Defining and measuring quality in endoscopy

Quality has been a key focus for gastroenterology, driven by a common desire to promote best practices among gastroenterologists and to foster evidence-based care for our patients. The movement to define and then measure aspects of quality for endoscopy was sparked by public demand arising from alarming reports about medical errors. Two landmark articles published in 2000 and 2001 led to a national imperative to address perceived areas of underperformance and variations in care across many fields of medicine.[1,2] Initial efforts to designate and require reporting a small number of basic outcome measures were mandated by the Centers for Medicare & Medicaid Services, and the process to develop performance measures for government reporting and "pay for performance" programs was initiated. Since that time, major external forces stemming from policy makers, payers, and ultimately patients have generated demand for a way to accurately define and measure the quality of the services endoscopists provide.

The path to quality improvement naturally begins with an effort to define those aspects of care that impact the quality of the patient experience. The quality goals include effective care and safety and further encompass other aims such as professionalism, equitable care, and increasingly, affordable care.[3]

To these ends, gastroenterology societies have been working to define the elements of high-quality endoscopy and to facilitate ways to measure it. Initially, this entailed developing, refining, and communicating evidence-based, procedure-related quality indicators. This effort began in 2005 with the work of the American Society for Gastrointestinal Endoscopy (ASGE)/American College of Gastroenterology (ACG) Task Force on Quality in Endoscopy. David Bjorkman, MD and John Popp, Jr, MD, then presidents of ASGE and ACG, respectively, believed that gastroenterologists should take the lead in defining quality in gastroenterology practice rather than have those outside our field define it for us. In heralding the project and its rationale, they wrote, "The ASGE and ACG recognize that if we do not develop evidence-based quality measures, an administrative or governmental agency without experience or insight into the practice of endoscopy will define these measures for us."[4] The task force they established published the first set of quality indicators for GI endoscopic procedures in April of 2006.[5-9]

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The expert panels that were convened in 2005 compiled a list of quality indicators that were deemed, at the time, to be both feasible to measure and associated with improved patient outcomes. Feasibility concerns precluded measures that required data collection after the date of endoscopy service. Accordingly, the majority of the initial indicators consisted of process measures, often related to documentation of important parameters in the endoscopy note. The evidence demonstrating a link between these indicators to improved outcomes was limited. In many instances, the 2005 task force relied on expert opinion. Setting performance targets based on community benchmarks was introduced, yet there was significant uncertainty about standard levels of performance. Reports citing performance data often were derived from academic centers, expert endoscopists, and carefully conducted, randomized, controlled studies. The infrastructure for collecting community-based outcome data at that time was limited, and very few endoscopists were regularly recording their performance variables.

Despite these limitations, 5 seminal articles were published in 2006: 1 on indicators common to all gastrointestinal endoscopy and the others on EGD, colonoscopy, ERCP, and EUS. These publications served as the basis for the dramatic transformation that has occurred since in the area of quality in endoscopy. These documents informed thinking about training and definitions of competency and guided the evolution of electronic endoscopy reporting for documentation. Perhaps the greatest impact has been the impetus they provided and the foundation they laid for the development of central data repositories to facilitate widespread benchmarking based on these very indicators.

As a result of the 2006 quality indicator documents, the GI Quality Improvement Consortium, Ltd (GIQuIC) established a data repository and benchmarking tool. This registry, a joint initiative of the ACG and ASGE, now has an expanding colonoscopy database that is a resource for the development of new quality measures, quality benchmarking, and clinical research. GIQuIC recently added EGD measures and is in the process of adding ERCP and unit-based measures to the registry. Data reports from registries are being used by endoscopists and endoscopy units in continuous quality improvement efforts, which was the primary goal of the initial project to define quality indicators.

Beyond this, data on variance in performance by using registries and other outcome studies have supported the adoption of GI-specific performance measures for government quality reporting programs. Increasingly, government, third-party payers, and patients are requiring data about the quality of the procedures we perform, and the

quality indicators continue to evolve to meet these expectations.

As our ability to measure actual outcomes has improved and as the stakeholders begin to expect information about real outcomes rather than surrogate process measures, our understanding and definition of what constitutes quality indicators for endoscopy has necessarily evolved. In 2005, Bjorkman and Popp stated, "Although providing the best possible patient care is our most important goal, we are poorly equipped to measure our ability to achieve that goal."[4] Since that time, we have risen to the challenge and continue to expand the menu of quality measures.

The 5 articles that appear in this journal issue reflect the new body of data established since 2006 about the factors that most impact patient outcomes and address the standard level of performance achieved in the community for these indicators. Some, but not all, of the feasibility challenges in measuring quality indicators have been overcome, making true outcome measurement more realistic than it was in 2006. Capturing information from days after endoscopy remains a challenge, particularly with regard to the measurement of delayed adverse events.

The updated list of quality indicators contained in these articles reflects gastroenterologists' increased ability to measure their performances as well as public and private payers' desire for them to report true outcomes. New research questions focus on indicators that demonstrate care that is effective, safe, equitable, and cost effective. We anticipate that these articles will continue to guide our efforts to measure and benchmark the key components of the procedures we perform. The ultimate purpose of gathering data on these indicators will be to identify performance gaps, which will allow us to focus our improvement efforts and deliver higher quality endoscopy care to our patients.

We sincerely thank the members of the task force who critically evaluated the literature and our endoscopic practice to provide these insightful reports. Their important contribution has provided us with the critical tools to confront a challenging future.

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All authors disclosed no financial relationships relevant to this publication.

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Abbreviations: ACG, American College of Gastroenterology; ASGE, American Society for Gastrointestinal Endoscopy; GIQuIC, Quality Improvement Consortium, Ltd.

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Quality indicators common to all GI endoscopic procedures

Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.[1] The American Society for Gastrointestinal Endoscopy (ASGE), the American College of Gastroenterology (ACG), and the American Gastroenterological Association (AGA) have continually promoted the ideal that all patients have access to high-quality GI endoscopy services. A high-quality endoscopy is an examination in which patients receive an indicated procedure, correct and relevant diagnoses are recognized or excluded, any therapy provided is appropriate, and all steps that minimize risk have been taken.

The quality of health care can be measured by comparing the performance of an individual or a group of individuals with an ideal or benchmark.[1] The particular parameter that is being used for comparison is termed a quality indicator. A quality indicator is often reported as a ratio between the incidence of correct performance and the opportunity for correct performance or as the proportion of interventions that achieve a predefined goal.[2] Quality indicators can be divided into three categories: (1) structural measures—these assess characteristics of the entire health care environment (eg, availability and maintenance of endoscopy equipment at a hospital), (2) process measures—these assess performance during the delivery of care (eg, proportion of patients who undergo biopsies when Barrett's Esophagus was suspected), and (3) outcome measures—these assess the results of the care that was provided (eg, proportions of patients diagnosed with colon cancer within five years of a screening colonoscopy).

METHODOLOGY

In 2006, the ASGE/ACG Task Force on Quality in Endoscopy published the first version of quality indicators common to all endoscopic procedures.[3] The present update integrates new data pertaining to previously proposed quality indicators and new quality indicators common to all endoscopic procedures. For the current report, we prioritized indicators that had wide-ranging clinical application, were associated with variation in practice and outcomes, and were validated in clinical studies. Clinical studies were identified through a computerized search of Medline followed by review of the bibliographies of all relevant articles. When such studies were absent, indicators were chosen by expert consensus. Although feasibility of measurement was a consideration, we hope that inclusion of highly relevant, but not yet easily measurable, indicators will promote their eventual adoption. Although a comprehensive list of quality indicators is proposed, we recognize that, ultimately, only a small subset might be widely used for continuous quality improvement, benchmarking, or quality reporting. As in 2006, the current task force concentrated its attention on parameters related solely to endoscopic procedures (Table 1). Although the quality of care delivered to patients is clearly influenced by many factors related to the facilities in which endoscopy is performed, characterization of unit-related quality indicators was not included in the scope of this effort.

The resultant quality indicators were graded on the strength of the supporting evidence (Table 2).[4] Each quality indicator was classified as an outcome or a process measure. Although outcome quality indicators are preferred, some can be difficult to measure in routine clinical practice, because they need analysis of large amounts of data and long-term follow-up and may be confounded by other factors. In such cases, the task force deemed it reasonable to use process indicators as surrogate measures of high-quality endoscopy. The relative value of a process indicator hinges on the evidence that supports its association with a clinically relevant outcome, and such process measures were emphasized.

The quality indicators for this update were written in a manner that lends them to be developed as measures. Although they remain quality indicators and not measures, this document also contains a list of performance targets for each quality indicator. The task force selected performance targets from benchmarking data in the literature when available. When data were unavailable to support establishing a performance target level, "N/A" (not available) was listed. However, when expert consensus considered failure to perform a given quality indicator a "never event," such as monitoring vital signs during sedation, then the performance target was listed as >98%. It is important to emphasize that the performance targets listed do not necessarily reflect the standard of care but rather serve as specific goals to direct quality improvement efforts (Table 3).

Quality indicators were divided into 3 time periods: preprocedure, intraprocedure, and postprocedure. For each category, key relevant research questions were identified.

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TABLE 1. Composition of the task force

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ASGE, American Society for Gastrointestinal Endoscopy; *ACG*, American College of Gastroenterology.

In order to guide continuous quality improvement efforts, the task force also recommended a high-priority subset of the indicators described, based on their clinical relevance and importance, on evidence that performance of the indicator varies significantly in clinical practice, and feasibility of measurement (a function of the number of procedures needed to obtain an accurate measurement with narrow confidence intervals and the ease of measurement). A useful approach for individual endoscopists is to first measure their performances with regard to these priority indicators. Quality improvement efforts would then move to different quality indicators if endoscopists are performing above recommended thresholds, or the employer and/or teaching center could institute corrective measures and remeasure performance of low-level performers.

Preprocedure quality indicators

The preprocedure period includes all contact between members of the endoscopy team with the patient before the administration of sedation or insertion of the endoscope. Common issues for all endoscopic procedures during this period include: appropriate indication, informed consent, risk assessment, formulation of a sedation plan, management of prophylactic antibiotics and antithrombotic drugs, and timeliness of the procedure.

1. *Frequency with which endoscopy is performed for an indication that is included in a published standard list of appropriate indications, and the indication is documented (priority indicator)*

   Level of evidence: 1C+
   Performance target: >80%
   Type of measure: process
   Standard indications for endoscopy are listed in the ASGE Appropriate Use of GI Endoscopy guideline.[5] An appropriate indication should be documented for each procedure, and, when it is not a standard indication listed in the current ASGE Appropriate Use of GI Endoscopy guideline, it should be justified in the documentation.

   Discussion: In general, endoscopy is indicated when the information gained or the therapy provided will improve patient outcomes and is not indicated when the risks of the procedure outweigh any possible benefit to the patient. ASGE published a list of accepted indications for endoscopic procedures in 2000.[6] This list was determined by a review of published literature and expert consensus and was updated in 2012.[5] There was little substantial change with regard to indications for EGD and colonoscopy in the update. Facilitation of cholangioscopy and pancreatoscopy were added as accepted indications for ERCP. Additional EUS indications were included, such as placement of fiducial markers, treatment of symptomatic pseudocysts, drug delivery, provision of access to the bile or pancreatic ducts, evaluation for chronic pancreatitis, perianal and perirectal disease, and screening patients at increased risk of pancreatic cancer. Studies have shown that when EGD and colonoscopy are done for appropriate indications, significantly more clinically relevant diagnoses

TABLE 2. Grades of recommendation*

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 are likely to be better under some circumstances
3	Unclear	Expert opinion only	Weak recommendation, likely to change as data becomes available

*Adapted from Guyatt G, Sinclair J, Cook D, et al. Moving from evidence to action. Grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, editors. Users' guides to the medical literature. Chicago: AMA Press; 2002. p. 599-608.

are made.[7-9,10] A quality improvement goal is to minimize the number of procedures without appropriate indications.

Open access endoscopy, where non-gastroenterologists schedule patients for endoscopy without prior consultation with the endoscopist is widely practiced.[11] Most studies have shown that open access endoscopies are done for appropriate indications.[12,13] A quality improvement goal is to establish processes that allow for feedback to referring physicians with regard to appropriateness of indication. Other quality improvements goals that are relevant to open access endoscopy include: availability of information about the procedure to patients in advance of the procedure, availability of clinical information to the endoscopist in advance of the procedure, reporting of endoscopic findings and recommendations to the referring physician, and establishment of appropriate follow-up.

2. *Frequency with which informed consent is obtained and fully documented*

   Level of evidence: 3

   Performance target: >98%

   Type of measure: process

   Consent should be obtained and documented for the procedure, except in cases of emergency, therapeutic privilege, waiver, or legal mandate. Consent should include a discussion of the sedation plan and risks associated with sedation, indication for the procedure, description of the procedure, likely benefits, common adverse events, alternatives to the procedure, and patient prognosis if treatment is declined. If sedation for the procedure is provided by an anesthesia provider, then a separate consent obtained by that provider may be appropriate.

   Discussion: Obtaining informed consent has several patient benefits. It facilitates a patient-centered process respecting patient autonomy and decision making. It allows the patient to receive the relevant information about the proposed procedure and to make an informed decision about whether or not to proceed with the recommended course of action. Finally, it provides the patient the opportunity to ask questions, increasing patient understanding and confidence in the health care team. ASGE guidelines on informed consent in endoscopy advise the endoscopist to obtain consent personally.[14] Consent may be supplemented by anatomic diagrams, brochures, and videos and by information provided by nurses and other assistants. A consent form designed specifically for a particular procedure that contains all the essential elements of consent may facilitate a full discussion with the patient.

TABLE 3. Summary of proposed quality indicators common to all endoscopic procedures*

Quality indicator	Grade of recommendation	Measure type	Performance target (%)
Preprocedure			
1. Frequency with which endoscopy is performed for an indication that is included in a published standard list of appropriate indications, and the indication is documented (priority indicator)	1C+	Process	>80
2. Frequency with which informed consent is obtained and fully documented	3	Process	>98
3. Frequency with which preprocedure history and directed physical examination are performed and documented	3	Process	>98
4. Frequency with which risk for adverse events is assessed and documented before sedation is started	3	Process	>98
5. Frequency with which prophylactic antibiotics are administered for appropriate indication (priority indicator)	Varies	Process	>98
6. Frequency with which a sedation plan is documented	Varies	Process	>98
7. Frequency with which management of antithrombotic therapy is formulated and documented before the procedure (priority indicator)	3	Process	N/A
8. Frequency with which a team pause is conducted and documented	3	Process	>98
9. Frequency with which endoscopy is performed by an individual who is fully trained and credentialed to perform that particular procedure	3	Process	>98
Intraprocedure			
10. Frequency with which photodocumentation is performed	3	Process	N/A
11. Frequency with which patient monitoring during sedation is performed and documented	3	Process	>98
12. Frequency with which the doses and routes of administration of all medications used during the procedure are documented	3	Process	>98
13. Frequency with which use of reversal agents is documented	3	Process	>98
14. Frequency with which procedure interruption and premature termination because of sedation-related issues is documented	3	Process	>98
Postprocedure			
15. Frequency with which discharge from the endoscopy unit according to predetermined discharge criteria is documented	3	Process	>98
16. Frequency with which patient instructions are provided	3	Process	>98

TABLE 3. Continued

Quality indicator	Grade of recommendation	Measure type	Performance target (%)
17. Frequency with which the plan for pathology follow-up is specified and documented	3	Process	>98
18. Frequency with which a complete procedure report is created	3	Process	>98
19. Frequency with which adverse events are documented	3	Process	>98
20. Frequency with which adverse events occur	3	Outcome	N/A
21. Frequency with which postprocedure and late adverse events occur and are documented	3	Outcome	N/A
22. Frequency with which patient satisfaction data are obtained	3	Process	N/A
23. Frequency with which communication with referring providers is documented	3	Process	N/A

N/A, Not available.
*This list of potential quality indicators is meant to be a comprehensive list of measurable endpoints. It is not the intention of the task force that all endpoints be measures in every practice setting. In most cases, validation may be required before a given endpoint may be adopted universally.

These forms may be especially useful for high-risk and complex procedures. The quality of informed consent has been an important medicolegal issue in a majority of ERCP procedures that resulted in litigation.[15] The optimal timing and location where informed consent is obtained is not known.

3. *Frequency with which preprocedure history and directed physical examination are performed and documented*
   Level of evidence: 3
   Performance target: >98%
   Type of measure: process
   Before sedation, a directed preprocedure history and physical examination should be performed and documented.

Discussion: ASGE and the American Society of Anesthesiologists (ASA) recommend a preprocedure assessment that includes a health history and directed physical examination that are performed before the patient is sedated and before endoscopy.[16-18] The Centers for Medicare & Medicaid Services and some accrediting bodies may not allow for documentation of a current patient history and physical examination to be solely on the endoscopy report and, therefore, separate documentation may be required. The history should focus on indications for the procedure as well as conditions that may affect the performance and safety of the procedure. The history also should emphasize sedation-related issues including (1) abnormalities of major organ systems; (2) previous adverse events with sedation or anesthesia; (3) medication allergies, current medications, and potential medication interactions; and (4) history of tobacco, alcohol or substance use or abuse.

The history should include the timing and nature of the patient's last oral intake. Although there are limited data on the impact of fasting on the risk of pulmonary aspiration, patients are generally required to cease oral intake after midnight before sedation and endoscopy. According to ASA practice guidelines, patients should not consume clear liquids for 2 hours, milk for 6 hours, a light meal for 6 hours, or a meal with fried or fatty food for 8 hours before sedation.[19] Patients with gastroparesis and achalasia may require a longer period of fasting to minimize risk of aspiration. The quantity of food consumed should be taken into consideration before determining actual period of fasting. Patients may take essential medications including bowel preparation before endoscopic procedures. A recent prospective observational study of colonoscopy patients demonstrated that residual volume of liquid in the stomach was minimal (< 25 mL) and similar whether patients split the bowel preparation or consumed all of the bowel preparation on the evening before the procedure.[20]

4. *Frequency with which risk for adverse events is assessed and documented before sedation is started*
   Level of evidence: 3
   Performance target: >98%
   Type of measure: process
   Before sedation is begun, a risk assessment for sedation-related adverse events is performed and documented. Stratification of patients by established methods such as the ASA score emphasizes the risk of sedation-related adverse events. This information should be used for decision making with regard to proceeding or deferring the procedure or modifying the procedure and sedation plan.

Discussion: The most commonly used scoring systems for stratifying risk before endoscopic procedures are the ASA score and the Mallampati score. The ASA score considers comorbid conditions and ranks patients on a 1 to 5 scale (1, normal and healthy to 5, critically ill and at substantial risk of death within 24 hours). Large studies that used endoscopy databases have shown that ASA scores[21] predict adverse events during endoscopy, primarily those that are related to sedation. The Mallampati score[22] uses a visual analogue scale to assess the upper airway. An increasing score correlates with difficulty encountered in endotracheal intubation. This score has not been validated as a risk stratification tool for endoscopic procedures, but it has gained clinical relevance with widespread use of deep sedation and, hence, possible need for urgent airway management.

5. *Frequency with which prophylactic antibiotics are administered for appropriate indication (priority indicator)*

   Level of evidence: varies by individual recommendation

   Performance target: >98%

   Type of measure: process

   Prophylactic antibiotics are administered only for selected settings for which they are indicated.

   Discussion: For most endoscopic procedures, prophylactic antibiotics are not indicated for prevention of bacterial endocarditis. ASGE updated its guidelines for the use of antibiotics before endoscopic procedures in 2008.[23] These differ substantially from previous guidelines in that GI endoscopy is no longer considered to be a significant risk factor for bacterial endocarditis. Therefore, antibiotics to prevent bacterial endocarditis are not recommended, even for patients who are at highest risk for endocarditis. Antibiotics are not recommended for patients having: cardiac conditions, synthetic vascular grafts, or other nonvalvular cardiovascular devices undergoing any endoscopic procedure (grade of recommendation = 1C+); biliary obstruction in the absence of cholangitis undergoing ERCP with anticipated complete drainage (grade of recommendation = 1C); solid lesions along the upper GI tract undergoing EUS-guided FNA (grade of recommendation = 1C); and prosthetic joints undergoing any endoscopic procedure (grade of recommendation = 1C).

   Prophylactic antibiotics are recommended in the following instances: (1) ERCP in patients in whom incomplete biliary drainage is anticipated (eg, primary sclerosing cholangitis) (grade of recommendation = 2C); (2) ERCP in patients with sterile pancreatic fluid collections that communicate with the pancreatic duct (eg, pseudocyst, necrosis) (grade of recommendation = 3); (3) ERCP in patients with posttransplant biliary strictures (grade of recommendation = 3); (4) EUS-guided FNA in patients with cystic lesions along the GI tract (grade of recommendation = 1C); (5) any endoscopic procedure in patients with cirrhosis and acute GI hemorrhage (grade of recommendation = 1B); and (6) percutaneous gastrostomy tube placement in all patients (grade of recommendation = 1A). Antibiotics may be indicated for ERCP if patients' clinical situations place them at higher risk of infection (eg, immune suppression, Caroli's disease). There are insufficient data to make recommendations for antibiotic prophylaxis for patients with solid lesions along the lower GI tract undergoing EUS-guided FNA.

   The American Heart Association guidelines concur with ASGE guidelines and, in addition, recommend prophylactic antibiotics for the first 6 months for patients who have undergone systemic vascular grafts.[24] ASGE guidelines differ from the recommendations of the American Academy of Orthopedic Surgeons (AAOS), which indicate that antibiotic prophylaxis should be given to patients with prosthetic joints before any invasive procedure known to cause bacteremia.[25] However, the AAOS recently changed its recommendations for patients with hip and knee prosthetic joint implants undergoing dental procedures, stating that the practitioner might consider discontinuing the practice of routinely prescribing prophylactic antibiotics.[25,26] ASGE guidelines do not address patients undergoing peritoneal dialysis, but the International Society for Peritoneal Dialysis recommends antibiotic prophylaxis and that the abdomen be emptied of fluid before colonoscopy with polypectomy.[27]

6. *Frequency with which a sedation plan is documented*

   Level of evidence: varies by individual recommendation

   Performance target: >98%

   Type of measure: process

   Before sedation is administered, the intended level of sedation is specified as no sedation, minimal sedation, moderate sedation, deep sedation, or general anesthesia.

   Discussion: Minimal sedation (or anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes and ventilatory and cardiovascular functions are unaffected.

   Moderate sedation (or conscious sedation) is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

   Deep sedation is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

   General anesthesia is a drug-induced loss of consciousness during which patients cannot be aroused, even by painful stimulation. The ability to independently maintain

ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

The ASA recommends that because sedation is a continuum, it may not be possible to predict how an individual patient will respond. Hence, physicians intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering moderate sedation should be able to rescue patients who enter a state of deep sedation, whereas those administering deep sedation should be able to rescue patients who enter a state of general anesthesia.[28]

7. *Frequency with which management of antithrombotic therapy is formulated and documented before the procedure (priority indicator)*

   Level of evidence: 3

   Performance target: N/A

   Type of measure: process

   Antithrombotic medication use by the patient is recorded, and a plan regarding periprocedural management of antithrombotic medications is documented and communicated to the patient and health care team.

   Discussion: ASGE guidelines regarding the management of patients taking antithrombotic agents undergoing endoscopy were updated in 2009.[29] In general, diagnostic endoscopic procedures are considered low risk for causing procedure-related bleeding and do not require cessation of antithrombotic agents. Some therapeutic endoscopic procedures are considered high risk for causing procedure-related bleeding and require cessation of some antithrombotic agents. Patients at high risk for thromboembolic adverse events may require bridge therapy, deferment of endoscopy, or consultation with a cardiologist. These high-risk conditions include atrial fibrillation associated with other cardiac conditions or a history of thromboembolism, mechanical mitral valve, coronary artery stent placed within a year, acute coronary syndrome, or non-stented percutaneous coronary intervention after myocardial infarction. Most endoscopic procedures can be performed safely without discontinuing aspirin. In the majority of nontherapeutic procedures, antithrombotic medications may be resumed immediately. In patients who have received endoscopic therapy, the timing of resumption needs to be individualized, taking into account the type of endoscopic therapy performed and the risk of thromboembolism. A quality improvement goal is to formulate and document a coordinated plan to manage antithrombotic medications for all patients taking these medications.

8. *Frequency with which a team pause is conducted and documented*

   Level of evidence: 3

   Performance target: >98%

   Type of measure: process

   Before administration of sedation or insertion of the endoscope, the endoscopy team pauses to confirm patient identity and type of procedure. This should be recorded.

   Discussion: A team pause (also referred to as time-out) before initiating any procedure requiring sedation or anesthesia is now mandated nationally by the Centers for Medicare & Medicaid Services and several accrediting organizations. The purpose of this pause is to verify that the correct patient is undergoing the desired procedure. If necessary, the pause may allow for reassessment of any history, laboratory test, or radiologic data that may affect the performance or safety of the endoscopic procedure. It also may provide an opportunity for the endoscopist to inform team members of the planned procedure and the potential for interventions or deviations from usual practice that would require special equipment.

9. *Frequency with which endoscopy is performed by an individual who is fully trained and credentialed to perform that particular procedure*

   Level of evidence: 3

   Performance Target: >98%

   Type of measure: process

   A quality endoscopy procedure is one performed by an endoscopist who has met objective measures for competency.

   Discussion: Achieving the desired objectives and minimizing adverse events ultimately define the quality of an endoscopic procedure. There is evidence that colonoscopy performed by a low-procedure–volume endoscopist is associated with an increased risk of perforation and bleeding.[30] The ASGE has published training and credentialing guidelines[31-35] that establish basic principles of competency, and these should be applied to the credentialing process wherever GI endoscopy is performed. Several important themes in this regard deserve emphasis: (1) objective measures of performance and not simply number of procedures performed in training should be used to define competency; (2) measures of competence, especially when well-established benchmarks are available, should be universal and not vary by specialty; (3) competency in one procedure should not necessarily imply competency in another; and (4) competency in a given endoscopic procedure should require that the endoscopist be able to perform minimum therapeutic maneuvers specific to that procedure (eg, standard polypectomy in colonoscopy and stent placement for distal biliary obstruction in ERCP).[32,36]

Preprocedure research questions

1. How often are procedures performed for inappropriate indications in clinical practice? What is the reason for performance of such procedures? Are there strategies that can minimize such procedures?
2. Do supplements such as pamphlets, videos, or interactive computer programs enhance patient understanding of the procedure during the consent process?

3. Do new preprocedure risk stratification tools that are specific for GI endoscopy need to be developed and validated?
4. Are referring physicians and endoscopists knowledgeable about new antibiotic prophylaxis guidelines?
5. What is the optimal and most cost-effective use of monitored anesthesia sedation for GI endoscopy? Does monitored anesthesia sedation influence endoscopists performance, endoscopy outcomes, or patient satisfaction?
6. What are the risks of stopping antithrombotic medications for endoscopy?
7. Can small colon polyps be removed in patients taking antithrombotic medications?
8. What are the optimal components of a team pause for endoscopy?
9. How prevalent is the use of recently proposed endoscopy-specific checklists, and does this process improve patient outcomes?

Intraprocedure quality indicators

The intraprocedure period extends from the administration of sedation, or insertion of the endoscope when no sedation is given, until the endoscope is removed. This period includes all the technical aspects of the procedure including completion of the examination and of therapeutic maneuvers. Common to most endoscopic procedures is the provision of sedation and need for patient monitoring.

10. *Frequency with which photodocumentation is performed*
    Level of evidence: 3
    Performance target: N/A
    Type of measure: process
    Photodocumentation of important anatomic landmarks and pathology should be performed.

Discussion: Although the effectiveness of endoscopic photography is unlikely to be proven in clinical studies, its use reflects current best practice and should be encouraged. Photographs of pathology may enhance patient understanding of the disease process, facilitate consultation with other physicians, and allow for precise comparisons during repeat procedures. This also may provide valuable information about the quality and completeness of prior evaluation when patients present at a later date with GI symptoms.

Cecal intubation rates of $\geq$95% are achievable in healthy adults.[37-39] Photodocumentation of the cecum is an integral part of the cecal intubation rate quality indicator and is included in the Physician Consortium for Performance Improvement/AGA/ASGE 2008 Endoscopy and Polyp Surveillance Measure Set. Photodocumentation of the cecum is the simplest and most practical method of verifying that a complete colonoscopy has been achieved.[40] It is recommended that key anatomical features like the appendiceal orifice with surrounding cecal strap fold and the cecum with ileocecal valve be photographed. Alternative images include the ileocecal valve orifice or the terminal ileum showing the presence of terminal ileal villi, circular valvulae conniventes, or lymphoid hyperplasia.[41] Photodocumentation of anatomic landmarks for other endoscopic procedures are not as well standardized but are encouraged.

11. *Frequency with which patient monitoring during sedation is performed and documented*
    Level of evidence: 3
    Performance target: >98%
    Type of measure: process
    During sedated endoscopic procedures the following parameters are monitored: oxygen saturation with pulse oximetry, pulse rate, and blood pressure. Blood pressure and pulse rate should be recorded at intervals no greater than 5 minutes.

Discussion: It is generally accepted that patient monitoring improves safety, even though none of the proposed monitoring parameters have been shown to improve outcome in well-designed studies. Patient monitoring recommendations for oximetry, pulse rate, and blood pressure are included in guidelines published by ASGE and ASA[17,42] and provide a means to detect potentially dangerous changes in a patient's cardiopulmonary status during sedation.[43] Although capnography monitoring has been shown to be associated with reduced hypoxemia in patients undergoing endoscopy under deep sedation with propofol there are no data yet to support the use of capnography monitoring in moderate sedation.[44]

12. *Frequency with which the doses and routes of administration of all medications used during the procedure are documented*
    Level of evidence: 3
    Performance target: >98%
    Type of measure: process
13. *Frequency with which use of reversal agents is documented*
    Level of evidence: 3
    Performance target: >98%
    Type of measure: process
    The use of reversal agents (eg, flumazenil, naloxone) should be recorded. This should be reported as the percentage of such events of all procedures using the same sedation agent (eg, the percent of time flumazenil was used for excessive sedation when midazolam was used as a sedative).

Discussion: As a surrogate to measuring airway management, some health care institutions have chosen to use the administration of reversal agents for an adverse event or unsafe procedure. The use of this indicator must be judicious because it may penalize physicians for use of these potentially life-saving medications. The task force strongly recommends that any use of this endpoint be accomplished in a nonpunitive manner so as not to discourage

the use of reversal agents. Although documentation of reversal agents used should be standard and such events scrutinized, it should be considered within the context of process improvement and not as an indirect measure of outcome.

14. *Frequency with which procedure interruption and premature termination because of sedation-related issues is documented*
    Level of evidence: 3
    Performance target: >98%
    Measure type: process
    Any sedation-related event including airway management that requires interruption and premature termination of the procedure should be documented.

Discussion: Clinical decision making in which the physician is constantly weighing the risks and benefits of the endoscopic procedure are the hallmark of good clinical care and are to be encouraged. Therefore, an aborted endoscopic procedure should not automatically be considered an adverse event. Such events should be scrutinized in a nonpunitive manner within the context of continuous quality improvement. When the cause of procedure interruption is related to oversedation or poor airway management, this should be recorded. As more sedation-related outcomes are studied, benchmarks for the outcome measure in the future may vary by procedure type, ASA classification, and type of sedation used.

Intraprocedure research questions

1. Do monitoring techniques, such as capnography, during routine endoscopic procedures under moderate and deep sedation improve detection of sedation-related adverse events with any impact on patient outcomes?
2. What is the optimal training requirement for gastroenterologists with regard to airway management and sedation?
3. What is the optimal sedation protocol for the following groups of patients: the obese, patients with sleep apnea, and patients classified as ASA class III or higher?
4. Does monitoring reversal agent administration as a quality indicator discourage their use and adversely affect patient outcomes?

Postprocedure quality indicators

The postprocedure period extends from the time the endoscope is removed to subsequent follow-up. Postprocedure activities include providing instructions to the patient, documentation of the procedure, recognition and documentation of adverse events, pathology follow-up, communication with referring physicians, and assessing patient satisfaction.

15. *Frequency with which discharge from the endoscopy unit according to predetermined discharge criteria is documented*
    Level of evidence: 3
    Performance target: >98%
    Measure type: process
    Documentation is required that the patient has met predetermined discharge criteria before discharge from the endoscopy unit.

Discussion: Every endoscopy unit should have a written policy regarding criteria the patient must meet before discharge from the unit.[43] Documentation that the patient has achieved these criteria should be made.

16. *Frequency with which patient instructions are provided*
    Level of evidence: 3
    Performance target: >98%
    Measure type: process
    Written discharge instruction should be provided in compliance with ASGE guidelines.[43]

Discussion: Clear written instructions should be provided to the patient before discharge. These instructions should include: diet restrictions, resumption or change in medications including antithrombotic agents, prescription of medications, return to activities such as driving, and contact information should an adverse event, question or emergency arise.[44] Patients should be informed of signs and symptoms of delayed adverse events potentially relating to the procedure performed that should prompt a call to the physician. Patients should be told how they will be informed of relevant biopsy results. Information concerning necessary follow-up appointments or lack of need for such should be included.

17. *Frequency with which the plan for pathology follow-up is specified and documented*
    Level of evidence: 3
    Performance target: >98%
    Measure type: process
    When biopsy specimens have been obtained, the management plan for the patient and notification of this plan to the referring physician should be documented.

Discussion: The pathology results frequently alter or determine subsequent management plans (eg, timing of surveillance colonoscopy, need for *Helicobacter pylori* treatment). Integration of pathology results into the care plan requires that the patient and the referring physician be notified of these findings and their implications. Patients may be notified by letter, electronically, by telephone call, or during a subsequent follow-up visit (with the endoscopist or other provider). Similarly, referring physicians should be notified of pathology results. The frequency with which patient and referring physicians actually receive pathology results and that these were integrated into a care plan is a more meaningful quality indicator than simple documentation of a notification plan. With increasing use and integration of electronic medical records, measurement of such more meaningful indicators may be readily possible in the future.

18. *Frequency with which a complete procedure report is created*

Level of evidence: 3
Performance target: >98%
Measure type: process
Procedure reports are required for every endoscopic procedure and should be accurate, succinct, and completed in a timely manner.

Discussion: Accurate and timely documentation of endoscopic findings and recommendations enhances patient care.[40] The task force emphasizes that the procedure report be detailed, yet succinct. Requiring the inclusion of unnecessary details (eg, amount of blood loss during screening colonoscopy) distracts from relevant findings. Standardization of the language and structure of endoscopic reports may improve communication between physicians, enhance performance improvement activities, advance research activities, and foster international collaboration. Electronic medical records and computerized endoscopic report generating systems may greatly aid in this task. Quality assessment and "pay for performance" programs that depend on the collection of reliable, reproducible data benefit from such standardization. One such scheme is the Minimal standard terminology for gastrointestinal endoscopy—MST 3.0. proposed by the World Organization of Digestive Endoscopy.[45] This document forms the basis for computer software by offering standard lists of terms to be used in the structured documentation of endoscopic findings. The Quality Assurance Task Group of the National Colorectal Cancer Roundtable also has developed a reporting and data system that is specific for colonoscopy.[40] The goal of this tool is to provide endoscopists with a quality improvement instrument and to provide referring physicians with a colonoscopy report that uses standard terms and provides evidence-based follow-up recommendations.

The following are the minimal elements of an endoscopy.[40]

1. Date of procedure
2. Patient identification data
3. Endoscopist(s)
4. Assistant(s) and trainee participation in procedure
5. Documentation of relevant patient history and physical examination (if not separately documented)
6. Confirmation of informed consent
7. Endoscopic procedure (both planned and performed are required)
8. Indication(s)
9. Type of endoscopic instrument
10. Medication (anesthesia, analgesia, sedation)
11. Anatomic extent of examination
12. Limitation(s) of examination
13. Tissue or fluid samples obtained
14. Findings
15. Diagnostic impression
16. Results of therapeutic intervention (if any)
17. Adverse events (if any)
18. Disposition
19. Recommendations for subsequent care

19. Frequency with which adverse events are documented

Level of evidence: 3
Performance target: >98%
Measure type: process
Adverse events should be classified according to their timing, level of certainty of attribution to the endoscopic procedure, and degree of consequent disturbance to the patient, and this should be documented.

Discussion: Improving the safety of endoscopy is a major goal of the ASGE, ACG, and AGA and is consistent with efforts spearheaded by the Institute of Medicine.[46] There is evidence suggesting that adverse event rates may be 2 to 3 times higher than previously documented and reported.[47] An ASGE task force proposed definitions and classification of endoscopy-related adverse events in an attempt to standardize data collection and reporting.[48] An adverse event is one that prevents completion of the planned procedure or results in admission to the hospital, prolongation of existing hospital stay, another procedure (needing sedation and/or anesthesia), or subsequent medical consultation. Adverse events can be subdivided based on timing as preprocedure, intraprocedure (from the administration of sedation, or insertion of the endoscope when no sedation is given, until the endoscope is removed), postprocedure (up to 14 days), and late (any time after 14 days). A level of certainty of attribution to the endoscopic procedure as definite, probable, possible, or unlikely should be recorded. Severity of adverse events should be graded by the degree of consequent disturbance to the patient and any changes in the plan of care as mild, moderate, severe, or fatal. Preprocedure and intraprocedure adverse events that are evident on completion of endoscopy should be recorded in the endoscopy report. Adverse events that are recognized later also should be recorded. Ideally, this documentation should be linked to the original endoscopy report as an addendum.

20. Frequency with which adverse events occur

Level of evidence: 3
Performance target: N/A
Measure type: outcome

Discussion: Periprocedural adverse events vary from mild postprocedure bloating to cardiopulmonary arrest. The rate of cardiopulmonary adverse events in large, national studies is between 0.01% and 0.6%.[49-52] Patient-related risk factors for cardiopulmonary adverse events include preexisting cardiopulmonary disease, advanced age, ASA class III or higher, and an increased modified Goldman score.[53] Prospective, multicenter registries report perforation rates of 0.01% to 0.04% for upper endoscopies, whereas the rate of perforation during colonoscopy is generally less than 0.1%.[54-57] In general, perforation rates >0.1% during screening colonoscopies or 0.2% for all colonoscopies should raise concerns as to whether

TABLE 4. Priority quality indicators common to all GI endoscopic procedures*

Frequency with which endoscopy is performed for an indication that is included in a published standard list of appropriate indications, and the indication is documented
Frequency with which prophylactic antibiotics are administered for appropriate indication
Frequency with which management of antithrombotic therapy is formulated and documented before the procedure

*See text for specific targets and discussion.

inappropriate practices are the cause of the perforations.[58] Perforation rates with ERCP range from 0.1% to 0.6%.[59-61] Early identification and expeditious management of a perforation have been shown to decrease associated morbidity and mortality.[54,56,61,62] Although perforation often requires surgery, endoscopic repair may be appropriate in select individuals.[63]

Hemorrhage is most often associated with polypectomy but can happen after ERCP with or without sphincterotomy, mucosal resection, gastrostomy placement, stent placement, or dilation.[49,51,52] When associated with polypectomy, hemorrhage may occur immediately or can be delayed for several weeks after the procedure.[64] A number of large studies have reported hemorrhage rates of 0.1% to 0.6% after colonoscopy.[56] For routine clinical practice, bleeding rates for polypectomy should be $<1\%$.[58] A study analyzing over 50,000 colonoscopies by using Medicare claims found that the rate of GI hemorrhage was significantly different with or without polypectomy: 2.1 per 1000 procedures coded as screening without polypectomy and 3.7 per 1000 for procedures coded as diagnostic without polypectomy, compared with 8.7 per 1000 for any procedures with polypectomy.[65]

21. *Frequency with which postprocedure and late adverse events occur and are documented*
    Level of evidence: 3
    Performance target: N/A
    Measure type: outcome
    Attempts should be made to contact patients about 14 days after endoscopy to determine whether any adverse events had occurred after discharge from the endoscopy unit and whether these were attributable to the procedure.

Discussion: The task force recognizes the challenges of collecting complete and reliable data on postprocedure and late adverse events resulting from endoscopy. To emphasize the importance of collecting and recording postprocedure and late adverse events, this is stated as a separate quality indicator. The significant added cost and use of human resources necessary to perform 14-day follow-up remain an obstacle. Voluntary reporting of adverse events alone is neither ideal nor sufficient because 15% to 45% of adverse events go unrecognized or unreported.[57,66,67] This task force also recommends that endoscopy report generators allow these data to be included as an addendum to the endoscopy report. When absence of any adverse event is confirmed by direct patient contact, such information should be added.[45,48] We anticipate that adherence to this quality indicator will become more easily accomplished with future integration of interoperable electronic health records, practice management systems, and endoscopy report writers, which will allow searchable data warehouses to identify delayed adverse events.

22. *Frequency with which patient satisfaction data are obtained*
    Level of evidence: 3
    Performance target: N/A
    Measure type: process
    Information on patient satisfaction is collected by use of a validated and standardized questionnaire.

Discussion: ASGE, in its publications "Quality and outcomes assessment in gastrointestinal endoscopy," recommends the use of a validated questionnaire of patient satisfaction (GHAA 9) modified for use after endoscopic procedures.[46,68,69] For smaller practices, it may be reasonable to offer surveys to all patients, whereas, in other settings, a random sample may be appropriate. It is anticipated that these survey results will be reviewed within a continuous quality improvement process. As greater percentages of patients provide satisfaction feedback and as benchmarks for patient satisfaction surveys are defined, true outcome indicators of patient satisfaction may become feasible.

23. *Frequency with which communication with referring providers is documented*
    Level of evidence: 3
    Performance target: N/A
    Measure type: process
    The results of the endoscopic procedure and follow-up recommendations must be communicated to the referring provider or primary care physician, and this communication should be documented.

Discussion: Lack of communication of endoscopic results with other care providers may result in patient mismanagement. It is the responsibility of the endoscopist to provide results and recommendations regarding therapy, further diagnostic testing, and follow-up to the referring physician, primary provider, or other relevant health care providers. This may be done by letter, facsimile, telephone call, secure e-mail, or forwarded electronic medical record communication. In particular, patients with confirmed or suspected malignancies need documentation of plans for further follow-up, staging, and treatment.

Postprocedure research questions

1. How often do patients comply with instructions on resumption of driving after sedation? Can patients drive after being given propofol sedation?
2. Does giving a copy of the procedure report directly to the patient affect patient satisfaction or compliance with follow-up recommendations?
3. Does the use of standardized terminology improve communication and compliance with postprocedure recommendations?
4. Would the practice of using required fields to report quality indicators improve the reliability of data obtained from the computerized reports for benchmarking and quality reporting?
5. What factors improve patient satisfaction with endoscopy?

Priority quality indicators

The recommended priority indicators that are common to all endoscopic procedures are (1) appropriate indication—endoscopy performed for an appropriate indication, (2) prophylactic antibiotics—prophylactic antibiotics administered only for selected settings in which they are indicated, and (3) antithrombotic therapy—antithrombotic medication use by the patient recorded and a plan regarding management of antithrombotic medications in place (Table 4). For each of these indicators, reaching the recommended performance target is considered strongly associated with important clinical outcomes. These indicators can be measured readily in a manageable number of examinations.

Conclusions

Quality assurance and pay-for-performance programs are increasingly playing a vital role in health care policy. By providing incentives to good clinical practices and by penalizing unnecessary and suboptimal care, policymakers rationalize that clinical outcomes will improve while reducing health care spending. For practitioners to differentiate between good and suboptimal clinical care, these programs require need-validated and robust quality indicators. These programs now influence practice patterns and reimbursement. The law of unintended consequences applies to measurement of quality, therefore, it is paramount that endoscopists and their representative organizations remain intimately involved in the development of these quality indicators. Our goal is to develop a rational and evidence-based system of benchmarks for every quality indicator. The benchmark will be set such that every well-trained endoscopist committed to patient care will be able to meet them without undue burden. However, the benchmarks will need to be set high enough to identify underperforming providers who may benefit from remediation. It is anticipated that endoscopy units will select a subset of these indicators most appropriate for their needs. These indicators should then be measured and reported. If the benchmarks associated with these indicators already are being met, then another set of indicators should be chosen to further the process of continuous quality improvement. If performance falls below the benchmarks, then remediation programs should be developed and implemented. Indicators should be remeasured periodically to determine the effectiveness of such programs.

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Abbreviations: AAOS, American Academy of Orthopedic Surgeons; ACG, American College of Gastroenterology; AGA, American Gastroenterological Association; ASA, American Society of Anesthesiologists; ASGE, American Society for Gastrointestinal Endoscopy.

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Quality indicators for EGD

EGD is used widely for the diagnosis and treatment of esophageal, gastric, and small-bowel disorders. When properly performed, it is generally safe and well-tolerated for the examination of the upper GI tract. Included among the many accepted indications for EGD are evaluation of dysphagia, GI bleeding, peptic ulcer disease, medically refractory GERD, esophageal strictures, celiac disease, and unexplained diarrhea. During EGD evaluation, diagnostic biopsies can be performed as well as therapies to achieve hemostasis and dilation or stenting for significant strictures. In 2009, an estimated 6.9 million EGD procedures were performed in the United States at an estimated cost of $12.3 billion dollars. From 2000 to 2010, a 50% increase in EGD utilization was observed among Medicare recipients.[1]

The quality of health care can be measured by comparing the performance of an individual or a group of individuals with an ideal or benchmark.[2] The particular parameter that is being used for comparison is termed a quality indicator. Quality indicators may be reported as a ratio between the incidence of correct performance and the opportunity for correct performance or as the proportion of interventions that achieve a predefined goal.[3] Quality indicators can be divided into 3 categories: (1) structural measures—these assess characteristics of the entire health care environment (eg, participation by a physician or other clinician in a systematic clinical database registry that includes consensus endorsed quality measures), (2) process measures—these assess performance during the delivery of care (eg, frequency with which appropriate prophylactic antibiotics are given before placement of a PEG tube), and (3) outcome measures—these assess the results of the care that was provided (eg, rates of adverse events after EGD).

METHODOLOGY

In 2006, the American Society for Gastrointestinal Endoscopy (ASGE)/American College of Gastroenterology (ACG) Task Force on Quality in Endoscopy published the first version of quality indicators for EGD.[4] The present update integrates new data pertaining to previously proposed quality indicators and new quality indicators for performing EGD. Indicators that had wide-ranging clinical application, were associated with variation in practice and outcomes, and were validated in clinical studies were prioritized. Clinical studies were identified through a computerized search of Medline followed by review of the bibliographies of all relevant articles. When such studies were absent, indicators were chosen by expert consensus. Although feasibility of measurement was a consideration, it is hoped that inclusion of highly relevant, but not yet easily measurable, indicators would promote their eventual adoption. Although a comprehensive list of quality indicators is proposed, ultimately, only a small subset might be widely used for continuous quality improvement, benchmarking, or quality reporting. As in 2006, the current task force concentrated its attention on parameters related solely to endoscopic procedures. Although the quality of care delivered to patients is clearly influenced by many factors related to the facilities in which endoscopy is performed, characterization of unit-related quality indicators was not included in the scope of this effort.

The resultant quality indicators were graded on the strength of the supporting evidence (Table 1). Each quality indicator was classified as an outcome or a process measure. Although outcome quality indicators are preferred, some can be difficult to measure in routine clinical practice, because they need analysis of large amounts of data and long-term follow-up and may be confounded by other factors. In such cases, the task force deemed it reasonable to use process indicators as surrogate measures of high-quality endoscopy. The relative value of a process indicator hinges on the evidence that supports its association with a clinically relevant outcome, and such process measures were emphasized.

The quality indicators for this update were written in a manner that lends them to be developed as measures. Although they remain quality indicators and not measures, this document also contains a list of performance targets for each quality indicator. The task force selected performance targets from benchmarking data in the literature when available. When data were unavailable to support establishing a performance target level, "N/A" (not available) was listed. However, when expert consensus considered failure to perform a given quality indicator a "never event," such as monitoring vital signs during sedation, then the performance target was listed as >98%. It is important to emphasize that the performance targets listed do not necessarily reflect the standard of care but rather serve as specific goals to direct quality improvement efforts.

Quality indicators were divided into 3 time periods: preprocedure, intraprocedure, and postprocedure. For each category, key relevant research questions were identified.

In order to guide continuous quality improvement efforts, the task force also recommended a high-priority subset of the

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TABLE 1. Grades of recommendation*

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

*Adapted from Guyatt G, Sinclair J, Cook D, et al. Moving from evidence to action. Grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, editors. Users' guides to the medical literature. Chicago: AMA Press; 2002. p. 599-608.

indicators described, based on their clinical relevance and importance, on evidence that performance of the indicator varies significantly in clinical practice, and feasibility of measurement (a function of the number of procedures needed to obtain an accurate measurement with narrow confidence intervals [CI] and the ease of measurement). A useful approach for individual endoscopists is to first measure their performances with regard to these priority indicators. Quality improvement efforts would then move to different quality indicators if endoscopists are performing above recommended thresholds, or the employer and/or teaching center could institute corrective measures and remeasure performance of low-level performers.

Recognizing that certain quality indicators are common to all GI endoscopic procedures, such items are presented in detail in a separate document, similar to the process in 2006.[5] The preprocedure, intraprocedure, and postprocedure indicators common to all endoscopy are listed in Table 2. Those common factors will be discussed only in this document insofar as the discussion needs to be modified specifically to relate to EGD.

Preprocedure quality indicators

The preprocedure period includes all contact between members of the endoscopy team and the patient before the administration of sedation or insertion of the endoscope. Common issues for all endoscopic procedures during this period include: appropriate indication, informed consent, risk assessment, formulation of a sedation plan, management of prophylactic antibiotics and antithrombotic drugs, and timeliness of the procedure.[5] Preprocedure quality indicators specific to EGD include the following:

1. *Frequency with which EGD is performed for an indication that is included in a published standard list of appropriate indications, and the indication is documented*
   Level of evidence: 1C+
   Performance target: >80%
   Type of measure: process
   Discussion: The accepted indications for EGD are reviewed in detail in a recently updated document by the ASGE Standards of Practice Committee (Table 3).[6] The indications for EGD have expanded to include endoscopic therapy for Barrett's esophagus (BE), intraoperative evaluation of reconstructed anatomic reconstructions typical of modern foregut surgery, and management of operative adverse events. Performing EGD for an accepted indication is associated with a statistically higher rate of clinically relevant findings.[7,8] In one

TABLE 2. Summary of proposed quality indicators common to all endoscopic procedures*[,23]

Quality indicator	Grade of recommendation	Measure type	Performance target (%)
Preprocedure			
1. Frequency with which endoscopy is performed for an indication that is included in a published standard list of appropriate indications, and the indication is documented (priority indicator)	1C+	Process	>80
2. Frequency with which informed consent is obtained and fully documented	3	Process	>98
3. Frequency with which preprocedure history and directed physical examination are performed and documented	3	Process	>98
4. Frequency with which risk for adverse events is assessed and documented before sedation is started	3	Process	>98
5. Frequency with which prophylactic antibiotics are administered only for selected settings in which they are indicated (priority indicator)	Varies	Process	>98
6. Frequency with which a sedation plan is documented	Varies	Process	>98
7. Frequency with which management of antithrombotic therapy is formulated and documented before the procedure (priority indicator)	3	Process	N/A
8. Frequency with which a team pause is conducted and documented	3	Process	>98
9. Frequency with which endoscopy is performed by an individual who is fully trained and credentialed to perform that particular procedure	3	Process	>98
Intraprocedure			
10. Frequency with which photodocumentation is performed	3	Process	N/A
11. Frequency with which patient monitoring among patients receiving sedation is performed and documented	3	Process	>98
12. Frequency with which the doses and routes of administration of all medications used during the procedure are documented	3	Process	>98
13. Frequency with which use of reversal agents is documented	3	Process	>98
14. Frequency with which procedure interruption and premature termination because of oversedation or airway management issues is documented	3	Process	>98
Postprocedure			
15. Frequency with which discharge from the endoscopy unit according to predetermined discharge criteria is documented	3	Process	>98
16. Frequency with which patient instructions are provided	3	Process	>98

TABLE 2. Continued

Quality indicator	Grade of recommendation	Measure type	Performance target (%)
17. Frequency with which the plan for pathology follow-up is specified and documented	3	Process	>98
18. Frequency with which a complete procedure report is created	3	Process	>98
19. Frequency with which immediate adverse events requiring interventions are documented	3	Process	>98
20. Frequency with which immediate adverse events requiring interventions including hospitalization occur	3	Outcome	N/A
21. Frequency with which delayed adverse events leading to hospitalization or additional procedures or medical interventions occur within 14 days	3	Outcome	N/A
22. Frequency with which patient satisfaction data are obtained	3	Process	N/A
23. Frequency with which communication with referring providers is documented	3	Process	N/A

N/A, Not available.
*This list of potential quality indicators is meant to be a comprehensive list of measurable endpoints. It is not the intention of the task force that all endpoints be measures in every practice setting. In most cases, validation may be required before a given endpoint may be adopted universally.

study, the odds ratio (OR) for finding a clinically relevant lesion by using an appropriate indication was 1.34 (95% CI, 1.04-1.74).[7] This process measure requires documentation in the procedure report. When a procedure is performed for a reason that is not listed in Table 3, justification for the procedure should be documented.

2. *Frequency with which informed consent is obtained, including specific discussions of risks associated with EGD, and fully documented*
   Level of evidence: 3
   Performance target: >98%
   Type of measure: process
   In addition to the risks associated with all endoscopic procedures, the consent should address the relevant and substantial adverse events pertaining to each specific EGD procedure.
   Discussion: As with any procedure that abides by the accepted biomedical ethical principle of patient autonomy, consent must be obtained from the patient or guardian before EGD on the same day as the procedure (or as required by local law or institutional policy). Adequate time must be allotted to discuss the risks, benefits, and alternatives to the procedure for the patient to voluntarily make a fully informed decision. In rare exceptions, such as in a life-threatening emergency, informed consent can be abridged or omitted. Further guidance on informed consent can be found in a position statement by the ASGE Standards of Practice of Committee.[9] The particular risks associated with EGD include bleeding, perforation, infection, cardiopulmonary adverse events, missed diagnosis, missed lesions, intravenous site adverse events, chest pain, sore throat, aspiration, and reaction to local anesthetic spray.[10-12] As a quality indicator, informed consent is a process measure based on expert opinion and supported by principles of biomedical ethics. A clinical study that correlates the presence or absence of informed consent with clinical outcomes has not been, and is not likely to be, performed.
3. *Frequency with which appropriate prophylactic antibiotics are given in patients with cirrhosis with acute upper GI bleeding before EGD (priority indicator)*
   Level of evidence: 1B
   Performance target: >98%
   Type of measure: process
   Discussion: A Cochrane systematic review of 12 studies showed a relative risk (RR) reduction of death (RR 0.79; 95% CI, 0.63-0.98), bacterial infections (RR 0.36; 95% CI, 0.27-0.49), and rebleeding (RR 0.53; 95% CI, 0.38-0.74) with antibiotic prophylaxis for patients with cirrhosis and acute upper GI bleeding.[13] Independent of performing EGD, antibiotic prophylaxis should be administered in this population.[14] Oral fluoroquinolones can be recommended safely for most patients, but intravenous ceftriaxone may be preferred in advanced cirrhosis and in areas of high fluoroquinolone resistance.[15-17] Antibiotic selection may change over time as new agents become available and drug resistance patterns change. This is a process measure for which an evidence-based correlation of a clinically beneficial outcome exists.

TABLE 3. Indications and contraindications for EGD[6]

1. EGD is generally indicated for evaluating:	A. Upper abdominal symptoms, which persist despite an appropriate trial of therapy B. Upper abdominal symptoms associated with other symptoms or signs suggesting serious organic disease (eg, anorexia and weight loss) or in patients aged >45 years C. Dysphagia or odynophagia D. Esophageal reflux symptoms, which are persistent or recurrent despite appropriate therapy E. Persistent vomiting of unknown cause F. Other diseases in which the presence of upper GI pathology might modify other planned management. Examples include patients who have a history of ulcer or GI bleeding who are scheduled for organ transplantation, long-term anticoagulation, or chronic nonsteroidal anti-inflammatory drug therapy for arthritis and those with cancer of the head and neck G. Familial adenomatous polyposis syndromes H. For confirmation and specific histologic diagnosis of radiologically demonstrated lesions: 1. Suspected neoplastic lesion 2. Gastric or esophageal ulcer 3. Upper tract stricture or obstruction I. GI bleeding: 1. In patients with active or recent bleeding 2. For presumed chronic blood loss and for iron deficiency anemia when the clinical situation suggests an upper GI source or when colonoscopy result is negative J. When sampling of tissue or fluid is indicated K. In patients with suspected portal hypertension to document or treat esophageal varices L. To assess acute injury after caustic ingestion M. Treatment of bleeding lesions such as ulcers, tumors, vascular abnormalities (eg, electrocoagulation, heater probe, laser photocoagulation, or injection therapy) N. Banding or sclerotherapy of varices O. Removal of foreign bodies P. Removal of selected polypoid lesions Q. Placement of feeding or drainage tubes (peroral, PEG, or percutaneous endoscopic jejunostomy) R. Dilation of stenotic lesions (eg, with transendoscopic balloon dilators or dilation systems by using guidewires) S. Management of achalasia (eg, botulinum toxin, balloon dilation) T. Palliative treatment of stenosing neoplasms (eg, laser, multipolar electrocoagulation, stent placement) U. Endoscopic therapy for intestinal metaplasia V. Intraoperative evaluation of anatomic reconstructions typical of modern foregut surgery (eg, evaluation of anastomotic leak and patency, fundoplication formation, pouch configuration during bariatric surgery) W. Management of operative adverse events (eg, dilation of anastomotic strictures, stenting of anastomotic disruption, fistula, or leak in selected circumstances)
2. EGD is generally not indicated for evaluating:	A. Symptoms that are considered functional in origin (there are exceptions in which an endoscopic examination may be done once to rule out organic disease, especially if symptoms are unresponsive to therapy) B. Metastatic adenocarcinoma of unknown primary site when the results will not alter management C. Radiographic findings of: 1. Asymptomatic or uncomplicated sliding hiatal hernia 2. Uncomplicated duodenal ulcer that has responded to therapy 3. Deformed duodenal bulb when symptoms are absent or respond adequately to ulcer therapy
3. Sequential or periodic EGD may be indicated:	A. Surveillance for malignancy in patients with premalignant conditions (ie, Barrett's esophagus)
4. Sequential or periodic EGD is generally not indicated for:	A. Surveillance for malignancy in patients with gastric atrophy, pernicious anemia, or prior gastric operations for benign disease B. Surveillance of healed benign disease such as esophagitis or gastric or duodenal ulcer C. Surveillance during repeated dilations of benign strictures unless there is a change in status

4. *Frequency with which appropriate prophylactic antibiotics are given before placement of a PEG tube*
   Level of evidence: 1A
   Performance target: >98%
   Type of measure: process
   Discussion: A Cochrane systematic review incorporating over 1000 patients in 10 clinical trials showed a decreased peristomal infection rate with antibiotic prophylaxis.[18] Antibiotics that cover cutaneous sources of bacterial infection such as intravenous cefazolin should be administered 30 minutes before the procedure.[19] Where methicillin-resistant *Staphylococcus aureus* is highly prevalent, screening with decontamination should be performed.[20]
5. *Frequency with which a proton pump inhibitor (PPI) is used for suspected peptic ulcer bleeding (priority indicator)*
   Level of evidence: 1B
   Performance target: >98%
   Type of measure: process
   Discussion: When possible, the intravenous PPI should be started on presentation with bleeding and before EGD. Intravenous PPI treatment before EGD reduces the proportion of high-risk stigmata seen at index endoscopy (OR 0.67; 95% CI, 0.54-0.84) and need for endoscopic therapy (OR 0.68; 95% CI, 0.50-0.93) when compared with controls. In a Cochrane review of 6 randomized clinical trials, however, no statistically significant difference in mortality (OR 1.12; 95% CI, 0.72-1.73) between PPI and control treatment was observed.[21]
6. *Frequency with which vasoactive drugs are initiated before EGD for suspected variceal bleeding*
   Level of evidence: 1B
   Performance target: >98%
   Type of measure: process
   Discussion: In a meta-analysis of 30 clinical trials involving over 3000 patients, the use of vasoactive medications and their analogues, such as terlipressin and octreotide, was associated with a lower risk of 7-day mortality (RR 0.74; 95% CI, 0.57-0.95) and a significant improvement in hemostasis (RR 1.21; 95% CI, 1.13-1.30).[22] There was no difference in efficacy among the different vasoactive medications.

Preprocedure research questions

1. What is the optimal antithrombotic management before therapeutic EGD procedures?
2. What are the adverse event rates of physicians relative to recently updated antibiotic prophylaxis recommendations for cardiac conditions, synthetic vascular grafts, nonvalvular cardiac devices, and orthopedic prostheses?
3. Is there sufficient interoperator and intraoperator variability in risk stratification to explain sedation-related adverse events?
4. What is the optimal sedation regimen and setting for EGD in patients with obesity and sleep apnea?
5. What are barriers to wider use of EGD without patient sedation?
6. How often do endoscopists in the community comply with surveillance guidelines for nondysplastic BE?
7. How often is endoscopy performed for other than an appropriate indication in the community, and what are the barriers to wider adherence to recommendations regarding indications?

Intraprocedure quality indicators

The intraprocedure period extends from the administration of sedation, or insertion of the endoscope when no sedation is given, to the removal of the endoscope. This period includes all the technical aspects of the procedure including completion of the examination and therapeutic maneuvers. Common to most endoscopic procedures is the provision of sedation and need for patient monitoring.[23] Intraprocedure quality indicators specific to performance of EGD include the following:

7. *Frequency with which a complete examination of the esophagus, stomach, and duodenum, including retroflexion in the stomach, is conducted and documented*
   Level of evidence: 3
   Performance target: >98%
   Type of measure: process
   Discussion: Except in cases of esophageal or gastric outlet obstruction, every EGD should include complete visualization of all the organs of interest from the upper esophageal sphincter to the second portion of the duodenum. Complete examination may require efforts to clear material from the stomach or esophagus, as in assessment for the source of upper GI hemorrhage. Written documentation should confirm the extent of the examination. If a clinically significant abnormality is encountered, photodocumentation is indicated. In studies of the learning curve of EGD, over 90% of trainees successfully perform technically complete EGD after 100 cases, and technical proficiency may be accelerated through the use of simulators.[24,25] It is reasonable to expect that any practicing endoscopist be capable of visualizing the organs of interest with rare exception. Given the recent increase in gastric cardia cancers, this should include retroflexion in the stomach in all cases.[26]
8. *Among those with nonbleeding gastric ulcers, frequency with which gastric biopsy specimens are taken to exclude malignancy*
   Level of evidence: 2C
   Performance target: >80%
   Type of measure: process
   Discussion: Careful attention to the presence of mucosal abnormalities during EGD is crucial. The acquisition of adequate and appropriate samples demonstrates an understanding of the importance of a complete and thorough examination. Biopsy specimens from gastric ulcers are required to assess for the possibility of malignancy. The optimal number and type

(maximum-capacity vs standard) has not been determined; however, a single biopsy may not detect malignancy in as many as 30% of those with gastric cancer. Four or more biopsies detect >95% of malignancies.[27] In the setting of acute GI bleeding, the endoscopist may choose to defer biopsy of the ulcer, provided that a subsequent endoscopy is planned.

9. *Frequency with which BE is appropriately measured when present*
   Level of evidence: 2C
   Performance target: >98%
   Type of measure: process
   Discussion: BE may be present in up to 5% to 15% of high-risk patients (eg, older white men with GERD symptoms) undergoing upper endoscopy.[28] The risk of progression to dysplasia or cancer may be related to the length of Barrett's epithelium.[29,30] In addition, in patients eventually needing endoscopic therapy for BE, the amount of involved tissue may influence both the endoscopic approach and the choice of sedation modality. Therefore, it is important to characterize and document the length and location of the salmon-colored mucosa during EGD. Although a single measurement may describe the total length of the BE in the tubular esophagus, the Prague classification is a validated, widely used, more descriptive system that describes both the circumferential and maximal extent of the BE.[31,32] This system defines the distance from the top of the gastric folds to the most proximal extent of the BE as the maximal (M) extent of the BE. The distance from the top of the gastric folds to the most proximal extent of the circumferential involvement of the BE is the circumferential (C) measurement. Assessment of the endoscopic involvement of columnar tissue is essential because intestinal metaplasia of the Z line may occur in up to 18% of individuals with GERD symptoms and does not, without accompanying endoscopic findings, constitute BE.[33] Intestinal metaplasia of the Z line is not known to carry sufficient cancer risk to warrant surveillance programs when this is diagnosed. Accordingly, it is important that when the presence of BE tissue is suspected, these landmarks are clearly documented.
10. *Frequency with which biopsy specimens are obtained in cases of suspected BE*
    Level of evidence: 2C
    Performance target: >90%
    Type of measure: process
    Discussion: Criteria for the diagnosis of BE are debated. Although some professional societies in other countries consider any columnar epithelium in the tubular esophagus consistent with the diagnosis of BE,[34] professional societies in the United States have traditionally required specialized or intestinal epithelium with goblet cells to fulfill the diagnosis,[35,36] and only such patients to be candidates for surveillance protocols. Recent data suggest that patients with intestinalized metaplasia of the esophagus are at 5-fold increased risk of progression to high-grade dysplasia or cancer compared with those with columnar-lined esophagus without goblet cells.[37] Although the endoscopic appearance may suggest BE, a definitive diagnosis cannot be made without pathology confirmation. For patients with known BE undergoing EGD with no contraindication to endoscopic biopsy, an adequate number of biopsy specimens should be obtained to exclude dysplasia. Although the optimal number of biopsy specimens has not been defined, 4-quadrant biopsies every 1 to 2 centimeters throughout the length of the BE tissue are recommended.[28,36] Acquisition of fewer biopsy specimens than those suggested by this protocol is associated with a reduced likelihood of detecting dysplasia, after controlling for segment length.[38]
    Recent evidence has suggested that the time that the endoscopist spends inspecting the BE may be an important determinant of the yield of an endoscopic surveillance examination.[39] Longer inspection times may be associated with increased detection of either high-grade dysplasia or the detection of suspicious lesions. Confirmation of this finding and prospective validation that increased inspection time leads to the identification of lesions (and not that the identification of lesions leads to longer inspection) may allow the future use of this metric as a quality indicator.
    Most advanced neoplasia found on endoscopic examinations is found not on random biopsy but on targeted biopsy of lesions that are suspicious for neoplasia, because of nodularity, ulceration, depression, changes in vascularity, or other findings. Previous work suggests that use of advanced imaging modalities, such as narrow-band imaging, might allow for identification of areas suspicious for neoplasia. This would lead to a decreased number of esophageal biopsies necessary to survey the patient.[40] If so, this quality metric may require future alteration to reflect best practices.
11. *Frequency with which the type of upper GI bleeding lesion is described, and the location is documented*
    Level of evidence: 3
    Performance target: >80%
    Type of measure: process
12. *Frequency with which, during EGD examination revealing peptic ulcers, at least one of the following stigmata is noted: active bleeding, nonbleeding visible vessels (pigmented protuberance), adherent clot, flat spot, and clean-based*
    Level of evidence: 1A
    Performance target: >98%
    Type of measure: process
13. *Frequency with which, unless contraindicated, endoscopic treatment is given for ulcers with active bleeding or with nonbleeding visible vessels (priority indicator)*
    Level of evidence: 1A
    Performance target: >98%

Type of measure: process

Discussion: The completion of therapeutic procedures is a logical and obvious target for quality metrics in upper endoscopy. It is impossible prospectively to define and create metrics for all potential therapeutic maneuvers in upper endoscopy for the purpose of quality monitoring. Nonetheless, given the clinical importance and commonplace nature of the management of GI bleeding, monitoring processes and outcomes related to these conditions will likely reflect the quality of overall clinical care. Practitioners performing EGD in the setting of upper GI bleeding should be trained, equipped, and prepared to therapeutically manage the bleeding source when found.

The first task of the therapeutic endoscopist is to find and define the location of the bleeding site. In the majority of patients, a bleeding site can be determined after careful examination.[41-43] However, because of impaired visualization because of blood, or occasionally because of intermittent bleeding from a lesion without obvious endoscopic stigmata, such as a Dieulafoy's lesion, the cause of bleeding may not be identified. For situations in which a bleeding site is not initially identified because of copious amounts of blood, the use of intravenous erythromycin or metoclopramide, as well as repositioning the patient, may aid in identification of a site.[44,45] The bleeding site's description should be detailed enough to allow a subsequent endoscopist to find the site. A detailed description of the lesion also is necessary, including documentation of stigmata associated with different risks of rebleeding.[46]

Ulcers should be classified as actively bleeding (with spurting lesions having a more ominous prognosis than oozing lesions), nonbleeding visible vessel, adherent clot, flat spot, and clean-based ulcer. These stigmata provide prognostic information on rebleeding rates and need for subsequent intervention. They dictate management strategies including level of care and need for endoscopic therapy. In general, endoscopic attempts at hemostasis should be performed in those with spurting or oozing ulcers as well as in those with nonbleeding visible vessels. In patients with adherent clots, vigorous irrigation with or without suctioning may allow identification of underlying stigmata of hemorrhage. If irrigation does not dislodge the clots, these lesions should be considered for endoscopic therapy. Meta-analysis of multiple trials demonstrates that endoscopic therapy markedly decreases the risk of further bleeding and also decreases the need for surgery.[47] Appropriate risk stratification in peptic ulcer bleeding requires knowledge of not only the stigmata but also of their different rates of rebleeding in various clinical scenarios. For practices with a low volume of EGD for bleeding, it may be appropriate to measure on a unit basis rather than per endoscopist.

14. *Frequency with which achievement of primary hemostasis in cases of attempted hemostasis of upper GI bleeding lesions is documented*

    Level of evidence: 3

    Performance target: >98%

    Type of measure: process

    Discussion: Prognosis in the patient with active GI bleeding depends in part on the success of initial intervention. Patients in whom hemostasis is not achieved are more likely to require subsequent interventional radiology or surgery and are at increased risk of mortality compared with those undergoing successful intervention.[48-50] In many prospective series evaluating various modalities for managing actively bleeding upper GI lesions, primary hemostasis rates from 90% to 100% have been achieved.[46] In order to gauge and track successful hemostasis, it will be necessary for endoscopists to clearly record whether or not their efforts to achieve primary hemostasis in high-risk endoscopic stigmata are successful. At present, there are no currently accepted standards of hemostasis attainment in community practice from which to assign an evidenced-based performance target. However, by tracking the rate of primary hemostasis and comparing to benchmark data, endoscopists will be able to engage in quality improvement in the area of GI bleeding management.

15. *Frequency with which a second treatment modality is used (eg, coagulation or clipping) when epinephrine injection is used to treat actively bleeding or nonbleeding visible vessels in patients with bleeding peptic ulcers*

    Level of evidence: 1A

    Performance target: >98%

    Type of measure: process

    Discussion: Multiple modalities may be used in the treatment of peptic ulcer bleeding. Current practices include the use of injection in conjunction with a second modality, such as multipolar coagulation, heater probe thermal coagulation, endoscopic clipping, argon plasma coagulation, or various other therapies.[46] The success or failure of such treatments should be documented when practical and clearly described. Epinephrine injection alone should not be considered adequate because multiple studies have documented the superiority of combined modality therapy over epinephrine alone.[51,52]

    Treating peptic ulcers with active bleeding or nonbleeding visible vessels is associated with significantly reduced rebleeding rates and should therefore be attempted in most instances. Additionally, there are supportive data for the endoscopic removal of adherent clots and subsequent treatment of underlying stigmata,[53-55] and this practice should be considered for all patients with adherent clots.

16. *Frequency with which variceal ligation is used as the first modality of treatment for the endoscopic treatment of esophageal varices*

Level of evidence: 1A
Performance target: >98%
Type of measure: process

Discussion: In bleeding from esophageal varices, banding is preferred over sclerotherapy for safety and efficacy.[56,57] Octreotide infusion should be instituted in patients with acute variceal bleeding who do not have a contraindication to the medication.[58,59] After the initial treatment, follow-up plans should include repeat endoscopy with repeat treatment until varices are eradicated. Postprocedure plans also should include some recommendation concerning the use of beta blockers for prevention of recurrent bleeding or a statement about why they are contraindicated.[60,61]

17. *Frequency with which at least 4 intestinal biopsy specimens are taken from patients in whom celiac disease is suspected*

Level of evidence: 1C
Performance target: >90%
Type of measure: process

Discussion: In patients with clinical signs, symptoms, and suspected celiac disease, small-intestine biopsies often are instrumental in ascertaining the diagnosis. Similarly, biopsies may help elucidate the response to therapy. Because of the potentially patchy nature of the disease, in patients in whom celiac disease is suspected, at least 4 biopsy specimens should be taken to maximize accuracy of diagnosis, and some should include the duodenal bulb.[62] Biopsies of the duodenal bulb may improve diagnostic yield by detecting the most severe villous atrophy within the duodenum.[63]

Intraprocedure research questions

1. The structures of the oropharynx can be observed during EGD, and examination of this area may be of particular importance in patients at high risk for squamous cell cancers of the esophagus and head and neck.[64] Should complete visualization of a routine EGD include the oropharynx?
2. Do patients with endoscopic stigmata of BE, but no specialized metaplasia on biopsy, suffer from an increased risk of neoplasia, and if so, what is the magnitude of that risk?
3. Which patients with BE benefit from endoscopic ablative therapies?
4. Does increasing the time duration of the inspection of BE result in an improvement in the yield of BE surveillance examinations, and if so, what is the minimum inspection time necessary for optimal diagnostic yield?
5. What are the most effective therapies for patients with recurrent strictures or those resistant to therapy?
6. What is the rate of successful primary hemostasis for major stigmata of nonvariceal bleeding in community practice? What is the utility of newer endoscopic modalities in treating acute upper GI bleeding?
7. What are the variations in practice in the community with regard to performance of duodenal biopsies to rule out celiac disease and from what sites in the duodenum?
8. How often is dual therapy used when epinephrine is used? Is there variation in rates of surgery among community endoscopists?
9. Does case volume affect primary hemostasis or delayed rebleeding rates? Is there variation in rates of interventional radiology and surgery use among community endoscopists?
10. How often is surveillance recommended among patients with abnormalities confined to the Z line?
11. Are recommendations to measure and perform biopsies in suspected BE followed in clinical practice?

Postprocedure quality indicators

The postprocedure period extends from the time the endoscope is removed to subsequent follow-up. Postprocedure activities include providing instructions to the patient, documentation of the procedure, recognition and documentation of adverse events, pathology follow-up, communication with referring physicians, and assessing patient satisfaction.[23] Postprocedure quality indicators specific to performance of EGD include the following:

18. *Frequency with which PPI therapy is recommended for patients who underwent dilation for peptic esophageal strictures*

Level of evidence: 1A
Performance target: >98%
Type of measure: process

19. *Frequency with which patients diagnosed with gastric or duodenal ulcers are instructed to take PPI medication or an H2 antagonist*

Level of evidence: 1A
Performance target: >98%
Type of measure: process

Discussion: PPIs, when used in patients who have had peptic strictures, reduce the need for future dilations.[65,66] Treatment with antisecretory therapy is indicated for patients with newly identified gastric or duodenal ulcers.[67,68]

20. *Frequency with which plans to test for* Helicobacter pylori *infection for patients diagnosed with gastric or duodenal ulcers are documented (priority indicator)*

Level of evidence: 1A
Performance target: >98%
Type of measure: process

Discussion: *H pylori* is a common cause of gastric and duodenal ulcer disease. Successful eradication of this organism results in dramatically reduced rates of ulcer recurrence.[69] ASGE guidelines pertaining to the role of endoscopy for peptic ulcer disease recommends that all patients with gastric or duodenal ulcers should be assessed for this infection.[70]

TABLE 4. Summary of proposed quality indicators for EGD*

Quality indicator	Grade of recommendation	Type of measure	Performance target (%)
Preprocedure			
1. Frequency with which EGD is performed for an indication that is included in a published standard list of appropriate indications, and the indication is documented	1C+	Process	>80
2. Frequency with which informed consent is obtained, including specific discussions of risks associated with EGD, and fully documented	3	Process	>98
3. Frequency with which appropriate prophylactic antibiotics are given in patients with cirrhosis with acute upper GI bleeding before EGD (priority indicator)	1B	Process	>98
4. Frequency with which appropriate prophylactic antibiotics are given before placement of a PEG tube	1A	Process	>98
5. Frequency with which a PPI is used for suspected peptic ulcer bleeding (priority indicator)	1B	Process	>98
6. Frequency with which vasoactive drugs are initiated before EGD for suspected variceal bleeding	1B	Process	>98
Intraprocedure			
7. Frequency with which a complete examination of the esophagus, stomach, and duodenum, including retroflexion in the stomach, is conducted and documented	3	Process	>98
8. Among those with nonbleeding gastric ulcers, frequency with which gastric biopsies are done to exclude malignancy	2C	Process	>80
9. Frequency with which Barrett's esophagus is appropriately measured when present	2C	Process	>98
10. Frequency with which biopsies are obtained in cases of suspected Barrett's esophagus	2C	Process	>90
11. Frequency with which type of upper GI bleeding lesion is described, and the location is documented	3	Process	>80
12. Frequency with which, during EGD examination revealing peptic ulcers, at least one of the following stigmata is noted: active bleeding, nonbleeding visible vessels (pigmented protuberance), adherent clot, flat spot, and clean-based	1A	Process	>98
13. Frequency with which, unless contraindicated, endoscopic treatment is given to ulcers with active bleeding or with nonbleeding visible vessels (priority indicator)	1A	Process	>98
14. Frequency with which achievement of primary hemostasis in cases of attempted hemostasis of upper GI bleeding lesions is documented	3	Process	>98
15. Frequency with which a second treatment modality is used (eg, coagulation or clipping) when epinephrine injection is used to treat actively bleeding or nonbleeding visible vessels in patients with bleeding peptic ulcers	1A	Process	>98

TABLE 4. Continued

Quality indicator	Grade of recommendation	Type of measure	Performance target (%)
16. Frequency with which variceal ligation is used as the first modality of treatment for the endoscopic treatment of esophageal varices	1A	Process	>98
17. Frequency with which at least 4 intestinal biopsies are done from patients in whom celiac disease is suspected	1C	Process	>90
Postprocedure			
18. Frequency with which PPI therapy is recommended for patients who underwent dilation for peptic esophageal strictures	1A	Process	>98
19. Frequency with which patients diagnosed with gastric or duodenal ulcers are instructed to take PPI medication or an H2 antagonist	1A	Process	>98
20. Frequency with which plans to test for *H pylori* infection are documented for patients diagnosed with gastric or duodenal ulcers (priority indicator)	1A	Process	>98
21. Frequency with which patients with evidence of rebleeding from peptic ulcer disease after endoscopic treatment undergo repeat upper endoscopy	1B	Process	>98
22. Frequency with which patients are contacted to document the occurrence of adverse events after EGD	3	Process	N/A

PPI, Proton pump inhibitor.
*This list of potential quality indicators was meant to be a comprehensive listing of measurable endpoints. It is not the intention of the task force that all endpoints be measured in every practice setting. In most cases, validation may be required before a given endpoint may be universally adopted.

21. *Frequency with which patients with evidence of recurrent bleeding from peptic ulcer disease after endoscopic treatment undergo repeat upper endoscopy*
    Level of evidence: 1B
    Performance target: >98%
    Type of measure: process
    Discussion: Despite adequate endoscopic therapy for a bleeding peptic ulcer, rebleeding can occur in up to one third of patients. Repeat endoscopy for recurrent bleeding is effective and should be done unless contraindicated.[71,72] This should be documented and communicated with the primary providers. Routine second-look endoscopy in the absence of rebleeding is not recommended.[26,72,73]
22. *Frequency that patients are contacted to document the occurrence of adverse events after EGD*
    Level of evidence: 3
    Performance target: N/A
    Type of measure: process
    Discussion: As more therapeutic EGD procedures occur (EMR, endoscopic submucosal dissection [ESD]), endoscopists should develop a mechanism to capture and track not only immediate but also delayed endoscopic adverse events (from 14 days to 1 month). Such a practice would promote patient safety—a principle supported by the ASGE, ACG, American Gastroenterological Association, and the Institute of Medicine.[11,74,75] Tracked adverse events should include cardiopulmonary events, infections, perforation, bleeding, and abdominal pain requiring medical attention or intervention. In the future, individual adverse events could be developed into separate quality indicators once further data are obtained for benchmarking. For EGD, these might include specific adverse event rates such as skin infections after PEG tube placement, aspiration pneumonia after EGD with hemostasis, and stricture formation after esophageal mucosal resection or ablation.

Postprocedure research questions

1. What is the long-term outcome from following surveillance recommendations for BE, and how will targeted biopsy techniques that use new technology affect the yield and efficacy of surveillance?
2. Are there variations in rebleeding rates from peptic ulcer disease after endoscopic therapy, and can this be used to identify high performers of quality upper endoscopy?

TABLE 5. Priority quality indicators for EGD*

Frequency with which, unless contraindicated, endoscopic treatment is performed for ulcers with active bleeding or with nonbleeding visible vessels
Frequency with which plans to test for *Helicobacter pylori* infection are documented for patients diagnosed with gastric or duodenal ulcers
Frequency with which appropriate prophylactic antibiotics are given in patients with cirrhosis with acute upper GI bleeding who undergo EGD
Frequency with which a proton pump inhibitor is used for suspected peptic ulcer bleeding

*See text for specific targets and discussion.

3. What are the sources of variability in adverse event rates after endoscopic intervention for upper GI bleeding, and how can they be diminished?
4. What is the optimal management of anticoagulation regimens in patients undergoing EGD with hemostasis of upper GI bleeding requiring chronic anticoagulation in the periprocedure and postprocedure bleeding periods?
5. What is the incidence of incomplete mucosal resection by using advanced imaging techniques to identify margins?
6. What are the best strategies to minimize adverse events after EMR and ESD?
7. What are the rates in the community of aspiration pneumonia after endoscopic hemostasis of acute upper GI bleeding, stricture formation after esophageal ablation or mucosal resection, and post-PEG wound infections?
8. Is actively tracking patients for the occurrence of adverse events after endoscopy cost effective?

Priority indicators for EGD

A summary of discussed quality indicators for EGD is listed in Table 4. Among these for EGD, recommended priority indicators are (1) frequency with which, unless contraindicated, ulcers with active bleeding or with nonbleeding visible vessels are treated endoscopically, (2) frequency with which plans for assessing *H pylori* infection for patients diagnosed with gastric or duodenal ulcers are documented, (3) frequency with which appropriate prophylactic antibiotics are given in patients with cirrhosis with acute upper GI bleeding before EGD, and (4) frequency with which a PPI is used for suspected peptic ulcer bleeding (Table 5). Among all indicators, these were chosen based on combined availability of strength of supporting evidence, measurement feasibility, and evidence of substantial variation in performance.[76-78] There are very limited data on practice variation for the majority of these EGD indicators, representing an important research area.

Simple educational and corrective measures can improve performance. The primary purpose of measuring quality indicators is to improve patient care by identifying poor performers and retraining them or removing privileges to perform EGD if performance cannot be improved.

Conclusion

This update on quality indicators for EGD incorporates new information to provide a relevant list for endoscopists who want to perform high-quality upper endoscopy. Similar to those from the original version published in 2006, the indicators are classified as preprocedure, intraprocedure, and postprocedure indicators, and this is summarized in Table 4. The proposed indicators vary in the level of supporting evidence, and several are based solely on expert opinion. For practical and ethical reasons, some indicators may be impossible to validate, such as performing and documenting informed consent and patient monitoring during moderate sedation. The absence of evidence does not equate to evidence of no benefit.

For EGD, the proposed quality measures are predominantly process measures. Many of these process measures are good surrogates of outcomes, based on evidence that links them to clinically recognized outcomes. The future direction of quality indicator development will include relevant outcome measures and a more robust evidence base to support proposed performance targets. The proposed research questions address this deficit of evidence.

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Abbreviations: ACG, American College of Gastroenterology; ASGE, American Society for Gastrointestinal Endoscopy; BE, Barrett's esophagus; ESD, endoscopic submucosal dissection; PPI, proton pump inhibitor.

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Quality indicators for colonoscopy

Colonoscopy is widely used for the diagnosis and treatment of colon disorders. Properly performed, colonoscopy is generally safe, accurate, and well-tolerated. Visualization of the mucosa of the entire large intestine and distal terminal ileum usually is possible during colonoscopy. Polyps can be removed during colonoscopy, thereby reducing the risk of colon cancer. Colonoscopy is the preferred method to evaluate the colon in most adult patients with large-bowel symptoms, iron deficiency anemia, abnormal results on radiographic studies of the colon, positive results on colorectal cancer (CRC) screening tests, post-polypectomy and post-cancer resection surveillance, and diagnosis and surveillance in inflammatory bowel disease. In addition, colonoscopy is the most commonly used CRC screening test in the United States.[1] Based on 2010 data, over 3.3 million outpatient colonoscopies are performed annually in the United States, with screening and polyp surveillance accounting for half of indications.[2]

Optimal effectiveness of colonoscopy depends on patient acceptance of the procedure, which depends mostly on acceptance of the bowel preparation.[3] Preparation quality affects the completeness of examination, procedure duration, and the need to cancel or repeat procedures at earlier dates than would otherwise be needed.[4,5] Ineffective preparation is a major contributor to costs.[6] Meticulous inspection[7,8] and longer withdrawal times[9-14] are associated with higher adenoma detection rates (ADR). A high ADR is essential to rendering recommended intervals[15] between screening and surveillance examinations safe.[16,17] Optimal technique is needed to ensure a high probability of detecting dysplasia when present in inflammatory bowel disease.[17-21] Finally, technical expertise and experience will help prevent adverse events that might offset the benefits of removing neoplastic lesions.[22]

Recent studies report that colonoscopy is less effective in preventing proximal colon cancer and cancer deaths (ie, colon cancer proximal to the splenic flexure) compared with distal cancer (ie, colon cancer at or distal to the splenic flexure).[23-28] Decreased protection against right-sided CRC is likely due to multiple factors. These include missed adenomas or incompletely resected adenomas; suboptimal bowel preparation; precancerous lesions that are endoscopically subtle or difficult to remove, such as sessile serrated polyps and flat and/or depressed adenomas, and differences in tumorigenesis between right-sided and left-sided cancers. Improving prevention of right-sided colon cancer is a major goal of colonoscopy quality programs.

Five studies have established that gastroenterologists are more effective than surgeons or primary care physicians at preventing CRC by colonoscopy.[27,29-32] This most likely reflects higher rates of complete examinations (ie, cecal intubation)[30] and higher rates of adenoma detection among gastroenterologists.[33,34] All endoscopists performing colonoscopy should measure the quality of their colonoscopy. Institutions where endoscopists from multiple specialties are practicing should reasonably expect all endoscopists to participate in the program and achieve recommended quality benchmarks.

The quality of health care can be measured by comparing the performance of an individual or a group of individuals with an ideal or benchmark.[35] The particular parameter that is being used for comparison is termed a quality indicator. A quality indicator often is reported as a ratio between the incidence of correct performance and the opportunity for correct performance[4] or as the proportion of interventions that achieve a predefined goal.[35] Quality indicators can be divided into 3 categories: (1) structural measures—these assess characteristics of the entire health care environment (eg, participation by a physician or other clinician in systematic clinical database registry that includes consensus endorsed quality measures), (2) process measures—these assess performance during the delivery of care (eg, ADR and adequate biopsy sampling during colonoscopy for chronic ulcerative colitis), (3) outcome measures—these assess the results of the care that was provided (eg, the prevention of cancer by colonoscopy and reduction in the incidence of colonoscopic perforation).

METHODOLOGY

In 2006, the American Society for Gastrointestinal Endoscopy (ASGE)/American College of Gastroenterology (ACG) Task Force on Quality in Endoscopy published their first version of quality indicators for colonoscopy.[36] The present update integrates new data pertaining to previously proposed quality indicators and new quality indicators for performing colonoscopy.[36] Indicators that had wide-ranging clinical application, were associated with

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TABLE 1. Grades of recommendation*

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

*Adapted from Guyatt G, Sinclair J, Cook D, et al. Moving from evidence to action. Grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, editors. Users' guides to the medical literature. Chicago: AMA Press; 2002. p. 599-608.

variation in practice and outcomes, and were validated in clinical studies were prioritized. Clinical studies were identified through a computerized search of Medline followed by review of the bibliographies of all relevant articles. When such studies were absent, indicators were chosen by expert consensus. Although feasibility of measurement was a consideration, it is hoped that inclusion of highly relevant, but not yet easily measurable indicators, would promote their eventual adoption. Although a comprehensive list of quality indicators is proposed, it is recognized that, ultimately, only a small subset might be widely used for continuous quality improvement, benchmarking, or quality reporting. As in 2006, the current task force concentrated its attention on parameters related to endoscopic procedures; whereas the quality of care delivered to patients is clearly influenced by many factors related to the facilities in which endoscopy is performed, characterization of unit-related quality indicators was not included in the scope of this effort.

The resultant quality indicators were graded on the strength of the supporting evidence (Table 1). Each quality indicator was classified as an outcome or a process measure. Although outcome quality indicators are preferred, some can be difficult to measure in routine clinical practice, because they need analysis of large amounts of data and long-term follow-up and may be confounded by other factors. In such cases, the task force deemed it reasonable to use process indicators as surrogate measures of high-quality endoscopy. The relative value of a process indicator hinges on the evidence that supports its association with a clinically relevant outcome, and such process measures were emphasized.

The quality indicators for this update were written in a manner that lends them to be developed as measures. Although they remain quality indicators and not measures, this document also contains a list of performance targets for each quality indicator. The task force selected performance targets from benchmarking data in the literature when available. When no data were available to support establishing a performance target level, "N/A" (not available) was listed. However, when expert consensus considered failure to perform a given quality indicator a "never event" such as monitoring vital signs during sedation, then the performance target was listed as >98%. It is important to emphasize that the performance targets listed do not necessarily reflect the standard of care but rather serve as specific goals to direct quality improvement efforts.

Quality indicators were divided into 3 time periods: preprocedure, intraprocedure, and postprocedure. For each category, key relevant research questions were identified.

In order to guide continuous quality improvement efforts, the task force also recommended a high-priority

subset of the indicators described, based on their clinical relevance and importance, evidence that performance varies significantly in clinical practice, and feasibility of measurement (a function of the number of procedures needed to obtain an accurate measurement with narrow confidence intervals and the ease of measurement). A useful approach for an individual endoscopist is to first measure their performances with regard to these priority indicators. Quality improvement efforts would move to different quality indicators if the endoscopists are performing above recommended thresholds, or the employer and/or teaching center could institute corrective measures and remeasure performance of low-level performers.

Recognizing that certain quality indicators are common to all GI endoscopic procedures, such items are presented in detail in a separate document, similar to the process in 2006.[37,38] The preprocedure, intraprocedure, and postprocedure indicators common to all endoscopy are listed in Table 2. Those common factors will be discussed in this document only insofar as the discussion needs to be modified specifically to relate to colonoscopy.

Preprocedure quality indicators

The preprocedure period includes all contacts between members of the endoscopy team and the patient before the administration of sedation or insertion of the endoscope. Common issues for all endoscopic procedures during this period include: appropriate indication, informed consent, risk assessment, formulation of a sedation plan, management of prophylactic antibiotics and antithrombotic drugs, and timeliness of the procedure.[38] Preprocedure quality indicators specific to performance of colonoscopy include the following:

1. *Frequency with which colonoscopy is performed for an indication that is included in a published standard list of appropriate indications, and the indication is documented*
   Level of evidence: 1C+
   Performance target: >80%
   Type of measure: process
   The ASGE has published appropriate indications for colonoscopy (Table 3).[39] An appropriate indication should be documented for each procedure, and when it is a nonstandard indication, it should be justified in the documentation. When performing colonoscopy for average-risk CRC screening or colon polyp surveillance, endoscopists should specifically document whether the patient had a colonoscopy previously, date of the last colonoscopy (or document that the date of that procedure is not available), and any histologic findings from polyps removed during that colonoscopy.
   Discussion: In 2012, the ASGE updated its indications for endoscopic procedures.[39] This list was determined by a review of published literature and expert consensus. Studies have shown that when colonoscopy is done for appropriate reasons, significantly more clinically relevant diagnoses are made.[40-42] In these studies, which divided indications into appropriate, uncertain, and inappropriate and looked at high-volume European centers, 21% to 39% were classified as inappropriate. It is likely that this can be improved to a <20% inappropriate rate.[43] The European Panel on the Appropriateness of Gastrointestinal Endoscopy Internet guideline is a useful decision support tool for determining the appropriateness of colonoscopy.[43] The goal is to minimize the number of inappropriate procedures.[44-46]
2. *Frequency with which informed consent is obtained, including specific discussions of risks associated with colonoscopy, and fully documented*
   Level of evidence: 1C
   Performance target: >98%
   Type of measure: process
   In addition to the risks associated with all endoscopic procedures, the consent should address the relevant and substantial adverse events pertaining to each specific colonoscopy procedure.
   Discussion: As with all other endoscopic procedures, consent must be obtained before the procedure from the patient or guardian (or as required by local law or per policy of the institution). It must include a discussion of the risks, benefits, and alternatives to the procedure. The most common risks of colonoscopy include bleeding, perforation, infection, sedation-related adverse events, missed lesions, and intravenous site adverse events.
3. *Frequency with which colonoscopies follow recommended post-polypectomy and post-cancer resection surveillance intervals and 10-year intervals between screening colonoscopies in average-risk patients who have negative examination results and adequate bowel cleansing (priority indicator)*
   Level of evidence: 1A
   Performance target: ≥90%
   Type of measure: process
   Discussion: For colonoscopy to be both effective and cost-effective and to minimize risk, the intervals between examinations should be optimized. Intervals between examinations can be effective in prevention of incident CRC only when the colon is effectively cleared of neoplasia. Therefore, detailed and effective examination of the colon, as discussed in the following, is critical to the effectiveness and safety of recommended intervals between colonoscopy. The recommended intervals assume cecal intubation, adequate bowel preparation, and careful examination.
   In the average-risk population (persons aged ≥50 years without other risk factors for CRC or who have only one first-degree relative with CRC and that cancer was diagnosed at age >60 years), colonoscopic screening is recommended in all past and current guidelines at 10-year intervals.[15,47,48] A German case-control study

TABLE 2. Summary of proposed quality indicators common to all endoscopic procedures[30,a]

Quality indicator	Grade of recommendation	Measure type	Performance target (%)
Preprocedure			
1. Frequency with which endoscopy is performed for an indication that is included in a published standard list of appropriate indications, and the indication is documented (priority indicator)	1C+	Process	>80
2. Frequency with which informed consent is obtained and fully documented	3	Process	>98
3. Frequency with which preprocedure history and directed physical examination are performed and documented	3	Process	>98
4. Frequency with which risk for adverse events is assessed and documented before sedation is started	3	Process	>98
5. Frequency with which prophylactic antibiotics are administered for appropriate indication (priority indicator)	Varies	Process	>98
6. Frequency with which a sedation plan is documented	Varies	Process	>98
7. Frequency with which management of antithrombotic therapy is formulated and documented before the procedure (priority indicator)	3	Process	N/A
8. Frequency with which a team pause is conducted and documented	3	Process	>98
9. Frequency with which endoscopy is performed by an individual who is fully trained and credentialed to perform that particular procedure	3	Process	>98
Intraprocedure			
10. Frequency with which photodocumentation is performed	3	Process	N/A
11. Frequency with which patient monitoring during sedation is performed and documented	3	Process	>98
12. Frequency with which the doses and routes of administration of all medications used during the procedure are documented	3	Process	>98
13. Frequency with which use of reversal agents is documented	3	Process	>98
14. Frequency with which procedure interruption and premature termination due to sedation-related issues is documented	3	Process	>98
Postprocedure			
15. Frequency with which discharge from the endoscopy unit according to predetermined discharge criteria is documented	3	Process	>98
16. Frequency with which patient instructions are provided	3	Process	>98
17. Frequency with which the plan for pathology follow-up is specified and documented	3	Process	>98

TABLE 2. Continued

Quality indicator	Grade of recommendation	Measure type	Performance target (%)
18. Frequency with which a complete procedure report is created	3	Process	>98
19. Frequency with which adverse events are documented	3	Process	>98
20. Frequency with which adverse events occur	3	Outcome	N/A
21. Frequency with which postprocedure and late adverse events occur and are documented	3	Outcome	N/A
22. Frequency with which patient satisfaction data are obtained	3	Process	N/A
23. Frequency with which communication with referring provider is documented	3	Process	N/A

N/A, Not available.
*This list of potential quality indicators is meant to be a comprehensive list of measurable endpoints. It is not the intention of the task force that all endpoints be measured in every practice setting. In most cases, validation may be required before a given endpoint may be adopted universally.

found that a negative screening colonoscopy result was associated with >20 years of protection against colorectal cancer.[49] In cohorts of average-risk persons who underwent an initial colonoscopy with a negative result, a repeat colonoscopy 5 years later had a very low yield.[50,51] Two studies of flexible sigmoidoscopy found a protective effect of endoscopy with polypectomy lasting 10 years and 16 years and could not exclude longer durations of protection.[52,53] Thus, although colonoscopy is not perfectly protective, its protective effect is prolonged. These data support the 10-year interval, but many American colonoscopists systematically perform screening colonoscopy at 5-year intervals in average-risk individuals.[54] This practice is not cost-effective, exposes patients to excess risk, and cannot be justified.

When performing colonoscopy for CRC screening, endoscopists should document under "indication for procedure" whether the patient previously had a colonoscopy, date of the last colonoscopy, and any histologic findings from polyps removed during that colonoscopy if that information is available. This documentation should demonstrate that colonoscopy for CRC screening or colon polyp surveillance is being performed at an appropriate interval.

Evidence from surveys indicates that post-polypectomy surveillance colonoscopy in the United States is frequently performed at intervals that are shorter than those recommended in guidelines,[55-60] that knowledge of guideline recommendations is high, and lack of guideline awareness is unlikely to account for overuse of colonoscopy. Assessments of actual practice identified both overuse of surveillance examination in low-risk patients and underuse in high-risk patients.[61] An assessment of Medicare colonoscopy codes demonstrated systematic overuse of colonoscopy for screening and post-polypectomy surveillance by some physicians.[54] These surveys underscore the importance of measuring intervals between examinations in continuous quality improvement programs. Surgeons were more likely to use short intervals than were gastroenterologists,[55] emphasizing the need for all specialties practicing colonoscopy to participate in quality programs. Primary care and other referring physicians can reasonably expect surveillance recommendations to reflect post-polypectomy surveillance recommendations or to be accompanied by an explanation indicating why the recommended interval differs from the guideline.

Intervals between examinations are recommended based on the best available evidence and experience that indicates a balance between the protective effect of high-quality clearing colonoscopy with the risks and cost of colonoscopy. Intervals are determined by the numbers, size, and specific histology of precancerous lesions.[15] Patients with sessile polyps >2 cm in size that are removed piecemeal have a high risk for residual polyp at the polypectomy site and require short-term follow-up at 3 to 6 months[15] and a second examination a year later to rule out a late recurrence of polyp at the site.[62]

Recommended post-polypectomy surveillance intervals for sessile serrated polyps (also called sessile serrated adenomas) and traditional serrated adenomas currently are based on limited evidence and will be subject to updating as new evidence appears.[15] Serrated lesions include hyperplastic polyps, sessile serrated polyps, and traditional serrated adenomas. Serrated lesions, particularly the sessile serrated polyp, are considered

TABLE 3. Appropriate indications for colonoscopy[39]

Evaluation of an abnormality on barium enema or other imaging study that is likely to be clinically significant, such as a filling defect or stricture
Evaluation of unexplained GI bleeding
Hematochezia
Melena after an upper GI source has been excluded
Presence of fecal occult blood
Unexplained iron deficiency anemia
Screening and surveillance for colon neoplasia
Screening of asymptomatic, average-risk patients for colon neoplasia
Examination to evaluate the entire colon for synchronous cancer or neoplastic polyps in a patient with treatable cancer or neoplastic polyp
Colonoscopy to remove synchronous neoplastic lesions at or around the time of curative resection of cancer followed by colonoscopy at 1 year and, if examination normal, then 3 years, and, if normal, then 5 years thereafter to detect metachronous cancer
Surveillance of patients with neoplastic polyps
Surveillance of patients with a significant family history of colorectal neoplasia
For dysplasia and cancer surveillance in select patients with long-standing ulcerative or Crohn's colitis
For evaluation of patients with chronic inflammatory bowel disease of the colon, if more precise diagnosis or determination of the extent of activity of disease will influence management
Clinically significant diarrhea of unexplained origin
Intraoperative identification of a lesion not apparent at surgery (eg, polypectomy site, location of a bleeding site)
Treatment of bleeding from such lesions as vascular malformation, ulceration, neoplasia, and polypectomy site
Intraoperative evaluation of anastomotic reconstructions (eg, evaluation for anastomotic leak and patency, bleeding, pouch formation)
As an adjunct to minimally invasive surgery for the treatment of diseases of the colon and rectum
Management or evaluation of operative adverse events (eg, dilation of anastomotic strictures)
Foreign body removal
Excision or ablation of lesions
Decompression of acute megacolon or sigmoid volvulus
Balloon dilation of stenotic lesions (eg, anastomotic strictures)
Palliative treatment of stenosing or bleeding neoplasms (eg, laser, electrocoagulation, stenting)
Marking a neoplasm for localization

the precursors of a substantial group of CRCs that arise predominantly in the proximal colon. At this time, consensus post-polypectomy surveillance intervals for sessile serrated polyps are similar to recommended intervals for adenomas and are based on size and number of lesions.[15] Serrated lesions of all types should be counted to identify patients who meet the criteria for serrated polyposis, formerly known as hyperplastic polyposis syndrome, for which colonoscopy is recommended at 1 to 2–year intervals.[15]

Patients who have suspected colon bleeding after a negative colonoscopy result may require repeat examinations at intervals shorter than those recommended. However, the use of fecal occult blood testing by using guaiac-based tests for the first 5 years after a colonoscopy is inappropriate because the positive predictive value of guaiac-based fecal occult blood testing during that interval is extremely low.[63] Additional study of fecal immunochemical testing for blood in this setting as an adjunct to colonoscopy is warranted.[64]

Colonoscopies performed for screening or surveillance at intervals shorter than those recommended in guidelines and without an appropriate explanation for the shortened interval should be considered to have an inappropriate indication.

4. *Frequency with which ulcerative colitis and Crohn's colitis surveillance is recommended within proper intervals*
   Level of evidence: 2C
   Performance target: ≥90%
   Type of measure: process
   Discussion: In ulcerative colitis and Crohn's colitis, surveillance refers to interval examinations in patients with long-standing disease who have undergone an initial examination in which dysplasia was not detected. The term also is used when patients who are asymptomatic are prospectively entered into interval colonoscopy programs based on the duration of disease. Surveillance does not refer to diagnostic examinations or examinations in previously diagnosed patients to assess symptoms. Both ulcerative colitis and Crohn's colitis of long duration are associated with an increased risk of colorectal cancer.[65,66] Surveillance colonoscopy often is recommended beginning 7 to 10 years after the onset of symptoms when ulcerative colitis extends beyond the rectum or in Crohn's disease when more than one third of the colon is involved. There are no randomized trials to support the effectiveness of surveillance colonoscopy in ulcerative colitis or Crohn's colitis, but case-control studies in ulcerative colitis indicate a survival benefit for patients who participate in surveillance.[67,68] Surveys of practitioners in the United States[69] and the United Kingdom[70] demonstrate that many practitioners are not familiar with surveillance recommendations, have a poor understanding of dysplasia, and make inappropriate recommendations in response to findings of dysplasia.[69,70]
   Patients should undergo surveillance colonoscopy, which has emerged as a standard of medical care in the United States. The onset of disease is considered to be the onset of symptoms for the purpose of initiating surveillance for both ulcerative colitis and Crohn's colitis. Because the yield of dysplasia or cancer during ulcerative colitis surveillance is relatively low and not cost-effective,[71] it is important to avoid overuse of surveillance colonoscopy during the first 20 years.[72] At between 7 and 20 years of disease, intervals of 2 to 3 years are generally adequate, assuming the absence of primary sclerosing cholangitis and a colon that is without severe scarring.[71] Indeed, recent studies continue to indicate that the risk for CRC in chronic ulcerative colitis has been overestimated in previous decades.[18,73] Shorter intervals between examinations are indicated for patients with long-duration disease and may be initiated earlier in the course of disease in patients with established risk modifiers, such as a family history of CRC or a personal history of primary sclerosing cholangitis.[71] Persons with primary sclerosing cholangitis who are discovered to have asymptomatic ulcerative colitis should begin surveillance at the time ulcerative colitis is diagnosed. Patients with endoscopically abnormal colons (eg, endoscopic scarring, pseudopolyp formation or cobblestoning, chronic severe inflammation) are at increased risk for development of cancer, compared with patients with endoscopically normal colons.[74] Thus, patients with endoscopically normal colons, or with only mild abnormalities, can be triaged to longer intervals of surveillance of at least 2 to 3 years, at least during the interval from 7 to 20 years after the onset of symptoms, and assuming the absence of primary sclerosing cholangitis.[74]

Preprocedure research questions

1. Why do physicians fail to follow recommended guidelines for screening and surveillance intervals? Are they concerned about missed lesions? Is there fear of litigation? What interventions will maximize adherence to guideline recommendations?
2. Which serrated lesions in the proximal colon are clinically important? What are cost-effective intervals for follow-up after removal of sessile serrated polyps and large (>10 mm) hyperplastic polyps?
3. Does the incidence of splenic injury during colonoscopy warrant inclusion in the informed consent process?
4. What is the current understanding among clinicians of surveillance guidelines for ulcerative colitis and Crohn's colitis?
5. How will new reimbursement models affect compliance with recommended surveillance intervals?
6. Can and should surveillance interval recommendations be adjusted for endoscopists with high-level versus low-level baseline ADRs? Does the presence of 3 small adenomas warrant high-risk surveillance for endoscopists with high ADRs?

Intraprocedure quality indicators

Quality evaluation of the colon consists of intubation of the entire colon and a detailed mucosal inspection. Cecal intubation improves sensitivity and reduces costs by eliminating the need for radiographic procedures or repeat colonoscopy to complete the examination. Careful mucosal inspection is essential to effective CRC prevention and reduction of cancer mortality. The detection of neoplastic lesions is the primary goal of most colonoscopic examinations.

Cost-benefit analyses of colonoscopy for the detection of neoplastic lesions are well within acceptable rates (approximately $20,000 per year of life saved).[75] However, adverse events, repeat procedures, and inappropriate surgical intervention for endoscopically removable polyps can reduce this benefit significantly. It is incumbent on endoscopists to evaluate their practices and make improvements wherever possible to reduce the costs associated with neoplasia detection.

The intraprocedure period extends from the administration of sedation, or insertion of the endoscope when no sedation is given, to the removal of the endoscope. This

period includes all the technical aspects of the procedure including completion of the examination and of therapeutic maneuvers. Common to most endoscopic procedures is the provision of sedation and need for patient monitoring.[38] Intraprocedure quality indicators specific to performance of colonoscopy include the following:

5. *Frequency with which the procedure note documents the quality of preparation*
   Level of evidence: 3
   Performance target: >98%
   Type of measure: process
   Quality of bowel preparation is based on ability to visualize the mucosa after retained stool and fluid have been suctioned away.
   Discussion: The endoscopist should document the quality of the bowel preparation in each colonoscopy.[76,77] Terms commonly used to characterize bowel preparation include *excellent, good, fair,* and *poor*. In clinical practice, these terms do not have standardized definitions.[78] They are given standardized definitions in clinical trials of bowel preparation,[79] but these trials often take into account retained fluid, which is of little interest to the examination because it can be readily suctioned. Some practitioners use the terms *adequate* or *inadequate*. The ASGE/ACG task force recommends that the examination be considered adequate if it allows detection of (within the technical limitations of the procedure) polyps >5 mm in size.[80] Another option is to use independently validated preparation scores, such as the Boston Bowel Preparation Scale[81] or the Ottawa Bowel Preparation Scale.[82] However, the Ottawa scale also takes into account retained material that can be removed before examination. Regardless of the scoring system used, endoscopists should document the quality of bowel preparation based on ability to identify polyps after retained fluid or stool has been suctioned.
   If bowel cleansing is inadequate to identify polyps >5 mm in size, and the procedure is being performed for CRC screening or colon polyp surveillance, then the procedure should be repeated in 1 year or less.[15] Adequate preparation carries the implication that the recommended interval before the next colonoscopy will be consistent with guidelines.[15]
   Poor bowel preparation is a major impediment to the effectiveness of colonoscopy. Poor preparation prolongs cecal intubation time and withdrawal time and reduces detection of both small[4] and large[4,5,83] polyps. In every colonoscopic practice, some colonoscopies must be repeated at intervals shorter than those recommended[15,84] based on inadequate preparation. The economic burden of repeating examinations because of inadequate bowel preparation is substantial.[6]
6. *Frequency with which the bowel preparation is adequate to allow the use of recommended surveillance or screening intervals*
   Level of evidence: 3
   Performance target: ≥85% of outpatient examinations
   Type of measure: process
   We recommend that the percentage of outpatient examinations with inadequate bowel preparation that require repeat colonoscopy in ≤1 year should not exceed 15%.[5] Measurement of an individual practitioner's percentage of examinations requiring repetition because of inadequate preparation is recommended. Endoscopists who have >15% of examinations with inadequate bowel preparation should re-examine their bowel preparation protocols, including patient education, choice of purgative, and protocol for administering the purgative, including use of the split-dose protocol. Recent clinical trials of even low-volume preparations (which have lower effectiveness than 4-liter preparations) suggest that these rates of adequate preparation are readily achievable in outpatients by using split-dose preparation.[85,86] Socioeconomic factors and language barriers in some patient populations may require increased educational efforts before the colonoscopy to achieve this level of success.
   The most important determinant of preparation quality is the interval between the end of the preparation ingestion and the start of the procedure.[87] Quality diminishes as the interval increases, and the right side of the colon is particularly affected. We recommend that all patients be prescribed split-dosing of bowel preparations, meaning that half the preparation is given on the day of the examination.[87] For afternoon colonoscopies, the entire preparation can be ingested on the day of examination.[88] According to fasting guidelines of the American Society of Anesthesiologists, patients should have nothing by mouth for 2 hours after ingestion of clear liquids.[89] We recommend that rule be followed for ingestion for split-dose and same-day preparations. This recommendation is supported by prospective observational studies that demonstrate that residual volume of liquid in the stomach is minimal (<25 mL) and similar whether patients split the bowel preparation or consume all of the bowel preparation on the evening before the procedure.[90] However, because this study[90] excluded patients with gastroparesis, longer intervals may be prudent in those with conditions such as gastroparesis or achalasia (increased risk of larger volumes of retained fluid), those with central nervous system dysfunction that might be more inclined to aspirate, or in those with cardiac, pulmonary, or immunologic disease in whom a small aspiration event might be devastating.
   Patients should receive instruction to begin the second half of split-dose preparations 4 to 5 hours before their scheduled procedure start time, and they should be finished with ingestion by at least 2 hours before that time.[89] Because the quality of preparation deteriorates as the preparation-to-procedure interval increases,

patients scheduled in the early morning (before 9 AM) who refuse to begin ingestion 4 to 5 hours before the scheduled time can begin ingestion of the second half of the preparation late on the evening before (after 11 PM) and maintain reasonable preparation quality, although true split dosing is preferred.

7. *Frequency with which visualization of the cecum by notation of landmarks and photodocumentation of landmarks is documented in every procedure (priority indicator)*

   Level of evidence: 1C

   Performance targets:

   cecal intubation rate with photography (all examinations), ≥90%

   cecal intubation rate with photography (screening), ≥95%

   Type of measure: process

   Discussion: In the United States, colonoscopy is almost always undertaken with the intent to intubate the cecum. Cecal intubation is defined as passage of the colonoscope tip to a point proximal to the ileocecal valve, so that the entire cecal caput, including the medial wall of the cecum between the ileocecal valve and appendiceal orifice, is visible. The need for cecal intubation is based on the persistent finding that a substantial fraction of colorectal neoplasms are located in the proximal colon, including the cecum. Low cecal intubation rates have been associated with higher rates of interval proximal colon cancer.[30] Techniques of cecal intubation are discussed elsewhere.[91] Cecal intubation should be documented by naming the identified cecal landmarks. Most importantly, these include the appendiceal orifice and the ileocecal valve. For cases in which there is uncertainty as to whether the cecum has been entered, visualization of the lips of the ileocecal valve (ie, the orifice) or intubation of the terminal ileum will be needed. Experienced colonoscopists can verify cecal intubation in real time in 100% of their cases,[92] because there is no other portion of the GI tract with similar appearance. It can be helpful to document other landmarks, such as the cecal sling fold or intubation of the terminal ileum.

   Photography of the cecum is mandated. Still photography of the cecum may not be convincing in all cases because of variations in cecal anatomy.[92] Thus, the ileocecal valve may not be notched or may not have a lipomatous appearance. Nevertheless, still photography is convincing in a substantial majority of cases, and its use allows verification of cecal intubation rates of individual endoscopists in the continuous quality improvement program. The best photographs of the cecum to prove intubation are of the appendiceal orifice, taken from a distance sufficiently far away that the cecal strap fold is visible around the appendix, and a photograph of the cecum taken from distal to the ileocecal valve.[92] Photographs of the terminal ileum are sometimes convincing if they show villi, circular valvulae conniventes, and lymphoid hyperplasia, but they are less likely to be effective compared with the earlier-mentioned photographs.[92] Videotaping of the cecum is not necessary in clinical practice, because its feasibility remains low at this time; however, the appearance of the cecum is unmistakable in real time, and videotaping of the cecum can be a very effective way of documenting cecal intubation for an examiner whose rates of cecal intubation require verification.[92]

   Effective colonoscopists should be able to intubate the cecum in ≥90% of all cases[93] and ≥95% of cases when the indication is screening in a healthy adult.[94-106] Colonoscopy studies in screening patients in the United States, and at times from outside the United States, have reported cecal intubation rates of 97% or higher.[94-106]

   Cases in which procedures are aborted because of poor preparation or severe colitis need not be counted in determining cecal intubation rates, provided that photodocumentation is provided to support the decision to abort the examination. It is also not necessary to count cases in which the initial intent of the procedure is colonoscopic treatment of a benign or malignant stricture or a large polyp in the colon distal to the cecum (provided that complete colon imaging by some method has been performed previously). All other colonoscopies, including those in which a previously unknown benign or malignant stricture is encountered, should be counted.

8. *Frequency with which adenomas are detected in asymptomatic, average-risk individuals (screening) (priority indicator)*

   Level of evidence: 1C

   Performance targets: ADR for male/female population, ≥25% (for men ≥30%, for women ≥20%)

   Type of measure: outcome

   Discussion: An enormous amount of literature has identified evidence of failed detection by colonoscopists including failure to detect adenomas in tandem colonoscopy studies[107] and in CT colonography studies that used segmental unblinding.[108,109] Colonoscopy fails to prevent all CRC in colonoscopy cohorts followed for up to 3 years after the procedure,[23-28] with most of the post-colonoscopy cancers attributable to missed lesions,[110] and contributions from incomplete polypectomy[111] as well as variation in growth patterns and rates.[112,113] There is evidence of marked variation in the detection of adenomas by colonoscopists within practice groups.[114-117] This variation became the rationale for the creation of targets for adenoma detection, originally proposed in 2002[80] and largely adopted by the ASGE/ACG task force in 2006.[36,118] The proposed measure for detection was the fraction of patients undergoing screening colonoscopy who had one or more adenomas detected, now known as the adenoma

detection rate or ADR.[36,80,118] The recommended targets for ADR were based on screening colonoscopy studies and were set at levels slightly below the mean detection rates of adenomas in those studies.[80] Thus, the recommendation has previously been that individual colonoscopists should identify one or more adenomas in at least 25% of men and 15% of women aged ≥50 years undergoing screening colonoscopy.[36,80,118] The rationale to set these targets below the mean prevalence of adenomas and well below the true prevalence of adenomas (as defined by autopsy studies and high-level detectors during colonoscopy) was very limited, and these initial targets reflected a clear bias that the greatest contributors to failure to prevent cancer are endoscopists with very low ADRs. In 2010, a Polish study of screening colonoscopy provided validation for the targets, finding that patients undergoing colonoscopy by physicians with ADRs below 20% had hazard ratios for development of post-colonoscopy cancer >10 times higher than patients of physicians with ADRs above 20%.[16] However, this study had limited power to establish that cancer protection continues to improve when ADRs rise above 20%. One other study found that physicians with high polypectomy rates protected patients from right-sided cancer better than physicians with low polypectomy rates.[30] Recent studies report ADRs that are much higher than the original targets and have, in some cases, exceeded 50%.[119,120] There had been evidence that individual examiners reach ADRs above 40%.[114,115] These observations suggest that raising the ADR target above 20% for a male/female population might have benefit, but evidence that increasing the target results in either improved cancer prevention or increased detection of advanced lesions has been lacking. Recently, Corley et al[121] presented the association of ADR in 223,842 patients undergoing 264,792 colonoscopies by 136 gastroenterologists. Patients were followed from their baseline examinations for either 10 years or until they had another colonoscopy with negative results, left the health care system, or were diagnosed with CRC. The ADRs of the gastroenterologists ranged from 7.4% to 52.5% and were arranged in quintiles for study purposes. The patients ultimately developed 712 interval cancers. The unadjusted risks for interval cancer in the ADR quintiles from highest to lowest were 4.8, 7.0, 8.0, 8.6, and 9.8 cases per 10,000 person-years of follow-up. Patients of physicians in the highest ADR quintile had an adjusted risk of interval cancer of 0.52 (95% CI, 0.39-0.69) compared with patients of physicians in the lowest ADR quintile. There was a 3% reduction in CRC incidence and a 5% reduction in cancer mortality for each 1% increase in ADR. Higher ADRs were associated with a reduced risk of both proximal and distal cancer and reduced risk in both men and women.[121] Based on this new evidence, the task force now recommends a new minimum target for overall ADR (ADR in a male/female population aged ≥50 years undergoing screening colonoscopy) of at least 25%. Because some endoscopists perform colonoscopy for primarily male or female patients (eg, endoscopists in Veterans Affairs hospitals or female endoscopists with largely female patient populations), an ADR target of 30% is recommended for men and 20% for women. Colonoscopy programs may choose to calculate individual colonoscopists' ADRs for male and female patients separately in some instances. Data from a registry of screening patients indicate that these targets are at the mean level of performance in current gastroenterology practice (Irving Pike, personal communication based GIQuIC registry) and, thus, are already achieved by many endoscopists in routine colonoscopic practice. All colonoscopists should have their ADRs measured, and colonoscopists with ADRs below 25% overall must take steps to improve performance. Although these new targets represent current understanding of ADR performance needed to optimize CRC prevention, they should not be considered a standard of care. Rather, they should be used as performance targets in the quality improvement process.

The principal factors that determine adenoma prevalence are age and sex; both are accounted for in the recommended targets (ADR should be measured in patients aged ≥50 years, and there are separate targets for men and women). Other influences on adenoma prevalence include cigarette smoking, obesity, and diabetes mellitus.[47] Adjustment of the target ADR for different prevalences of these factors is not currently recommended.

ADR is considered the primary measure of the quality of mucosal inspection and the single most important quality measure in colonoscopy. There is a substantial interaction between ADR and recommended intervals for screening and surveillance, so that optimal patient safety cannot be correctly predicted without knowledge of both an adequate ADR and adherence to recommended intervals. Colonoscopists with high ADRs clear colons better and bring patients back at shorter intervals because the recommended intervals are shorter when precancerous lesions are detected. Colonoscopists with low ADRs fail to identify patients with precancerous lesions and find fewer patients with multiple lesions, putting patients at risk for cancer by failure to clear the colon and recommending inappropriately long intervals between examinations. This interaction emphasizes the essential nature of knowing the ADR of individual colonoscopists to ensure adequate patient protection.[122]

One issue regarding ADR is whether it represents the best overall measure of the quality of mucosal inspection with regard to discrimination of quality, feasibility of measurement, and resistance to gaming (induction

of behaviors directed toward meeting the target but not toward optimizing detection of precancerous lesions and cost effectiveness). ADR does require manual entry of pathology data in most instances, which requires additional work for the endoscopist or endoscopy unit. A second problem is that it rewards a "one and done" approach to colonoscopy: after identifying one polyp with the endoscopic appearance of an adenoma, the endoscopist stops examining the remaining mucosa as carefully. In some cases one and done results from reimbursement policies that typically pay for only one polypectomy regardless of the number of polypectomies performed. Several alternatives to ADR have been proposed, and two deserve mention here.

The polyp detection rate (PDR) is the number of patients with ≥ 1 polyp removed during screening colonoscopy in patients aged ≥ 50 years. PDR has the advantage of not requiring manual entry of pathology data and correlates well with ADR in several studies.[123-126] Conversion rates for PDR to ADR have been proposed.[123] A Canadian study demonstrated a correlation between polypectomy rates and cancer protection.[30] However, whether PDR remains an accurate correlate to ADR when used prospectively in quality improvement programs has not been studied. Furthermore, PDR could be susceptible to gaming, in that it includes removal of the only class of colorectal polyps not considered to have a risk of becoming cancer (ie, distal colon diminutive hyperplastic polyps). Unlike ADR, PDR can be measured by using claims data by payers or others outside the institution performing colonoscopy. Given the ease of application of PDR, prospective studies of its use are desirable and considered necessary to establish its appropriateness. Until these studies are performed, PDR is not endorsed as a quality indicator to be used independently of ADR.

A second measure that warrants consideration is the adenoma per colonoscopy (APC) rate, which is now commonly used in clinical trials of detection.[119,120] APC reflects inspection over the entire length of the colon better than ADR and provides greater separation between endoscopists.[114] APC might lead to increased pathology costs if colonoscopists were expected or inclined to put each polyp in a different container to prove APC, but this problem could be overcome by use of photography to prove detection of multiple adenomas. APC also overcomes the problem of "one and done." Currently, APC is considered to be the most promising alternative to ADR, and additional study is recommended to identify best thresholds and establish mechanisms to ensure that it does not lead to increased costs.

In the future, ADR may be stratified based on size of adenoma (ADR for adenomas ≥ 1 cm), location of adenoma (ADR for right-sided versus left-sided adenomas), or polyp histology. The importance of separate targets for serrated lesions deserves particular attention. Targets for ADR were established by using studies reporting detection of conventional adenomas and do not apply to serrated lesions.[80] Certainly, the terminology is confusing (eg, a sessile serrated polyp/adenoma is not an adenoma—the great majority of these lesions have no dysplasia). These lesions are in a separate class from conventional adenomas and should not be counted toward the ADR. Recent evidence has shown that there is more variation between members of the same gastroenterology group in detection of these lesions[127,128] than is seen for conventional adenomas,[114-117] indicating that missing polyps is a greater problem for these lesions than it is for conventional adenomas. Additional support for the concept that missed serrated lesions are important is the finding that post-colonoscopy cancers are more likely to be CIMP-high, MSI-high, and located in the proximal colon.[112,113] Whether there should be a separate detection target for serrated lesions is the subject of current investigation, with one study suggesting a target of 5% for all serrated lesions (hyperplastic plus sessile serrated polyps) in the proximal colon.[129] A new target may not be needed if ADR and proximal colon serrated lesion detection are sufficiently correlated.[127,128] Further, the target would need to be set for proximal serrated lesions because targeting distal colon hyperplastic lesions is undesirable. A proximal colon target would be subject to substantial problems with lesion location and perhaps gaming of location. The best target would be sessile serrated polyps, but the pathologic distinction between sessile serrated polyp and hyperplastic polyp is subject to marked interobserver variation in pathologic interpretation,[130,131] making sessile serrated polyps nonviable as a detection target. Finally, although ADR and PDR have been shown to correlate with colon cancer protection, this has not yet been demonstrated for other proposed markers.

Future approaches to measurement of the quality of mucosal inspection may have to account for an evolving approach to diminutive polyp management called "resect and discard."[132,133] Resect and discard means that endoscopists would estimate the pathology of diminutive polyps based on visual examination by using image enhancement and then resect and dispose of the lesions without submitting tissue to pathology for histologic evaluation. Under these circumstances, a high-quality endoscopic image would serve as the record of the polyp and the endoscopic estimation of its pathologic type.

The goal of most colonoscopies is the detection and prevention of CRC. ADR is now designated an outcome measure because of the extensive evidence that it correlates directly with CRC and predicts effective prevention of CRC.[16,30,121] This correlation is partly because

colonoscopists with higher ADRs are more likely to be accurate when they designate patients as having polyp-free colons. In addition, however, adenoma detection and resection directly prevent CRC and CRC mortality.[30,134] Because CRC prevention is an ideal outcome, and because effective polyp detection or resection are clearly established as the mechanism by which colonoscopy produces prevention, ADR is now designated an outcome measure.

9a. *Frequency with which withdrawal time is measured*
Level of evidence: 2C
Performance target: >98%
Type of measure: process

9b. *Average withdrawal time in negative-result screening colonoscopies*
Level of evidence: 2C
Performance target: ≥6 minute average
Type of measure: process
Withdrawal time should be measured in all colonoscopy examinations, with the performance target being a ≥6 minute average withdrawal time in negative-result screening colonoscopies.
Discussion: Studies have demonstrated increased detection of significant neoplastic lesions in colonoscopic examinations in which the average withdrawal time is ≥6 minutes. We recommend that mean withdrawal time should be ≥6 minutes in normal-result colonoscopies performed for CRC screening in average-risk patients with intact colons. However, withdrawal time is secondary to ADR as a quality measure. Reporting mean withdrawal times to colonoscopists with ADRs above targets may not be essential or useful. The primary utility of withdrawal time may be in correcting performance of colonoscopists with substandard ADRs.[135] Retrospective studies, which are of substantial value in understanding behaviors associated with detection, clearly demonstrate an association between longer withdrawal time and higher detection rates.[7-14] Careful examination of the colon takes time, which is why studies show an association between time and detection. Any colonoscopist may benefit from education regarding withdrawal technique, and better technique is likely to be accompanied by increased withdrawal time. Therefore, we recommend that the withdrawal phase of colonoscopy in patients without previous surgical resection, and in whom no biopsies or polypectomies are performed, should last ≥6 minutes on average. Each of the previous recommendations has specified that the application of this standard to an individual case is not appropriate,[36,80,118] because colons differ in length, and in some instances a very well-prepared colon of relatively short length and without prominent haustral markings can be carefully examined in <6 minutes. This caveat is reiterated here, but colonoscopists should be aware that anecdotal cases abound where the 6-minute standard has been applied to medicolegal cases involving a post-colonoscopy cancer and alleged negligent performance of colonoscopy.

10. *Frequency with which biopsy specimens are obtained when colonoscopy is performed for an indication of chronic diarrhea*
Level of evidence: 2C
Performance target: >98%
Type of measure: process
Discussion: Patients with microscopic colitis (collagenous and lymphocytic colitis) may have normal-appearing mucosa at colonoscopy. The diagnosis requires biopsy of otherwise unremarkable appearing colon. All patients undergoing colonoscopy for the evaluation of chronic diarrhea should have biopsy specimens obtained. The optimal number and location of biopsies is not established, but ≥8 are recommended. Inclusion of samples from the proximal colon improves the sensitivity for collagenous colitis.[17,136]

11. *Frequency of recommended tissue sampling when colonoscopy is performed for surveillance in ulcerative colitis and Crohn's colitis*
Level of evidence: 1C
Performance target: ≥98%
Type of measure: process
Performance of pancolonic chromoendoscopy with targeted biopsies or 4 biopsies per 10-cm section of involved colon (or approximately 32 biopsies in cases of pan-ulcerative colitis)
Discussion: Systematic biopsy of the colon and terminal ileum can assist in establishing the extent of ulcerative colitis and Crohn's disease and in differentiating ulcerative colitis from Crohn's disease. Recent randomized controlled trials have established that pancolonic chromoendoscopy with targeted biopsies results in fewer biopsies and better identification of dysplasia.[19-21] Alternatively, a systematic biopsy protocol can be used.[74] The recommended protocol includes biopsies in 4 quadrants from each 10 centimeters of the colon, which typically results in 28 to 32 biopsies. The procedure report in ulcerative colitis surveillance examinations should note the number and locations of biopsies from flat mucosa and the location and endoscopic appearance of any mass or suspicious polypoid lesions that called for biopsy or removal.

12. *Frequency with which endoscopic removal of pedunculated polyps and sessile polyps <2 cm is attempted before surgical referral*
Level of evidence: 3
Performance target: >98%
Type of measure: outcome
Mucosally based pedunculated polyps and sessile polyps <2 cm in size should not be sent for surgical resection without an attempt at endoscopic resection or documentation of endoscopic inaccessibility.

Discussion: Colonoscopists should be able to perform biopsy and routine polypectomy. Consistent referral of small "routine" colorectal polyps identified during diagnostic colonoscopy for repeat colonoscopy and polypectomy by others is unacceptable. On the other hand, referral of technically difficult polyps to other more experienced endoscopists for endoscopic resection is encouraged.

In some centers, polyps <2 cm in size have been referred for surgical resection,[137] but such are almost invariably endoscopically resectable, if not in routine colonoscopic practice then by expert colonoscopists.[138] Consistent referral of sessile polyps <2 cm in size for surgical resection is inappropriate. In some cases, these polyps may be difficult to access or properly position for polypectomy, and referral to another, more experienced endoscopist may be appropriate.

Endoscopists should not attempt removal of polyps they consider beyond their skills or comfort levels and should feel comfortable in referring such polyps to other endoscopists for a second opinion (eg, review of photographs) or endoscopic resection. Many sessile polyps >2 cm in size are removable endoscopically, depending on their location within the colon, their size, and the ability to access them endoscopically.[139,140] Endoscopic resection is more cost effective and safer than surgical resection.[137] If referral to another endoscopist is anticipated for resection of a large sessile lesion, then the endoscopist should avoid snare resection of any part of the polyp if possible, because such a partial resection will result in a false-positive non-lifting sign that can make the subsequent attempt at endoscopic resection more difficult. Essentially all mucosa-based pedunculated polyps can be removed endoscopically. All polyps referred for surgical resection should be photographed to document the need for surgical resection in the continuous quality improvement process. Review of photographs by a second, more experienced endoscopist can be useful to ensure the appropriateness of surgical referral. When surgical referral is pursued, correlation of photographs and endoscopic and pathologic measurements of polyp size should be undertaken to confirm the appropriateness of surgical referral.

Both benign and malignant lesions sent for surgical resection that are not in an area that can be indentified with certainty by endoscopy (eg, the cecum and proximal ascending colon where the cecum is still endoscopically visible and the rectum) should be marked with ample submucosal injection of carbon black in 3 to 4 quadrants to ensure resection of the correct segment. If the tattoo cannot be located during surgery, intraoperative colonoscopy is needed to resolve the correct location.

Intraprocedure research questions

1. What is the most clinically relevant rating system for bowel preparation quality?
2. What tools can improve patient and physician awareness and use of split-dose and same-day dosing of bowel preparation?
3. What factors are associated with an increased risk of having an inferior bowel preparation, and what interventions can overcome such variations?
4. Can PDR replace ADR when used prospectively without distorting behaviors (eg, increasing resection of distal colon hyperplastic polyps or normal polypoid tissue)?
5. Does improving ADR (or PDR) as part of a quality improvement effort result in lower CRC rates?
6. Is there significant interobserver variation when photodocumentation of cecal landmarks is reviewed?
7. Is APC a practical and cost-effective measure of the quality of mucosal inspection?
8. Are ADR and proximal serrated lesions correlated? Is a separate detection target for proximal colon serrated lesions necessary and practical to implement?
9. Should surveillance follow-up recommendations be altered when colonoscopy is performed by endoscopists with high ADRs? For example, would patients in this category with 3 or more adenomas, all of which are diminutive tubular adenomas, still require follow-up colonoscopy in 3 years?
10. Does detection of advanced lesions continue to increase as the overall ADR increases?
11. For screening programs that use fecal occult blood or immunochemistry testing to select patients for colonoscopy, can ADR be used as a quality metric and at what benchmarks?
12. Which technical adjuncts or imaging tools, if any, improve adenoma detection, especially by colonoscopists with low ADRs?
13. What is the optimal duration of the withdrawal phase by using white-light colonoscopy (ie, at what duration does detection of clinically significant neoplasms plateau)?
14. Does chromoendoscopy improve targeted biopsies over high-definition white-light colonoscopy in chronic ulcerative colitis?
15. What is the degree of adherence to recommended biopsy protocols or use of chromoendoscopy for inflammatory bowel disease in community practice?
16. How often are patients with polyps <2 cm inappropriately undergoing surgical rather than endoscopic resection?
17. How are large (>2 cm) colon polyps managed in community practice, and does this management differ among colonoscopists in different specialties (eg, gastroenterologists vs surgeons)?
18. What is the success rate of endoscopic resection of large sessile polyps (>2 cm) in community practice?
19. What polypectomy methods optimize completeness of resection of serrated lesions?

20. How will the need to document ADR for quality reporting influence the development of optical biopsy for the interpretation of small polyps?

Postprocedure quality indicators

The postprocedure period extends from the time the endoscope is removed to subsequent follow-up. Postprocedure activities include providing instructions to the patient, documentation of the procedure, recognition and documentation of adverse events, pathology follow-up of, communication with referring physicians, and assessing patient satisfaction.[38] Postprocedure quality indicators specific to performance of colonoscopy include the following:

13. *Incidence of perforation by procedure type (all indications versus CRC screening/polyp surveillance) and post-polypectomy bleeding*

    Level of evidence: 1C

    Performance targets:

    Incidence of perforation—all examinations, < 1:500

    Incidence of perforation—screening, < 1:1000

    Incidence of post-polypectomy bleeding, <1%

    Type of measure: outcome

    Perforation rates also may be stratified based on use of therapeutic polypectomy with snare or application of cautery with forceps versus cold biopsy forceps only.

    Discussion: Perforation is generally considered the most serious adverse event presenting in the short term during or after colonoscopy. About 5% of colonoscopic perforations are fatal.[141-143] Published rates of colonoscopic perforation vary widely,[141-154] and few studies on this topic have been reported in the past 5 years. A population-based study of Medicare patients reported an overall risk of perforation of 1 in 500, but risk of less than 1 in 1000 screening patients.[145] Expected perforation rates in screening patients are lower because the patients are generally healthy and tend not to have associated colon conditions that have been associated with perforation, including pseudoobstruction, ischemia, severe colitis, radiation, stricture formation, bulky colorectal cancers, more severe forms of diverticular disease, and chronic corticosteroid therapy.

    Considering all of the available data, perforation rates >1 in 500 overall or >1 in 1000 in screening patients should initiate review by an endoscopy unit medical director or another expert to determine whether insertion or polypectomy practice are inappropriate.

    Technical factors that result in perforation as well as those steps that prevent perforation are not fully understood or proven effective. Generally accepted advice includes the following. The colonoscopist should not continue to push against fixed resistance. Loops and bends in the insertion tube should be removed as soon as possible. Consider use of a more flexible instrument (eg, pediatric colonoscope or upper endoscope) when there is severe diverticular disease, sigmoid fixation, radiated colon, Crohn's colitis, or otherwise significantly diseased colon. Avoidance of electrocautery in resection of diminutive polyps and some small (6-9 mm) polyps, in favor of cold resection techniques (particularly cold snaring), has proven remarkably safe.[155,156] Submucosal injection likely reduces risk during EMR. A guidewire passed through strictures before an attempt to push an endoscope through can prevent the instrument tip from sliding off the stricture and dissecting the adjacent colon wall. Caution should be used in dilating long strictures. In general, graded dilation with inspection of strictures before increasing dilator size can help control the depth of tear created. Insufflation of carbon dioxide rather than air may reduce the risk of barotrauma perforations, particularly in patients with partial obstruction or with pseudoobstruction. Perforations that are recognized during the procedure may be effectively closed by the use of metallic hemostatic clips[157] or by large clips that are mounted over the end of the endoscope for application.[158]

    Perforation rates can be very difficult to track over time, especially in colonoscopists with low procedure volumes. An alternative approach is to have the circumstances of all perforations reviewed and tracked by the endoscopy unit medical director or by an outside expert. This "sentinel event" approach can lead to changes in systems and changes in physician practice that reduces patient risk in future examinations.

    Bleeding is the most common adverse event of polypectomy.[141-143,159,160] Bleeding can be immediate (during the procedure) or delayed. In general, the use of blended or cutting current is associated with an increased risk of immediate bleeding, whereas pure low-power coagulation is associated with a greater risk of delayed bleeding.[161,162] In clinical practice, the use of pure low-power coagulation or blended current are both common, and the use of pure cutting current for polypectomy is rare.[163]

    Endoscopic series suggests that the overall risk of post-polypectomy bleeding should be <1%.[141,142,159,160] Overall, bleeding rates that exceed 1% should prompt review by experts from within or outside the institution regarding whether polypectomy practices are appropriate. In general, the risk of bleeding increases with polyp size, proximal colon location, anticoagulation, and use of antiplatelet agents such as clopidogrel.[164] For polyps >2 cm in size, particularly in the proximal colon, bleeding rates may exceed 10%.[62,138,159,160,165]

    Technical measures that help reduce immediate bleeding include epinephrine injection for sessile or pedunculated polyps[166,167] and detachable loops for

TABLE 4. Summary of proposed quality indicators for colonoscopy*

Quality indicator	Grade of recommendation	Measure type	Performance target (%)
Preprocedure			
1. Frequency with which colonoscopy is performed for an indication that is included in a published standard list of appropriate indications, and the indication is documented	1C+	Process	>80
2. Frequency with which informed consent is obtained, including specific discussions of risks associated with colonoscopy, and fully documented	1C	Process	>98
3. Frequency with which colonoscopies follow recommended post-polypectomy and post-cancer resection surveillance intervals and 10-year intervals between screening colonoscopies in average-risk patients who have negative examination results and adequate bowel cleansing (priority indicator)	1A	Process	≥90
4. Frequency with which ulcerative colitis and Crohn's colitis surveillance is recommended within proper intervals	2C	Process	≥90
Intraprocedure			
5. Frequency with which the procedure note documents the quality of preparation	3	Process	>98
6. Frequency with which bowel preparation is adequate to allow the use of recommended surveillance or screening intervals	3	Process	≥85 of outpatient examinations
7. Frequency with which visualization of the cecum by notation of landmarks and photodocumentation of landmarks is documented in every procedure (priority indicator)	1C	Process	
Cecal intubation rate with photography (all examinations)			≥90
Cecal intubation rate with photography (screening)			≥95
8. Frequency with which adenomas are detected in asymptomatic average-risk individuals (screening) (priority indicator)	1C	Outcome	
Adenoma detection rate for male/female population			≥25
Adenoma detection rate for male patients			≥30
Adenoma detection rate for female patients			≥20
9a. Frequency with which withdrawal time is measured	2C	Process	>98
9b. Average withdrawal time in negative-result screening colonoscopies	2C	Process	≥6 min
10. Frequency with which biopsy specimens are obtained when colonoscopy is performed for an indication of chronic diarrhea	2C	Process	>98

TABLE 4. Continued

Quality indicator	Grade of recommendation	Measure type	Performance target (%)
11. Frequency of recommended tissue sampling when colonoscopy is performed for surveillance in ulcerative colitis and Crohn's colitis	1C	Process	>98
12. Frequency with which endoscopic removal of pedunculated polyps and sessile polyps <2 cm is attempted before surgical referral	3	Outcome	>98
Postprocedure			
13. Incidence of perforation by procedure type (all indications vs colorectal cancer screening/polyp surveillance) and post-polypectomy bleeding	1C	Outcome	
Incidence of perforation—all examinations			<1:500
Incidence of perforation—screening			<1:1000
Incidence of post-polypectomy bleeding			<1%
14. Frequency with which post-polypectomy bleeding is managed without surgery	1C	Outcome	≥90
15. Frequency with which appropriate recommendation for timing of repeat colonoscopy is documented and provided to the patient after histologic findings are reviewed	1A	Process	≥90

*This list of potential quality indicators is meant to be a comprehensive listing of measurable endpoints. It is not the intention of the task force that all endpoints be measured in every practice setting. In most cases, validation may be required before a given endpoint may be adopted universally.

pedunculated polyps.[167,168] Cold resection techniques have not been associated with delayed hemorrhage from diminutive polyps and some small (6-9 mm) polyps. Effective methods of reducing delayed bleeding from large sessile and flat lesions remains uncertain but, as noted earlier, the risk may be related to cautery type. Some experts advocate the use of microprocessor-controlled alternating coagulation and/or cutting currents to limit thermal injury and reduce the delayed bleeding risk when these lesions are resected,[140] but controlled evidence is lacking.

14. *Frequency with which post-polypectomy bleeding is managed without surgery*

Level of evidence: 1C

Performance target: ≥90%

Type of measure: outcome

In ongoing bleeding, repeat colon examination and endoscopic treatment of polypectomy sites results in successful hemostasis.

Discussion: In general, >90% of post-polypectomy bleeding can be managed without surgery. Immediate post-polypectomy bleeding can generally be treated effectively by endoscopic means and should seldom require operative treatment. Immediate bleeding from the stalk of a pedunculated polyp after transection can be treated by re-grasping the stalk and holding it for 10 or 15 minutes. This causes spasm in the bleeding artery. Immediate bleeding also can be treated by application of clips or by injection of epinephrine,[169] followed by application of multipolar cautery.[170] Immediate bleeding is not considered an adverse event unless it results in hospitalization, transfusion, or surgery.

Risk factors for delayed bleeding include large polyp size, proximal colon location, anticoagulation, and possibly the use of low-power coagulation current for electrocautery.[159,160] Delayed bleeding frequently stops spontaneously.[170] In-hospital observation may be appropriate if the patient has comorbidities or lives far from the treating physician. Repeat colonoscopy in patients who have stopped bleeding is optional and should be performed at the discretion of the colonoscopist. Patients who present with delayed bleeding and are continuing to pass bright red blood usually are having an ongoing arterial hemorrhage. Prompt repeat colonoscopy, which may be performed without bowel preparation,[170] is warranted. Treatment can be by application of clips[169] or injection in combination with multipolar cautery.[170] Multipolar cautery is generally applied at low power, without forceful tamponade (especially in the proximal colon) and is

TABLE 5. Priority quality indicators for colonoscopy*

Frequency with which adenomas are detected in asymptomatic average-risk individuals (screening)
Frequency with which colonoscopies follow recommended post-polypectomy and post-cancer resection surveillance intervals and 10-year intervals between screening colonoscopies in average-risk patients who have negative examination results and adequate bowel cleansing
Frequency with which visualization of the cecum by notation of landmarks and photodocumentation of landmarks is documented in every procedure

*See text for specific targets and discussion.

continued until there is subjective cessation of bleeding. Findings in the base of the bleeding polypectomy site can include an actively bleeding visible vessel, a non-bleeding visible vessel, an apparent clot without bleeding, or an apparent clot with bleeding. Repeat bleeding seldom occurs after post-polypectomy bleeding has stopped spontaneously or from endoscopic therapy.

15. *Frequency with which appropriate recommendation for timing of repeat colonoscopy is documented and provided to the patient after histologic findings are reviewed*

    Level of evidence: 1A

    Performance standard: ≥90%

    Type of measure: process

    Discussion: Colonoscopic screening is recommended in all current guidelines at 10-year intervals in the average-risk population,[15,47,48,171] at 5 to 10–year intervals among patients with 1 or 2 small (<10 mm) tubular adenomas, at 5-year intervals when there is a history of advanced adenomas on previous colonoscopies, and at 3-year-intervals for patients with ≥ 3 small adenomas, an adenoma with villous features or high-grade dysplasia, or an adenoma ≥1 cm in size. However, assessments of Medicare colonoscopy codes demonstrated systematic overuse of colonoscopy for screening and polyp surveillance by some physicians.[54] This practice is not cost effective and it exposes patients to excess risk, and its systematic performance cannot be justified.

    Endoscopists should specifically document a recommendation for a repeat colonoscopy at 10-year intervals after a normal screening colonoscopy in an average-risk patient. If polyps are removed, then the pathology data should be used to document recommendations regarding timing for repeat colonoscopy.

Post-procedure research questions

1. How many perforations are avoidable by improved training, altered technique, or new or improved technology?
2. Do perforation rates vary in clinical practice by specialty or by extent of training or duration of experience?
3. Do different types of electrocautery used for polypectomy current definitely affect adverse event rates and to what extent?
4. Does prophylactic clipping of non-bleeding, large polypectomy sites prevent delayed adverse events?
5. Does cold snare resection definitely reduce adverse events from resection of small polyps?
6. Does submucosal injection definitely reduce large sessile polyp perforation rates?
7. Which polypectomy maneuvers can be performed safely in patients who must continue to take anticoagulants or antiplatelet agents?
8. Are delayed bleeding rates reduced by the use of clips or loops after polypectomy among patients who need to resume anticoagulation therapy?
9. Does application of cautery to the edge of large, piecemeal-resected polyps reduce the incidence of incomplete polypectomy?
10. Does the application of chromoendoscopy or optical contrast endoscopy reduce the incidence of incomplete polypectomy?
11. Can software programs be developed to reliably integrate pathology data fields directly into the endoscopy database and eliminate the need for manual entry?

Priority indicators for colonoscopy

For colonoscopy, the recommended priority indicators are (1) ADR, (2) use of recommended intervals between colonoscopies performed for average-risk CRC screening and colon polyp surveillance, and (3) cecal intubation rate with photographic documentation (Table 5). For each of these indicators, reaching the recommended performance target is considered strongly associated with important clinical outcomes. These indicators can be measured readily in a manageable number of examinations and, for each, there is evidence of substantial variation in performance.[122] In addition, there is evidence for both ADR and the use of recommended screening and surveillance intervals that simple educational and corrective measures can improve performance.[172]

Correction of poor performance

The primary purpose of measuring quality indicators is to improve patient care by identifying poor performers and retraining them or removing privileges to perform colonoscopy if performance cannot be improved. When individual colonoscopists have ADRs below the recommended threshold, they must demonstrate improvement. Corley[172] recently reviewed the developing literature on improving detection. Retrospective studies provide overwhelming evidence that withdrawal time is positively associated with detection,[7-14] but forcing colonoscopists to observe longer withdrawal times is generally not effective in improving detection,[172] probably because studies with negative results typically have not included specific instruction about how the increased time should be used.[173]

If endoscopists with low ADRs are not using split-dose preparation, they should immediately switch to split dosing. The two most effective interventions regarding colonoscopy skills for improving ADR have both involved education,[135,174] which should include information on the spectrum of precancerous lesions. The task force recommends instruction in the Paris classification[175] to emphasize the importance of flat and depressed lesions and review of photographs of flat and depressed conventional adenomas[176] and serrated lesions.[177] Education also should include instruction in withdrawal technique that has been repeatedly associated with improved detection, including probing the proximal sides of folds, cleaning up pools of retained fluid and mucus, and ensuring adequate distention of the entire colon.[7,178]

Finally, technical adjuncts to imaging can be considered.[179] Electronic chromoendoscopy (Olympus narrow-band imaging, Fujinon Intelligent Chromo Endoscopy, Pentax i-scan) has been ineffective in improving detection, but the investigators were typically endoscopists with high ADRs.[179] One study suggested that narrow-band imaging induced a learning effect that improved white-light detection in endoscopists with low ADRs.[180] Conventional chromoendoscopy has produced gains in detection of tiny adenomas and, in a large recent randomized trial, produced a nearly significant increase in detection of advanced adenomas.[181] A recent meta-analysis indicated that cap-fitted colonoscopy produces small gains in detection of small adenomas.[182] A tandem study found improved detection with the Third-Eye Retroscope, but failed to control withdrawal times in the two study arms.[183] These technologies should be tested specifically for their capacity to improve detection by endoscopists with low ADRs. Pending such studies, even case studies of their effect on endoscopists with low ADRs would be of interest.

Colonoscopists who cannot improve their detection rates to reach recommended ADR thresholds through education and technical measures should have their colonoscopy privileges removed, because current evidence indicates that low-level detection endangers patients.[16] This recommendation holds for colonoscopists of all specialties.

Conclusion

Reduction in variation in quality has emerged as an important priority for colonoscopy practice. The continuous quality improvement process should be instituted and embraced in all colonoscopy practices. This article summarizes current evidence and expert consensus on quality indictors to be used in this process (Table 4). The task force has created a comprehensive list of potential quality indicators along with a set of performance targets based on benchmarking data where available. These proposals reflect a significant evolution from the first set of indicators described in 2006,[36] both in terms of what is feasible to measure and in terms of evidence about best practices and association with outcome. For the first time, the task force recommends 3 priority quality indicators that every colonoscopy practice should track (Table 5). Practices that are initiating the quality process should focus on the priority indicators first. The performance of high-quality colonoscopy and its documentation in a quality improvement program is the most important role of the colonoscopist in the multi-specialty effort to reduce CRC incidence and mortality.

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Abbreviations: ACG, American College of Gastroenterology; ADR, adenoma detection rate; APC, adenoma per colonoscopy; ASGE, American Society for Gastrointestinal Endoscopy; CRC, colorectal cancer; PDR, polyp detection rate.

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Communication from the ASGE Quality Assurance in Endoscopy Committee

QUALITY INDICATORS FOR GI ENDOSCOPIC PROCEDURES

Quality indicators for ERCP

ERCP is one of the most technically demanding and high-risk procedures performed by GI endoscopists. It requires significant focused training and experience to maximize success and to minimize poor outcomes.[1,2] ERCP has evolved from a purely diagnostic to a predominately therapeutic procedure.[3] ERCP and ancillary interventions are effective in the non-surgical management of a variety of pancreaticobiliary disorders, most commonly the removal of bile duct stones and relief of malignant obstructive jaundice.[4] The American Society for Gastrointestinal Endoscopy (ASGE) has published specific criteria for training and granting of clinical privileges for ERCP, which detail the many skills that must be developed to perform this procedure in clinical practice with high quality.[5-7]

The quality of health care can be measured by comparing the performance of an individual or a group of individuals with an ideal or benchmark.[8] The particular parameter that is being used for comparison is termed a quality indicator. A quality indicator often is reported as a ratio between the incidence of correct performance and the opportunity for correct performance or as the proportion of interventions that achieve a predefined goal.[9] Quality indicators can be divided into 3 categories: (1) structural measures—these assess characteristics of the entire health care environment (eg, rates of participation by a physician or other clinician in a systematic clinical database registry that includes consensus endorsed quality measures), (2) process measures—these assess performance during the delivery of care (eg, rate of cannulation of the desired duct), and (3) outcome measures—these assess the results of the care that was provided (eg, rates of adverse events such as pancreatitis after ERCP).

METHODOLOGY

In 2006, the ASGE/American College of Gastroenterology (ACG) Task Force on Quality in Endoscopy published the first version of quality indicators common to all endoscopic procedures.[10] The present update integrates new data pertaining to previously proposed quality indicators and new quality indicators common to all endoscopic procedures. We prioritized indicators that had wide-ranging clinical application, were associated with variation in practice and outcomes, and were validated in clinical studies. Clinical studies were identified through a computerized search of Medline followed by review of the bibliographies of all relevant articles. When such studies were absent, indicators were chosen by expert consensus. Although feasibility of measurement was a consideration, we hoped that inclusion of highly relevant, but not yet easily measurable, indicators would promote their eventual adoption. Although a comprehensive list of quality indicators is proposed, we recognize that, ultimately, only a small subset might be used widely for continuous quality improvement, benchmarking, or quality reporting. As in 2006, the current task force concentrated its attention on parameters related solely to endoscopic procedures. Although the quality of care delivered to patients is clearly influenced by many factors related to the facilities in which endoscopy is performed, characterization of unit-related quality indicators was not included in the scope of this effort.

The resultant quality indicators were graded on the strength of the supporting evidence (Table 1).[11] Each quality indicator was classified as an outcome or a process measure. Although outcome quality indicators are preferred, some can be difficult to measure in routine clinical practice, because they need analysis of large amounts of data and long-term follow-up and may be confounded by other factors. In such cases, the task force deemed it reasonable to use process indicators as surrogate measures of high-quality endoscopy. The relative value of a process indicator hinges on the evidence that supports its association with a clinically relevant outcome, and such process measures were emphasized.

The quality indicators for this update were written in a manner that lends them to be developed as measures. Although they remain quality indicators and not measures, this document also contains a list of performance targets for each quality indicator. The task force selected performance targets from benchmarking data in the literature when available. When no data was available to support establishing a performance target level, "N/A" (not available) was listed. However, when expert consensus considered failure to perform a given quality indicator a "never event," such as monitoring vital signs during sedation, then the performance target was listed as >98%. It is important to emphasize that the performance targets listed do not necessarily reflect the standard of care but rather serve as specific goals to direct quality improvement efforts.

Quality indicators were divided into 3 time periods: preprocedure, intraprocedure, and postprocedure. For each category, key relevant research questions were identified.

In order to guide continuous quality improvement efforts, the task force also recommended a high-priority

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TABLE 1. Grades of recommendation*,[12]

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

*Adapted from Guyatt G, Sinclair J, Cook D, et al. Moving from evidence to action. Grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, editors. Users' guides to the medical literature. Chicago: AMA Press; 2002. p. 599-608.

subset of the indicators described, based on their clinical relevance and importance, evidence that performance varies significantly in clinical practice, and feasibility of measurement (a function of the number of procedures needed to obtain an accurate measurement with narrow confidence intervals and the ease of measurement). A useful approach for individual endoscopists is to first measure their performances with regard to these priority indicators. Quality improvement efforts would then either move to different quality indicators if endoscopists are performing above recommended thresholds, or the employer and/or teaching center could institute corrective measures and re-measure performance of low-level performers.

Recognizing that certain quality indicators are common to all GI endoscopic procedures, such items are presented in detail in a separate document, similar to the process in 2006.[12] The pre-procedure, intra-procedure, and post-procedure indicators common to all endoscopy are listed in Table 2. Those common factors will be discussed in this document only insofar as the discussion needs to be modified specifically to relate to ERCP.

Preprocedure quality indicators

The preprocedure period includes all contact between members of the endoscopy team and the patient before the administration of sedation. Common issues for all endoscopic procedures during this period include: appropriate indication, thorough administration of informed consent, risk assessment, formulation of a sedation plan, clinical decision making with regard to prophylactic antibiotics and management of antithrombotic drugs, and timeliness of the procedure.[12] Preprocedure quality indicators specific to performance of ERCP include the following:

1. *Frequency with which ERCP is performed for an indication that is included in a published standard list of appropriate indications and the indication is documented (priority indicator)*

   Level of evidence: 1C+

   Performance target: >90%

   Type of measure: process

   ERCP should be performed for appropriate indications as defined in previously published guidelines.[3,4,13] An appropriate indication should be documented for each procedure, and when it is a nonstandard indication the reasons for this should be made sufficiently clear in the documentation.

   Discussion: The indications for ERCP are covered in detail in separate publications.[13,14] Table 3 contains a list of the vast majority of acceptable indications for ERCP.[15] Table 4 contains a list of all proposed quality indicators for ERCP. The task force selected a higher performance target for ERCP (>90%) as opposed to other endoscopic

TABLE 2. Summary of proposed quality indicators common to all endoscopic procedures[9,12]

Quality indicator	Grade of recommendation	Measure type	Performance target (%)
Preprocedure			
1. Frequency with which endoscopy is performed for an indication that is included in a published standard list of appropriate indications, and the indication is documented (priority indicator)	1C+	Process	>80
2. Frequency with which informed consent is obtained and fully documented	3	Process	>98
3. Frequency with which preprocedure history and directed physical examination are performed and documented	3	Process	>98
4. Frequency with which risk for adverse events is assessed and documented before sedation is started	3	Process	>98
5. Frequency with which prophylactic antibiotics are administered only for selected settings in which they are indicated (priority indicator)	Varies	Process	>98
6. Frequency with which a sedation plan is documented	Varies	Process	>98
7. Frequency with which management of antithrombotic therapy is formulated and documented in print before the procedure (priority indicator)	3	Process	N/A
8. Frequency with which a team pause is conducted and documented	3	Process	>98
9. Frequency with which endoscopy is performed by an individual who is fully trained and credentialed to perform that particular procedure	3	Process	>98
Intraprocedure			
10. Frequency with which photodocumentation is performed	3	Process	N/A
11. Frequency with which patient monitoring among patients receiving sedation is performed and documented	3	Process	>98
12. Frequency with which the doses and routes of administration of all medications used during the procedure are documented	3	Process	>98
13. Frequency with which use of reversal agents is documented	3	Process	>98
14. Frequency with which procedure interruption and premature termination because of oversedation or airway management issues is documented	3	Process	>98
Postprocedure			
15. Frequency with which discharge from the endoscopy unit according to predetermined discharge criteria is documented	3	Process	>98

TABLE 2. Continued

Quality indicator	Grade of recommendation	Measure type	Performance target (%)
16. Frequency with which patient instructions are provided	3	Process	>98
17. Frequency with which the plan for pathology follow-up is specified and documented	3	Process	>98
18. Frequency with which a complete procedure report is created	3	Process	>98
19. Frequency with which immediate adverse events requiring interventions are documented	3	Process	>98
20. Frequency with which immediate adverse events requiring interventions including hospitalization occur	3	Outcome	N/A
21. Frequency with which delayed adverse events leading to hospitalization or additional procedures or medical interventions occur within 14 days	3	Outcome	N/A
22. Frequency with which patient satisfaction data are obtained	3	Process	N/A
23. Frequency with which communication with referring providers is documented	3	Process	N/A

N/A, Not available.
*This list of potential quality indicators is meant to be a comprehensive list of measurable endpoints. It is not the intention of the task force that all endpoints be measures in every practice setting. In most cases, validation may be required before a given endpoint may be adopted universally.

procedures (>80%) to reflect the higher incidence of serious adverse events after ERCP. Clinical settings in which ERCP is generally *not* indicated include the following:

Abdominal pain without objective evidence of pancreaticobiliary disease by laboratory or noninvasive imaging studies.[16,17] In this setting, the yield of ERCP is low, the risk of adverse events is significant, and those adverse events are disproportionately severe.[18] When considered in this patient group, ERCP should be undertaken only after appropriate patient consultation and consent. If the diagnosis of sphincter of Oddi dysfunction is being considered, ERCP generally should be performed in a setting capable of performing sphincter of Oddi manometry and placing prophylactic pancreatic stents, although the efficacy of manometry in this setting has not been established.[19,20] A recent, randomized, controlled, multicenter, clinical trial (EPISOD) presented in abstract form suggested that ERCP is not likely to be efficacious in sphincter of Oddi type III in which there are no objective measures of pancreaticobiliary pathology.[21]

Routine ERCP before cholecystectomy. Preoperative ERCP in patients undergoing cholecystectomy should be reserved for patients with cholangitis or biliary obstruction or the presence of bile duct stones as confirmed by imaging studies or highly suspected by clinical criteria.[22,23]

Relief of biliary obstruction. ERCP is not generally indicated for relief of biliary obstruction in patients with potentially resectable malignant distal bile duct obstruction in whom surgical resection will not be delayed by neoadjuvant therapy or other preoperative assessments or treatments. Preoperative biliary decompression has not been shown to improve postoperative outcomes in patients who are to proceed directly to surgery, and it may worsen outcomes according to some studies, although in current clinical practice preoperative biliary decompression is widely performed.[24] Most patients with pancreatic cancer undergo preoperative biliary drainage for tissue acquisition via brushing, to relieve pruritus, to allow for neoadjuvant chemoradiation therapy, or to accommodate delays before surgery, including preoperative evaluation and optimization, and this should be considered appropriate care.[25]

2. *Frequency with which informed consent is obtained, including specific discussions of risks associated with ERCP, and fully documented*
   Level of evidence: 1C
   Performance target: >98%
   Type of measure: process
   In addition to the risks associated with all endoscopic procedures, the consent should address the relevant and substantial adverse events pertaining to

TABLE 3. Appropriate indications for ERCP[15]

The jaundiced patient suspected of having biliary obstruction (appropriate therapeutic maneuvers should be performed during the procedure)
The patient without jaundice whose clinical and biochemical or imaging data suggest pancreatic duct or biliary tract disease
Evaluation of signs or symptoms suggesting pancreatic malignancy when results of direct imaging (eg, EUS, US, computed tomography [CT], magnetic resonance imaging [MRI]) are equivocal or normal
Evaluation of pancreatitis of unknown etiology
Preoperative evaluation of the patient with chronic pancreatitis and/or pseudocyst Evaluation of the sphincter of Oddi by manometry
Empirical biliary sphincterotomy without sphincter of Oddi manometry is not recommended in patients with suspected type III sphincter of Oddi dysfunction
Endoscopic sphincterotomy: Choledocholithiasis. Papillary stenosis or sphincter of Oddi dysfunction To facilitate placement of biliary stents or dilation of biliary strictures Sump syndrome Choledochocele involving the major papilla Ampullary carcinoma in patients who are not candidates for surgery Facilitate access to the pancreatic duct
Stent placement across benign or malignant strictures, fistulae, postoperative bile leak, or in high-risk patients with large unremovable common duct stones
Dilation of ductal strictures
Balloon dilation of the papilla
Nasobiliary drain placement
Pancreatic pseudocyst drainage in appropriate cases
Tissue sampling from pancreatic or bile ducts
Ampullectomy of adenomatous neoplasms of the major papilla
Therapy of disorders of the biliary and pancreatic ducts
Faciliation of cholangioscopy and/or pancreatoscopy

each specific ERCP procedure. Informed consent for ERCP should focus on at least 6 possible adverse outcomes: (1) pancreatitis, (2) hemorrhage, (3) infection, (4) cardiopulmonary events, (5) allergic reaction, and (6) perforation. It is also advisable that patients be informed of the possibility that the procedure may not be successful and that additional procedures may be warranted. The patient should be informed that adverse events could be severe in nature.

Discussion: Some ERCP adverse events are unique from those that occur with standard luminal endoscopy. A review of the adverse events specific to ERCP has been published previously.[26] The expected rate of post-ERCP pancreatitis is generally between 1% and 7% for most average-risk patients.[27-30] There are several situations in which this rate may be significantly higher, most notably in patients with known or suspected sphincter of Oddi dysfunction. Adverse events in these patients can approach 20% to 30%, with severe pancreatitis also being more likely.[31]

Numerous factors, both patient-related and procedure-related, may influence the risk for post-ERCP pancreatitis and need to be taken into account when endoscopists are planning for the procedure and obtaining informed consent. Cholangitis occurs in $<1\%$ of patients after ERCP, and cholecystitis complicates 0.2% to 0.5% of ERCPs. Hemorrhage is most commonly an adverse event of endoscopic sphincterotomy and has been reported to occur in 0.8% to 2% of cases. Perforations may be guidewire-induced, sphincterotomy-induced, or endoscope-induced. The overall incidence of perforation during ERCP has been reported to be 0.1% to 0.6%.[32]

3. *Frequency with which appropriate antibiotics for ERCP are administered for settings in which they are indicated*
   Level of evidence: 2B
   Performance target: $>98\%$
   Type of measure: process

Prophylactic antibiotics for ERCP are administered for settings in which they are indicated, as described in published guidelines.[33,34]

Discussion: Detailed guidelines for the administration of antibiotics before ERCP have been published previously. In brief, preprocedure antibiotics for ERCP should be considered in patients with known or suspected biliary obstruction in which complete relief of the obstruction is not anticipated (such as with primary sclerosing cholangitis) or in patients undergoing immunosuppression after liver transplantation, patients with active bacterial cholangitis, patients with pancreatic pseudocysts, and in other clinical situations.[35] Antibiotics should be considered in patients who pose any additional concerns about the risk of infection.

4. *Frequency with which ERCP is performed by an endoscopist who is fully trained and credentialed to perform ERCP*

   Level of evidence: 3

   Performance target: >98%

   Type of measure: process

   Discussion: Although all endoscopy must be performed by individuals who are trained and competent in order to provide safe and effective quality examinations, this has particular importance for ERCP because of the higher complexity of the procedure and rate of potential severe adverse events. Data also indicate that operators of varying skill, experience, and procedure volume have varying outcomes with respect to adverse events.[36]

5. *Frequency with which the volume of ERCPs performed per year is recorded per endoscopist*

   Level of evidence: 1C

   Performance target: >98%

   Type of measure: process

   Discussion: Individual endoscopist ERCP case volume has been associated with variance in both procedure success rates and adverse event rates and, accordingly, should be recorded. An Austrian group showed that endoscopists with <50 annual ERCPs had lower success rates and more adverse events during ERCP than physicians performing higher procedure volumes.[37] Similarly, investigation has shown that endoscopists who performed at least one sphincterotomy per week had significantly fewer ERCP-related adverse events. When compared with those who performed fewer ERCP procedures, endoscopists who performed >1 sphincterotomy per week (which can be viewed as a surrogate for performing more ERCP procedures overall) had lower rates of all adverse events (8.4% vs 11.1%; $P = .03$) and severe adverse events (0.9% vs 2.3%; $P = .01$).[38] Although the actual procedure success rates and adverse event rates are more direct measures of an individual endoscopist's quality in ERCP, this and other ERCP benchmarking data suggest that individual case volume may predict such outcomes and, therefore, should be tracked.[39]

Additionally, the reliability of performance measures will vary, based on the volume of cases reported. For example, the deep bile duct cannulation rate may not be a meaningful figure for an individual who performs only a very small number of cases per year. For that reason, it is important to keep track of procedure volume to properly interpret outcome data.

Preprocedure research questions

1. How often is ERCP performed outside of accepted clinical indications?
2. How often are prophylactic antibiotics administered when needed for ERCP?
3. What is the incidence of infection when antibiotics are not administered as recommended?
4. How many ERCPs per year are required to reliably render performance data for parameters such as cannulation rate and adverse event rates figures?
5. Does formalized training and/or cumulative procedure experience overcome limitations associated with lower current case volume?

Intraprocedure quality indicators

The intraprocedure period for ERCP extends from the administration of sedation to the removal of the endoscope. This period includes all the technical aspects of the procedure including completion of the examination and of therapeutic maneuvers. Common to most endoscopic procedures is the provision of sedation and need for patient monitoring.[12] Intraprocedure quality indicators specific to performance of ERCP include the following:

6a. *Frequency with which deep cannulation of the ducts of interest is documented*

   Level of evidence: 1C

   Performance target: >98%

   Type of measure: process

6b. *Frequency with which deep cannulation of the ducts of interest in patients with native papillae without surgically altered anatomy is achieved and documented (priority indicator)*

   Level of evidence: 1C

   Performance target: >90%

   Type of measure: process

Discussion: Cannulation of the desired duct is the foundation of successful ERCP. The achievement (or lack thereof) of cannulation of the desired duct should be recorded in all cases. Actual cannulation rates should approximate benchmark cannulation rates for patients presenting with similar indications. Cannulation of the duct of interest with a high success rate and with associated low adverse event rate is achieved by experts in ERCP and requires adequate training and continued experience in ERCP. Deep cannulation is achieved when the tip of the catheter, usually over a guidewire, is passed beyond the papilla into the desired duct. This allows effective injection of contrast material to visualize the duct system of interest and the introduction of instruments to perform diagnostic and therapeutic maneuvers. Successful cannulation may avoid

the need for a second ERCP or percutaneous transhepatic cholangiography to complete the study, with resultant avoidance of morbidity. Reports from the 1990s indicate that successful cannulation rates ≥95% are consistently achieved by experienced endoscopists, and rates ≥80% are a goal of training programs in ERCP, although these data include patients who have undergone prior biliary sphincterotomy and are of limited applicability.[40,41] More recent data demonstrate that tracking deep biliary cannulation success rates in patients with native papillary anatomy only is a better assay of competency and the ability to perform ERCP independently after training.[42] Thus, although ≥90% is an overall appropriate target for successful cannulation, no consensus has yet been reached as to the benchmark in cannulation success rates necessary to become a quality ERCP performer. A recent meta-analysis with a random-effects model suggests that cannulation rates in practice, even at tertiary-care centers, may be <90% (in the mid 80% range) and also suggests significant variability in cannulation rates across the developed world.[43] Nevertheless, the expert consensus of the ASGE/ACG task force on this topic and review of the aforementioned literature published before mid-2013 suggest that physicians with consistently suboptimal cannulation rates (<80% success) should consider undergoing further training or discontinuing their ERCP practices.

Calculation of cannulation rates for most purposes should exclude examinations that failed because of inadequate sedation, retained gastric contents, prior abdominal surgeries such as pancreaticoduodenectomy, gastrojejunostomy, and hepaticojejunostomy, and obstruction of the antrum and the proximal duodenum. The cannulation rate should be measured specifically in patients with intact major duodenal papillae. Cannulation rates in patients who have undergone prior sphincterotomy should not be measured. Accordingly, the outcome indicator for cannulation is limited to patients with normal anatomy.

In general, for all indications, competent ERCP endoscopists should expect to cannulate the duct of interest in >90% of ERCP procedures of mild-to-moderate difficulty. Some investigators have attempted to stratify ERCP based on perceived difficulty. In the future, such stratification by difficulty may help standardize quality assurance programs in ERCP across varying patient populations.[19,44-46] It has been suggested that ERCP endoscopists with lower levels of expertise should not attempt complex or difficult ERCP cases without the assistance of a more experienced endoscopist, but this approach has not been validated.[47]

7. *Frequency with which fluoroscopy time and radiation dose are measured and documented*
   Level of evidence: 2C
   Performance target: >98%
   Type of measure: process
   Fluoroscopy time or dose should be recorded for all ERCPs.

   Discussion: Because ERCP, by definition, requires radiation exposure to the patient, this exposure should be reduced to the lowest level to allow the procedure to be completed in a safe and timely manner in accordance with the "as low as reasonably achievable" principle. One study has demonstrated that experienced endoscopists have significantly shorter fluoroscopy times when compared with those of less experienced endoscopists.[48] It should be noted that different machines will deliver different amounts of radiation and that the adjustment of the number of frames per second can significantly affect the total radiation dose, which is thought to be a better measure than simple fluoroscopy time. Additional factors that affect dose include patient body habitus, use of copper filtration, distance of patient to the radiation source, magnification, oblique views, and spot images. Furthermore, some ERCP procedures are more difficult than others and require a longer overall fluoroscopy time and a greater radiation dose. Fluoroscopy time and radiation dose usually are recorded by the fluoroscopy machine itself and can be incorporated into the ERCP procedure note if readily available.

8. *Frequency with which common bile duct stones <1 cm in patients with normal bile duct anatomy are extracted successfully and documented (priority indicator)*
   Level of evidence: 1C
   Performance target: ≥90%
   Type of measure: outcome

   Discussion: For cases of intended stone extraction, the endoscopist should document whether complete stone extraction is achieved. The documentation should include sufficient information about stones size, location, presence of strictures, and presence of post-surgical anatomy to allow proper comparisons in subsequent benchmarking efforts. The rate of successful common bile duct stone extraction should be recorded and tracked. Individual stone extraction rates should approximate benchmark rates for patients presenting with similar indications.

   Expert endoscopy centers can achieve bile duct clearance rate for all bile duct stones in well over 90% of patients.[49] This includes large stones (>2 cm) and includes use of additional techniques such as mechanical, laser, or electrohydraulic lithotripsy when standard techniques fail. It should now be expected that competent ERCP endoscopists can clear the duct of small to medium–sized common bile duct stones up to 1 cm in diameter in >90% of cases by using sphincterotomy and balloon or basket stone extraction in patients with otherwise normal biliary anatomy.[50] As with cannulation outcome, this indicator is narrowly defined for stones of a particular size range and patients with normal anatomy. Outcome for difficult stones (larger diameter, stones above strictures, intrahepatic duct stones, and stones in patients with post-surgical anatomy) should be tracked as well, and benchmarking efforts should compare outcome across similar clinical situations. In the case of difficult stone disease, one option for less

experienced endoscopists is to place a temporary stent to allow for biliary decompression, stabilization, and transfer of the patient to a tertiary-care center.

9. *Frequency with which stent placement for biliary obstruction in patients with normal anatomy whose obstruction is below the bifurcation is successfully achieved and documented (priority indicator)*
   Level of evidence: 1C
   Performance target: ≥90%
   Type of measure: outcome

   Discussion: Indications for placement of a biliary stent to treat an obstruction most commonly include malignancy, non-extractable or large common bile duct stones, and benign strictures (chronic pancreatitis, post-biliary surgery). Relief of obstructive jaundice from pancreatic cancer or other causes of biliary obstruction remains a common indication for ERCP. Relief of biliary obstruction is mandatory in those with cholangitis and in any patient with clinical jaundice whose biliary tree has undergone instrumentation and introduction of contrast material. For cases of intended stent placement, the endoscopist should document whether or not successful stent placement is achieved. The documentation should include sufficient information about indication, stricture location, stent size and type, and the presence of post-surgical anatomy to allow proper comparisons in subsequent benchmarking efforts.

   Stent placement in patients with obstructive processes below the bifurcation is technically easier to achieve than in those with hilar obstruction. Competent ERCP endoscopists should be able to place a biliary stent for relief of non-hilar biliary obstruction in >90% of patients.[45,51] This indicator is narrowly defined because of better available benchmarking data for stents placed below the bifurcation in patients with normal anatomy. Success rates for stenting in other more difficult situations such as hilar tumors and posttransplant anastomotic strictures should be tracked for benchmarking purposes. This will allow specific performance targets to be set for these indications in the future.

Intraprocedure research questions

1. How accurate is an a priori assessment of the difficulty of the ERCP in predicting success rates?
2. Is the use of precut sphincterotomy associated with improved cannulation rates or reduced need for repeat procedures in clinical practice?
3. What are the direct and indirect costs to the health care system for a failed ERCP?
4. To what extent can preprocedure imaging and EUS increase the technical success of therapeutic ERCP?
5. What is an acceptable rate of negative findings during ERCP for the indication of suspected stones in the era of MRCP, EUS, and intraoperative cholangiograms?
6. Is there an association between success rate in the placement of pancreatic duct stenting to prevent post-ERCP pancreatitis or facilitate biliary cannulation and improved overall ERCP outcomes? In the community, what is the success rate for placing temporary pancreatic duct stents?
7. How effective are remediation efforts triggered by low technical success rates or high adverse event rates in ERCP, and what are the most effective ways to address these problems?

Postprocedure quality indicators

The postprocedure period extends from the time the endoscope is removed to subsequent follow-up. Postprocedure activities include providing instructions to the patient, documentation of the procedure, recognition and documentation of adverse events, communication of results to the referring provider, follow-up of pathology, and assessing patient satisfaction.[12] Postprocedure quality indicators specific to the performance of ERCP include the following:

10. *Frequency with which a complete ERCP report that details the specific techniques performed, particular accessories used, and all intended outcomes is prepared*
    Level of evidence: 3
    Performance target: >98%
    Type of indicator: process
    ERCP reports should document successful cannulation and, if feasible, correlative fluoroscopic images. Photodocumentation of key aspects of the procedure should be included. Whether or not the primary goal of the procedure was achieved also should be documented. The report should clearly convey the events and overall outcome of the procedure.

Discussion: The ERCP procedure report should document whether deep cannulation of the desired duct was achieved and what type of device was used to cannulate (sphincterotome, cannula, balloon catheter, etc). One or more radiographic images should be included in the report if the documentation software allows this, although this may not be the case in all institutions. Photodocumentation of endoscopically identified abnormalities is considered advisable by the task force. Documentation with representative radiographic images and endoscopic photographs is the ideal way to provide objective evidence of what was performed during the procedure. Frequency of unintended cannulation and injection of the pancreatic duct also should be recorded in the procedure note. All other elements of a complete procedure note are discussed in the document covering quality indicators common to all GI endoscopic procedures.[12] Proper documentation of these findings helps clinicians who are involved directly with patient medical care to make appropriate decisions on patient management.

11. *Frequency with which acute adverse events and hospital transfers are documented*
    Level of evidence: 3
    Performance target: >98%
    Type of measure: process

TABLE 4. Summary of proposed quality indicators for ERCP*

Quality indicator	Grade of recommendation	Measure type	Performance target (%)
Preprocedure			
1. Frequency with which ERCP is performed for an indication that is included in a published standard list of appropriate indications and the indication is documented (priority indicator)	1C+	Process	>90
2. Frequency with which informed consent is obtained, including specific discussions of risks associated with ERCP, and fully documented	1C	Process	>98
3. Frequency with which appropriate antibiotics for ERCP are administered for settings in which they are indicated	2B	Process	>98
4. Frequency with which ERCP is performed by an endoscopist who is fully trained and credentialed to perform ERCP	3	Process	>98
5. Frequency with which the volume of ERCPs performed per year is recorded per endoscopist	1C	Process	>98
Intraprocedure			
6a. Frequency with which deep cannulation of the ducts of interest is documented	1C	Process	>98
6b. Frequency with which deep cannulation of the ducts of interest in patients with native papillae without surgically altered anatomy is achieved and documented (priority indicator)	1C	Process	>90
7. Frequency with which fluoroscopy time and radiation dose are measured and documented	2C	Process	>98
8. Frequency with which common bile duct stones <1 cm in patients with normal bile duct anatomy are extracted successfully and documented (priority indicator)	1C	Outcome	≥90
9. Frequency with which stent placement for biliary obstruction in patients with normal anatomy whose obstruction is below the bifurcation is successfully achieved and documented (priority indicator)	1C	Outcome	≥90
Postprocedure			
10. Frequency with which a complete ERCP report that details the specific techniques performed, particular accessories used, and all intended outcomes is prepared	3	Process	>98
11. Frequency with which acute adverse events and hospital transfers are documented	3	Process	>98
12. Rate of post-ERCP pancreatitis (priority indicator)	1C	Outcome	N/A
13. Rate and type of perforation	2C	Outcome	≤0.2
14. Rate of clinically significant hemorrhage after sphincterotomy or sphincteroplasty in patients undergoing ERCP	1C	Outcome	≤1
15. Frequency with which patients are contacted at or greater than 14 days to detect and record the occurrence of delayed adverse events after ERCP	3	Process	>90

N/A, not avalilable.

*This list of potential quality indicators was meant to be a comprehensive listing of measurable endpoints. It is not the intention of the task force that all endpoints be measured in every practice setting. In most cases, validation may be required before a given endpoint may be universally adopted.

Immediately recognized adverse events are reported in the procedure note along with the acute management plan.

Discussion: Recognized adverse events should be documented. Bleeding, allergic reactions, cardiopulmonary reactions (including aspiration), perforation, and post-ERCP pancreatitis are the main outcomes of concern.

12. *Rate of post-ERCP pancreatitis (priority indicator)*

Level of evidence: 1C

Performance target: N/A

Type of measure: outcome

The incidence of acute post-ERCP pancreatitis should be recorded and tracked.

Discussion: Post-ERCP pancreatitis rates are dependent on the type of ERCP performed. Endoscopists who perform sphincter of Oddi manometry are likely to have higher rates of post-ERCP pancreatitis compared with those of endoscopists who do not. The current rate of ERCP-induced pancreatitis in clinical practice is variable and affected by operator skill and experience as well as the type of ERCP procedures being undertaken, and, for that reason, it is difficult to set a single performance target for all ERCPs for this indicator. Post-ERCP pancreatitis is defined as abdominal pain after ERCP consistent with pancreatitis, with a concurrent serum amylase and lipase level of ≥ 3 times the upper limit of normal.[52] Typical rates of post-ERCP pancreatitis are commonly 1% to 7%, excluding certain high-risk patient subsets such as those with known or suspected sphincter of Oddi dysfunction and those undergoing pancreatic endotherapy, who may warrant special prophylaxis for post-ERCP pancreatitis including pancreatic stent placement or prophylactic use of nonsteroidal anti-inflammatory drugs.[16,18,27,53,54] It should be noted that the value of this agent in patients with normal sphincter of Oddi function is not firmly established. Nonetheless, if available, the use of rectal indomethacin should be considered. It is unclear at this time whether rectal indomethacin should be used in all or just selected patients.

13. *Rate and type of perforation*

Level of evidence: 2C

Performance target: $\leq 0.2\%$

Type of measure: outcome

The rate of ERCP-related perforation should be recorded and tracked.

Discussion: Perforation occurs during ERCP with a frequency between 0.1% and 0.6%.[27] Simple guidewire perforations of the duodenal wall rarely require surgery and almost always can be addressed with conservative management (nothing by mouth status, intravenous fluids, antibiotics). Bile duct or pancreatic duct perforations, although rare, can be managed via stenting.[38,55] Esophageal and gastric perforations, although rare, may require surgery if endoscopic closure is not possible. Full thickness small perforations of the duodenum, especially retroperitoneal, can be managed conservatively if they are recognized clinically, which can sometimes be difficult. Some retroperitoneal perforations will require surgical intervention. Established risk factors for perforation during ERCP include Billroth II or Roux en Y anatomy, presumed sphincter of Oddi dysfunction, intramural contrast material injection, sphincterotomy, biliary stricture dilation, and prolonged procedures.[30,56] In patients undergoing ERCP who have normal anatomy, the expected perforation rate is $<1\%$. Perforation may result from mechanical rupture of the esophagus, stomach, or duodenum from instrument passage; from sphincterotomy or passage of guidewires; or from other therapeutic procedures. Perforation may be intra-abdominal or retroperitoneal. Because perforation occurs so infrequently, the denominator of cases performed required to generate reliable individual endoscopist perforation rates is unknown and may be problematic.

14. *Rate of clinically significant hemorrhage after sphincterotomy or sphincteroplasty in patients undergoing ERCP*

Level of evidence: 1C

Performance target: $\leq 1\%$

Type of measure: outcome

The rate of ERCP-related hemorrhage should be recorded and tracked.

Discussion: ERCP-related hemorrhage has been shown via meta-analysis to occur in approximately 1% of cases, with most cases involving mild, intraluminal bleeding.[57] Bleeding can be immediate or delayed, and many techniques exist to achieve endoscopic hemostasis for visually identified bleeding. Bleeding rates are increased in patients who require warfarin. There are insufficient data to definitively comment on bleeding rates in patients requiring some of the newer anticoagulants. Aspirin may be used safely in patients undergoing ERCP.[58] Most ERCP-related bleeding is related to sphincterotomy or the use of electrocautery. Post-sphincterotomy bleeding generally is defined as immediate bleeding requiring endoscopic or other intervention or delayed bleeding recognized by clinical evidence (such as melena), with a drop in hemoglobin level or need for blood transfusion within 10 days after ERCP.[59] The expected rate of major post-sphincterotomy bleeding can be as high as 2%.[38] Risk factors that increase the risk of post-sphincterotomy bleeding include coagulopathy, cholangitis, anticoagulant therapy within 3 days after the procedure, and low endoscopist case volume (<1 per week).[38] However, the risk of postprocedure bleeding is higher when other therapeutic maneuvers are performed, such as ampullectomy and transmural pseudocyst drainage.[60,61] The risk of major bleeding from a diagnostic ERCP or therapeutic ERCP without sphincterotomy or transmural puncture (eg, stent placement alone) is near zero, even in patients who are therapeutically anticoagulated.

15. *Frequency with which patients are contacted at or greater than 14 days to detect and record the occurrence of delayed adverse events after ERCP*

Level of evidence: 3

TABLE 5. Priority quality indicators for ERCP*

Frequency with which ERCP is performed for an appropriate indication and documented
Rate of deep cannulation of the ducts of interest in patients with native papillae without surgically altered anatomy
Success rate of extraction of common bile duct stones <1 cm in patients with normal bile duct anatomy
Success rate for stent placement for biliary obstruction for patients with biliary obstruction below the bifurcation in patients with normal anatomy
Rate of post-ERCP pancreatitis

*See text for specific targets and discussion.

Performance target: >90%
Type of indicator: process
Efforts to contact patients within 14 days should help identify any adverse events and will help with overall data tracking.

Discussion: Most centers have a formalized means for following-up with patients, and these often have several arms. Nurses or other staff often make routine follow-up calls to patients 24 to 48 hours after endoscopy. Physicians may call to review pertinent pathology results and to make further plans or call to follow-up on unsuspected adverse events identified in the routine follow-up call. Efforts to monitor and improve the collection of delayed data on post-ERCP adverse events should generate more reliable outcome data for this procedure in the future. Such efforts to call patients at 14 days, however, may impact the cost of the procedure.

Postprocedure research questions

1. What are the rates of pancreatitis, bleeding, and perforation in tertiary-care referral centers versus community practices?
2. How does the procedure indication and degree of difficulty influence adverse event rates?
3. Does routine use of anesthesia providers alter the probability of ERCP-related adverse events? Does it alter the success rate of the procedure?
4. What are the rates of delayed bleeding adverse events among patients resuming anti-platelet therapy after sphincterotomy and sphincteroplasty?
5. What is the most effective method to identify and track post-procedure adverse events?

Priority indicators for ERCP

For ERCP, the recommended priority indicators are appropriate indication, cannulation rate, stone extraction success rate, stent insertion success rate, and frequency of post-ERCP pancreatitis (Table 5). For each of these indicators, reaching the recommended performance target is strongly associated with important clinical outcomes. These indicators can be measured readily in a manageable number of examinations, and for each there is evidence of substantial variation in performance.[62]

For motivated individuals who are made aware of below-standard procedure outcomes, educational and corrective measures can improve performance. The primary purpose of measuring quality indicators is to improve patient care by identifying poor performers who then might be given an opportunity for additional training or cease to perform ERCP if performance cannot be improved.

Conclusion

The task force has attempted to compile a comprehensive list of evidence-based potential quality indicators for ERCP. We recognize that not every indicator is applicable to every practice setting. We suggest that endoscopists who perform ERCP focus on quality indicators most strongly related to outcomes or on the outcomes themselves, such as rate of cannulation, success rates of stone extraction and stent placement, and rates of post-ERCP pancreatitis. Other indicators, such as the rates of perforation, bleeding, cholangitis, repeat ERCP, ERCP-related cardiopulmonary events, and ERCP-related mortality also should be tracked, if possible.

The task force recommends that the aforementioned quality indicators be periodically reviewed in continuous quality improvement programs. Findings of deficient performance can be used to educate endoscopists and/or provide opportunities for additional training and mentorship. Additional monitoring can be undertaken to document improvement in performance. This task force looks forward to a future in which formalized quality improvement activities in ERCP will be commonplace.

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Abbreviations: ACG, American College of Gastroenterology; ASGE, American Society for Gastrointestinal Endoscopy.

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Quality indicators for EUS

EUS has become integral to the diagnosis and staging of GI and mediastinal mass lesions and conditions. EUS-guided FNA (EUS-FNA) allows the endoscopist to obtain tissue or fluid for cytologic and chemical analysis, adding to the procedure's utility. Furthermore, the recent development of EUS-guided core biopsy techniques enables histologic sampling in selected cases and for obtaining tissue for molecular analysis in neoadjuvant and palliative settings. The clinical effectiveness of EUS and EUS-FNA depends on the judicious use of these techniques.

The quality of health care can be measured by comparing the performance of an individual or a group of individuals with an ideal or benchmark.[1] The particular parameter that is being used for comparison is termed a quality indicator. Quality indicators often are reported as ratios between the incidence of correct performance and the opportunity for correct performance or as the proportion of interventions that achieve a predefined goal.[2] Quality indicators can be divided into 3 categories: (1) structural measures—these assess characteristics of the entire health care environment (eg, availability and maintenance of endoscopy equipment at a hospital), (2) process measures—these assess performance during the delivery of care (eg, diagnostic rates of malignancy in patients undergoing EUS-FNA of pancreatic masses), (3) outcome measures: these assess the results of the care that was provided (eg, frequency of infection after EUS with FNA of cystic lesions).

METHODOLOGY

In 2006, the American Society for Gastrointestinal Endoscopy (ASGE)/American College of Gastroenterology (ACG) Task Force on Quality in Endoscopy published the first version of quality indicators for EUS.[3] The present update integrates new data pertaining to previously proposed quality indicators and new quality indicators for performing EUS. We prioritized indicators that had wide-ranging clinical application, were associated with variation in practice and outcomes, and were validated in clinical studies. Clinical studies were identified through a computerized search of Medline followed by review of the bibliographies of all relevant articles. When such studies were absent, indicators were chosen by expert consensus. Although feasibility of measurement was a consideration, we hope that inclusion of highly relevant, but not yet easily measurable, indicators will promote their eventual adoption. Although a comprehensive list of quality indicators is proposed, we recognize that, ultimately, only a small subset might be widely used for continuous quality improvement, benchmarking, or quality reporting. As in 2006, current the task force concentrated its attention on parameters related solely to endoscopic procedures. Although the quality of care delivered to patients is clearly influenced by many factors related to the facilities in which endoscopy is performed, characterization of unit-related quality indicators was not included in the scope of this effort.

The resultant quality indicators were graded on the strength of the supporting evidence (Table 1). Each quality indicator was classified as an outcome or a process measure. Although outcome quality indicators are preferred, some can be difficult to measure in routine clinical practice, because they need analysis of large amounts of data and long-term follow-up and may be confounded by other factors. In such cases, the task force deemed it reasonable to use process indicators as surrogate measures of high-quality endoscopy. The relative value of a process indicator hinges on the evidence that supports its association with a clinically relevant outcome, and such process measures were emphasized.

The quality indicators for this update were written in a manner that lends them to be developed as measures. Although they remain quality indicators and not measures, this document also contains a list of performance targets for each quality indicator. The task force selected performance targets from benchmarking data in the literature when available. When no data were available to support establishing a performance target level, "N/A" (not available) was listed. However, when expert consensus considers failure to perform a given indicator a "never event," such as monitoring vital signs during sedation, then the performance target was listed as >98%. It is important to emphasize that the performance targets listed do not necessarily reflect the standard of care but rather serve as specific goals to direct quality improvement efforts.

Quality indicators were divided into 3 time periods: preprocedure, intraprocedure, and postprocedure. For each category, key relevant research questions were identified.

In order to guide continuous quality improvement efforts, the task force also recommended a high-priority subset of the indicators described, based on their clinical relevance and importance, evidence that performance

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TABLE 1. Grades of recommendation*

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

*Adapted from Guyatt G, Sinclair J, Cook D, et al. Moving from evidence to action. Grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, editors. Users' guides to the medical literature. Chicago: AMA Press; 2002. p. 599-608.

varies significantly in clinical practice, and feasibility of measurement (a function of the number of procedures needed to obtain an accurate measurement with narrow confidence intervals [CI] and the ease of measurement). A useful approach for individual endoscopists is to first measure their performance with regard to these priority indicators. Quality improvement efforts would then move to different quality indicators if endoscopists are performing above recommended thresholds, or the employer and/or teaching center could institute corrective measures and remeasure performance of low-level performers.

Recognizing that certain quality indicators are common to all GI endoscopic procedures, such items are presented in detail in a separate document, similar to the process in 2006.[4] The preprocedure, intraprocedure, and postprocedure indicators common to all endoscopy are listed in Table 2. Those common factors will be discussed in this document only insofar as the discussion needs to be modified specifically related to EUS.

Preprocedure quality indicators

The preprocedure period includes all contact between members of the endoscopy team with the patient before the administration of sedation. Common issues for all endoscopic procedures during this period include: appropriate indication, informed consent, risk assessment, formulation of a sedation plan, clinical decision making with regard to prophylactic antibiotics and management of antithrombotic drugs, and timeliness of the procedure.[5] Preprocedure quality indicators specific to performance of EUS include the following:

1. *Frequency with which EUS is performed for an indication that is included in a published standard list of appropriate indications, and the indication is documented*

   Level of evidence: 1C

   Performance target: >80%

   Type of measure: process

   The ASGE has published appropriate indications for EUS (Table 3).[6] An appropriate indication should be documented for each procedure, and, when it is not a standard indication listed in the current ASGE Appropriate Use of GI Endoscopy guideline, it should be justified in the documentation.

   Discussion: Acceptable indications for EUS have been published recently.[6,7] Although there are many instances in which EUS can be performed, the value of the procedure in the care of any particular patient depends on its impact on management, improvement in outcomes, and the superiority of EUS over other available imaging or surgical procedures. This implies a certain degree of clinical judgment in choosing when and if to perform EUS in relation to other procedures, making rigid indications impractical. Expert opinion

TABLE 2. Summary of proposed quality indicators common to all endoscopic procedures[a,2]

Quality indicator	Grade of recommendation	Measure type	Performance target (%)
Preprocedure			
1. Frequency with which endoscopy is performed for an indication that is included in a published standard list of appropriate indications, and the indication is documented	1C+	Process	>80
2. Frequency with which informed consent is obtained and fully documented	3	Process	>98
3. Frequency with which preprocedure history and directed physical examination are performed and documented	3	Process	>98
4. Frequency with which risk for adverse events is assessed and documented before sedation is started	3	Process	>98
5. Frequency with which prophylactic antibiotics are administered for appropriate indication	Varies	Process	>98
6. Frequency with which a sedation plan is documented	Varies	Process	>98
7. Frequency with which management of antithrombotic therapy is formulated and documented before the procedure	3	Process	N/A
8. Frequency with which a team pause is conducted and documented	3	Process	>98
9. Frequency with which endoscopy is performed by an individual who is fully trained and credentialed to perform that particular procedure	3	Process	>98
Intraprocedure			
10. Frequency with which photodocumentation is performed	3	Process	N/A
11. Frequency with which patient monitoring during sedation is performed and documented	3	Process	>98
12. Frequency with which the doses and routes of administration of all medications used during the procedure are documented	3	Process	>98
13. Frequency with which use of reversal agents is documented	3	Process	>98
14. Frequency with which procedure interruption and premature termination because of sedation-related issues is documented	3	Process	>98
Postprocedure			
15. Frequency with which discharge from the endoscopy unit according to predetermined discharge criteria is documented	3	Process	>98
16. Frequency with which patient instructions are provided	3	Process	>98
17. Frequency with which the plan for pathology follow-up is specified and documented	3	Process	>98
18. Frequency with which a complete procedure report is created	3	Process	>98

TABLE 2. Continued

Quality indicator	Grade of recommendation	Measure type	Performance target (%)
19. Frequency with which adverse events are documented	3	Process	>98
20. Frequency with which adverse events occur	3	Outcome	N/A
21. Frequency with which postprocedure and late adverse events occur and are documented	3	Outcome	N/A
22. Frequency with which patient satisfaction data are obtained	3	Process	N/A
23. Frequency with which communication with referring providers is documented	3	Process	N/A

N/A, Not available.
*This list of potential quality indicators is meant to be a comprehensive list of measurable endpoints. It is not the intention of the task force that all endpoints be measures in every practice setting. In most cases, validation may be required before a given endpoint may be adopted universally.

has identified specific clinical situations for which EUS is deemed an appropriate diagnostic or therapeutic procedure (Table 3).[6] EUS generally is not indicated for staging of tumors shown to be metastatic by other imaging methods (unless the results are the basis for therapeutic decisions or unless the procedure is performed to confirm a diagnosis by tissue sampling). It is fully expected that certain indications may change with time. In addition, the appropriate use of EUS also depends, in part, on the availability of other imaging methods, because not all patients will have reasonable access to alternatives to EUS. For this reason, 100% compliance with predetermined indications is considered restrictive.

The inclusion of an indication in the procedure documentation for all cases is a useful quality measure for two reasons. First, it provides a justification for the procedure and serves as a means of tracking compliance with accepted indications. Second, the indication places the remainder of the procedure report in a specific context wherein certain endosonographic landmarks and finding characteristics logically should follow. For example, detailed descriptions of the pancreas may not be necessary when the indication for EUS is esophageal cancer staging. However, once esophageal cancer staging is provided as the indication, certain components of the examination, such as tumor (T) and node (N) staging, including celiac axis visualization (except in cases when the tumor cannot be safely traversed), are expected and their subsequent inclusion would reflect a thorough EUS.

2. *Frequency with which consent is obtained, including specific discussions of risks associated with EUS, and fully documented*

Level of evidence: 3
Performance target: >98%
Type of measure: process
The consent should address the relevant and substantial adverse events pertaining to each specific EUS procedure in addition to the risks associated with all endoscopic procedures.
Discussion: EUS and EUS-FNA present risks of unique adverse events beyond those associated with standard endoscopy. A review of the adverse events specific to EUS have been published previously and are detailed in the following section.[8,9] In most instances, EUS requires passage of large echoendoscopes or endoscopes with relatively rigid portions. Although EUS is associated with an increased risk of perforation, this adverse event is rare. Esophageal or duodenal perforations are rare adverse events associated with EUS.[8-15] The incidence of cervical esophageal perforation during intubation ranges from 0.03% to 0.06%.[11,12] Perforation risk also may be higher when staging esophageal cancer, particularly in the setting of before-EUS dilation of an obstructing malignancy (range 0%-24%).[14,16-18] Perforation related to dilation of malignant esophageal strictures for complete EUS examination is rare when the procedure is performed cautiously by experienced operators.[16] Dilation of esophageal cancer, advanced patient age, difficult esophageal intubation, and lack of operator experience have been identified as risk factors for esophageal perforation.[8,11,14] FNA introduces an increased risk of bleeding (0.5%), infection (<1%),[8-10,13-15,19-22] and pancreatitis (≤2% and greater for cystic lesions compared with solid lesions).[8-10,19,21,23-26] Tumor seeding along the FNA tract has been reported in very rare circumstances.[27-32] Routine performance of bile duct EUS-FNA for primary tumor diagnosis (cholangiocarcinoma) is not recommended in surgical candidates because of the small risk of tumor seeding and negative impact on transplant

TABLE 3. Appropriate indications for EUS[4,7]

Staging of tumors of the GI tract, pancreas, bile ducts, and mediastinum including lung cancer
Evaluating abnormalities of the GI tract wall or adjacent structures
Tissue sampling of lesions within, or adjacent to, the wall of the GI tract
Evaluation of abnormalities of the pancreas, including masses, pseudocysts, and chronic pancreatitis
Evaluation of abnormalities of the biliary tree
Placement of radiologic (fiducial) markers into tumors within or adjacent to the wall of the GI tract
Treatment of symptomatic pseudocysts by creating an enteral-cyst communication
Providing access into the bile ducts or pancreatic duct, either independently or as an adjunct to ERCP
Evaluation for perianal and perirectal disorders (anal sphincter injuries, fistulae, abscesses)
Evaluation of patients at increased risk of pancreatic cancer
Celiac plexus block or neurolysis

candidacy or outcomes after resection for patients with resectable disease.[33] Celiac plexus neurolysis or celiac plexus block carry unique risks of transient hypotension (1%) and diarrhea (4%-15%), in addition to standard risks.[8] The consent form used by the endosonographer should be comprehensive enough to include these adverse events.

3. *Frequency with which appropriate antibiotics are administered in the setting of FNA of cystic lesions*
   Level of evidence: 2C
   Performance target: N/A
   Type of measure: process
   Discussion: There have been no randomized trials conducted to determine the need for prophylactic antibiotics in the setting of EUS-FNA. The risk of bacteremia after EUS-FNA is low (0%-6%) and comparable with that of diagnostic endoscopy.[22,34-36] This holds true for patients undergoing EUS-FNA of the rectum and perirectal space. In a prospective study of 100 patients who underwent EUS-FNA for lower GI tract lesions, the incidence of bacteremia was 2%.[22] In general, the risk of clinically significant infectious adverse events after EUS-FNA of solid lesions is very low (range 0%-0.6%).[13-15,19-22] Infectious adverse events were reported in 0.04% of patients undergoing EUS-FNA in a recent systematic review.[10] The rate of infection related to EUS-FNA of pancreatic cysts was relatively low (0.5%) as well and was attributed to the routine use of prophylactic antibiotics.[10] On the other hand, EUS-FNA of mediastinal cysts is associated with high rates of infectious adverse events including life-threatening mediastinitis.[8] The recommendation of administering antibiotics before EUS-FNA of pancreatic cysts has been challenged in a retrospective study that showed no protective effect from periprocedural prophylactic antibiotics in patients undergoing EUS-FNA of pancreatic cysts.[37] The ASGE suggests antibiotics before EUS-FNA of mediastinal cysts and advises against administration of prophylactic antibiotics before EUS-FNA of pancreatic and peripancreatic cystic lesions.[38] Prophylaxis, when deemed necessary, involves administration of an antibiotic such as a fluoroquinolone administered before the procedure and continued for 3 to 5 days postprocedure. Administration of prophylactic antibiotics for lower GI tract lesions should be made on a case-by-case basis. ASGE advises against antibiotic prophylaxis before diagnostic EUS or EUS-FNA of solid lesions in the lower GI tract.[38,39]

4. *Frequency with which EUS examinations are performed by trained endosonographers*
   Level of evidence: 3
   Performance target: >98%
   Type of measure: process
   Discussion: Although it is beyond the scope of this article to discuss training requirements and competency assessment, a trained endosonographer is defined as one who has undergone formal training and gained the necessary technical and cognitive skills. Training in EUS requires the development of technical and cognitive skills beyond that required for standard endoscopic procedures. The value of EUS in provision of patient care is directly proportional to the training, skill, and experience of the endosonographer. Recognizing the specialized nature of EUS and EUS-FNA, ASGE has published specific criteria for the training of, and the granting of clinical privileges for, individuals who want to perform these procedures.[40-42] These guidelines have not been validated and do not account for different rates at which people learn. Unfortunately, there is a dearth of data on the intensity and length of training, the requisite curriculum and extent of theoretical learning, and minimum number of procedures required to ensure competency. Given the variability in

diagnostic yield associated with relative experience and training in this procedure, it is a reasonable expectation that the likelihood of a high-quality procedure is increased by having a fully trained endosonographer perform the examination.

Preprocedure research questions

1. Does EUS impact patient management decisions for each specific indication?
2. Does EUS improve patient outcomes for each specific indication?
3. What is the absolute impact of prophylactic antibiotics on the risk of infection after FNA of cystic lesions?
4. How often is EUS performed for nonstandard indications in clinical practice?
5. Is there a difference in findings or outcomes when EUS is performed for non-standard indications?
6. How much training is required for individuals performing EUS before they can achieve staging accuracy and diagnostic FNA yields comparable to those of published literature?

Intraprocedure quality indicators

The intraprocedure period extends from the administration of sedation to the removal of the endoscope. This period includes all the technical aspects of the procedure including completion of the examination and of therapeutic maneuvers. Common to most endoscopic procedures is the provision of sedation and need for patient monitoring. Intraprocedure quality indicators specific to performance of EUS include the following:

5. *Frequency with which the appearance of relevant structures, specific to the indication for the EUS, is documented*
   Level of evidence: 3
   Performance target: >98%
   Type of measure: process
   Documentation for each of the following indications should include the following items:
   1. In the setting of esophageal cancer staging without obstruction, location of the gastroesophageal junction and visualization of the celiac axis and left lobe of the liver (to rule out metastatic disease) should be documented.
   2. In the setting of evaluating for the presence of pancreaticobiliary disease, visualization of the entire pancreas (describing features of chronic pancreatitis and pancreatic cysts when present) along with evaluation of the pancreatic duct should be documented. Description of biliary abnormalities (eg, stones, dilation) should be documented.
   3. In the setting of EUS for lower GI tract indications such as rectal cancer, location of the tumor and visualization of surrounding structures such as iliac vessels, genitourinary structures, and sphincter apparatus and evaluation for lymphadenopathy should be documented.

   Discussion: To maximize clinical efficacy, EUS should provide all pertinent information relevant to the procedure's indication. The endosonographer must visualize specific structures depending on the disease process being investigated and should subsequently document these findings in writing or with photographic documentation.

6a. *Frequency with which all GI cancers are staged with the American Joint Committee on Cancer (AJCC)/Union for International Cancer Control (UICC) TNM staging system*[43,44] *(priority indicator)*
   Level of evidence: 3
   Performance target: >98%
   Type of measure: process

6b. *Frequency with which pancreatic mass measurements are documented along with evaluation for vascular involvement, lymphadenopathy, and distant metastases*
   Level of evidence: 3
   Performance target: >98%
   Type of measure: process

6c. *Frequency with which EUS wall layers involved by subepithelial masses are documented*
   Level of evidence: 3
   Performance target: >98%
   Type of measure: process
   Discussion: A diagnosis based on EUS findings, with or without cytology from FNA, requires not only an accurate localization and description of sonographic findings but also an accurate interpretation of these findings within the individual patient's clinical context. Currently, the AJCC/UICC TNM (tumor, node, metastasis) systems are the most widely used methods for staging GI malignancies.[43,44] Therefore, to maximize the utility of EUS in the setting of cancer staging, the elements necessary to assign both T and N stages should be obtained during the procedure and documented in writing and with saved images. This includes measurements of the mass, because T staging may depend on tumor size as in pancreatic cancer. Examination should include evaluation of vascular involvement (eg, portal vein/superior mesenteric vein and celiac axis, hepatic artery and superior mesenteric artery involvement in pancreatic cancer) and distant metastasis, which also impacts the T stage and candidacy for resectability. In the setting of subepithelial lesions, the differential diagnosis is based on wall layer of origin, echo characteristics, and size of lesion. Therefore, these findings should be documented in every report.
   Several recent reports have described the accuracy of T and N staging with EUS in relation to cancers of the pancreas, esophagus, stomach, and rectum. Accurate staging of pancreatic cancer plays an integral role in the initial decision making process for patients

with pancreatic cancer. In pancreatic cancer, results from contemporary studies have reported accuracy of T staging ranging from 62% to 67%, [45-48] with earlier studies reporting higher accuracy rates (85%-94%).[49-51] In the absence of distant metastasis, the presence and degree of contact between the tumor and the peripancreatic vessels is of paramount importance in determining surgical resectability. In a meta-analysis, the sensitivity and specificity of EUS in diagnosing vascular invasion was 73% (95% CI, 68.8-76.9) and 90% (95% CI, 87.9-92.2).[52] Results from available data with regard to accuracy of EUS in predicting vascular invasion are variable, with a wide range suggesting the operator dependency and variability. The task force acknowledges this and hence does not make accuracy of vascular invasion as a quality indicator but recommends documentation of vascular invasion as a quality indicator. Similarly, variable rates of accuracy for N staging have been reported in pancreatic cancer (range 40%-85%).[45,47,48,50,51,53,54] In esophageal cancer, sensitivity and specificity of EUS for T staging has ranged from 81% to 92% and 94% to 99%, respectively.[55] Although the role of EUS has been questioned in the setting of Barrett's-esophagus–related neoplasia (high-grade dysplasia and intramucosal cancer),[56,57] EUS has moderate accuracy rates in differentiating mucosal (T1a) versus submucosal (T1b) esophageal cancer, although this is largely being supplanted by EMR and/or endoscopic submucosal dissection and direct pathology staging.[58] Sensitivity and specificity of EUS for N staging was 80% (95% CI, 75-84) and 70% (95% CI, 65-75) in a meta-analysis.[59] In gastric cancer, a recent meta-analysis reported high accuracy rates in differentiating T1-2 from T3-4 disease (sensitivity 86% [95% CI, 81-90] and specificity 91% [95% CI, 89-93]. EUS for lymph node status was less reliable sensitivity 69% [95% CI, 63-74] and specificity 84% [95% CI, 81-88]).[60] The sensitivity and specificity for T staging in rectal cancer was 88% and 98% for T1, 81% and 96% for T2, 96% and 91% for T3, and 95% and 98% for T4 cancer, respectively.[61] However, recent studies have questioned these high accuracy rates and have suggested that magnetic resonance imaging may have similar accuracy rates in the T and N staging of rectal cancer.[62,63]

7a. *Percentage of patients with distant metastasis, ascites, and lymphadenopathy undergoing EUS-guided FNA who have tissue sampling of both the primary tumor and lesions outside of the primary field when this would alter patient management*
Level of evidence: 1C
Performance target: >98%
Type of measure: process

7b. *Diagnostic rate of adequate sample in all solid lesions undergoing EUS-FNA (adequate sample is defined by the presence of cells and/or tissue from the representative lesion in question)*
Level of evidence: 3
Performance target: ≥85%
Type of measure: outcome

7c. *Diagnostic rates and sensitivity for malignancy in patients undergoing EUS-FNA of pancreatic masses (priority indicator)*
Level of evidence: 1C
Performance target: Diagnostic rate of malignancy in patients undergoing EUS-FNA of all pancreatic masses, ≥70% and sensitivity of malignancy among patients with pancreatic cancer, ≥85%
Type of measure: outcome
Discussion: The additional clinical information obtained from FNA can increase the diagnostic accuracy of EUS significantly by confirming a pathologic diagnosis, by obtaining more accurate nodal staging in malignancy, and by yielding fluid for various analyses, including chemical analyses, tumor markers, and bacterial and/or fungal stains or culture. FNA is not feasible or appropriate in all conditions. Sampling a lymph node by traversing the primary tumor with the FNA needle should be avoided, because this may result in a false-positive lymph node cytology result and can potentially seed a previously benign lymph node with malignant cells from the primary tumor. The need for pretreatment FNA of pancreas tumors is variable. The primary value of FNA is to confirm malignancy, particularly when chemoradiotherapy is considered prior to or in lieu of surgery or to exclude lesions such as metastases to the pancreas, mass-forming pancreatitis, non-adenocarcinoma histology, and lymphoma. However, when FNA is appropriate, the endosonographer should make every effort to obtain adequate cytologic material to confirm a diagnosis.
Accuracy of EUS-FNA has been evaluated in several studies in patients with cancers of the pancreas, esophagus, stomach, bile duct, and rectum. Data from these studies provide a benchmark for quality performance measurement in EUS. A multicenter, retrospective study that included 1075 patients who underwent EUS-FNA of solid pancreatic masses at 21 centers (81% academic) with 41 endosonographers reported an overall diagnostic rate of malignancy of 71% (95% CI, 69-74).[64] Sensitivity and specificity that uses the criterion standard of either surgical pathology or long-term follow-up are ideal benchmarks for pancreatic EUS-FNA performance. A recent meta-analysis that included studies that met this criterion reported a pooled sensitivity of 85% (95% CI, 84-86) and specificity of 98% (95% CI, 97-99), with higher accuracy of EUS-FNA reported in prospective, multicenter studies.[65]
In the setting of esophageal cancer in the thoracic esophagus, malignant celiac axis lymph nodes no longer confer M1a status and, per the new staging system, a regional lymph node has been redefined to include any paraesophageal node extending from

cervical nodes to celiac nodes.[66] EUS-FNA for lymph node staging in esophageal cancer is an accurate staging modality with sensitivity of 83% (95% CI, 70-93), specificity of 93% (95% CI, 77%-99%), and accuracy of 87% (95% CI, 77-94) as reported in a prospective study that included 76 consecutive patients with pathologic evaluation of resected lymph nodes.[67] Retrospective studies that focused primarily on celiac lymph nodes reported sensitivity of 88% to 100%, specificity of 100%, and accuracy rates ranging from 87% to 100% for detection of lymph node metastases.[68-71]

Several studies have reported the use of EUS-FNA for the diagnosis of cholangiocarcinoma in the setting of indeterminate extrahepatic strictures. Reported sensitivity ranges from 29% to 89%[72-77] with a higher sensitivity reported for distal compared with proximal strictures (81% vs 59%; $P = .04$) in a single study.[77] The conventional criteria for malignant lymph nodes at EUS (size >1 cm, round, hypoechoic, and homogenous) have a poor predictive value in malignant lymphadenopathy associated with cholangiocarcinoma.[78] Hence, given the potential for avoiding unnecessary neoadjuvant therapy and staging laparotomy, a low threshold for sampling lymphadenopathy in this situation should be maintained. EUS-FNA should be performed only when results are likely to alter decision making (primary surgical resection or definitive or neoadjuvant chemoradiation). EUS-FNA also should be performed in patients with suspected distant metastases, given the potential to significantly change patient management.

The involvement of an on-site cytopathologist during EUS-FNA may help limit the number of FNA passes taken and increase the overall diagnostic accuracy of the procedure, although data are inconclusive.[9,79-85] The impact of on-site cytopathology evaluation in terms of diagnostic yield, number of passes, repeat procedures, and procedure time has not been studied in a randomized, controlled trial. However, it is recognized that not all endosonographers will have access to this degree of service. Therefore, for situations in which an on-site cytopathologist or cytotechnologist is not available, 5 to 7 FNA passes for pancreas masses and 2 to 4 passes for lymph nodes or suspected liver metastases are advised.[86-88] Other methods to increase cytologic adequacy and accuracy have not been definitively shown to be superior. EUS-FNA can be performed by using 25-gauge, 22-gauge, or 19-gauge needles. Randomized, controlled trials comparing 25-gauge and 22-gauge needles demonstrated no difference in diagnostic accuracy between the two groups.[89-91] A recent meta-analysis of 8 studies involving 1292 patients undergoing EUS-FNA (25-gauge, 565 patients and 22-gauge, 799 patients) showed that a 25-gauge needle was more sensitive than a 22-gauge needle for diagnosing pancreatic malignancy (pooled sensitivity, 25-gauge: 0.93 [95% CI, 0.91-0.96] vs 22-gauge: 0.85 [95% CI, 0.82-0.88]).[92] A randomized, controlled trial comparing 19-gauge and 22-gauge needle systems in patients undergoing EUS-FNA of pancreatic masses demonstrated a higher diagnostic accuracy rate and the presence of superior cellular material by using the 19-gauge needle. However, a significantly lower technical success rate was reported by using the 19-gauge needle system.[93] Large needle gauges (19-gauge) provide a larger specimen but are limited to transgastric biopsy in most cases and for EUS-guided interventions such as pseudocyst drainage. Few randomized, controlled trials have demonstrated no advantage in the routine use of a stylet during EUS-FNA.[94-96] In recent years, the technique of performing EUS-FNA passes without the use of a stylet has gained popularity but has not been adopted by all endosonographers. Use of traditional true-cut biopsy has not been shown to be superior to FNA and is associated with a high failure rate in transduodenal puncture.[9] Recent availability of small-gauge core biopsy needles (25-gauge and 22-gauge) and flexible 19-gauge needles offers an opportunity for research.

Intraprocedure research questions

1. What are the thresholds for accurate T and N staging of GI malignancies?
2. How do community practices compare with academic centers with regard to EUS staging and EUS-FNA accuracy?
3. Under what circumstances does FNA change patient management?
4. What is the optimal technique for performing EUS-FNA, and what are the variables that impact obtaining adequate specimens?
5. How does on-site cytopathology evaluation during EUS-FNA impact diagnostic yield, number of passes, repeat procedures, and procedure time?
6. What are the optimal methods for tissue processing of FNA specimens?

Postprocedure quality indicators

The postprocedure period extends from the time the endoscope is removed to subsequent follow-up. Postprocedure activities include providing instructions to the patient, documentation of the procedure, recognition and documentation of adverse events, pathology follow-up, communication with referring physicians, and assessing patient satisfaction.[5] Postprocedure quality indicators specific to performance of EUS include the following:

8. *Frequency with which the incidence of adverse events after EUS-FNA (acute pancreatitis, bleeding, perforation, and infection) is documented*
   Level of evidence: 3
   Performance target: >98%
   Type of measure: process

9. *Incidence of adverse events after EUS-FNA (acute pancreatitis, bleeding, perforation, and infection) (priority indicator)*
   Level of evidence: 1C
   Performance target: acute pancreatitis <2%, perforation <0.5%, clinically significant bleeding <1%
   Type of measure: outcome
   Discussion

A. Overall and specific adverse event rates. The overall safety of EUS-FNA is well-established, with a low overall adverse event rate. The main adverse events include acute pancreatitis, bleeding, and infection. Two other adverse events that merit mention include tumor seeding and false-positive EUS-FNA cytology results.

Variable rates of morbidity related to EUS-FNA have been reported, ranging from 0% to 2.5%.[13-15,19-21] A recent systematic review that included 10,941 patients reported an overall EUS-FNA specific morbidity rate of 0.98% (107/10,941) and mortality rate of 0.02% (2/10,941).[10] Patients undergoing EUS-FNA of the pancreas for evaluation of pancreatic masses, cystic lesions, or lesions of the pancreatic duct are at risk of developing pancreatitis, likely as a result of direct tissue injury as the needle traverses pancreatic tissue. The incidence of pancreatitis in this setting, including data from prospective series, has ranged between 0% and 2%.[19,21,23-26] The rate of pancreatitis was 0.44% (36/8246) in a systematic review, mild-moderate severity in most patients.[10] Acute clinically significant bleeding related to EUS-FNA is a rare adverse event, and incidence has ranged from 0 to 0.5%.[10,13-15,19-21] Mild intraluminal bleeding has been reported in up to 4% of cases,[97] extraluminal bleeding in 1.3% to 2.6% of cases,[26,98] and intracystic bleeding in up to 6% of cases during EUS-FNA of pancreatic cysts.[99] The risk of clinically significant infectious adverse events after EUS-FNA of solid lesions is very low (range 0%-0.6%).[13-15,19-22] Infectious adverse events were reported in 5 of 10,941 (0.04%) patients in a recent systematic review.[10] The rate of infection related to EUS-FNA of pancreatic cysts is relatively low (0.5%) and is attributed to the routine use of prophylactic antibiotics.[10] On the other hand, EUS-FNA of mediastinal cysts is associated with high rates of infectious adverse events including life-threatening mediastinitis.[8]

B. Tumor seeding after EUS-FNA. Needle track seeding or implantation metastasis has been reported after EUS-FNA and deserves special mention. This adverse event has been described as case reports.[27-31] However, the true incidence of this adverse event is difficult to assess because of the high mortality of patients ineligible for potentially curable therapy. In addition, tumor seeding may occur at sites that are outside the field of primary resection. In a prospective study of 140 patients undergoing EUS, which included patients with cancer and benign lesions, the luminal fluid aspirated through the accessory channel before and after FNA was submitted for cytologic analysis. Cytology examination of the luminal fluid showed positive results for malignancy in 48% of patients and 10% in patients with extraluminal cancer. Post-FNA luminal fluid cytology was unexpectedly positive in 3 of 26 pancreatic cancer patients. This suggests that EUS-FNA may withdraw malignant cells from the tumor into the GI lumen and potentially cause seeding from the target organ.[32] Another retrospective study demonstrated a higher rate of peritoneal carcinomatosis related to pancreatic cancer in patients undergoing percutaneously guided FNA compared with EUS-FNA (16.3% vs 2.2%; $P < .025$).[100] The concern for tumor seeding is of greatest relevance in patients with suspected cholangiocarcinoma and EUS-FNA of the primary tumor and is considered as a contraindication to liver transplantation for cholangiocarcinoma. A recent study evaluated the incidence of tumor seeding in 191 patients with locally unresectable hilar cholangiocarcinoma undergoing liver transplant evaluation. There were 16 patients who underwent transperitoneal FNA (16 percutaneous, 3 EUS)—6 were positive for malignancy, 9 negative, and 1 had equivocal results. During operative staging, peritoneal metastasis was seen in 5 of 6 (83%) patients with positive FNA versus 0 of 9 (0%) with negative FNA. Peritoneal metastasis was significantly higher in patients with positive preoperative FNA compared with those not undergoing transperitoneal sampling (5/6 [83%] vs 14/175 [8%]; $P = .009$).[33]

C. False-positive EUS-FNA cytology results. The incidence of false-positive EUS-FNA cytology results ranges from 1.1% to 5.3%.[101-103] In a study that matched 377 EUS-FNA cytology results of positive or suspicious with surgical specimens in patients who had not received any neoadjuvant chemoradiation, a false-positive rate of 5.3% (increased to 7.2% if false-suspicious included) was reported. The false positive rate was higher in non-pancreatic FNA compared with pancreatic FNA (15% vs 2.2%; $P = .0001$). Discordant results were then blindly assessed by 3 cytopathologists, and reasons for false-positive results included epithelial cell contamination and pathology misinterpretation.[101] Another retrospective study that involved 367 patients with solid pancreatic lesions in whom EUS-FNA cytology results were positive or suspicious for malignancy resulting in surgical resection, the false positive rate was 1.1% (3.8% if false-suspicious included). These false-positive results were attributed to pathology misinterpretation in the setting of chronic pancreatitis.[102]

D. Risk factors for adverse events related to EUS-FNA. Given the rarity of EUS-FNA–related adverse events, studies assessing predictors for adverse events are hampered by the lack of power to evaluate risk factors. Prospective studies report a higher cumulative FNA-related morbidity rate compared with retrospective studies (59/3426 [1.72%] vs 48/7515 [0.64%]). These findings hold true for FNA-related adverse events of pancreatic lesions (mass and cystic lesion).[10] EUS-FNA of cystic lesions in the pancreas is associated with a higher rate of adverse events compared with EUS-FNA of solid lesions, although it is still quite low.[10,13] The number of passes is not associated with the risk of adverse events.[9] Similarly, needle

TABLE 4. Summary of proposed quality indicators for EUS*

Quality indicator	Grade of recommendation	Type of measure	Performance target (%)
Preprocedure			
1. Frequency with which EUS is performed for an indication that is included in a published standard list of appropriate indications and the indication is documented	1C	Process	>80
2. Frequency with which consent is obtained, including specific discussions of risks associated with EUS, and fully documented	3	Process	>98
3. Frequency with which appropriate antibiotics are administered in the setting of FNA of cystic lesions	2C	Process	N/A
4. Frequency with which EUS exams are performed by trained endosonographers	3	Process	>98
Intraprocedure			
5. Frequency with which the appearance of relevant structures, specific to the indication for the EUS, is documented	3	Process	>98
6a. Frequency with which all gastrointestinal cancers are staged with the American Joint Committee on Cancer (AJCC)/Union for International Cancer Control (UICC) TNM staging system (priority indicator)	3	Process	>98
6b. Frequency with which pancreatic mass measurements are documented along with evaluation for vascular involvement, lymphadenopathy and distant metastases	3	Process	>98
6c. Frequency with which EUS wall layers involved by subepithelial masses are documented	3	Process	>98
7a. Percentage of patients with distant metastasis, ascites, and lymphadenopathy undergoing EUS-guided FNA who have tissue sampling of both the primary tumor diagnosis and lesions outside of the primary field when this would alter patient management	1C	Process	>98
7b. Diagnostic rate of adequate sample in all solid lesions undergoing EUS-FNA (adequate sample is defined by the presence of cells/tissue from the representative lesion in question)	3	Outcome	≥85
7c. Diagnostic rates and sensitivity for malignancy in patients undergoing EUS-FNA of pancreatic masses (priority indicator)	1C	Outcome	Diagnostic rate: ≥70 Sensitivity: ≥85
Postprocedure			
8. Frequency with which the incidence of adverse events after EUS-FNA (acute pancreatitis, bleeding, perforation and infection) is documented	3	Process	>98
9. Incidence of adverse events after EUS-FNA (acute pancreatitis, bleeding, perforation and infection) (priority indicator)	1C	Outcome	Acute pancreatitis: <2% Perforation: <0.5% Clinically significant bleeding: <1%

N/A, Not available.

*This list of potential quality indicators was meant to be a comprehensive listing of measurable endpoints. It is not the intention of the task force that all endpoints be measured in every practice setting. In most cases, validation may be required before a given endpoint may be universally adopted.

TABLE 5. Priority quality indicators for endoscopic ultrasound*

Frequency with which all GI cancers are staged with the AJCC/UICC TNM staging system
Diagnostic rates and sensitivity for malignancy in patients undergoing EUS-guided FNA of pancreatic masses
The incidence of adverse events after EUS-guided FNA (acute pancreatitis, bleeding, perforation, and infection)

AJCC, American Joint Committee on Cancer; *UICC,* Union for International Cancer Control; *TNM,* tumor, node, metastasis.
*See text for specific targets and discussion.

gauge does not appear to increase the risk of adverse events, although these studies were not powered to detect a difference in this endpoint.[91,93] EUS-guided true-cut biopsies appear to have a similar safety profile compared with standard EUS-FNA.[104-106] However, EUS-guided true-cut biopsies are not routinely performed transduodenally and for lesions <2 cm. The safety of a core biopsy needle was described in a recent randomized, controlled trial comparing a 22-gauge EUS-FNA needle to a 22-gauge EUS-fine needle biopsy needle.[107]

Postprocedure research questions

1. What are the estimates of adverse events related to EUS-FNA in community practices?
2. What are the true estimate and clinical significance of tumor seeding and false positive rates after EUS-FNA?
3. What is the incidence of the adverse events of EUS-guided core biopsies, and do such biopsies improve outcomes over standard FNA sampling?
4. Is it feasible to incorporate data regarding surgical pathology and long-term follow-up in patients undergoing EUS?
5. How can the diagnostic yield of EUS-FNA be improved?
6. What is the frequency with which EUS alters patient management and long-term outcomes?[108-111]

Priority indicators for EUS

For EUS, the recommended priority indicators among all the proposed indicators (Table 4) are:

1. Frequency with which all GI cancers are staged with the AJCC/UICC TNM staging system
2. Diagnostic rates of malignancy and sensitivity in patients undergoing EUS-FNA of pancreatic masses
3. The incidence of adverse events after EUS-FNA (bleeding, perforation, and acute pancreatitis) (Table 5)

For each of these indicators, reaching the recommended performance target is considered strongly associated with important clinical outcomes. These indicators can be measured readily in a manageable number of examinations, and for each there is evidence of substantial variation in performance.[112,113]

There is evidence that simple educational and corrective measures can improve endoscopist performance. The primary purpose of measuring quality indicators is to improve patient care by identifying poor performers and retraining them so that they might be able to meet the performance targets for these important aspects of the procedure.

Conclusion

The quality indicators proposed in this document were selected, in part, because of their ease of implementation, monitoring, and reporting (Table 4). The task force has attempted to create a comprehensive list of potential quality indicators. We recognize that not every indicator will be applicable to every practice setting. Facilities should select the subset most appropriate to their individual needs. We recognize that the field of EUS continues to expand, with the possible appearance of new indications and adverse events. Therefore, these quality indicators should be updated as the need arises. With the increasing demand for EUS, the number of physicians performing this complex procedure will continue to grow. It is the hope of the ACG, ASGE, and AGA that these measures and targets not only guide practicing endoscopists who perform EUS but also that they be incorporated into the training of new endosonographers to ensure that all patients receive the highest quality care possible.

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Abbreviations: ACG, American College of Gastroenterology; AJCC, American Joint Committee on Cancer; ASGE, American Society for Gastrointestinal Endoscopy; EUS-FNA, EUS-guided FNA; TNM, tumor, node, metastasis; UICC, Union for International Cancer Control.

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