



GUIDELINE



AGA INSTITUTE



Guidelines for safety in the gastrointestinal endoscopy unit

EXECUTIVE SUMMARY

Historically, safety in the gastrointestinal (GI) endoscopy unit has focused on infection control, particularly around the reprocessing of endoscopes. Two highly publicized outbreaks in which the transmission of infectious agents were related to GI endoscopy have highlighted the need to address potential gaps along the endoscopy care continuum that could impact patient safety.

In 2009, the Centers for Medicare and Medicaid Services (CMS) Conditions for Coverage eliminated the distinction between a sterile operating room and a non-sterile procedure room. Hence, GI endoscopy units are now held to the same standards as sterile operating rooms by CMS¹ without evidence demonstrating that safety or clinical outcomes in endoscopy are thereby improved. Although the American Society for Gastrointestinal Endoscopy (ASGE) has previously published guidelines on staffing, sedation, infection control, and endoscope reprocessing for endoscopic procedures (Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2011; Infection control during GI endoscopy; Minimum staffing requirements for the performance of GI endoscopy; Multisociety sedation curriculum for gastrointestinal endoscopy),²⁻⁵ the purpose of this document is to present recommendations for endoscopy units in implementing and prioritizing safety efforts and to provide an endoscopy-specific guideline by which to evaluate endoscopy units. As a general principle, requirements for safety ought to be rooted in evidence that demonstrates a benefit in outcomes. When data are absent, these requirements may be derived from experts with experience in the safe delivery of care in the GI endoscopy setting. Additionally, consideration should be given to the promotion of efficient care and cost containment, with avoidance of requirements unsupported by evidence that then contribute to rising healthcare costs.

Over the past 2 years, surveyors have called into question accepted practices at many accredited endoscopy units seeking reaccreditation. Many of these issues relate to the Ambulatory Surgical Center Conditions for Coverage set forth by CMS and the lack of distinction between the sterile operating room and the endoscopy setting. The following is a summary of issues that have been faced by endoscopy units throughout the country along with the ASGE position and accompanying rationale.

ISSUES AND RATIONALE

1. Issue: Structural requirements for 40-inch doors and room sizes >400 square feet required of sterile operating rooms

Position: Standard 36-inch doors, if they accommodate patient transport mechanisms, and room sizes 180 square feet are adequate and safe for endoscopy units because they do not use the same large equipment or number of staff as the operating room.⁶
2. Issue: Requirement for a written policy on traffic patterns in the endoscopy unit

Position: The unit should define low-risk exposure and high-risk exposure areas and activities within the endoscopy unit and describe the attire and personal protective equipment (PPE) that should be worn in each area. Endoscopy staff can move freely throughout the unit provided that there is appropriate use and changing of PPE.
3. Issue: Requirement for endoscopy personnel to don full sterile operating room PPE, including new scrubs, hair covers, and booties

Position: It is recommended that staff directly engaged in GI endoscopy or in processes in which splash or contamination could occur wear gloves, face and/or eye shields, and impervious gowns. Units should develop policies that are consistent with Occupational Safety and Health Administration and state-mandated recommendations for wearing face and/or eye shields or masks.⁷ Scrubs or other attire may be worn from home because endoscopy is not a sterile procedure.

Likewise, there is no need for hair covers or booties. Staff must remove and appropriately discard used PPE before leaving the procedure area.

4. Issue: Supervision of moderate sedation
Position: Moderate sedation may be administered safely under the supervision of a non-anesthesia physician who is credentialed and privileged to do so.
5. Issue: Role of capnography
Position: There is inadequate data to support the routine use of capnography when moderate sedation is the target.
6. Issue: Requirement that 2 nurses (1 monitoring, 1 circulating) are present when moderate sedation is performed
Position: When moderate sedation is the target, a nurse should monitor the patient and can perform interruptible tasks. If more technical assistance is required, a second assistant (nurse, licensed practical nurse [LPN], or unlicensed assistive personnel [UAP]) should be available to join the care team.
7. Issue: Staffing requirements when sedation and monitoring is provided by anesthesia personnel
Position: When sedation and monitoring are provided by anesthesia personnel, a single additional staff person (nurse, LPN, or UAP) is sufficient to assist with the technical aspects of the procedure.
8. Issue: Technical capabilities of technicians
Position: Unlicensed technicians who have received initial orientation and ongoing training and are deemed competent by their units, can assist with and participate in tissue acquisition during the endoscopic procedure, including but not limited to the opening and closing of forceps, snares, and other accessories.

BACKGROUND

The overall risk of transmission of healthcare-associated infections during the performance of endoscopic procedures is estimated to be very low.⁸ Historically, according to the Centers for Disease Control and Prevention, most cases have occurred from a breach in proper cleaning and disinfection of endoscopic equipment. Despite the low risk of healthcare-associated infections from endoscopic procedures, outbreaks of certain hospital-based healthcare-associated infections, such as *Clostridium difficile* and methicillin-resistant *Staphylococcus aureus*, have brought healthcare-associated infections to the attention of hospital administrators and other stakeholders and have raised the public's concern over safety in hospitals. In addition, several highly publicized cases of hepatitis C infection in the outpatient endoscopy setting have heightened interest in ensuring safety in ambulatory endoscopy centers and office-based endoscopy units. The outbreak of hepatitis C among patients undergoing endoscopy at 2 facilities owned by a single physician in Nevada was attributed to improper injection

techniques, whereas an infection control breach among patients who underwent colonoscopy at 2 U.S. Department of Veterans Affairs medical centers in Florida and Tennessee was attributed to installation of an improper irrigation valve on the endoscope and failure to change irrigation tubing between cases.^{9,10} Although the risk of infections from endoscopic procedures, regardless of the setting, remains low, these cases highlight the need to address potential gaps along the endoscopy care continuum that may impact patient safety outcomes.²⁻⁵

Changes to the CMS Ambulatory Surgical Center Conditions for Coverage that went into effect in 2009 eliminated the distinction between a sterile surgical room and a non-sterile procedure room, providing further impetus for this guideline. As a result of these conditions, non-sterile procedure environments, including endoscopy units, are now held to the same standards as sterile operating rooms even though requirements for facilities, infection control, staffing, and sedation applicable to the sterile operating room may not be relevant or necessary for endoscopy units. To date, the Association of periOperative Registered Nurses and other organizations have set standards for sterile operating environments.¹¹ This document is endorsed by organizations with specific expertise in the safe delivery of care in the non-sterile, GI endoscopy environment, which recognize the important distinction between the endoscopy and sterile operating room settings. Safety in the GI endoscopy unit begins with clear and effective leadership that fosters a culture of safety including team work, openness in communication, and efforts to minimize adverse events. Although issues of governance and culture are important, they are outside the scope of this document. [Table 1](#) provides a summary of the key strategies to maintain safety in the GI endoscopy unit.

FACILITIES

Facilities are the foundation of a unit, the layout of which should provide a safe environment for patients and staff. Facilities should be designed to comply with local and state building codes as well as the National Fire Protection Association (NFPA) 101 Life Safety Code.¹² The specific version of the Code will depend on currently accepted practice for CMS and state regulations.^{13,14} Recommendations for facility standards are largely based on expert opinion and put into practice by accreditation bodies; however, no association with patient outcomes has been shown.

Recommendations for architectural layout

Each unit should have a designated flow for the safe physical movement of dirty endoscopes that does not cross-contaminate clean endoscopes coming out of the cleaning process and their storage. Although circular flow

TABLE 1. Summary of the key strategies to maintain safety in the GI endoscopy unit

Each unit should have a designated flow for the safe physical movement of dirty endoscopes and other equipment.
Procedure rooms vary in size, with more complex procedures requiring greater space for more specialized equipment and, in some cases, additional staff.
Before starting an endoscopic procedure, the patient, staff, and performing physician should verify the correct patient and procedure to be performed.
A specific infection prevention plan must be implemented and directed by a qualified person.
Gloves and an impervious gown should be worn by staff engaged in direct patient care during the procedure.
The unit should have a terminal cleansing plan that includes methods and chemical agents for cleansing and disinfecting the procedural space at the end of the day.
For patients undergoing routine endoscopy under moderate sedation, a single nurse is required in the room in addition to the performing physician.
Complex procedures may require additional staff for efficiency but not necessarily for safety.
At a minimum, patient monitoring should be performed before the procedure, after administration of sedatives, at regular intervals during the procedure, during initial recovery, and before discharge.
For cases in which moderate sedation is the target, the individual responsible for patient monitoring may perform brief interruptible tasks.
For cases in which moderate sedation is the target, there is currently inadequate data to support the routine use of capnography.

is preferable, some units may be constrained by the existing footprint of the facility.

Recommendations for the endoscopic procedure room. Endoscopic procedure rooms vary in size, with more complex procedures such as ERCP requiring greater space for more specialized equipment and possibly additional staff. For endoscopy, procedure rooms should not be held to the same standards as sterile operating rooms, which require space for anesthesia support and a greater number of staff members and bulkier equipment, none of which are essential for the performance of endoscopy. Standard endoscopic procedures require less space, with requirements varying from as little as 180 square feet to 300 square feet.⁶

The following are issues within the endoscopic procedure room that are related to patient safety:

1. Actual marking of the site is not required for endoscopic procedures because endoscopy does not involve lateral right-left distinction levels such as those found in spinal procedures or those done on multiple structures such as fingers or toes. Before starting an endoscopic procedure, the patient, staff, and performing physician should verify the correct patient and procedure to be performed.
2. A reliable and adequate source for oxygen is required. Sources may include in-wall or free-standing oxygen. In some units, carbon dioxide may be used for insufflation of the GI lumen, but this is not a requirement.
3. A suction source for the equipment and patient must be present either in-wall or portable. For tubing and portable suction, the manufacturer's guidelines must be followed.
4. An uninterruptible source of power, supplied either by a generator or battery source is required. The purpose of a secondary power source is to allow completion of the current procedure in the event that the primary power source malfunctions. Procedures should not be started when the only source of power is the secondary source.
5. Units must practice fire safety in adherence with the NFPA 101 Life Safety Code, which also dictates the number and type of electrical outlets tied to the generator.¹² The NFPA 101 Life Safety Code recommends that not all outlets be tied to the generator in case the generator fails to disengage once power is restored.
6. The unit's defibrillator and crash cart should be checked at the beginning of each day to ensure that all components are functional, fully stocked, and readily accessible.
7. The routine monitoring of temperature and humidity within the endoscopic procedure area, although advocated by CMS to theoretically curtail growth of microorganisms and reduce fire hazard, has not been associated with safety outcomes in endoscopic units. In the absence of published guidelines on the optimal ranges for these parameters, routine monitoring of temperature and humidity is not currently warranted.¹
8. Puncture-resistant containers for biohazardous materials and sharps should be located so that sharps are not passed over the patient.¹⁵
9. If special therapeutic procedures are planned, specific room features may be required, such as leaded walls when flat-table fluoroscopy is utilized.¹⁶

Recommendations for the endoscopic recovery area

1. The recovery bays should provide privacy and sufficient space for monitoring and care. The minimum space per bay has not been established. Unit facilities must be able to provide the level of recovery appropriate to the level of sedation utilized.¹⁷

Recommendation for storage of supplies

1. Sterile supply items such as intravenous (IV) solutions should be protected from splash contamination during environmental cleaning (8-10 inches off the floor), damage from compression (stacking only ridged containers), and water damage (no storage under sinks).
2. Units should have a process for periodically verifying that supplies marked with an expiration date have not expired. Compliance with this process should be documented.

INFECTION CONTROL

ASGE has published several guidelines detailing ways to minimize the risk of transmission of infection within the endoscopy unit.^{2,18} In addition to meticulous endoscope reprocessing, a specific infection prevention plan must be implemented to prevent the transmission of pathogens in the unit and to provide guidance should a breach occur. Active Infection Prevention Surveillance programs and ongoing educational and competency evaluation of staff regarding activities within the preprocedure, intraprocedure, and postprocedure phases are necessary to ensure overall safety of patients and health-care workers. Infection prevention plans for a specific unit must be directed by a qualified person. Although state regulations may vary, CMS allows the unit to designate the specific training and competency of the individual.

The infection prevention plan must be documented in writing and should include a set of policies and procedures appropriate for and targeted to the specific procedures performed in addition to likely sources of nosocomial infection in the unit. The plan should include a process for the ongoing assessment of compliance with the program and methods for correction.

Standard precautions, the minimum infection prevention practices applicable to all patient care regardless of the suspected or confirmed infection status of the patient, are the foundation of a sound infection prevention strategy. These include:

1. Hand hygiene
2. PPE
3. Safe medication administration practices
4. Safe handling of potentially contaminated equipment or surfaces in the patient environment.¹⁹

Recommendations for hand hygiene

Proper hand washing is considered to be the cornerstone of preventing the transmission of pathogens.

1. Hand hygiene should be performed before patient contact (even if gloves are to be worn); after patient contact and before exiting the patient care area; after contact with blood, body fluids, or contaminated surfaces (even if gloves are worn); before performing invasive procedures (ie, placement or access of intravascular lines); and after glove removal.²⁰
2. The use of soap and water is required when hands are visibly soiled and after caring for patients with known or suspected infectious causes of diarrhea such as *C difficile*. Otherwise, the use of alcohol-based hand agents is adequate.²¹

Recommendations for PPE

The unit should have written policies and procedures regarding PPE that defines activities in which PPE should be worn and the appropriate type.²² For sterile environments, the use of PPE is commonly dictated by the traffic pattern and location of care, defined as unrestricted, semi-restricted, and restricted areas.²³ In contrast, in the non-sterile endoscopy environment, the use of PPE is dependent on the degree to which staff have the potential to come into direct contact with patients and their bodily fluids during specific activities, rather than the location of care. The risk of exposure can be categorized into low-risk exposure and high-risk exposure, which are defined as follows:

1. Low-risk exposure: Any personnel not in direct contact with a contaminated endoscope, device or bodily fluid or with the potential for splash contamination. For example, personnel entering the procedure area for a brief period of time who are not involved in direct patient care are considered at low-risk exposure.
2. High-risk exposure: Any personnel working in direct contact with a contaminated endoscope, device, or bodily fluid or any personnel in direct patient care with the potential to come into contact with a contaminated endoscope, device, or bodily fluid.

Low-risk exposure activities require no PPE. Personnel whose exposure status may change during an endoscopy procedure should have immediate access to PPE should the need arise. High-risk exposure activities require the use of gloves and impervious gowns. Because of the potential for splash exposure to the face, individual units should develop policies based on Occupational Safety and Health Administration and state-mandated recommendations for wearing face and/or eye shields or masks.²² Hair and shoe covers and gown classifications above Association for the Advancement of Medical Instrumentation level 1 are often included in PPE recommendations.²⁴ These items generally are mandated for the sterile operating room environment, but there is no evidence to

support their requirement or benefit in the non-sterile endoscopy environment.

1. Staff must remove and appropriately discard used PPE before leaving the procedure room. PPE should not be reused or worn to care for more than 1 patient.
2. Scrub attire may be worn from home, because endoscopic procedures are performed in a non-sterile environment.
3. Individuals may elect to wear regular clothing covered by an impervious gown. There is no requirement to change clothing once the individual arrives at work.
4. If clothing under the procedure room attire is contaminated with a significant amount of blood or body fluids, the items should be placed in a bag, identified as a potential biohazard, then sent for cleaning to a laundry facility capable of properly cleaning and disinfecting clothing used in healthcare settings.

Recommendations for safe medication administration practices

Safe medication administration practices promote safety in medication administration and have become a highly scrutinized activity within healthcare,²⁵ in part because of evidence of pathogen transmission resulting from the improper use or reuse of syringes, multiple-dose drug vials, and IV equipment. The Centers for Disease Control and Prevention and ASGE have issued guidelines outlining safe injection practices.^{3,19,26} Units should adhere to the following:

1. Preparing medications for multiple patients should be done in an area away from direct patient care or procedure rooms.
2. Units should appropriately label all medications, including those used for sedation, unless the medication is for immediate use (prepared and administered immediately without leaving the provider's hand).²⁶
3. Medications marked either on the container or noted in the package insert as "single patient use" should be used for a single patient only and any remaining drug should be discarded.
4. Units should use new fluid administration sets (eg, IV tubing) for each patient.
5. Units should prepare and administer injections by using aseptic technique (ie, cleansing the access diaphragms of medication vials with 70% alcohol before inserting a device in the vial). Single-dose vials, ampules, bags, or bottles of IV solution should be used for a single patient only.
6. Use of a single-dose vial is preferred over multiple-dose vials, particularly when medications will be administered to multiple patients.³
7. If a multiple-dose vial will be used for more than 1 patient, they should remain in a centralized medication area and should not enter the patient procedure area. These should be dated when opened and

discarded according to protocols, in compliance with nationally accepted guidelines, such as those published by the Centers for Disease Control and Prevention.²⁷

8. Units should not re-use a syringe to enter a medication vial or solution, even with a new needle.
9. Units should not use the same syringe to administer medications to multiple patients regardless of whether the needle is changed or an intervening length of IV tubing is used.
10. Units should dispose of used syringes and needles at the point of use in a sharps container that is closable, puncture-resistant, and leak-proof.²⁸
11. Units should develop a clearly defined policy for the management of sharps and sharps-related injuries, including the reporting of blood and body fluid exposures. This should be in compliance with federal, state, and local guidelines.
12. Units should maintain a log of sedation medications wasted between patients that can be used to reconcile used and wasted vials at the end of the day.
13. If tubes of lubricant are used for more than one examination, the unit should observe appropriate infection control habits and discard any tube that has potentially been contaminated.
14. Although the multiple-society guideline recommends using sterile water in the irrigation bottle, it is acceptable to use tap water because this has been shown to be safe.²⁹ The rates of bacterial cultures are no different with the use of tap water versus sterile water, and neither has been associated with clinical infections.^{30,31}
15. Units should follow federal and state requirements for the protection of healthcare personnel from exposure to blood-borne pathogens.

Recommendations for safe handling of potentially contaminated equipment or surfaces

Environmental cleaning of surfaces with an appropriate Environmental Protection Agency-labeled disinfectant is mandatory, especially for surfaces that are most likely to become contaminated with pathogens, such as those in close proximity to the patient (eg, side rails) and other frequently touched surfaces in the unit. Facility policies and procedures should address prompt and appropriate cleaning and decontamination of spills of blood or other potentially infectious material.^{20,32} Units should:

1. Maintain material safety data sheets for all chemicals used for cleaning and disinfection. These sheets should detail the safe and proper use and emergency protocol for a chemical. Material safety data sheets should be used for training staff on each chemical's safe use.
2. Follow the manufacturer's directions for surface disinfection of patient care items.

- Appropriate contact time of disinfectant to achieve germicidal kill should be followed.
 - Alcohol should not be used to clean environmental surfaces.
3. Properly clean and disinfect surfaces that are frequently touched by personnel or dirty equipment in the endoscopic procedure area at the beginning of the day, between cases, and during terminal cleansing. Frequently-touched surfaces may include endoscopy keyboards and video monitors and consoles.

Recommendations for terminal cleansing

Terminal cleansing involves the cleaning of surfaces to physically remove soil and biofilm, followed by proper disinfection. Typically, this requires use of 2 distinct agents because chemical disinfectants are not effective at cleansing, and cleansing agents are not effective at disinfecting surfaces.

1. The unit should have a terminal cleansing plan that includes methods and chemical agents for cleansing and disinfecting the procedural space at the end of the day.
2. Agents for terminal cleansing should have efficacy in spore removal, which may differ from requirements for agents used in sterile operating rooms.
3. Before the first case of the day, staff should verify that all procedural and recovery areas have been properly cleansed.
4. A training and competency assessment program should be in place for staff members who are involved in terminal cleansing to ensure proper and safe handling and use of the chemicals.

Recommendations for reusable medical equipment

The reprocessing protocol of reusable medical equipment such as endoscopes and endoscopic accessories must be strictly followed.³ The details of reprocessing according to their Spaulding Classification are well described.³³ These policies should be a part of the unit's policies and procedures and core competency assessment.

Single-use devices as determined by the manufacturer label or packaging insert may not be reprocessed unless they are specifically listed in the U.S. Food and Drug Administration (FDA) 510(k) database. If so, they must be reprocessed by entities that have complied with FDA regulatory requirements and have received FDA clearance to reprocess specific single-use devices.³⁴

Written policies and procedures regarding infection control for a unit should be documented.

STAFFING

Staffing requirements for the performance of GI endoscopy should be based on what is required to create a safe

environment for the patient and to ensure the safe performance of the endoscopic procedure. The minimum safe staffing of an endoscopy room is outlined in the ASGE *Minimum staffing requirements for the performance of GI endoscopy*.⁴ For patients undergoing routine endoscopy under moderate sedation, a single registered nurse (RN) is required. There is no evidence that staffing beyond a single RN improves the safety of the patient. There are some circumstances in which additional assistance can be helpful for the technical aspects of the procedure, such as in ERCP, yet there are no published safety or clinical outcomes data to support the routine use of a circulating nurse for endoscopic procedures. Guidelines for staffing requirements in other settings, such as the sterile operating room, do not apply to the endoscopic procedure room because of inherent differences in these settings.³⁵

Both patient and procedural factors should be considered in determining staffing requirements. Patient factors that affect staffing requirements include the level of sedation that is planned (ie, whether the patient is receiving no sedation, moderate sedation, or deep sedation) and the medical condition of the patient, which is determined from the history and physical examination and is reflected in the American Society of Anesthesiologists (ASA) Physical Status Classification System score of the patient. Procedural factors include the anticipated length of the procedure and whether the procedure is intended to be diagnostic or whether a therapeutic intervention is planned. Complex interventional procedures, such as EUS and ERCP may require additional staff for efficiency, but there is no evidence to suggest that this improves safety or patient outcomes.

Recommendations for preprocedure staffing

1. Staffing models in the preprocedure area should support activities required to prepare patients for endoscopy.
2. The ratio of RNs to patients in preprocedure care is variable depending on the complexity of the patient mix.

Recommendations for intraprocedure staffing based on level of sedation⁴

1. No sedation—One assistant (RN, LPN, or UAP) other than the physician performing the procedure should be present to assist with the technical aspects of the procedure.
2. Moderate sedation (also known as conscious sedation)—Sedation should be directed by a physician who is credentialed and privileged to do so. Moderate sedation can be administered by an RN. During the period in which the patient is sedated, the RN must monitor the patient for vital sign changes, hypoxemia, and comfort. The RN may assist with minor, interruptible tasks. In the event that more intense technical assistance is

required, a second assistant (RN, LPN, or UAP) should be available to join the care team for the technical aspects of the procedure.

3. Deep sedation—Most institutions require that deep sedation be administered by an anesthesia professional such as an anesthesiologist, certified registered nurse anesthetist (CRNA), or anesthesiologist assistant who is credentialed and privileged to do so. In this situation, the anesthesia provider should be responsible for administering sedation and monitoring the patient. A second staff person (RN, LPN, or UAP) is required to assist with technical aspects of the procedure.^{4,17}

Recommendations for postprocedure staffing

1. An RN is required to monitor patients who have received sedation until the patient is stabilized and to assess for adverse events related to the endoscopic procedure.
2. Once the patient is stable, postprocedure activities such as providing food or drinks and assistance in changing clothes can be performed by an RN, LPN, or UAP.
3. The ratio of RNs to patients in the postprocedure setting is variable depending on the complexity of the patient mix.

Recommendations for training

1. Sedation—Sedation should be administered by an RN under the supervision of the endoscopist who is credentialed and privileged to do so or by anesthesia personnel (physician or CRNA) who are credentialed and privileged to do so. These individuals should be specifically trained in endoscopic sedation, including the modes of action and adverse events of the sedative agents being used. This training should be documented. The staff administering sedation must have the knowledge and skills to recognize when the sedation level becomes deeper than planned and to manage and support patients' cardiopulmonary responses to sedation accordingly. On verification of the RN's training, the unit should document the privileging of the RN to provide moderate sedation under the direct supervision of a physician. LPNs and UAPs are not qualified to administer sedation.
2. Technical assistance—Technical assistance can be provided by a variety of staff members, including UAPs, LPNs, RNs, and GI technicians. Training in the use of endoscopic equipment, accessories, and ancillary equipment should be documented and include an objective assessment of initial competence and annual competency testing thereafter to ensure and document that skills are maintained.
3. Basic and advanced cardiac life support—All staff with clinical responsibilities must have basic life support certification. At least one individual with advanced cardiac life support certification must be present in the unit when patients are present.

4. A written policy on staff training along with the type and frequency of core competency assessment should be documented.

ENDOSCOPIC SEDATION

Sedation can improve the quality of GI endoscopy, the likelihood of a thorough and complete examination, patient satisfaction, and patient willingness to undergo examination or reexamination. The choice of specific sedation agents and the level of sedation targeted should be determined on a case-by-case basis by the endoscopist in consultation with the patient. Endoscopy without sedation may be appropriate in some instances. For a detailed discussion including supporting evidence, please refer to the 2008 ASGE guideline: *Sedation and Anesthesia in GI Endoscopy*.¹⁷

Recommendations for the sedation-related environment

1. Units should comply with applicable federal and state laws regarding licensure and/or certification of all staff involved in the administration and monitoring of sedation and document training and competencies.
2. Established discharge criteria should be attained before discharge from the endoscopy unit. Patients who received IV sedation during their endoscopic procedure should be discharged in the presence of a responsible individual. A written policy on discharge requirements should be documented.
3. An agreement should exist between the unit and a hospital facility for the transfer of patients who require escalation of care. A written transfer agreement should be documented.
4. A focused history and physical examination, including the patient's current medications and ASA classification, should be completed before the start of the procedure.¹⁷

Recommendations for sedation-related equipment

1. All sedation-related equipment, before initial use and then at intervals dictated by the manufacturer's guidelines, should be examined and verified to be in proper working order by a qualified biotechnician.³⁶
2. Oxygen, suction for the mouth, and electronic equipment that can monitor and display pulse, blood pressure, oxygen saturation, and continuous electrocardiographic rhythm assessment should be available in the procedure room. A written policy for equipment checks and maintenance should be in place. A log to monitor compliance should be maintained.

Recommendations for patient monitoring

1. All patients undergoing endoscopy should be monitored, the frequency of which depends on procedural and patient factors (eg, type of sedation, duration and complexity of procedure, patient condition). At a minimum, monitoring should be performed before the procedure, after administration of sedatives, at regular intervals during the procedure, during initial recovery, and just before discharge.⁵
2. Units should have procedures in place to rescue patients who are sedated deeper than intended.^{5,17,37,38}
3. When the target level is moderate sedation (also known as conscious sedation):
 - The individual assigned responsibility for patient monitoring may perform brief, interruptible tasks.^{4,5}
 - Minimal monitoring requirements include electronic assessment of blood pressure, respiratory rate, heart rate, and pulse oximetry combined with visual monitoring of the patient's level of consciousness and discomfort.
 - Currently, there are inadequate data to support the routine or required use of capnography during endoscopic procedures in adults when moderate sedation is the target.^{5,39,40}
4. When deep sedation is targeted:
 - The individual responsible for patient monitoring must be dedicated solely to that task and may not perform any other function during the procedure.^{4,5}
 - The use of capnography in EUS, ERCP, and colonoscopy to assess the adequacy of ventilation may reduce the incidence of hypoxemia and apnea,^{41,42} but its impact on the frequency of other sedation-related adverse events such as bradycardia and hypotension is unknown. As such, capnography may be considered for the performance of endoscopy under deep sedation. However, there is no safety data to date to support the universal use of capnography in such cases.
 - Documentation of the clinical assessments and monitoring data during sedation and recovery is required.

Recommendations for medications

1. Written policies detailing the methods of drug storage, monitoring of drug inventory and expiration dates, and documentation of compliance with these policies are required.
2. There should be an individual qualified by training and licensure (such as a physician or pharmacist) who is directly responsible for overseeing medication usage in the unit.
3. Medications should be securely stored under environmental conditions consistent with the manufacturer's instructions on the label. The use of single-dose vials for

all sedative and analgesic medications is strongly recommended.

4. Controlled substances should be stored in a double-locked cabinet, and a daily medication log compliant with state and federal regulations should be maintained. Disposal of unused narcotics and other controlled drugs should be witnessed by 2 individuals and documented.
5. Medications should be given only under the order of the supervising physician or anesthesia professionals when applicable.
6. Reversal agents for opioids and benzodiazepines should be readily available.
7. A written policy should be in place for the identification, documentation, and review of adverse drug reactions.

Recommendations for emergency management

1. Appropriate pharmaceutical agents, oxygen, oral suction, laryngoscope, Ambu bag, and defibrillator should be readily available in the unit.
2. Units should train and periodically provide in-service education for staff in the use of equipment for emergency management.⁴ Training and assessment of competency should be documented.

DISCLOSURES

All authors disclosed no financial relationships relevant to this article.

Abbreviations: ASA, American Society of Anesthesiologists; ASGE, American Society for Gastrointestinal Endoscopy; CMS, Centers for Medicare and Medicaid Services; CRNA, certified registered nurse anesthetist; FDA, U.S. Food and Drug Administration; GI, gastrointestinal; IV, intravenous; LPN, licensed practical nurse; NFPA, National Fire Protection Association; PPE, personal protective equipment; RN, registered nurse; UAP, unlicensed assistive personnel.

REFERENCES

1. Federal Centers for Medicare and Medicaid Services Publication 100-07, State Operations Manual, Ambulatory Surgical Centers Condition for Coverage, 416.2-416.52. Available at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_l_ambulatory.pdf. Accessed January 2, 2014.
2. ASGE Quality Assurance in Endoscopy Committee, Petersen BT, Chennat J, Cohen J, et al. Multisociety guideline on reprocessing flexible gastrointestinal endoscopes. *Gastrointest Endosc* 2011;73:1075-84.
3. ASGE Standards of Practice Committee, Banerjee S, Shen B, Nelson DB, et al. Infection control during GI endoscopy. *Gastrointest Endosc* 2008;67:781-90.
4. ASGE Standards of Practice Committee, Jain R, Ikenberry SO, Anderson MA, et al. Minimum staffing requirements for the performance of GI endoscopy. *Gastrointest Endosc* 2010;72:469-70.
5. Vargo JJ, DeLegge MH, Feld AD, et al. Multisociety sedation curriculum for gastrointestinal endoscopy. *Gastrointest Endosc* 2012;76:e1-25.
6. Health Guidelines Revision Committee. Guidelines for the design and construction of health care facilities. Washington DC: The Facility Guidelines Institute; 2010.

7. Recommended practices for surgical attire. In: Perioperative standards and recommended practices. Denver: Association of Perioperative Registered Nurses, Inc; 2011. p. 57-72.
8. Nelson DB. Infectious disease complications of GI endoscopy: Part II, exogenous infections. *Gastrointest Endosc* 2003;57:695-711.
9. Labus B, Armour P, Middaugh J, et al. Southern Nevada Health District Outbreak Investigation Team. Outbreak of hepatitis C at outpatient surgical centers. Public Health Investigation Report. Las Vegas: Southern Nevada Health District; 2009.
10. Centers for Disease Control and Prevention Web site. Healthcare-Associated Hepatitis B and C Outbreaks Reported to the Centers for Disease Control and Prevention in 2008-2011, 2012. Available at: <http://www.cdc.gov/hepatitis/Outbreaks/HealthcareHepOutbreakTable.htm>. Accessed January 2, 2014.
11. Blanchard J, Braswell M. Association of periOperative Registered Nurses Recommended Practices for Surgical Attire. In: Perioperative Standards and Recommended Practices, 2010. Denver: Association of periOperative Registered Nurses; 2010.
12. National Fire Protection Association. NFPA 101: Life Safety Code 2012 edition. Quincy (Mass): National Fire Protection Association; 2011.
13. Marasco JA, Marasco RF. Designing the ambulatory endoscopy center. *Gastrointest Endosc Clin N Am* 2002;12:185-204, v. 6.
14. Ganz RA. Regulation and certification issues. *Gastrointest Endosc Clin N Am* 2002;12:205-14.
15. Society of Gastroenterology Nurses and Associates. Manual of Gastrointestinal Procedures. 6th ed. Chicago: Society of Gastroenterology Nurses and Associates, Inc; 2009.
16. National Council on Radiation Protection and Measurements. Structural shielding design for medical x-ray imaging facilities (NCRP Report No. 147). Bethesda (MD): National Council on Radiation Protection and Measurements; 2004.
17. ASGE Standards of Practice Committee. Sedation and anesthesia in GI endoscopy. *Gastrointest Endosc* 2008;68(5):815-26.
18. ASGE policy on the use of single-dose and multiple-dose vials and solution containers. July 2012. American Society for Gastrointestinal Endoscopy Web site. Available at: <http://www.asge.org/assets/0/47668/71294/f271942b-0529-4145-b317-9597d5009ecd.pdf>. Accessed January 2, 2014.
19. Centers for Disease Control and Prevention. Guide to infection prevention for outpatient settings: minimum expectations for safe care. May, 2011. CDC Web site. Available at: <http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-guidelines.html>. Accessed January 2, 2014.
20. Rutala WA, Weber DJ; Centers for Disease Control and Prevention Healthcare Infection Control Practices Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities, 2008. CDC Web site. Available at: http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed January 2, 2014.
21. Boyce JM, Pittet D. Centers for Disease Control and Prevention Healthcare Infection Control Practices Advisory Committee and HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Guideline for hand hygiene in health-care settings. *MMWR* 2002;51(RR-16):1-44.
22. Decker MD. The OSHA bloodborne hazard standard. *Infect Control Hosp Epidemiol* 1992;13:407-17.
23. Association of periOperative Registered Nurses. Recommended practices for traffic patterns in the perioperative practice setting. *AORN J* 2006;83:681-6.
24. Anonymous. Association for the Advancement of Medical Instrumentation AAMI PB70:2012: liquid barrier performance and classification of protective apparel and drapes in health care facilities. Available at: http://www.aami.org/publications/AAMINews/Sep2012/PB70_AAMI_protective%20barrier_standard.html. Accessed January 2, 2014.
25. Garner JS. Hospital Infection Control Practices Advisory Committee. Guideline for isolation precautions in hospitals. *Infect Control Hosp Epidemiol* 1996;17:53-80.
26. Siegel JD, Rhinehart E, Jackson M, et al. Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings. Available at: <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>. Accessed January 2, 2014.
27. Centers for Disease Control and Prevention. Protect patients against preventable harm from improper use of single-dose/single-use vials. May, 2012. Available at: <http://www.cdc.gov/injectionsafety/cdcposition-singleusevial.html>. Accessed January 2, 2014.
28. Centers for Disease Control and Prevention. National Center for Infectious Diseases (U.S.), Division of Healthcare Quality Promotion. Workbook for designing, implementing, and evaluating a sharps injury prevention program. Atlanta: Centers for Disease Control and Prevention; 2008.
29. Agrawal D, Rockey DC. Sterile water in endoscopy: habit, opinion, or evidence. *Gastrointest Endosc* 2013;78:150-2.
30. Wilcox CM, Waites K, Brookings ES. Use of sterile compared with tap water in gastrointestinal endoscopic procedures. *Am J Infect Control* 1996;24:407-10.
31. Puterbaugh M, Barde C, Van Enk R. Endoscopy water source: tap or sterile water? *Gastroenterol Nurs* 1997;20:203-6.
32. Sehulster L, Chinn RY; Centers for Disease Control and Prevention Healthcare Infection Control Practices Advisory Committee. Guidelines for environmental infection control in health-care facilities. *MMWR* 2003;52(RR10):1-42.
33. Favero MS, Bond WW. Disinfection of medical and surgical materials. In: Block SS, editor. Disinfection, sterilization, and preservation. Philadelphia: Lippincott Williams & Wilkins; 2001. p. 881-917.
34. U.S. Food and Drug Administration. Guidance for Industry and FDA Staff—Medical Device User Fee and Modernization Act of 2002, validation data in premarket notification submissions (510(k)s) for reprocessed single-use medical devices. Washington, DC: U.S. Food and Drug Administration; 2006.
35. Association of periOperative Registered Nurses. Guidance statement: Perioperative staffing. In: Perioperative standards and recommended practices for inpatient and ambulatory settings. Denver: AORN; 2013. p. 543-8.
36. National Fire Protection Association 99: Health Care Facilities Code 2012 Edition. Chapter 10 Electrical Equipment: Performance Criteria and Testing for Patient Care-Related Electrical Appliances and Equipment, p.94-7.
37. Federal Centers for Medicare and Medicaid Services. Publication 100-107, State Operations Manual, Hospitals Conditions of Participation, 482.52. Available at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf. Accessed January 2, 2014.
38. Amornyotin S. Sedation and monitoring for gastrointestinal endoscopy. *World J Gastrointest Endosc* 2013;5:47-55.
39. Vargo JJ, Cohen LB, Rex DK, et al. Position statement: nonanesthesiologist administration of propofol for GI endoscopy. *Gastroenterology* 2009;137:2161-7.
40. American Society for Gastrointestinal Endoscopy, American College of Gastroenterology, American Gastroenterologic Association. Joint Statement. Universal adoption of capnography for moderate sedation in adults undergoing upper endoscopy and colonoscopy has not been shown to improve patient safety or clinical outcomes and significantly increases costs for moderate sedation. 2012.
41. Qadeer MA, Vargo JJ, Dumot JA, et al. Capnographic monitoring of respiratory activity improves safety of sedation for endoscopic cholangiopancreatography and ultrasonography. *Gastroenterology* 2009;136:1568-76.
42. Beitz A, Riphaut A, Meining A, et al. Capnographic monitoring reduces the incidence of arterial oxygen desaturation and hypoxemia during propofol sedation for colonoscopy: a randomized, controlled study (ColoCap Study). *Am J Gastroenterol* 2012;107:1205-12.

Prepared by:
ASGE ENSURING SAFETY IN THE GASTROINTESTINAL ENDOSCOPY UNIT
TASK FORCE
Audrey H. Calderwood, MD, Co-Chair
Frank J. Chapman, MBA, Co-Chair
Jonathan Cohen, MD
Lawrence B. Cohen, MD
James Collins, BS, RN, CNOR
Lukejohn W. Day, MD
Dayna S. Early, MD

This document is a product of the ASGE Ensuring Safety in the Gastrointestinal Endoscopy Unit Task Force. This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy. This document was reviewed and endorsed by the American Association for the Study of Liver Diseases, American College of Gastroenterology, American Gastroenterological Association Institute, Ambulatory Surgery Center Association, American Society of Colon and Rectal Surgeons, and Society of American Gastrointestinal and Endoscopic Surgeons.

Endoscopedia

GIE now has a blog! Keep up with GIE news by following us at www.endoscopedia.com.