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Quality indicators common to all GI endoscopic procedures

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The field of endoscopy has evolved substantially in recent years, with advances in procedural capabilities, technologies, and delivery models. One constant, however, has been the commitment of professional societies, including the American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG)—the 2 co-sponsors of this series—to the delivery of high-quality endoscopic care. This commitment is reflected, in part, by quality indicator documents, which aim to provide endoscopists and practices a framework through which quality improvement efforts can be operationalized.

Generally speaking, quality in health care is the degree to which health services for individuals and populations increase the likelihood of a desired outcome and are consistent with current professional knowledge.¹ In the endoscopic context, a high-quality procedure is one that is clearly indicated, during which relevant diagnoses are established or excluded, any therapy provided is appropriate and effective, and harm is minimized to the greatest extent possible. Toward this ideal, quality indicators have been developed to compare the performance of an individual or a group of individuals with available benchmarks.

DISCLOSURE

All authors disclosed no financial relationships.

Quality indicators can be divided into 3 categories: structural measures, assessing characteristics of the entire healthcare environment (eg, availability and maintenance of endoscopy equipment at a hospital); process measures, assessing performance during the delivery of care (eg, proportion of patients who undergo biopsy sampling when Barrett's esophagus is suspected); and outcome measures, assessing the results of the care that is provided (eg, proportion of patients who survive ≥ 30 days after endoscopic therapy for a bleeding gastric ulcer). By developing evidence-based quality measures; establishing performance targets, known as benchmarks, that reflect high-quality practice; measuring performance against these benchmarks; and implementing interventions to improve this performance, the quality of care delivered at the endoscopist, practice, and field levels can be maximized.

Herein we present the quality indicators considered fundamental to the conduct of any endoscopic procedure. As such, most of these indicators are attached to a performance target of $>98\%$, implying they should be achieved in nearly every case. The indicators that are unique to EGD, colonoscopy, EUS, and ERCP are presented in detail in separate documents dedicated to these procedures.²⁻⁵ Revised versions of these documents are forthcoming.

METHODOLOGY

This work represents the third iteration of the ASGE/ACG quality indicators documents. The first version of this document was published by the ASGE/ACG Task Force on Quality in Endoscopy in 2006⁶ and was revised in 2015.⁷ To the greatest extent possible, this current revision integrates new data relevant to existing quality indicators and introduces new indicators as appropriate based on interval progress in the field. This document focuses on quality indicators that are common to all GI endoscopic procedures (Table 1).

As in preceding versions, we prioritized indicators that have wide-ranging clinical implications and have been validated in clinical studies. Unlike the documents pertaining to procedure-specific indicators, variation in practice and outcomes was not prioritized in this document because most indicators that pertain to all endoscopic procedures are expected to occur almost universally with minimal variability. When supportive data were absent, indicators the task force perceived to be of major clinical importance were chosen by expert consensus. Substantial progress has been made in the last decade in our ability to measure performance; however, feasibility and efficiency challenges remain. Nevertheless, the task force elected to include a limited number of highly relevant but not yet easily measurable indicators to promote their eventual adoption.

As before, quality indicators are divided according to 3 time periods: preprocedure, intraprocedure, and postprocedure. Additionally, each quality indicator is classified as an outcome or process measure. Although outcome measures are generally considered more impactful toward improving quality of care, some can be difficult or impossible to measure in routine clinical practice because of the need for large amounts of data and/or long-term follow-up and because their measurement or interpretation may be confounded by other factors. In such cases, we provide process indicators as surrogate measures of high-quality endoscopic practice. The relative value of a process indicator hinges on the evidence that

supports its association with a clinically relevant outcome, and measures with a strong association were emphasized. The measures in this document pertain directly to endoscopic care. Of course, the quality of care delivered to patients is influenced by additional factors, including those related to the facilities in which endoscopy is performed. These structural measures are covered in a separate document dedicated to unit-level quality.⁸

The process and outcome measures included in this series of documents are attached to a performance target, and therefore each measure is considered a quality indicator. When possible, the task force selected performance targets based on published benchmarking data, informed by literature review. For most indicators in this particular document, expert consensus considered failure to perform a given quality indicator a “never event,” and thus the performance target was expressed as >98%, because only in very unusual circumstances would the quality indicator not be fulfilled.

For this revision, the task force critically appraised existing quality indicators and determined whether to maintain or remove them by consensus, based on several factors including ongoing relevance and strength of evidence. For indicators for which it was deemed necessary, the authors conducted a literature search through a systematic search of PubMed (U.S. National library of Medicine, National Institutes of Health) from January 2014 (the date of the last update of this document) through December 2022. The search strategies for each indicator included a combination of subject headings (MeSH in PubMed) and pertinent keywords. English language restrictions were applied. To identify additional articles, the authors reviewed PubMed’s “similar articles” and manually searched reference lists of relevant articles. For each indicator, based on a revised literature review when appropriate, the strength of recommendation was re-evaluated according to a previously used framework (Table 2). Within this framework, the strength of each quality indicator is divided across a spectrum from “1A,” denoting a strong quality indicator that can be applied to most clinical settings, to “3,” denoting a weak quality indicator because of an absence of evidence requiring the reliance on expert opinion only. The strength of recommendation for each indicator was established by consensus of the authors.

It is important to emphasize that the included quality indicators and associated performance targets do not necessarily reflect the standard of care, credentialing requirements, or training standards, and it is a misuse to apply any of the indicators in this document as such. Rather, the quality indicators are designed and intended to serve as a framework for quality improvement efforts. To guide continual improvement for endoscopists and units in varying phases of their quality journey, the task force again recognized a subset of indicators deemed “priority indicators” based on their clinical relevance, importance, 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). We recommend that quality improvement efforts initially focus on the priority indicators and then progress to include other indicators once it is ascertained that endoscopists are performing above recommended thresholds, either at baseline or after corrective interventions.

PREPROCEDURE QUALITY INDICATORS

The preprocedure period begins at the time of first contact between the patient and members of the endoscopy team and ends at the time of administration of sedation (or insertion of the endoscope in unsedated procedures). Quality indicators for all endoscopic procedures that apply during this period are appropriate indication, informed consent, risk assessment, management of prophylactic antibiotics and antithrombotic drugs, and team pause.

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)

Strength of recommendation: 1C

Performance target: >95%

Type of measure: process

Standard indications for each endoscopic procedure are listed in the quality indicator document dedicated to that procedure. For every endoscopy, an appropriate indication that appears in 1 of these standard lists should be documented. When a procedure is performed for a nonstandard reason, the rationale for the procedure 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 the benefits clearly outweigh any potential harms. Studies have shown that when EGD and colonoscopy are done for appropriate indications, significantly more clinically relevant diagnoses are made.^{9–12} Similarly, ERCP is most likely to result in harm when performed in patients who least require the procedure.^{13,14} In this revision of the quality indicator documents, indications have been added for bariatric and third-space endoscopy (EGD and colonoscopy documents) and interventional endosonography (EUS document). The indications for ERCP have been revised (ERCP document).

Open access endoscopy, in which nongastroenterologists schedule patients for endoscopy without prior consultation with the endoscopist, has been widely practiced for over 2 decades.¹⁵ Most studies have shown that open access endoscopies are usually done for appropriate indications.^{16,17} However, ongoing quality improvement efforts related to open access endoscopy should include developing mechanisms for effective feedback to referring physicians regarding indication appropriateness and establishing processes that allow efficient triage of some open access referrals to the clinic if necessary.

2. Frequency with which informed consent is obtained and documented

Strength of recommendation: 3

Performance target: >98%

Type of measure: process

Consent should always be obtained and documented before the procedure, except in some cases of emergency. Consent should include a discussion of the sedation plan, indication for the procedure, description of the procedure, likely benefits, common adverse events, alternatives to the procedure, and patient prognosis if treatment is declined. In emergency cases, when the patient is unable to provide consent and a legal representative is not available, institutional procedures to ensure the patient's best interest should be applied (eg, dual physician consent). If sedation for the procedure is provided by an anesthesia provider, then a separate consent for sedation and anesthesia obtained by that provider may be appropriate.

Discussion. Obtaining informed consent has myriad patient and provider benefits. It facilitates a patient-centered process that respects 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 healthcare team. ASGE guidelines on informed consent in endoscopy state that consent may be obtained by any member of the gastroenterology team (including nurse, advanced practice provider, or trainee) who are thoroughly knowledgeable of and able to communicate the indication(s), risks, benefits, and alternatives of that procedure, except where local and state mandate dictates otherwise.¹⁸ Consent may be supplemented by anatomic diagrams, brochures, web-based materials, and videos as well as 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 comprehensive discussion with the patient. These forms may be especially useful for high-risk and complex procedures. The quality of informed consent has been an important medicolegal issue in most ERCP procedures that resulted in litigation, underscoring the importance of high-quality consent, especially for procedures associated with a higher risk of adverse events.^{19,20}

3. Frequency with which preprocedure history and directed physical examination are performed and documented

Strength of recommendation: 3

Performance target: >98%

Type of measure: process

Before sedation, a focused preprocedure history and directed physical examination should be performed and documented.

Discussion. The ASGE and 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.^{21,22} 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 abnormalities of major organ systems; previous adverse events with

sedation or anesthesia; medication allergies, current medications, and potential medication interactions; and history of tobacco, alcohol, or substance use or abuse. A focused physical examination that informs the conduct of the procedure should be performed by the endoscopist. This should include, at the very least, an abdominal examination as a baseline assessment for comparison in the event that an adverse event, such as a perforation, is suspected during or after the procedure. Auscultation of the heart and lungs is indicated when sedation is administered by the endoscopist and there is concern about the patient's cardiopulmonary status, such as in the case of known heart failure or chronic obstructive pulmonary disease. An assessment of neurologic status allows a baseline for comparison after sedation to assess for cerebrovascular events or medication-induced adverse effects.

The history should also include the timing and nature of the patient's last oral intake. 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.²² Patients with gastroparesis, achalasia, and bowel obstruction may require a longer period of fasting to minimize the risk of aspiration. Unit policies pertaining to nothing by mouth status and medication management in patients taking glucagon-like peptide 1 receptor agonists and other weight loss drugs that may delay gastric emptying will evolve as clinical data emerge.

Patients may take essential medications (with the possible exception of anticoagulation; see quality indicator 6) including bowel preparation before endoscopic procedures. Prospective studies have observed that patients undergoing colonoscopy have minimal residual fluid in the stomach (<25 mL), and this was similar whether patients split the bowel preparation or consumed all the preparation on the evening before the procedure.^{23,24}

4. Frequency with which a sedation plan that includes risk for sedation-related adverse events is developed and documented before sedation is initiated

Strength of recommendation: 3

Performance target: >98%

Type of measure: process

Before any endoscopic procedure, a sedation plan that includes a risk assessment for sedation-related adverse events should be considered and documented. The intended level of sedation should be specified as no sedation, minimal sedation, moderate sedation, deep sedation (ie, monitored anesthesia care), or general anesthesia. Additionally, stratification of patients by established methods such as the ASA score demonstrates a commitment to minimizing harm and informs decision-making regarding proceeding with or deferring the procedure and modifying the procedural approach and/or sedation plan. Even when sedation is administered by an anesthesiologist, input from the endoscopist can be critical to clarify the risk-to-benefit ratio and inform the optimal anesthesia approach.

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 scale from 1 to 5 (1 = normal and healthy to 5 = critically ill and at substantial risk of death within 24 hours). Large database studies have shown that ASA scores predict adverse events during endoscopy, primarily those related to sedation.²⁵ The Mallampati score is based on a visual assessment of the upper airway. A higher score correlates with increased difficulty encountered in endotracheal intubation. This score has not been rigorously validated as a risk stratification tool for endoscopic procedures, but it has gained clinical relevance with the widespread use of deep sedation and hence a possible need for urgent airway management.²⁶

Sedation is a continuum, and it may not be possible to predict how an individual patient will respond. Therefore, the ASA recommends that physicians aiming 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.

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

Strength of recommendation: varies according to procedure

Performance target: >98%

Type of measure: process

Prophylactic antibiotics should be administered in select settings for which existing evidence supports that they are beneficial. This quality indicator aims primarily to ensure that antibiotics are given in scenarios in which they have been proven beneficial; however, the judicious use of antibiotics to minimize unnecessary administration is an equally important clinical care and quality improvement priority.

Discussion. GI endoscopy is not considered to be a significant risk factor for clinically important bacteremia. Therefore, according to ASGE guidelines, antibiotics to prevent bacterial endocarditis or other infectious adverse events are not recommended, even for patients who are at the highest risk for these conditions.²⁷ Antibiotics are also not recommended for patients with cardiac conditions, synthetic vascular grafts, or other nonvalvular cardiovascular devices undergoing any endoscopic procedure; biliary obstruction in the absence of cholangitis undergoing ERCP with anticipated complete drainage; solid lesions along the upper GI tract and colon undergoing EUS-guided fine-needle sampling; and prosthetic joints undergoing any endoscopic procedure.²⁷

In contrast, prophylactic antibiotics are recommended in the following scenarios: ERCP in patients in whom incomplete biliary drainage is anticipated (eg, primary sclerosing cholangitis), ERCP in patients who have undergone orthotopic liver transplantation, ERCP in patients undergoing cholangioscopy, any endoscopic procedure in patients with cirrhosis and acute GI hemorrhage (given the high incidence of concurrent bacterial infectious adverse events), PEG tube placement in all patients, colonoscopy or flexible sigmoidoscopy

in patients undergoing peritoneal dialysis, and EUS-guided FNA of a mediastinal or pancreatic cystic lesion.²⁷ This last indication remains controversial and will be addressed in more detail in the EUS document. Additional indications for antibiotic prophylaxis are listed in the procedure-specific documents. Antibiotic management is classified as a preprocedure quality indicator, recognizing that antimicrobial decisions are also made during the procedure as appropriate indications arise.

6. Frequency with which a plan for the management of antithrombotic therapy is formulated and documented before the procedure (priority indicator)

Strength of recommendation: 3

Performance target: 95%

Type of measure: process

A plan regarding the periprocedural management of antithrombotic medications should be formulated and documented ahead of the procedure and communicated to the patient and healthcare team. Antithrombotic medication use should be queried and recorded at the time of the procedure.

Discussion. Current combined ACG and Canadian Association of Gastroenterology guidelines pertaining to the management of antithrombotic medications in patients undergoing endoscopy provide the most recent evidence-based guidance on the use of these agents in the periprocedural period.²⁸ In general, diagnostic endoscopic procedures (even those involving mucosal biopsy sampling) are considered to be of low risk for procedure-related bleeding and do not require cessation of antiplatelet and anticoagulant agents. Some therapeutic endoscopic procedures are considered high risk for causing procedure-related bleeding, and thus most such cases without extenuating circumstances require cessation of anticoagulants. Some evidence suggests that certain interventions traditionally believed to require the interruption of anticoagulation, such as cold snare resection of small polyps in patients on clopidogrel, may not require medication cessation,^{29,30} and this should be considered in the management plan.

Patients at high risk for thromboembolic adverse events may require bridge therapy, deferment of endoscopy, and/or consultation with a specialist. These high-risk conditions include atrial fibrillation associated with other cardiac conditions (eg, heart failure or valvular disease) 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. In most nontherapeutic procedures, antithrombotic medications may be resumed immediately if they were discontinued. In patients who have undergone interventions with a high bleeding risk, the timing of resumption needs to be individualized, taking into account the type of endoscopic therapy performed and the risk of thromboembolism. Almost all endoscopic procedures can be performed safely on an 81- to 325-mg daily dose of aspirin, and recent guidelines recommend against periendoscopic interruption of this medication when prescribed for secondary cardiovascular prevention.²⁸ Existing evidence suggests that aspirin is frequently stopped

inappropriately before endoscopic procedures and that educational interventions can reduce this phenomenon,^{31,32} representing a potentially important quality improvement initiative in certain endoscopy units.

7. Frequency with which a team pause is performed and documented

Strength of recommendation: 3

Performance target: >98%

Type of measure: process

Before the procedure, the team must pause to confirm patient identity and procedure type. This should be performed and recorded either before administering sedation or before inserting the endoscope, in accordance with institutional policies.

Discussion. A team pause (also referred to as a timeout) before initiating any procedure requiring sedation or anesthesia is 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 and that procedure-related documentation, such as report and images, are connected to the intended patient. If necessary, the pause may allow for reassessment of clinical, laboratory, or radiologic data that may affect the performance or safety of the endoscopic procedure. It may also provide the endoscopist an opportunity to offer team members additional details regarding the planned procedure and inform them of potential deviations from usual practice that would require special attention or equipment.

8. Frequency with which endoscopy is performed or supervised by an individual who is fully trained and appropriately credentialed to perform that particular procedure

Strength of recommendation: 3

Performance Target: >98%

Type of measure: process

A quality endoscopic procedure is one that is performed by an endoscopist who is credentialed on the basis of having met and maintained objective measures for competency. Competency is most commonly achieved through subspecialty training programs but can also be the result of postgraduate training pathways.

Discussion. Achieving the desired objectives and minimizing adverse events ultimately define the quality of an endoscopic procedure. Existing evidence supports the presence of a strong volume-outcomes relationship across multiple procedure types, with low-volume providers incurring an increased risk of perforation and bleeding during colonoscopy and lower procedural success during ERCP.^{33–35} However, objective measures of competency are important in addition to training and procedural volume to ensure that providers are appropriately credentialed to perform endoscopic procedures. Indeed, ASGE credentialing guidelines recommend that objective criteria and direct observation, and not simply

the number of procedures performed in training or practice, should be used to define competency.³⁵ Other important themes pertinent to competency emphasized in these credentialing guidelines are as follows: measures of competence, especially when well-established benchmarks are available, should be universal and not vary by provider specialty; competency in 1 procedure should not necessarily imply competency in another; and competency in a given endoscopic procedure should require that the endoscopist is able to perform minimum therapeutic maneuvers specific to that procedure (eg, standard polypectomy in colonoscopy and stent placement for distal biliary obstruction in ERCP).^{36,37}

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 endoscopy as well as the cognitive decision-making required for the successful and safe completion of the procedure. Common to most endoscopic procedures is the provision of sedation and/or anesthesia and need for patient monitoring.

9. Frequency with which photo documentation is performed

Strength of recommendation: 3

Performance target: 95%

Type of measure: process

Photo documentation of important anatomic landmarks and pathology should be performed as a quality assurance activity and to improve communication and longitudinal GI care.

Discussion. Although the value 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 communication 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 approaching 100% are achievable in healthy adults.^{38–40} Photo documentation of the cecum is the simplest and most practical method of verifying that a complete colonoscopy has been achieved and is fundamental to calculating the cecal intubation rate quality indicator.⁴¹ It is recommended that key anatomic features like the appendiceal orifice with surrounding cecal strap fold and a view of the cecum with ileocecal valve should 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.⁴² During ERCP, endoscopic photos of the papilla, before and after an intervention (eg, sphincterotomy or stent placement), and of any pathologic findings should be obtained. Additionally, a fluoroscopic image of the abdomen before initiating the procedure (scout film) and representative images of important pancreaticobiliary findings

are valuable. The goals of photo documentation for other procedures are listed in the procedure-specific documents.

10. Frequency with which patient monitoring during sedation is performed and documented

Strength of recommendation: 3

Performance target: >98%

Type of measure: process

Oxygen saturation with pulse oximetry, heart rate, and blood pressure should be monitored during all sedated endoscopic procedures. Blood pressure and heart rate should be recorded at intervals ≤ 5 minutes. Electrocardiographic monitoring is indicated in patients undergoing deep sedation and general anesthesia.

Discussion. It is generally accepted that patient monitoring during sedation improves safety. Patient monitoring recommendations for oximetry, pulse, and blood pressure are included in guidelines published by the ASGE and ASA and provide a means to detect dangerous and potentially actionable changes in a patient's cardiopulmonary status during sedation.^{21,43} Capnographic monitoring has been associated with reduced apnea and hypoxemia in randomized trials of patients undergoing endoscopy under deep sedation with propofol and can be considered in this context.^{44–46}

11. Frequency with which procedure interruption and premature termination because of sedation-related issues is documented

Strength of recommendation: 3

Performance target: >98%

Measure type: process

Any sedation-related event, including use of reversal agents and airway management, that requires interruption and/or premature termination of the procedure should be documented.

Discussion. Clinical decision-making in which the physician is constantly weighing the risks and benefits of continuing the endoscopic procedure is the hallmark of good clinical care and should be encouraged. Both excessive use of reversal agents and frequent premature termination of procedures have been proposed as surrogate markers of suboptimal sedation practices. However, such events should not automatically be considered adverse events because the administration of these potentially life-saving medications and/or the decision to abort an endoscopic procedure may actually represent excellent clinical judgement depending on the circumstances.

Although this quality indicator should be documented and tracked to identify unsafe practices and related targets for improvement, it is critical to emphasize that penalizing clinicians for using these potentially life-saving interventions may have potentially

devastating unintended consequences. Instead, such events and related metrics should be evaluated in a nonpunitive manner within the context of process improvement and not as an indirect measure of outcome. The goal should be to reduce the number of events that require interruption or termination but not to discourage sound clinical judgement (including reversal and termination) in the context of a potential emergency.

This measure is intended to apply to cases in which sedation is delivered by endoscopy personnel. However, collaborative efforts between the endoscopy team and anesthesia colleagues to minimize risk when an anesthesiologist or anesthesiologist is involved are naturally encouraged as well.

12. Frequency with which endoscopic specimen verification is performed and documented

Strength of recommendation: 3

Performance target: >98%

Measure type: process

Ensuring that specimens obtained during endoscopy are placed in the proper container, labeled correctly, align with the endoscopy report, and are delivered to the appropriate laboratory is fundamental to high-quality care and required by credentialing bodies.

Discussion. The mishandling of pathologic specimens can result in preventable harm, including missed diagnoses, delayed or improper treatment, and increased costs. The appropriate handling of specimens is a complex process involving multiple steps that are subject to potential human and systems errors, the most frequent of which appear to be miscommunication and lack of standardization.^{47–49} However, quality improvement interventions have been shown to reduce the rate of specimen errors.^{48,49}

The ASGE document on quality indicators for GI endoscopy units identified the presence of a policy on reconciliation of specimen requisition to ensure physician and staff agree on specimen labeling as a meaningful and feasible quality measure.⁸ This verification process, which involves effective communication between endoscopist and staff, is mandated by national accreditation standards and should be performed for every specimen container. Additional quality improvement activities in this area might focus on other aspects of the specimen continuum, such as delivery to the laboratory or measuring the rate of mislabeled or mishandled specimens.

POSTPROCEDURE QUALITY INDICATORS

The postprocedure period extends from the time the endoscope is removed until subsequent follow-up. Postprocedure activities include procedure documentation; postprocedure monitoring; providing instructions to the patient; recognizing, documenting, and rescuing patients from adverse events; pathology follow-up; communication with referring physicians; and assessing patient satisfaction.

13. Frequency with which discharge from the endoscopy unit according to predetermined discharge criteria is documented

Strength of recommendation: 3

Performance target: >98%

Measure type: process

Documentation affirming that the patient has met predetermined discharge criteria is required 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.^{21,50} These criteria generally include attaining a prespecified level of consciousness, demonstrating certain hemodynamic parameters, and being free of excess pain or other untoward symptoms and signs. Confirmation that the patient has satisfied these criteria should be documented.

14. Frequency with which patient instructions are provided

Strength of recommendation: 3

Performance target: >98%

Measure type: process

Written discharge instruction should be provided in compliance with the ASGE guidelines.⁸

Discussion. Clear written instructions should be provided to the patient before discharge. These instructions should include any dietary restrictions, resumption or change in medications (including antithrombotic agents and new prescriptions), return to activities such as driving, and contact information should a question, concern, or emergency arise.⁵⁰ Patients should be informed of signs and symptoms of delayed adverse events that should prompt a call to the clinician and exactly how to contact the clinical team. Patients should also be told how they will be informed of relevant biopsy sample results. Information concerning necessary follow-up appointments or lack of need for such should be included.

15. Frequency with which endoscopic findings, pathology results, and follow-up recommendations are communicated to the patient and appropriate providers

Strength of recommendation: 3

Performance target: >98%

Measure type: process

The findings of the endoscopic procedure and follow-up recommendations should be communicated to the patient and all relevant providers in a timely fashion. When histopathologic specimens have been obtained, the results and associated management implications should also be communicated with the patient and appropriate providers.

Discussion. To optimize outcomes, all results related to the endoscopic procedure should be communicated in a timely fashion. Lack of clear communication with patients can result in confusion, mistrust, and inappropriate and inadequate subsequent action on their part. Similarly, lack of communication with care providers may result in misunderstanding, misalignment, and patient mismanagement. Pathology results frequently 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 their care team are notified of these findings and their implications. Patient communication should begin in the recovery area after the procedure through direct conversation and by provision of the procedure report and discharge instructions. Important concepts may be reinforced when necessary though follow-up communications provided by telephone, mail, electronic communication, or patient medical record portal. In particular, patients with confirmed or suspected malignancies need to have plans for further follow-up, staging, and treatment documented. Appropriate members of the patient's care team should also be notified of all results, implications, and recommendations by letter, facsimile, telephone call, secure e-mail, or forwarded electronic medical record communication. The frequency with which patients and referring physicians receive complete information is a meaningful quality indicator that will be more measurable with increasing use and integration of electronic medical records.

16. Frequency with which a complete procedure report is created

Strength of recommendation: 3

Performance target: >98%

Measure type: process

An accurate, detailed, and timely procedure report is required for every endoscopic procedure.

Discussion. The accurate and timely documentation of endoscopic findings and recommendations enhances patient care.⁴¹ The report should be detailed yet succinct, because the inclusion of unnecessary information may distract from relevant findings. Standardization of the language and structure of endoscopic reports may improve communication between physicians, enhance performance improvement efforts, advance research activities, and foster collaboration. Electronic medical records and computerized endoscopic report-generating systems greatly aid in this task. Quality assessment and value-based care programs that depend on the collection of accurate, reproducible data benefit from such standardization. The minimal necessary elements of an endoscopy report are as follows⁴¹:

1. Date of procedure
2. Patient identification data
3. Endoscopist(s), including trainees, participating in procedure
4. Assistant(s) participating in procedure

5. Relevant patient history and physical examination (if not separately documented)
6. Confirmation of informed consent and team pause
7. Endoscopic procedure (both planned and performed)
8. Indication(s)
9. Type of endoscopic instrument(s) used
10. Medications administered, including dose and route of administration
11. Anatomic extent of examination
12. Quality of visualization (ie, preparation for colonoscopy or retained food in EGD)
13. Limitation(s) of examination (or absence of limitations)
14. Tissue or fluid samples obtained
15. Findings
16. Diagnostic impression
17. Results of therapeutic intervention (if any)
18. Adverse events (if any)
19. Disposition
20. Recommendations for subsequent care

17. Frequency with which adverse events are documented (priority indicator)

Strength of recommendation: 3

Performance target: >98%

Measure type: process

Identified adverse events should be classified according to their timing, level of certainty of attribution to the endoscopic procedure, and degree of consequent impact on the patient, and this should be documented.

Discussion. Improving the safety of endoscopy is a major goal of the ASGE and ACG and is consistent with efforts spearheaded by the Institute of Medicine.⁵¹ Comprehensive capture and consistent documentation of adverse events are fundamental quality assurance activities because they provide endoscopists and practices the information necessary to track quality relative to past performance and to compare outcomes (and contribute meaningfully) to benchmarking data. Even for some adverse events that cannot be reliably compared between providers and centers (eg, post-ERCP pancreatitis), efforts to reduce the incidence of adverse events relative to one's past performance (or maintain high-quality performance) are valuable. Improved capture and documentation of adverse events, which are known to be

underestimated,⁵² will result in more optimal internal control and benchmarking targets for quality improvement efforts.

An adverse event is one that prevents completion of the planned procedure or results in admission to the hospital, prolongation of the existing hospital stay, another invasive procedure, or subsequent medical consultation. An ASGE task force proposed definitions and classification of endoscopy-related adverse events in an attempt to standardize data collection and reporting.⁵³ Adverse events can be subdivided based on timing as preprocedure, intraprocedure, postprocedure (up to 14 days), and late (any time after 14 days). When documenting an adverse event, the level of certainty that the adverse event was attributable to the endoscopic procedure (ie, definite, probable, possible, or unlikely) should be recorded. Expert panels have recently developed causality attribution systems for ERCP-related adverse events⁵⁴ and postcolonoscopy bleeding,⁵⁵ and similar efforts pertaining to other procedures would be valuable for quality assurance and improvement and research purposes. The severity of adverse events (mild, moderate, severe, or fatal) should be graded by the degree of consequent disturbance to the patient and any changes in the plan of care. Preprocedure and intraprocedure adverse events that are evident at the completion of the 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.

To accurately document adverse event rates, delayed events that occur after the patient has been discharged from the endoscopy unit must be captured. Reliance on notification of an adverse event by the patient or another provider is likely inadequate because 15% to 45% of adverse events go unrecognized or unreported.^{56,57} Instead, active efforts to contact patients and identify delayed adverse events, ideally 2 weeks after the procedure, are recommended with the goal of accurate documentation of adverse events. Recognizing that the significant added effort and cost necessary to perform 14-day follow-up remain obstacles, we anticipate that compliance with 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. Additionally, patient-facing smartphone applications designed to allow seamless communication between the patient and endoscopy personnel may limit the administrative burden associated with these efforts.

18. Frequency with which adverse events occur

Strength of recommendation: 1C

Performance target: varies according to procedure

Measure type: outcome

Discussion. Adverse events vary from mild postprocedure bloating to cardiopulmonary arrest. The rate of cardiopulmonary adverse events in large observational studies is between .01% and 1.1% for general endoscopic procedures but up to 5% for ERCP.^{58–60} Perforation is exceedingly rare during diagnostic upper endoscopy (~ 1 in 25,000 cases) but can

occur in up to 1% of cases with therapeutic intervention.⁵⁸ The rate of perforation during screening colonoscopy is generally less than .1%.^{61–63} Perforation rates with EUS and ERCP range from .1% to .6%.^{60,64} Hemorrhage is most often associated with polypectomy but can happen after ERCP with or without sphincterotomy, mucosal resection, gastrostomy placement, or dilation, among other scenarios. For routine clinical practice, bleeding rates for colonoscopy should be well less than 1% for screening and diagnostic procedures, could be in the range of 1% when polypectomy across the full spectrum of lesion sizes is considered,⁶⁵ and is expected to be well under 1% when cold snare resection is used as the primary tool for lesions ≤ 10 mm.⁶⁶ Naturally, the rate of delayed bleeding is increased after EMR or endoscopic submucosal dissection and other complex therapeutic interventions. The rate of bleeding after ERCP with sphincterotomy is .3% to 2%.⁶⁰

Given the clinical importance of significant cardiopulmonary events, perforation (that is not identified and treated intraprocedurally), and major hemorrhage, tracking the rates of these events relative to aforementioned benchmarks is a worthwhile quality improvement activity. These and other adverse event indicators (eg, post-ERCP pancreatitis), as they pertain to quality improvement efforts, are discussed in much greater detail in the procedure-specific quality indicator documents, which should serve as the reference standard for each individual procedure.

19. Frequency with which patient satisfaction data are collected

Strength of recommendation: 3

Performance target: N/A

Measure type: process

Information on patient experience and satisfaction should be collected consistently using standardized and validated questionnaires.

Discussion. The ASGE, in its publication, “Quality and outcomes assessment in gastrointestinal endoscopy,” recommends the use of validated questionnaires of patient satisfaction modified for use after endoscopic procedures.⁶⁷ 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 experience and satisfaction may become feasible.

PRIORITY QUALITY INDICATORS

The recommended priority indicators common to all endoscopic procedures are appropriate indication, defined as endoscopy performed for an indication present within a standard list of appropriate indications; prophylactic antibiotics, which are prophylactic antibiotics administered only for select settings in which they are indicated; antithrombotic therapy, which is antithrombotic medication use recorded and a plan regarding management of

antithrombotic medications executed; and adverse events, with the plan to comprehensively capture and document adverse events (this could initially focus on preprocedure and intraprocedure periods, but ongoing efforts to develop practical and efficient solutions for capturing delayed adverse events are highly worthwhile). These indicators can be reliably measured in a manageable number of examinations, and their improvement is very likely to have a favorable impact on quality of care.

CONCLUSIONS

In this document, we review the quality indicators common to all endoscopic procedures. Most of these indicators address fundamental patient rights or provider responsibilities. Activities such as obtaining informed consent, ensuring a valid indication, and comprehensively and truthfully documenting adverse events are implicit in the covenant into which providers enter with patients. Given the fundamental nature of these indicators, the value of their enumeration and discussion might be questioned. However, data suggest a lack of compliance with these indicators remains. Procedures are still performed for questionable indications, adverse events are not always captured and documented, and communication between the endoscopist and patient and/or involved clinicians is sometimes lacking. For these reasons, strict attention to the quality indicators in this document and an active plan for improvement in areas of measured deficiency should be a central pillar of the successful practice of endoscopy. In many respects, the quality indicators in this document are the “building blocks” on which the other documents in this series stand. As the field of GI endoscopy continues to evolve, the ASGE and ACG plan to continually reassess this evidence and modify indicators accordingly.

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Abbreviations:

A5A	American Society of Anesthesiologists
ACG	American College of Gastroenterology
ASGE	American Society for Gastrointestinal Endoscopy

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TABLE 1.
Quality indicators common to all endoscopic procedures with associated performance targets

Quality indicator	Strength of recommendation	Measure type	Performance target (%)
<i>Preprocedure</i>			
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	>95
2. Frequency with which informed consent is obtained and 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 a sedation plan that includes risk for sedation-related adverse events is developed and documented before sedation is initiated	3	Process	>98
5. Frequency with which prophylactic antibiotics are administered for appropriate indications (priority indicator)	Varies	Process	>98
6. Frequency with which management of antithrombotic therapy is formulated and documented before the procedure (priority indicator)	3	Process	>95
7. Frequency with which a team pause is performed and documented	3	Process	>98
8. Frequency with which endoscopy is performed or supervised by an individual who is fully trained and appropriately credentialed to perform that particular procedure	3	Process	>98
<i>Intraprocedure</i>			
9. Frequency with which photo documentation is performed	3	Process	>95
10. Frequency with which patient monitoring during sedation is performed and documented	3	Process	>98
11. Frequency with which procedure interruption and premature termination because of sedation-related issues is documented	3	Process	>98
12. Frequency with which endoscopic specimen verification is performed and documented	3	Process	>98
<i>Postprocedure</i>			
13. Frequency with which discharge from the endoscopy unit according to predetermined discharge criteria is documented	3	Process	>98
14. Frequency with which patient instructions are provided	3	Process	>98
15. Frequency with which endoscopic findings, pathology results, and follow-up recommendations are communicated to the patient and appropriate providers	3	Process	>98
16. Frequency with which a complete procedure report is created	3	Process	>98
17. Frequency with which adverse events are documented (priority indicator)	3	Process	>98
18. Frequency with which adverse events occur	1C	Outcome	N/A
19. Frequency with which patient satisfaction data are collected	N/A	Outcome	N/A

Clinical implications of each strength of recommendation are as follows: 1A, strong recommendation, can be applied to most clinical settings; 1B, strong recommendation, likely to apply to most practice settings; 1C+, strong recommendation, can apply to most practice settings in most situations; 1C, intermediate-strength recommendation, may change when stronger evidence is available; 2A,

intermediate-strength recommendation, best action may differ depending on circumstances or patients' or societal values; 2B, weak recommendation, alternative approaches may be better under some circumstances; 2C, very weak recommendation, alternative approaches are likely to be better under some circumstances; 3, weak recommendation, likely to change as data become available.

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TABLE 2.

Strength of recommendation

Strength 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, IL: AMA Press; 2002. p. 599–608.