Title
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Journal
Gastrointestinal Endoscopy, 79(3)

ISSN
0016-5107

Authors
Force, ASGE Ensuring Safety in the Gastrointestinal Endoscopy Unit Task
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Publication Date
2014-03-01

DOI
10.1016/j.gie.2013.12.015

Peer reviewed

Published in final edited form as:
Gastrointest Endosc. 2014 March ; 79(3): 363–372. doi:10.1016/j.gie.2013.12.015.

Guidelines for Safety in the Gastrointestinal Endoscopy Unit

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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 where 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 CMS[1] without evidence demonstrating that safety or clinical outcomes in endoscopy are thereby improved. Although the 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, 3, 4, 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. Where data is 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 re-accreditation. Many of these issues relate to the Ambulatory Surgical Center (ASC) 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 ASGE's position and accompanying rationale.

- **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 in the operating room.[6]

- **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 that should be worn in each area. Endoscopy staff can move freely throughout the unit provided that there is appropriate use and changing of personal protective equipment.

- **Issue:** Requirement for endoscopy personnel to don full sterile operating room personal protective equipment including new scrubs, hair covers and booties.

  Position: It is recommended that staff directly engaged in GI endoscopy or in processes where splash or contamination could occur should wear gloves, face/eye shields, and an impervious gown. Units should develop policies that are consistent with OSHA and state-mandated recommendations for wearing face/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.

- **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.

- **Issue:** Role of capnography.

  Position: There is inadequate data to support the routine use of capnography where moderate sedation is the target.

- **Issue:** Requirement that 2 nurses (one monitoring, one 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, or unlicensed assistive personnel) should be available to join the care team.

- **Issues:** Staffing requirements when sedation and monitoring is provided by anesthesia personnel.

  Position: When sedation and monitoring is provided by anesthesia personnel, a single additional staff person (nurse, licensed practical nurse, or unlicensed assistive personnel) is sufficient to assist with technical aspects of the procedure.

- **Issue:** Technical capabilities of technicians.

  Position: Unlicensed technicians, who have received initial orientation and ongoing training, and are deemed competent by their unit, 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 (HAIs) 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 HAIs

from endoscopic procedures, recent outbreaks of certain hospital-based HAIs, such as *Clostridium difficile* (*C difficile*) and methicillin-resistant *Staphylococcus aureus* (MRSA), have brought HAIs 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 Veteran's Administration 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, 3, 4, 5]

Changes to the Centers for Medicare and Medicaid Services (CMS) ASC 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 (AORN) 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 gastrointestinal 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.

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

Recommendations for the Endoscopic Procedure Room—Endoscopic procedure rooms will vary in size, with more complex procedures, such as endoscopic retrograde cholangiopancretography (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, a greater number of staff members and bulkier equipment, none of which are essential for the

performance of endoscopy. Standard endoscopic procedures will 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:

- Actual marking of the site is not required for endoscopic procedures as endoscopy does not involve lateral right/left distinction levels such as those found in spinal procedures or 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.
- 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 gastrointestinal lumen, but this is not a requirement.
- 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.
- An uninterruptible source of power, supplied either by a generator or battery source is required. The purpose of a secondary power source is to finish the current procedure in the event the primary power source malfunctions. Procedures should not be started when the only source of power is the secondary source.
- Units must practice fire safety in adherence with the NFPA 101 Life Safety Code.[12]
- The number and type of electrical outlets tied to the generator is dictated by the NFPA 101 Life Safety Code, which recommends that not all outlets be tied to the generator in case the generator fails to disengage once power is restored.[12] 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.
- 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]
- Puncture resistant containers for biohazardous materials and sharps should be located so that sharps are not passed over the patient.[15]
- 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

- 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

- Sterile supply items such as intravenous (IV) solutions should be protected from splash contamination during environmental cleaning (8 to 10 inches off the floor), damage from compression (stacking only ridged containers), and water damage (no storage under sinks).

- 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 pre-, intra-, and post-procedure phases are necessary to ensure overall safety of patients and healthcare 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:

- Hand hygiene
- Personal protective equipment
- Safe medication administration practices
- 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.

- 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 (i.e., placement or access of intravascular lines) and after glove removal.[20]
- 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 Personal Protective Equipment—The unit should have a written policy and procedure regarding personal protective equipment (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 has 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:

- 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.
- 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. Due to the potential for splash exposure to the face, individual units should develop policies based on OSHA and state-mandated recommendations for wearing face/eye shields or masks.[8] Hair and shoe covers and gown classifications above AAMI Level 1 are often included in PPE recommendations.[24] These items are generally mandated for the sterile operating room environment but there is no evidence to support their requirement or benefit in the non-sterile endoscopy environment.

- 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 one patient.
- Scrub attire may be worn from home, as endoscopic procedures are performed in a non-sterile environment.
- 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.
- 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 the health care 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 (CDC) and ASGE have issued guidelines outlining safe injection practices.[19, 26] Units should adhere to the following:

- If a unit draws up medications for multiple patients, it should be done in an area away from direct patient care or procedure rooms.
- Units should appropriately label all medications, including those used for sedation unless the medication is for immediate use (defined as drawn up and administered immediately without leaving the provider's hand).[26]
- Units should limit the use of medications marked either on the container or noted in the package insert as "single patient use" to a single patient only and discard any remaining drug.
- Units should use new fluid administration sets (e.g., IV tubing) for each patient.

- Units should prepare and administer injections using aseptic technique (i.e., 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 only be used for a single patient.
- Use of a single-dose vial is preferred over multi-dose vials (MDV), particularly when medications will be administered to multiple patients.[3]
- If MDV will be used for more than one 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 CDC.[27]
- Units should not re-use a syringe to enter a medication vial or solution, even with a new needle.
- 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.
- 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]
- 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.
- Units should consistently 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.
- If tubes of lubricant are used for more than one exam, the unit should observe appropriate infection control habits and discard any tube that has potentially been contaminated.
- Although the multisociety guideline recommends using sterile water in the irrigation bottle, it is acceptable to use tap water as this has been shown to be safeinformed co.[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]
- Units should follow federal and state requirements for the protection of health care personnel from exposure to blood-borne pathogens.

Recommendations for Safe Handling of Potentially Contaminated Equipment or Surfaces—Environmental cleaning of surfaces is mandatory with an appropriate Environmental Protection Agency labeled disinfectant, emphasizing surfaces that are most likely to become contaminated with pathogens, such as those in close proximity to the patient (e.g., 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:

- Maintain Material Safety Data Sheets (MSDS) for all chemicals used for cleaning and disinfection. These sheets should detail the safe and proper use and emergency protocol for a chemical. MSDS should be used for training staff on each chemical's safe use.
- 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.
- 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, video monitors and consoles.

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.

- 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.
- Agents for terminal cleansing should have efficacy in spore removal, which may differ from requirements for agents used in sterile operating rooms.
- Before the first case of the day, staff should verify that all procedural and recovery areas have been properly cleansed.
- A training and competency assessment program should be in place for staff that is involved in terminal cleansing to ensure proper and safe handling and use of the chemicals.

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 (SUD) as determined by the manufacturer label or packaging insert may not be reprocessed unless they are specifically listed in the 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 SUDs.[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's *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 is 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 (i.e., 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 exam and is reflected in the American Society of Anesthesiology (ASA) classification of the patient. Procedural factors include the anticipated length of the procedure and whether the procedure is intended to be diagnostic or if a therapeutic intervention is planned. Complex interventional procedures, such as endoscopic ultrasound (EUS) and ERCP may require additional staff for efficiency, but there is no evidence to suggest that this improves safety or patient outcomes.

Staffing Recommendations for Pre-procedure care

- Staffing models in the pre-procedure area should support activities required to prepare patients for endoscopy.
- The ratio of RNs to patients in the pre-procedure is variable depending on the acuity of the patients.

Staffing Recommendations for Intra-procedure care based on level of sedation[4]

- No sedation—One assistant (RN, LPN, or unlicensed assistive personnel (UAP)) other than the physician performing the procedure should be present to assist with the technical aspects of the procedure.
- Moderate sedation (also known as conscious sedation)—Sedation should be directed by the physician who is credentialed and privileged to do so and 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.
- 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 are 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]

Staffing Recommendations for Post-procedure care

- 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.
- Once the patient is stable, post-procedure activities such as providing food or drinks and assistance in changing clothes can be performed by an RN, LPN or UAP.
- The ratio of RNs to patients in the post-procedure setting is variable depending on the acuity of the patients.

Training Recommendations

- 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 response to sedation accordingly. Upon verification of 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.

- 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.
- Basic and Advanced Cardiac Life Support - All staff with clinical responsibilities must have Basic Life Support (BLS) certification. At least one individual with Advanced Cardiac Life Support (ACLS) certification must be present in the unit when patients are present.
- A written policy on staff training along with 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 (re)examination. 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. Unsedated endoscopy may be appropriate in some instances. For a detailed discussion including supporting evidence, please refer to the 2008 ASGE guideline on *Sedation and Anesthesia in GI Endoscopy*.[17]

Recommendations for the Sedation-related Environment

- 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.
- 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.
- 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.
- A focused history and physical, including the patient's current medications and ASA classification, should be completed before the start of the procedure.[17]

Recommendations for Sedation-related Equipment

- All sedation-related equipment, before initial use and then 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]

- 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

- All patients undergoing endoscopy should be monitored, the frequency of which depends on procedural and patient factors (e.g., 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 procedure, during initial recovery, and just before discharge.[5]
- Units should have procedures in place to rescue patients who are sedated deeper than intended.[5, 17, 37, 38]
- 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 where moderate sedation is the target.[5, 39, 40]
- 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] and 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

- Written policies detailing the methods of drug storage, monitoring of drug inventory and expiration dates, and documentation of compliance with these policies are required.
- 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.

- 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.
- 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.
- Medications should be given only under the order of the supervising physician or anesthesia professionals where applicable.
- Reversal agents for opioids and benzodiazepines should be readily available.
- A written policy should be in place for the identification, documentation and review of adverse drug reactions.

Recommendations for Emergency Management

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

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Table 1

Summary of the key strategies to maintain safety in the gastrointestinal endoscopy unit

Each unit should have a designated flow for the safe physical movement of dirty endoscopes and other equipment.
Procedure rooms will 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 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.
In cases where moderate sedation is the target, the individual responsible for patient monitoring may perform brief interruptible tasks.
In cases where moderate sedation is the target, there is currently inadequate data to support the routine use of capnography.