



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.

TABLE 1. Composition of the task force

| ASGE representatives | ACG representatives |
|---|--|
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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 scores²¹ predict adverse events during endoscopy, primarily those that are related to sedation. The Mallampati score²² 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 guidelines³¹⁻³⁵ 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: Peri-procedural 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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