

GUIDELINE



Endoscopy by nonphysicians

This is one of a series of statements discussing the use of GI endoscopy in common clinical situations. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy (ASGE) prepared this text. In preparing this guideline, a search of the medical literature was performed by using PubMed, supplemented by accessing the "related articles" feature of PubMed. Additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When little or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts. Guidelines for appropriate use of endoscopy are based on a critical review of the available data and expert consensus at the time the guidelines are drafted. Further controlled clinical studies may be needed to clarify aspects of this guideline. This guideline may be revised as necessary to account for changes in technology, new data, or other aspects of clinical practice. The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence (Table 1).

This guideline is intended to be an educational device to provide information that may assist endoscopists in providing care to patients. This guideline is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment. Clinical decisions in any particular case involve a complex analysis of the patient's condition and available courses of action. Therefore, clinical considerations may lead an endoscopist to take a course of action that varies from these guidelines.

INTRODUCTION

GI endoscopy is defined as the direct visualization of the digestive tract, with or without therapy. Endoscopic technology has rapidly advanced over the past 40 years, becoming an integral part of clinical gastroenterology. The ASGE has continually promoted safe and responsible endoscopic practice. Guidelines were developed and disseminated regarding appropriate use of and training in endoscopy.²⁻⁴ The utilization of endoscopy for both

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diagnostic evaluation and screening has markedly increased over the last 2 decades. Many innovations have expanded indications for endoscopy. However, the largest factor to increase endoscopic volumes in recent years has been the adoption of colorectal cancer screening through colonoscopy. Some nonphysician endoscopists were initially trained in flexible sigmoidoscopy to help meet the demand for colorectal cancer screening. Although nonphysician endoscopists have been trained to perform colonoscopy and upper endoscopy, it is not known how often this is being practiced. ⁵⁻⁷ The purpose of this guideline is to address the issues surrounding endoscopic practice by nonphysicians.

BASIC CONCEPTS

Competent endoscopic practice requires thorough training in both the cognitive and technical aspects of endoscopy. Cognitive skills include knowledge of procedural indications and contraindications, risks, benefits, and alternatives, as well as accurate identification and interpretation of gross pathology. It includes the ability to assess the implications of information regarding the patient's condition and the capability to integrate endoscopic findings into clinical practice. Also, it includes the ability to recognize complications associated with endoscopy.

Technical skill refers to the ability to perform the physical aspects of endoscopy, such as insertion, advancement, maneuvering through the GI tract, biopsy, therapeutic interventions, and withdrawal of the instrument. Trained physician endoscopists include, but are not limited to, physicians with fellowship training in GI disease and formal training in endoscopy as defined in prior ASGE publications. Nonphysician endoscopists are defined as any nonphysician medical personnel who perform endoscopy, including but not limited to, nurses, nurse practitioners, physician assistants, and medical assistants.

DISCUSSION

The decision to use nonphysician endoscopists should be made based upon competence in endoscopy. Factors that have led the use of nonphysician endoscopists include availability of physician resources and the volume of procedural demand as dictated by local conditions. Physician endoscopists undergo extensive formal training in

Grade of recommendation	Clarity of benefit	Methodologic strength supporting evidence	Implications
1A	Clear	Randomized trials without important limitations	Strong recommendation; can be applied to most clinical settings
1B	Clear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Strong recommendation; likely to apply to most practice settings
1C+	Clear	Overwhelming evidence from observational studies	Strong recommendation; can apply to most practice settings in most situations
1C	Clear	Observational studies	Intermediate-strength recommendation; may change when stronger evidence is available
2A	Unclear	Randomized trials without important limitations	Intermediate-strength recommendation; best action may differ depending on circumstances or patients' or societal values
2B	Unclear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Weak recommendation; alternative approaches may be better under some circumstances
2C	Unclear	Observational studies	Very weak recommendation; alternative approaches likely to be better under some circumstances
3	Unclear	Expert opinion only	Weak recommendation; likely to change as data become available

the cognitive aspects of GI disease as well as the technical performance of endoscopic procedures. It is unlikely that nonphysician endoscopists routinely obtain this same level of cognitive training. The impact of this fact with regard to various endoscopic procedures and its effect on patient outcome is largely unknown. However, nonphysician endoscopists should be expected to receive the same volume and supervision during training of the technical aspects of performing endoscopic procedures as physician endoscopists. Achieving threshold numbers of procedures does not assure competence. As with physician endoscopists, nonphysician endoscopists require either direct or indirect supervision after the completion of training to assess competence and ongoing evaluation to ensure competence is maintained.

The majority of the literature that involves nonphysician endoscopists pertains to the performance of sigmoid-oscopy and specifically for the purposes of colorectal cancer screening. Flexible sigmoidoscopy requires fewer supervised examinations to attain objective measures of technical competency⁸ than other endoscopic procedures, does not require sedation, and is associated with an inherently low complication rate. Nonphysician endoscopists have been performing sigmoidoscopy since the

1970s. Several studies documented that, when nonphysician endoscopists are given thorough training, they can perform flexible sigmoidoscopy at a level comparable with physicians. 10-14

Colorectal cancer is an important health care issue in the United States. It is the third most common cancer, and it was estimated by the American Cancer Society that 148,810 new cases of colorectal cancer would occur in 2008. 15 During the 1990s, flexible sigmoidoscopy was a common screening modality for colorectal cancer. However, in 2001, Medicare expanded coverage for screening to include colonoscopy. Since that time, there has been a rapid increase in the use of colonoscopy for all persons who meet screening guidelines. In many areas of the United States colonoscopy has largely replaced flexible sigmoidoscopy as the primary screening modality. The incidence of colorectal cancer has been decreasing over the past 2 decades, with a rapid reduction from 1998 to 2004. 15 This change in incidence is likely because of the removal of colon polyps For this trend to continue, it is imperative that high-quality screening colonoscopy continues and that the demands for screening are met.

There have been limited reports of nonphysician endoscopists performing colonoscopy as well as upper

endoscopy.⁵⁻⁷ The prevalence of this practice is not well known. There are 3 prospective studies published from the United Kingdom that show that nurses are able to safely perform upper endoscopy without increased complications and with good patient acceptance compared with physicians. ¹⁶⁻¹⁸ Two of these studies prospectively assessed diagnostic accuracy through video taping. 17,18 Accuracy was at least comparable between the nurses and the physicians. However, one of these studies published an adequate examination rate of only 53% by physicians. 17 This would be considered below the standard of care in the United States. Another of these U.K. studies addressed patient outcomes at 1 year by using their own unique methodology and found no significant difference between the physician and the nurse endoscopists. Such prospective studies that address accuracy, safety, or outcomes with upper endoscopy or colonoscopy have not been published from the United States.

The requirements for EGD and colonoscopy are much greater than for flexible sigmoidoscopy. They must include management of sedation, recognition of findings, cognitive understanding of disease processes, and the ability to perform endoscopic therapy when indicated. They must also include the recognition of potential complications and potential therapy when indicated. A prolonged intensive training period is required to be competent in all of these areas. Minimum threshold numbers of procedures during training were published by the ASGE. 4 The thresholds for determination of endoscopic competence for nonphysicians should be equal to that expected of a physician. It is unclear at this time whether patient needs and demand for endoscopy merit nonphysicians performing procedures other than screening flexible sigmoidoscopy. Endoscopy by both physicians and nonphysicians should be subjected to a quality monitoring program as discussed in a prior ASGE guideline. 19

Video capsule endoscopy (VCE) was first reported in 2000 as a new technique for evaluation of the small bowel. Since that time, utilization of this procedure has increased considerably. VCE is unique because it does not require sedation or the presence of the endoscopist at the time of performing the procedure. In addition, the risk of capsule retention is independent of the reader. The review of these examinations is a time-intensive process. There were several studies that showed that the ability of nonphysician personnel to locate significant endoscopic abnormalities is similar to that of physicians. It also was shown that a significant cost savings is achieved when procedures are preread by a nonphysician reader. As a nonphysician reader.

Intensive training of the nonphysician endoscopist for any of the above procedures requires close supervision by a physician endoscopist. After completion of training, nonphysician endoscopists will need to continue to work under the direct or indirect supervision of a physician. Physicians may wish to consult with their own legal counsel on liability issues surrounding supervision of nonphysician endoscopists. Nurse practitioners and physician assistants generally carry their own malpractice insurance. However, registered nurses who perform endoscopy under the direct or indirect supervision of a physician do so under the medical license of that physician.

RECOMMENDATIONS

- 1. The performance of flexible sigmoidoscopy for colorectal cancer screening by nonphysician endoscopists is supported when intensive training occurs by a certified endoscopist. Level 1B
- 2. There are data to support the use of nonphysician personnel to preread VCE when subsequent review occurs by a trained physician. Level 1C+
- There are insufficient data to support nonphysician endoscopists to perform colonoscopy and upper endoscopy. Level 3

Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; VCE, video capsule endoscopy.

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