Ensuring Patient Safety and Optimizing Efficiency During Gastrointestinal Endoscopy

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ABSTRACT

The volume of outpatient gastrointestinal (GI) endoscopy has grown dramatically in the past three decades, fueled by advancing technologies and evolving payment policies. This magnifies the need to ensure high-quality, safe, and cost-effective endoscopic services. In recent years, publicized breaches in standards of care for GI endoscopy have intensified the focus on patient safety. Because of these patient safety concerns and changes in regulatory policies, some ambulatory surgery center surveyors and inspectors have held GI endoscopy suites to the same standards as hospital ORs. The American Society for Gastrointestinal Endoscopy and other endorsing organizations drafted the *Guidelines for Safety in the Gastrointestinal Endoscopy Unit*, which published in January 2014. These safety guidelines relevant to sedation, infection control, staffing, training, technical equipment, traffic patterns, and personal protective equipment differ from other published guidelines for the outpatient surgical setting. *AORN J* 99 (March 2014) 396-406. © AORN, Inc, 2014. http://dx.doi.org/10.1016/j.aorn.2013.10.022

Key words: *infection control, gastrointestinal endoscopy, GI endoscopy, endoscopy unit staffing, traffic patterns, personal protective equipment, PPE.*

Ensuring patient safety is the highest priority in the performance of gastrointestinal (GI) endoscopy, the majority of which is performed in the outpatient setting: hospital outpatient departments, ambulatory surgery centers (ASCs), or physicians' offices. The highest risks for patients undergoing endoscopic GI procedures are associated with sedation, infections, and adverse events such as aspiration, bowel perforation, or bleeding.[1-4] An additional priority includes the completion of a high-quality, cost-efficient endoscopic examination. In moving toward a value-based health care system, quality and safety are paramount, but cost efficiency and the mitigation of waste also must be achieved.

In the past three decades, the considerable growth of outpatient GI endoscopy has been facilitated by evolving medical technologies and the growing prevalence of ASCs and has been driven by the payment policies of the Centers for Medicare & Medicaid Services (CMS) and commercial payers.[5] Improvements in sedation, analgesia, and monitoring devices and advances in endoscopic technologies and minimally invasive therapeutic endoscopic techniques are just a few of the advancements that have fueled this growth.

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Since 1982, when CMS and, subsequently, commercial payers initiated payment for outpatient surgery in ASCs, both the types and volume of services provided in ASCs have grown, while procedure rates in hospital outpatient departments have been relatively stable.[6] The number of ASCs rose from only 239 in 1983 to 3,300 by 2006.[6] Between 1996 and 2006, the number of outpatient procedures performed in the ASC setting increased 300%.[6] In 2006, there were 53.3 million outpatient procedures performed during 34.8 million ambulatory surgical visits.[6] Of the 34.8 million visits, 19.9 million (57%) were performed in hospital outpatient departments and 14.9 million (43%) were performed in independent ASCs.[6] Of the total ambulatory surgical visits, GI endoscopy was second only to cataract surgery in total volume, with 5.7 million colonoscopies (16.4%) and 3.5 million upper endoscopies (10.1%).[6]

Since 2001, when CMS approved colonoscopy for colorectal cancer screening, the volume of outpatient colonoscopy has rapidly expanded.[5] In 2011, the Medicare Payment Advisory Commission reported that there was a 1.2% increase in the CMS case rate in 2009, with the number of CMS certified ASCs increasing 2.1% to a total of 5,260.[7] Payments from CMS for ASC services increased 5.1% per beneficiary to $3.2 billion in 2008.[7] From 2004 to 2009, there was a 5.1% annual growth in ASCs with an 8.1% annual growth in volume of services per CMS beneficiary.[7]

CONFLICTING STANDARDS

The volume of GI endoscopy procedures performed in the outpatient setting underscores the need to ensure high-quality, safe, and cost-effective services. It is increasingly important that health care providers recognize gaps in care that may lead to adverse events and suboptimal patient outcomes. In recent years, publicized breaches in endoscope reprocessing and infection risk have intensified the focus on patient safety in this setting.[8-10] In addition, the 2009 CMS Conditions for Coverage eliminated the distinction between the sterile conditions required in an OR and those conditions required in an endoscopic procedure room.[11] Despite the availability of published GI endoscopy guidelines, some endoscopy unit surveyors have held GI endoscopy procedure rooms to the same regulatory and safety standards as those required for an OR, making it difficult and unnecessarily expensive to comply. During the past several years, endoscopist members of the American Society for Gastrointestinal Endoscopy (ASGE) working in single-specialty GI endoscopy units have reported the following:

- State and CMS inspectors have required that a circulating nurse (RN) be in the procedure room in addition to the RN who is administering moderate sedation or in addition to the certified registered nurse anesthetist (CRNA) who is administering monitored anesthesia care.
- Facility inspectors have insisted that a trained GI medical technician is not qualified to assist GI endoscopists with tissue collection by forceps biopsy or snare polypectomy, and the medical technician is not allowed to handle pathology specimens. These technicians are not required to be certified but must provide proof of training to perform these functions and should be evaluated for competencies at least once per year.
- Surveyors also have insisted that sterile water is required for washing the scope lens and the bowel mucosa during endoscopic procedures in the absence of evidence that this provides any benefit.

These comments and experiences with surveyors applying OR and other empirical criteria to the GI endoscopy environment without evidence to demonstrate that the added cost and resources needed to comply contribute to patient safety or better outcomes prompted ASGE to create a guideline that better identifies acceptable practices in the endoscopy suite. AORN has consistently recognized that its standards