Communication from the ASGE Quality Assurance in Endoscopy Committee

GUIDELINE

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 CMS[1] 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.

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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