

AMERICAN GASTROENTEROLOGICAL ASSOCIATION

The American Gastroenterological Association Standards for Office-Based Gastrointestinal Endoscopy Services

The American Gastroenterological Association (AGA) standards for office-based gastrointestinal endoscopy were written in response to market changes in physician reimbursements for many endoscopic procedures that will continue to drive their performance into unregulated physician offices. The AGA believes that patient safety is best protected if these standards are adopted by sites that also comply with state/federal laws for licensure or are certified as an ASC and/or are accredited by a nationally recognized accreditation program (e.g., the Joint Commission on Accreditation of Healthcare Organization's [JCAHO] new Office-Based Surgery Standards). Heretofore, relevant practice standards for the performance of endoscopic procedures in these settings have not been available, a situation that the AGA believes puts patients at risk. These standards have been developed to reduce that risk.

As market dynamics, reimbursement and other policy changes combine to motivate the shifting of endoscopy services into the physician office setting, it is crucial to ensure that patients are afforded a level of safety and quality equivalent to that of the hospital and ambulatory center facility setting. These Standards may be used to assess the quality of physical plant and environment, support services, and patient care issues associated with endoscopy services for those adolescents and adults who can be safely treated in an office-based setting. Physicians providing office-based gastrointestinal endoscopic services should have proper training and be credentialed in a hospital and/or an ambulatory surgery center.^{1,2}

Indications/Appropriateness

Standard. The following procedures should not be undertaken in the office setting (this list is not inclusive):

1. Stent placement
2. ERCP
3. Endoscopic sphincterotomy
4. Endoscopic ultrasound with pseudocyst drainage
5. Removal of suspected foreign body
6. Endoscopic management of gastroesophageal reflux disease
7. Therapeutic hemostatic control of acute bleeding
8. Procedures deemed emergent
9. Procedures carrying a considerable risk of bleeding or major complications

Standard. An anesthesia risk class should be documented for each patient receiving intravenous sedation, using the American Society of Anesthesiologists (ASA) score.³

1. Patients with an ASA score of IV should not undergo in-office endoscopy.

2. Patients with an ASA score of III should be further assessed for their appropriateness to undergo in-office endoscopy.

Physical Environment

Standard. Applicable state and local building and other physical plant codes should be consulted and adhered to.

Standard. A patient changing area, including a storage locker for belongings and an easily accessible bathroom, compliant with the Americans with Disabilities Act, should be provided. The bathroom should not be in a common area.

Standard. A waiting area for accompanying family or others should be provided.

Standard. A private area for patient consultation should be available. Acceptable patient privacy should be maintained throughout the preprocedure, procedure, and recovery care.

Standard. A minimum of 200-square feet is a comfortable size for an endoscopy room. In all instances, the following must be accommodated:

1. Technique for reduced illumination from ambient light
2. Ability to fit a rolling stretcher through all doorways
3. Ability to move freely on both sides of the patient
4. Unimpeded view of all monitoring equipment

Abbreviations used in this paper: ACLS, Advanced Cardiac Life Support; AGA, American Gastroenterological Association; ASA, American Society of Anesthesiologists; BCLS, Basic Cardiac Life Support; JCAHO, Joint Commission on Accreditation of Healthcare Organizations.

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5. Sufficient storage for supplies and equipment
6. Adequate ventilation
7. Auditory and visual privacy
8. Mechanism to summon additional assistance to the room

Standard. There must be adequate provision to safely evacuate a sedated or unstable patient in the event of the need to transfer or evacuate on an emergent basis.

Infection Control and Protection From Pathogens

Standard. A staff hand-washing sink, separate from a secretion disposal sink, should be readily available.

Standard. Endoscopes should be cleaned to a high level of disinfection, as outlined in the Standards for Infection Control and Reprocessing of Flexible Gastrointestinal Endoscopes as issued by the Society of Gastroenterology Nurses and Associates.⁴ Reprocessing of endoscopes and other contaminated patient equipment should be done in a room separate from where endoscopic procedures are performed.

Standard. Equipment that has been cleaned should be physically separated from dirty equipment to avoid cross contamination.

Standard. All state and federal regulations with regard to potential occupational exposures, including the Occupational Safety & Health Administration (OSHA) Bloodborne Pathogens regulations⁵ should be adhered to, including but not limited to:

1. Provision of adequate ventilation in equipment cleaning areas
2. Written infection control procedures, regular staff training on the procedures, and a plan to monitor compliance
3. Appropriate plan for disposal of human waste, blood, and other potentially infectious materials

Patient Education and Informed Consent

Standard. The patient should be given preprocedure instructions, including any necessary preparation or medication changes, at the time of scheduling.

Standard. Informed consent, to include the nature of the procedure, risks, benefits, and alternatives, should be obtained before the procedure and documented in the medical record.

Standard. The patient should be given written discharge instructions, including any relevant limita-

tions on activity and contact information in case of untoward effect(s).

Standard. There should be a procedure for reporting results to the patient and referring physician.

Administration of Conscious Sedation (Sedation & Analgesia)

Standard. Any office endoscopy setting where a patient receives intravenous conscious sedation must comply with state and federal laws for licensure or certification as an ASC and/or be accredited by a nationally recognized accreditation program (e.g., JCAHO's Office-Based Surgery Standards).

Standard. Conscious sedation should be administered by an Advanced Cardiac Life Support (ACLS) certified physician, or licensed or certified nonphysician clinician under the direct supervision of a physician (to the extent that the latter is permitted under relevant state or local law) with training specific to the administration of conscious sedation in the endoscopy setting.⁶

Standard. Complete and document the anesthesia risk class.

Standard. Place intravenous access and maintain until the patient has recovered.

Standard. Once sedation has begun, at least one ACLS-certified physician or nonphysician clinician, trained to monitor and assess the patient's well-being, should be physically present in close proximity to the patient at all times.

Standard. A trained assistant, preferably Basic Cardiac Life Support (BCLS) certified, should be present in the room throughout the endoscopic procedure. If the procedure is particularly complex, such that the assistant's attention may become diverted from monitoring, a second assistant may be necessary. (If conscious sedation is not being used, a trained assistant, preferably BCLS certified, should be readily available throughout the procedure.)

Standard. Baseline heart rate, blood pressure, respiratory rate, and oxygen saturation should be documented before sedation. Heart rate and blood pressure should be monitored during the procedure, as well as after it, until the patient is stable. Oxygen saturation is to be monitored continuously during the procedure and until the patient is stable after the procedure.⁷ High-risk patients should also receive continuous electrocardiographic monitoring.

Standard. Patients should be continuously monitored in the recovery area.

Standard. Written discharge criteria should be established, including evaluation of responsiveness, vital

signs, and ability to tolerate fluids/swallow. Patients should not be discharged until assessed, and all criteria met.

Standard. On discharge, patients who have received conscious sedation must be accompanied by an adult.

Monitoring Equipment

Standard. Oxygen, oral suction, and electronic monitoring equipment that can monitor and display pulse, blood pressure, oxygen saturation, and continuous electrocardiographic rhythm assessment should be in the room, functioning and readily available.

Standard. A written policy for equipment checks and maintenance and a log to monitor compliance should be maintained.

Emergency Supplies, Equipment, and Procedures

Standard. Necessary pharmaceutical agents, oxygen, oral suction, laryngoscope, tracheostomy tray, ambu bag, defibrillator, electrocautery, and cautery backup should be functioning and readily available, and staff should be trained in their use.

Standard. The defibrillator should be checked on a daily basis when the office is open; other equipment should be checked according to the manufacturers' recommendations.

Standard. An agreement or contract should exist for ACLS-certified transport from the office to an emergency care facility willing to accept patients from the office.

Medications

Standard. All medications should be stored in a secure and environmentally controlled location.

Standard. Relevant provisions of the Controlled Substances Act⁸ must be adhered to.

Standard. Controlled substances should be stored in a double-locked cabinet and should be counted and signed for daily.

Standard. A written policy for the monitoring of pharmaceutical agents for date of expiration and a log to monitor compliance should be maintained.

Standard. Reversal agents should be readily available.

Personnel/Staff

Standard. Physicians performing office-based endoscopy should generally qualify for holding privileges in an institutional setting.⁷

Standard. Appropriately trained and certified nonphysician clinicians may perform flexible sigmoidoscopies for colorectal cancer screening, under the supervision of a physician.

Standard. Staff should be trained in care for patients undergoing endoscopy and periodically reassessed for competence.

Standard. Patient care staff should hold BCLS certification.

Standard. A registered nurse must be present in the recovery area.

Quality Assurance

Standard. There should be regular peer review of the appropriateness of procedures performed and their outcomes.

Standard. There should be a log or database of all procedures. Recognized procedure-related and sedation-related complications should be tabulated and regularly reviewed.

Standard. A written policy and procedure manual should be maintained and updated. Staff should receive training in all policies and procedures.

Standard. A written agreement should be in place with a Clinical Laboratory Improvement Act (CLIA)-certified laboratory for the processing of pathology and other specimens.

Standard. There should be a procedure for logging tissue samples and specimens, return of report, physician review, and patient and referring physician notification for all specimens.

Documentation

Standard. A medical record should be kept for each patient to include:

1. History and physical pertinent to the procedure and to determine the patient's risk classification
2. Indications for the procedure
3. Documentation of informed consent
4. Notation of any drug allergies and list of patient's current medications

Standard. Initial findings should be documented in the chart the day of the procedure. Subsequently, a signed report of procedure should be completed, to include:

1. Date of procedure
2. Procedure(s) performed
3. Extent of examination
4. Duration
5. Findings
6. Notation of tissue sampling

7. Therapeutic intervention
8. Procedure-related and sedation-related complications
9. Limitations of the examination
10. Endoscope number
11. Copies of photographs or digital images (if taken)

References

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8. The Comprehensive Drug Abuse Prevention and Control Act of 1970, October 27, 1970, P. L. 91-513, 84 Stat. 1236, and subsequent amendments.

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