganisms (Association for the Advancement in Medical Instrumentation [AAMI], 2010; Rutala et al., 2008).

Sterilization refers to a process resulting in the complete elimination or destruction of all forms of microbial life.

Training refers to the action of teaching a person a particular skill or type of behavior.

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, 2011).

Introduction

The field of gastroenterology continues to expand as new instruments, products, and procedures are introduced into the endoscopy arena. While the transmission of infectious organisms during gastrointestinal endoscopy is considered low, vigilance and utmost care in the prevention of infection is imperative in this setting.

Spaulding Classification

The Spaulding Classification of medical devices and level of disinfection system is universally used to determine what type of disinfection or sterilization is appropriate for medical devices (Peterson et al., 2011). Three classes – critical, semi-critical, and non-critical – stratify the risk of infection associated with each device. Critical devices break the mucosal barrier and should always be sterilized (e.g., reusable biopsy forceps). Semi-critical devices (e.g., endoscopes) come in contact with mucous membranes or non-intact skin and should be sterilized or receive high level disinfection. Non-critical devices are those that come into contact with intact skin (e.g., blood pressure cuffs and stethoscopes). These items can be cleaned with soap and water or disinfected with a germicide.

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 (Beilenhoff et al., 2008).

Infection prevention measures that can disrupt the chain of infection include:

1. cleaning, disinfection, and sterilization of medical equipment,
2. correct use of PPE,
3. personal hygiene,
4. engineering controls (e.g., ventilation, room design, water supply),
5. cleaning and disinfection of environmental surfaces,
6. adequate administrative control and support,
7. training and continuing education,
8. adequate written standardized operating procedures, and
9. 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, 2008; CDC, 2014).

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). Staff should understand the indications for washing hands with soap and water or when alcohol-based hand sanitizers are acceptable.

Health care providers should practice hand hygiene at key points in time to disrupt the transmission of microorganisms to patients. Key times include:

- before patient contact
- before clean/aseptic procedures;
- after body fluids exposure risks (even if gloves are worn);
- after touching a patient; and
- after touching a patient's surroundings (WHO, 2009).

Note that wearing gloves is not enough to prevent the transmission of pathogens in health care settings.

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 personnel.

Performance indicators for measuring the compliance of health care workers should be considered:

- Periodically monitor and record adherence of hand hygiene by direct observation.
- Monitor the volume of alcohol-based hand rub used in a dispenser.
- Monitor 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:

1. Fingernails

Fingernails can harbor pathogens which 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).

2. 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). However, further studies are needed to establish if wearing rings results in increased transmission of pathogens in health care.

2. Personal Protective Equipment (PPE)

PPE is defined as specialized clothing or equipment that does not permit blood or other potentially infectious material to pass through clothing or into skin, eyes, or mouth when worn by an employee as protection against hazard or spread of infection (ASGE, 2008; Food and Drug Administration (FDA), 2015; OSHA, 2012).

PPE must be selected based on the potential for exposure during a particular task performed in the GI setting. PPE includes:

- Gloves to protect hands;
- 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;
- 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 (FDA, 2015a). Staff must demonstrate competency in donning and removing the PPEs.

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 (OSHA, 2012).

Employers must implement an “exposure control plan” which outlines employee protection measures (OSHA, 2012). The exposure control plan must include the following actions:

- Proper use of protective clothing and equipment;
- Provision of training;
- Offer of Hepatitis B vaccination; and
- Implementation of controls such as safer medical devices (e.g., needleless system, sharps containers).

When an exposure to bloodborne pathogens occurs, the health care facility must have the appropriate resources available.

Communications Devices in the GI Setting

Cell phones, tablets, other personal communication and/or hand-held electronic devices equipment and their accessories should be cleaned with a low-level disinfectant

according to the manufacturer's instructions before and after being brought into the endoscopy setting. The collective evidence demonstrates that these types of communication devices 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) resulting from the transfer of microorganisms from the devices or hands of health care workers to patients (AORN, 2015; Pyrek, 2015). It is suggested that the health care members using these devices wash their hands before and after use.

Staff Attire in the GI setting

There are limited studies to support the need for GI setting staff to change their clothing once they arrive at work. Some studies support that controlled laundry of garments reduce the risk of transferring microorganisms from the health care facility to home (ASGE, 2014; Pyrek, 2015).

Environment

Disinfection practices may vary among different health care settings (i.e., hospital, clinic, ambulatory care, home). However, any setting is at risk for infection since patients seen in these settings may present with communicable diseases or other conditions. The Spaulding classification should be followed to ensure patient safety (Rutala et al., 2008).

The entire environment must be considered when developing infection prevention processes. An infection prevention program should include close collaboration between different groups involved in infection prevention and reprocessing in order to ensure that the processes and environment are safe and well maintained (Joint Commission, 2014).

The endoscopy unit should have enough space to accommodate people, activities, and growth. 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 (ASGE, 2014; Petersen & Ott, 2008).

Personnel in the GI setting are exposed to many potential hazards. Protection for the staff exposed to these hazards can best be accomplished by consistent application of safety practices (ASGE, 2010).

A well-established housekeeping plan should involve staff from infection prevention, environmental services, and the GI department to establish the appropriate frequency, cleaning, disinfection, and maintenance of the unit (Seavey, 2010). The development of guidelines and policies should include manufacturers' guidelines, infection prevention principles, and current, accepted evidence-based practice (Day & Kelsey, 2013).

Facilities are responsible for developing written policies or protocols which outline the responsibilities of endoscopy staff for routine and non-routine cleaning and/or disinfection of the environment. Staff should use appropriate PPE when performing any cleaning or disinfection. Supervisors or designee(s) should be responsible for ensuring that proper cleaning procedures are being followed. Consult your facility policies for terminal cleaning requirements.

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, 2008).

Non-critical patient care equipment is disinfected using an EPA-registered hospital disinfectant, following the label's safety precautions and directions, with attention to contact time (Rutala & Weber, 2008; Rutala & Weber, 2011). Disinfecting non-critical patient care surfaces should be done between each patient and when visibly soiled. When available, use disposable equipment on patients with contact precautions.

Infection prevention principles outside of the endoscopy unit must be adhered to, especially in cases where patients may be in isolation or in a high-risk area such as the operating room (OR).

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 infection transmission. Examples of these methods include:

1. Perform meticulous handwashing using soap and water (not alcohol-based hand sanitizers) and rigorous cleaning of the environment with an EPA-registered hospital disinfectant that has been approved for the elimination of *C. difficile* spores to prevent the spread of *C. difficile* (ASGE, 2008; Rutala et al., 2008).
2. Restrict room access following procedures with suspected or known airborne transmitted illness (e.g. tuberculosis) (AORN, 2015).
3. Enhance environmental cleaning for surfaces following care of patients with known pathogens (e.g. VRE, CRE) (AORN, 2015).

Personnel should be proactive, familiar with facility policies and guidelines, and work with infection prevention specialists to address possible scenarios.

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.

Reprocessing

It is important to note that endoscopes can be the means of facilitating pathogenic cross-contamination. The environment plays a key role here since disinfectants and cleaning materials themselves can be contaminated. Please refer to the most current SGNA *Standard of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes* for specific steps for reprocessing flexible endoscopes.

Inadequate cleaning, disinfection, and drying procedures; contaminated AERs and endoscope design flaws; or equipment damage all play a role in microbial transmission (Koveleva et al., 2013). Reprocessing steps must be followed stringently, and the environment well-maintained (Noronha & Brosnak, 2014).

Immediate pre-cleaning of the endoscope is required when the endoscope is withdrawn from the patient. Device-specific manufacturer's instructions for delayed reprocessing should be reviewed (Peterson et al., 2011). The transport container of a soiled endoscope should be closed and labeled as biohazardous to prevent exposure to staff and the environment (OSHA, 2012).

The reprocessing area should be physically separated 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 processed 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 separated from "clean" areas. The reprocessing work flow should be from dirty to clean to avoid cross-contamination (Petersen & Ott, 2008). There should be clean and soiled utility areas located outside of the reprocessing room.

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. It is also important that staff understand the concepts of negative airflow, when to use negative airflow, and how to properly use the negative airflow. Chemical vapors should not exceed allowable limits (Peterson et al., 2011). Air handling in procedure rooms should conform to current CDC guidelines (Alvarado & Reichelderfer, 2000). Temperature and humidity should be regulated according to local and facility requirements.

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. 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 Lab no greater than 10 seconds from the location of chemical use or storage (AORN, 2015; AAMI, 2015). The eye wash station must be activated weekly to ensure proper use during a potential chemical exposure. Refer to the eye wash manufacturer for proper maintenance of the device.

Endoscope cleaning brushes should be the appropriate size that assures contact with the surface (Peterson et al., 2011; Rutala et al., 2008). Any chemical sterilants used should be properly stored and handled (Alvarado & Reichelderfer, 2000). Material Safety Data Sheets (MSDS) should be readily available for chemicals used at the facility.

AERs must be effective, safe, reliable, and able to handle endoscope design and throughput (Beilenhoff et al., 2008). Follow manufacturer's instructions on the proper use and maintenance of an AER. Ensure that the AER is compatible with the endoscopes and accessories being reprocessed. Any special considerations for reprocessing not handled by the AER (such as the elevator on duodenoscopes) must follow manufacturer's instructions (FDA, 2009; CMS, 2015). Other factors that play a role in effective reprocessing using an AER include the water quality and temperature, the chemical used and tested minimum effective concentration [MEC], maintenance of filters, and contact disinfection time with the scopes. The use of cleaning monitors for automated washers may help to ensure adequate functioning (Alfa, 2013). The chemical and microbial quality of water should be specified, controlled, and monitored (Alfa, 2013; DeBrujin et al, 2009).

Storage areas and other critical areas should be clearly labeled (Joint Commission, 2014). There should be suitable storage areas for clean endoscopes so that they can hang freely and vertically. Scopes must be stored in a manner that prevents them from becoming recontaminated (Rutala & Weber, 2004). Storage cabinets should have doors, and the interior of the cabinets must be clean, free of debris, and dry (Alvarado & Reichelderfer, 2000). The route from the reprocessor machine to the storage cabinet should not cross through the soiled processing area.

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 (Peterson et al., 2011; Rutala et al., 2008). Lack of knowledge or unfamiliarity with endoscope channels, accessories, and specific steps required for reprocessing has been linked to a risk of infection transmission (Peterson et al., 2011).

Ensuring safety

Many factors can affect the safety and use of endoscopes. This may include the design and maintenance of endoscopes, inadequate or failure to fully adhere to manufacturer's instructions for reprocessing, lack of a standard process to evaluate cleaning efficacy, and the efficacy of AERs, and poor water quality.

Endoscope manufacturers are urged to develop instruments that facilitate thorough cleaning and disinfection (Alvarado & Reichelderfer, 2000). This includes AERs so that they are not potential sources of infection (Rutala & Weber, 2004). While the FDA is currently working with manufacturers to validate reprocessing steps, staff must have the manufacturer's reprocessing instructions readily available in order to guide them (FDA, 2015b).

Personnel should make every effort possible to complete endoscope reprocessing in a timely and efficacious manner (Edmiston & Spencer, 2014). Moisture promotes biofilm development (Kovaleva et al., 2013). Strict adherence to the reprocessing protocol is essential for infection prevention. Reprocessing protocols should be reviewed and updated according to manufacturer's instruction for use, institutional policy, and regulatory agencies. Consultation with an infection prevention advisor should be considered when modifications to the reprocessing protocol are made.

Ensuring consistent endoscope reprocessing should be a multidisciplinary effort involving infection prevention personnel, clinical staff, and Environment of Care (EC) professionals. An individual in the endoscopy setting should be designated and assigned to monitor compliance with the reprocessing protocol. Supervisory personnel must be familiar with the principles and practices of instrument reprocessing if they are to properly train and monitor staff.

Confirming the process

All settings where gastroenterology endoscopy procedures are performed need to have a manual or electronic system for tracing endoscopes and reusable endoscopic accessories from the patient use through the entire cleaning and disinfection process. Each phase of the process should be documented, along with the staff involved at each stage of scope handling.

Meticulous cleaning of the scope is required before high-level disinfection [HLD] or sterilization can take place. Follow manufacturer's instructions for endoscope-specific reprocessing steps. Resolve any inconsistencies between endoscope and AER manufacturer's instructions (Rutala & Weber, 2004; FDA, 2009).

"Visibly clean" is a method routinely used to assess the adequacy of manual cleaning (Alfa et al., 2012; 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, 2014). Rapid cleaning monitors are available. These monitors can provide documentation on cleaning efficacy but do not reflect microbial activity. Real-time testing of endoscope lumens/elevator channel should be done immediately after manual cleaning so that any improperly cleaned devices are re-cleaned prior to HLD. Facilities should consider the use of monitors to verify ongoing cleaning adequacy (Alfa, 2013).

Endoscopes and reusable accessories should be visually inspected during all stages of handling, including before, during, and after use, as well as after cleaning and before HLD. Damaged endoscopes and accessories should be removed from use for repair or disposal, as this may affect their function and interfere with adequate reprocessing (Peterson et al., 2011; FDA, 2009). Follow manufacturer's instructions when sending endoscopes out for repair to comply with special reprocessing or shipping considerations (Alvarado & Reichelderfer, 2000). All maintenance schedules and services as outlined by the manufacturer should be performed for endoscopes and AERs (FDA, 2009). 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 reusable 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, washer-disinfector, 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 (Peterson et al., 2011; Beilenhoff et al., 2008; FDA, 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, 2004; CDC, 2015). In terms of interval of storage, Schmelzer, Daniels, and Hough (in press, 2015) concluded that endoscopes can be stored for 7 days if they have been effectively reprocessed to remove all pathogens and almost all other microorganisms, and are stored in a way that keeps them completely dry and free from environmental and human contamination. Studies in the systematic review utilized cultures to verify reprocessing effectiveness. 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. Facilities should be aware of recent interim guidelines to consider on culturing of duodenoscopes to validate the cleaning process of these particular scopes (CDC, 2015).

Quality Assurance Measures

Quality assurance is of the highest priority in settings where gastrointestinal endoscopy is performed. Elements of the quality assurance program include supervision, training, annual competency review, methods of assuring the availability of appropriate equipment and supplies, and procedures for reporting infections (ASTM International [ASTM], 2007; AAMI, 2010; Rutala et al., 2008; Wadlowski, 2015).

Infection prevention policies and protocols need to be accessible to staff at all times. These infection prevention policies include but are not limited to hand hygiene, appropriate personal protective equipment, and cleaning and reprocessing of reusable medical equipment including flexible endoscopes and environmental cleaning.

All policies and protocols should be reviewed and updated according to institutional policy. If possible, consult with an infection prevention specialist before modifying existing policies or protocols. Supervisors and facility leaders should remain abreast on new guidelines that are often disseminated by regulatory agencies, professional organizations, or manufacturers.

Refer to the SGNA Resources for Quality and Safety for additional information.

Culture of Safety

Quality assurance is dependent on promoting a culture of patient safety, where all members of the gastroenterology endoscopy team are engaged in infection prevention measures (Sammer & James, 2011). Supervisors and other leaders need to support this culture of patient safety, while engaging and empowering staff to do the same. (Barnsteiner, 2011). All staff are part of the quality assurance continuum and need to understand their role in infection prevention. Team members need to be engaged in infection prevention benchmarking and the development of quality metrics. Facilities should conduct audits for quality metrics, providing timely feedback to staff regarding adherence. Special emphasis should be given to auditing all steps in the reprocessing protocol.

Infection Prevention Champions

Literature recommends that frontline staff engage in various quality improvement projects, including infection prevention (Kirchner et al., 2012; Riley & Cheema, 2010). When staff members are personally invested in infection prevention and uphold high performance standards, they can influence their peers to do the same.

To further strengthen the commitment to infection prevention, facilities are encouraged to consider the SGNA Infection Prevention Champions program. The program gives a strong, passionate individual on an endoscopy unit a chance to receive resources, support, and recognition through SGNA. Facilities will also receive actionable items for their own unit to strengthen their infection prevention program. See the SGNA website

for more information on this valuable program.

Staff Competency

Quality of care and patient safety are issues of primary concern in any health care environment (Lenburg et al., 2009). The health and safety of patients are influenced by the competency of staff. Lack of competency can lead to detrimental consequences for patients (Axley, 2008). Staff working in the GI setting must be competent in infection prevention measures. It is important for endoscopy staff to consistently demonstrate accountability and responsibility in their daily actions and practice regarding infection prevention. Managers and supervisors need to set clear expectations in proper infection prevention measures, provide the necessary resources, facilitate ongoing training, and monitor staff competence. If any practices demonstrate a lack of competence or behaviors inconsistent with proper infection prevention, immediate action (e.g. remediation or reassignment) should be implemented until competency can be validated to ensure patient safety.

All nurses and associates in the endoscopy unit need to take responsibility for making sure their competencies for infection prevention are current based on employers' infection prevention guidance. Competency validation should be done annually and whenever new techniques, accessories, or equipment are introduced into the endoscopy unit (FDA, 2009). If staff is not knowledgeable on the use of devices, patients are at risk (Swayzee & Rich, 2012).

Managers or supervisors are responsible for maintaining documentation on infection prevention training programs and competency validation for personnel. These records need to be readily available for review by the staff as well as internal and external reviewers such as the Joint Commission and/or regulatory agencies.

Competency Programs

Infection prevention education is critical in all endoscopy settings. In order to maintain adherence to infection prevention strategies, personnel working in endoscopy units must complete a comprehensive orientation and training program, which includes the proper set-up, disassembly, and reprocessing of endoscopes. Orientation programs, as well as ongoing education, need to be structured and designed for infection prevention and patient safety. All health care workers, including physicians, nurses, and assistive personnel, must be educated on appropriate infection prevention measures (Hong & Lim, 2013; SGNA, 2013).

Additional core components of an education program should cover the following topics:

- Standard precautions;
- Personal protective equipment;

- OSHA rules on occupational exposure to blood-borne pathogens;
- Reprocessing procedures for endoscopes and accessory equipment;
- Mechanisms of disease transmission;
- Maintenance of a safe work environment;
- Safe handling of high level disinfectants and sterilants; and
- Procedures for waste management (ASTM , 2007).

Training on reprocessing reusable medical equipment, such as endoscopes, must be done by a qualified individual. Temporary staff must not be allowed to reprocess equipment in a manual or automated system until competency has been established (Peterson et al., 2011). If facilities receive vendor-provided training for endoscopy personnel, Clinical Educators from the company should provide the instruction. It is not appropriate for a sales representative to provide training, without documented competency, on the reprocessing of endoscopes.

When using equipment in the GI setting from different manufacturers, each company must provide education and training for their respective product. However, it is the responsibility of the staff member to understand how each piece of equipment works together in the reprocessing continuum.

Response to Failure in Infection Prevention

Breaches in patient safety with serious potential infection risks should be reported to facility leadership so that affected individuals are notified and deficiencies are corrected (Moumtzoglou, 2010). GI settings should have written protocols or policies to address any patient exposure to potential infections. Infections related to endoscopic procedures should be reported to infection prevention; appropriate health agencies as required; the FDA; and the manufacturer of the equipment, reprocessing supply item ,or accessory in question (Rutala et al., 2008; Peterson et al., 2011). The source of infection needs to be able to be traced to a specific patient (Crawford, 2007).

Endoscopy equipment or device failures have the potential to place patients at risk for injuries, including potential infection in some cases. Endoscopy facilities should have written guidelines or policies on the roles and responsibilities within the organization to report device failures. Endoscopy managers or supervisors need to ensure that staff is completely familiar with facility policies and assumes their own personal responsibility to report device failures. Any device that fails must be reported to manufacturer. 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 (FDA, 2015b).

Summary

Ensuring infection prevention in the endoscopy setting requires a multi-factorial approach. Meticulous cleaning and adherence to reprocessing guidelines is key to disrupting potential contamination by pathogens. Ongoing competencies and staff engagement is essential in creating best practices and maintaining a safe environment for all personnel and patients.

SGNA supports further research and evidence-based practice in the area of infection prevention.

References

- Alfa, M. (2013). Monitoring and improving the effectiveness of cleaning medical and surgical devices. *American Journal of Infection Control*, 41(5 suppl), S56-S59.
- Alfa, M., Olson, N., DeGagne, P., & Simner, P. (2012). Development and validation of rapid use scope test strips to determine the efficacy of manual cleaning for flexible endoscope channels. *American Journal of Infection Control*, 40(9), 860-5.
- Alfa, M., Olson, N., & Murray, B. (2014). Comparison of clinically relevant benchmarks and channel sampling methods used to assess manual cleaning compliance for flexible gastrointestinal endoscopes. *American Journal of Infection Control*, 42(1), e1-e5.
- Alvarado, C., Reichelderfer M., & The Association for Professionals in Infection Control and Epidemiology Guidelines Committees. (2000). APIC guideline for infection prevention and control in flexible endoscopy. *American Journal of Infection Control*, 28(2), 138-55.
- American Institute of Architects Academy of Architecture for Health. (2001). Guidelines for Design and Construction of Hospitals and Health Care Facilities. Retrieved from <http://www.fgiguide.org/pdfs/2001guidelines.pdf>
- American Nurses Association. (2013). ANA Leadership Institute: Competency Model. Retrieved from <http://www.ana-leadershipinstitute.org/Doc-Vault/About-Us/ANA-Leadership-Institute-Competency-Model-pdf.pdf>
- American Society of Gastrointestinal Endoscopists. (2010). Minimizing occupational hazards in endoscopy: Personal protective equipment, radiation safety, and ergonomics. *Gastrointestinal Endoscopy*, 72(2), 227-235.
- American Society of Gastrointestinal Endoscopists. (2014). Guidelines for safety in the gastrointestinal endoscopy unit. *Gastrointestinal Endoscopy*, 79(3), 363-372.
- American Society of Gastrointestinal Endoscopists. (2008). Standards of Practice Committee. Infection control during GI endoscopy. *Gastrointestinal Endoscopy*, 67(6), 781-790.
- ASTM International. (2007). Standard practice for reprocessing of reusable, heat stable endoscopic accessory instruments (EAI) used with flexible endoscopes. West Conshohocken, PA: Author.
- Association for the Advancement of Medical Instrumentation. (2010). Chemical sterilization and high level disinfection in health care facilities (ANSI/AAMI ST58:2005/(R) 2010). Arlington, VA: Author.
- Association for the Advancement of Medical Instrumentation. (2015). ANSI/AAMI ST91:2015 Flexible and semi-rigid endoscope processing in health care facilities. Arlington, VA: Author.
- Association of periOperative Nurses. (2015). Guidelines for Perioperative Practice: AORN Guidelines and Tools for the Sterile Processing team. Denver, CO: Author.
- Association for Professionals in Infection Control. (2015). APIC Implementation Guide. Guide To Hand Hygiene Programs for Infection Prevention. Retrieved from <http://apic.org/Professional-Practice/Implementation-guides>
- Axley, L. (2008). Competency: A concept analysis. *Nursing Forum*, 43(4), 214-222. doi:10.1111/j.1744-6198.2008.00115.x
- Barnsteiner, J. (2011). Teaching the Culture of Safety. *OJIN: The Online Journal of Issues in Nursing*, 16(3), Manuscript 5. doi:10.3912/OJIN.Vol16No03Man05
- Beilenhoff, U., et al. (2008). ESGE-ESGENA guideline: Cleaning and disinfection in gastrointestinal endoscopy. *Endoscopy*, 40, 939-957.
- Chapman, W. (2010). The principles of decontamination in gastrointestinal endoscopy. *British Journal of Nursing*, 19(11), 700.

- Centers for Disease Control. (2002). Guideline for Hand Hygiene in Health-care Settings. MMWR 2002. 51(RR-16), 1-44. Retrieved from <http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>
- Centers for Disease Control. (2011). Guide to Infection Prevention for Outpatient Settings. Retrieved from <http://www.cdc.gov/HAI/pdfs/guidelines/Outpatient-Care-Guide-withChecklist.pdf>
- Centers for Disease Control. (2015). Duodenoscope Culture Method: Interim Culture Method for the Duodenoscope – Distal End and Instrument Channel. Retrieved from <http://www.cdc.gov/hai/settings/lab/lab-duodenoscope-culture-method.html>
- Centers for Medicare and Medicaid Center for Clinical Standards and Quality/Survey & Certification Group. (2015). Memorandum: Alert related to outbreaks of Carbapenem-Resistant Enterobacteriaceae (CRE) during gastrointestinal endoscopy, particularly Endoscopic Retrograde Cholangiopancreatography (ERCP). Retrieved from <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-32.pdf>
- Crawford, A. (2007). Decontamination and traceability of flexible endoscopes. *Journal of Perioperative Practice*, 17(6), 257.
- Day, M. & Kelsey, L. (2013). The how's and why's of infection prevention principles in the GI/endoscopy unit. *Infection Control Today*. Retrieved from <http://www.infectioncontrolday.com/articles/2013/05/the-hows-and-whys-of-infection-prevention-principles-in-the-gi-endoscopy-unit.aspx>
- De Bruijn, A.C.P. & van Drongelen, A.W. (2009). Quality of the final rinse water for endoscope washer disinfectors: A literature review. RIVM Letter report 360050019/2009. National Institute for Public Health and the Environment, Netherlands.
- Edmiston, C. & Spencer, M. (2014). Endoscope reprocessing in 2014: Why is the margin of safety so small? *AORN Journal*. 100(6), 609-615.
- Facilities Guidelines Institute (2014). Guidelines for Design and Construction of Hospitals and Outpatient Facilities. Retrieved from http://www.fgiguide.org/guidelines2014_HOP.php
- Joint Commission. (2014). Tips for improving endoscope reprocessing and preventing the risk of infection. Retrieved from http://www.jointcommission.org/assets/1/23/jconline_April_9_14.pdf
- Kyong, H.H. & Yun, J.L. (2013). Recent update of gastrointestinal endoscope reprocessing. *Clinical Endoscopy*, 46, 267-273.
- Kirchner, J.E., Parker, L.E., Bonner, L.M., Fickel, J.J., Yano, E.M., & Ritchie, M.J. (2012). Roles of managers, frontline staff and local champions, in implementing quality improvement: stakeholders' perspectives. *Journal of Evaluation in Clinical Practice*, 18(1), 63-69. doi:10.1111/j.1365-2753.2010.01518.x
- Kovaleva, J., Peters, F.T., van der Mei, H.C., & Degener, J.E. (2013). Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. *Clinical Microbiology Review*, 26(2), 231-254.
- Lenburg, C.B., Klein, C., Abdur-Rahman, V., Spencer, T., & Boyle, S. (2009). THE COPA MODEL: A comprehensive framework designed to promote quality care and competence for patient safety. *Nursing Education Perspectives*, 30(5), 312-317.
- Moumtzoglou, A. (2010). Factors impeding nurses from reporting adverse events. *Journal of Nursing Management*, 18(5), 542-547. doi:10.1111/j.1365-2834.2010.01049.x

- Noronha, A. & Brosnak, S. (2014). A 21st century nosocomial issue with endoscopes. *The BMJ*, 348:g2047. doi:10.1136/bmj.g2047
- Petersen, B. & Ott, B. (2008). Design and management of gastrointestinal endoscopy units in *Advanced Digestive Endoscopy: Practice and Safety*. P. Cotton & M.A Malden, Eds. [City, ST]: Blackwell Publishing.
- Petersen, B.T., Chennat, J., Cohen, J., Cotton, P.B., Greenwald, D.A., Kowalski... Romagnuolo, J., & Society for Healthcare Epidemiology of America, Rutala, W. A., ASGE Quality Assurance in Endoscopy Committee, Society for Healthcare Epidemiology of America, Gastrointestinal Endoscopy. (2011). Multisociety guideline on reprocessing flexible gastrointestinal endoscopes. *Gastrointestinal Endoscopy*, 73(6), 1075-1084.
- Pyrek, K. (2015). Getting back to basics in the OR through evidence-based practice. *Infection Control Today*, 19(3), 10-30.
- Riley, S. & Cheema, K. (2010). Quality observatories: Using information to create a culture of measurement for improvement. *Clinical Risk*, 16(3), 93-97. doi:10.1258/cr.2010.010002
- Rutala, W.A. & Weber, D.J. (2004). Reprocessing endoscopes: United States perspective. *Journal of Hospital Infection*, 56, S27-S39.
- Rutala, W.A. & Weber, D.J. (2007). How to assess risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. *Infection Control and Hospital Epidemiology*, 28(2), 146-155.
- Rutala, W.A. & Weber, D.J. (2011). Sterilization, high level disinfection and environmental cleaning. *Infectious Disease Clinics of North America*, 25(1), 45-76.
- Rutala, W.A., Weber, D.J., & The Healthcare Infection Control Practices Advisory Committee (HICPAC). (2008). Guideline for Disinfection and Sterilization in Healthcare Facilities. Retrieved from http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
- Sammer, C.E. & James, B.R. (2011). Patient safety culture: The nursing unit leader's role. *Online Journal of Issues In Nursing*, 16(3), 1. doi:10.3912/OJIN.Vol16No03Man03
- Schmelzer, M., Daniels, G., & Hough, H. (in press 2015). The length of time that flexible endoscopes which have undergone reprocessing with high-level disinfection can safely be stored before use: A systematic review. *JBIM Database of Systematic Reviews & Implementation Reports* (In Press).
- Seavey, R. (2010). Environmental Cleaning and Disinfection in the OR and Other Invasive Procedure Rooms. Retrieved from <http://multimedia.3m.com/mws/media/662110O/environmental-cleaning-and-disinfection-healthvie-2-10.pdf>
- Society of Gastroenterology Nurses and Associates, Inc. (2013). *Gastroenterology Nursing, A Core Curriculum*, (5th ed). Chicago, IL: Author.
- Swayze, S.C. & Rich, S.E. (2012). Promoting safe use of medical devices. *Journal of Issues in Nursing*, 17(1), 1. doi:10.3912/OJIN.Vol17No01PPT01
- United States Department of Labor, Occupational Safety & Health Administration. (2012). Occupational Safety and Health Standards, Toxic and Hazardous, Blood-borne pathogens. Substances 29 CFR 1910.1030. Retrieved from https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS
- United States Food and Drug Administration. (2009). Preventing Cross-Contamination in Endoscope Processing: FDA Communication, Safety Communication from FDA, CDC,

- and the VA. Retrieved from
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm>
- United States Food and Drug Administration. (2015a). Personal Protective Equipment for Infection Control. Retrieved from
<http://www.fda.gov/medicaldevices/productsandmedicalprocedures/generalhospitaldevicesandsupplies/personalprotectiveequipment/default.htm>
- United States Food and Drug Administration. (2015b). Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication. Retrieved from
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm>
- Wadlowski, L. (2015). The Joint Commission: Reporting breaches in disinfection. *Healthcare Executive*, 30(4). Retrieved from
http://www.nxtbook.com/nxtbooks/ache/he_20150708/index.php?startid=Cover1#/66
- World Health Organization. (2009). WHO Guidelines on Hand Hygiene in Health Care. Retrieved from
http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf?ua=1

Recommended Reading

- Association of periOperative Nurses. (2015). Perioperative Standards and Recommended Practices, Vol. 1. Conner, R. Burlingame, B., Denholm, B, Link, T. et al., Eds.
- Department of Veteran Affairs. (2011). Digestive Diseases – Endoscopy Services Design Guide. Retrieved from
<http://www.cfm.va.gov/til/dGuide/dgDigestiveEndoscopy.pdf>
- Institute of Medicine. (2015). International Infectious Disease Emergencies and Domestic Implications for the Public Health and Health Care Sectors. Washington (DC): National Academies Press (US).
- Kaylor, M.B., Wenning, P., & Eddy, C. (2015). Prevalence, knowledge, and concern about bed bugs. *Journal of Environmental Health*, 78(1), 20-24
- Lawrence, J. (2005). Encouraging best practice in infection control. *British Journal of Community Nursing*, 10(4), 156.
- Lewis, T. & Edwards, C. (2008). How clinical champions can improve quality. *Nursing Management - UK*, 14(10), 24-27.
- Pagar, J.M., Kaiser, H., & Chronister, C. (2007). Recommendations from the Quality Assurance Committee. *Review of Optometry*, 144(11), 27-34.
- Visrodia, K.H. et al. (2014). The use of rapid indicators for the detection of organic residues on clinically used gastrointestinal endoscopes with and without visually apparent debris. *Infection Control and Hospital Epidemiology*, 35(8), 987-94.