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## Measuring the quality of endoscopy

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The practice of gastrointestinal endoscopy is facing a crisis. There is decreasing reimbursement for endoscopic procedures in the face of increasing demand. We are challenged to assess the quality of the services we provide. Although providing the best possible patient care is our most important goal, we are poorly equipped to measure our ability to achieve that goal.

Our financial future is in jeopardy. Government payments, mainly in the form of Medicare and Medicaid, account for approximately 50% of all health care costs in the United States. In 2003, U.S. health care expenditures were \$1.7 trillion, representing 15.3% of the gross domestic product (GDP) and \$5670 per person.<sup>1</sup> These costs are projected to more than double to \$3.6 trillion in 2014, or 18.7% of the GDP. This is an average annual increase of 7.1%, 1.9% greater than the growth of the GDP. In the face of growing expenditures, Medicare physician payments have remained relatively flat. At the time of this writing, the physician fee schedule for Medicare has decreased 4.4% from 2005. Legislation to hold fees constant for 1 year has passed and is waiting for the President's signature. The recent addition of a Medicare prescription drug benefit will cost \$1.2 trillion over 10 years.<sup>2</sup> Payment trends in the private sector have followed those of Medicare. There are increasing efforts to shift both the cost and responsibility for health care spending to patients from both public and private payers.

During this time of financial stress there has also been increasing demand to track and improve patient outcomes. The Institute of Medicine (IOM) released its report, "To Err is Human: Building a Safer Health System" in 1999.<sup>3</sup> This report raised national awareness of medical complications, claiming that 44,000 to 98,000 people die each year as a result of medical errors. This was followed by the 2001 IOM report, "Crossing the Quality Chasm: A New Health System for the 21st Century," advocating widespread changes in health care to improve quality.<sup>4</sup> Some states have begun reporting provider-specific crude outcomes data, such as surgical mortality, to the public. In 1990 the nonprofit National Committee on Quality Assurance (NCQA) was established to evaluate the quality of health care plans. The NCQA also administers the Health Plan Employer Data and Information Set (HEDIS) to provide health care plan per-

formance information to consumers.<sup>5</sup> This has developed into a national database on provider performance that consists of more than 60 measures of performance of specific services in identified patient populations.<sup>6</sup> The rate of colorectal cancer screening is the only gastroenterology-related HEDIS measure. In response to public and legislative pressure, the Centers for Medicare and Medicaid Services (CMS) has announced its intent to link provider payment to performance, in a "pay for performance" (P4P) program. Hospitals are already required to report 10 performance indicators to CMS to receive full payment for their services. Demonstration projects for physician performance are underway, and the agency has begun to identify specific quality indicators.<sup>7</sup> Sixteen initial performance measures for physicians have been announced (none relating to endoscopy). In the near future, physicians will be required to track and report their performance in these areas to receive full Medicare payment. We can anticipate that reimbursement for endoscopy will also soon be linked to reporting and performance on quality measures.

When we address the issue of performance measures for endoscopy, it becomes clear that we have no reliable way to distinguish a high-quality endoscopic procedure done by a trained endoscopist from a procedure performed by an inadequately trained provider. Fortunately, adverse events are too rare to track as a meaningful indicator of quality. Direct observation of each procedure by an evaluator with formal training in endoscopy is impractical. We need objective, practical ways to grade our performance.

The ASGE and ACG recognize that if we do not develop evidence-based quality measures, an administrative or governmental agency without experience or insight into the practice of endoscopy will define these measures for us. We collaborated through a joint task force that reviewed data on quality measures for all major endoscopic procedures. After a year of intense effort they have developed the specific measures outlined in this report. It is clear from their efforts that we have limited data on endoscopic quality. The measures they propose are not perfect, or even applicable in all cases. Many areas for future study are identified. In the end, however, they have presented us with a series of practical quality measures that all endoscopists can use to assess and improve their performance. By adopting these recommendations we can begin to distinguish appropriate, high-quality endoscopy from inappropriate and poorly performed procedures. This will improve patient care, provide comparative information for consumers, and prepare us for the future, reporting requirements that will surely come.

We sincerely thank the task force chairs, Dr Douglas Faigel and Dr Irving Pike, for their hard work and leadership. We also thank the members of the task force who critically evaluated the literature and our endoscopic practice to provide these insightful reports. Their important contribution has provided us with the critical tools required to face a challenging future.

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# Quality indicators for gastrointestinal endoscopic procedures: an introduction

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ASGE/ACG Taskforce on Quality in Endoscopy

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The assurance that high-quality endoscopic procedures are performed has taken increased importance. A high-quality endoscopy ensures that the patient receives an indicated procedure, that correct and clinically relevant diagnoses are made (or excluded), that therapy is properly performed, and that all these are accomplished with minimum risk. The motivation for developing quality indicators for endoscopy begins with the desire to provide patients with the best possible care. These indicators may then be used in programs to improve the overall quality of endoscopic services.

The American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG), as leaders in promoting the highest quality patient care, formed a task force to identify end points that could be used to document high-quality endoscopic services. In most cases these end points will require validation before they can be generally adopted. The task force consisted of expert endoscopists selected by the board of directors of the ASGE and the ACG (Table 1). These documents were then reviewed and approved by the governing boards.

The task force developed quality indicators for the 4 major endoscopic procedures: colonoscopy, esophagogastroduodenoscopy (EGD), endoscopic retrograde cholangiopancreatography (ERCP), and endoscopic ultrasonography (EUS). Wherever possible, these indicators were chosen because there were published supporting data. These studies were identified through a computerized search of Medline followed by review of the bibliographies of relevant articles. When such data were absent, indicators were chosen by expert consensus. Our goal was to create a comprehensive list of potential quality indicators, recognizing that only a small subset may ultimately be implemented. The resultant quality indicators were graded on the strength of the supporting evidence (Table 2).<sup>1</sup>

For each endoscopic procedure, indicators were considered for 3 time periods: preprocedure, intraprocedure, and postprocedure. Preprocedure indicators include proper indication for the procedure, consent, antibiotic prophylaxis, etc. Intraprocedure indicators include completeness of the examination and completion of therapeutic procedures. Postprocedure indicators include follow-up

of pathology and recognition and management of complications. Our aim was to create indicators that in most cases could be extracted from the endoscopy report or procedural documentation. Although the endoscopist's goal may be to achieve 100% compliance with every indicator in every patient, it is recognized that this will not be practically achievable in all cases. In most cases, acceptable compliance levels are unknown and should be determined by prospective study.

Underlying this discussion of quality indicators is the assumption that adequate training and credentialing has taken place before a practitioner begins the practice of endoscopy. The ASGE has guidelines specifically addressing standards for training, assessing competence, and granting privileges to perform endoscopy.<sup>2</sup> It is the task force's recommendation that these guidelines be adopted by facilities where endoscopic procedures are performed.

Although each endoscopic procedure will have quality indicators specific to that procedure, there will be some common to all. This introduction will review the general principles and end points that are common to all endoscopic procedures. The following articles will focus on indicators unique to specific procedures.

## PREPROCEDURE QUALITY INDICATORS

The preprocedure period includes all contacts between the endoscopist, endoscopy nurses, and unit staff with the patient before the administration of sedation or insertion of the endoscope. Common issues for all endoscopic procedures during this period include proper indication, patient consent for the procedure, patient clinical status and risk assessment, steps to reduce risk such as through the use of prophylactic antibiotics, management of anticoagulants, and timeliness in the performance of the procedure.

1. Proper indication. In general, endoscopy is indicated when the information gained or the therapy provided will help the patient and is not indicated when the information or therapy will not have an impact on clinical decision making or outcome (Table 3).<sup>3</sup> An indication should be documented for each procedure, and when it is a nonstandard indication it should be justified in the documentation.

**Discussion.** The ASGE in 2000 published a list of accepted indications for endoscopic procedures.<sup>2</sup> This list was determined by a review of published literature and

**TABLE 1. Composition of the task force**

<b>ASGE representatives</b>	<b>ACG representatives</b>
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expert consensus. The specific indications for each procedure are different and the procedure indications should match the specific procedure being performed. Studies have shown that when EGD and colonoscopy are done for appropriate reasons, significantly more clinically relevant diagnoses are made.<sup>4-9</sup> A quality improvement goal is to minimize the number of inappropriate procedures. Acceptable compliance rates should be determined separately for each endoscopic procedure.

2. Proper consent. Consent should be obtained and documented for the procedure and any sedation or analgesia provided except in emergency situations with noncompetent patients. The consent should specifically address the most common complications. For all procedures these include bleeding, perforation, missed diagnosis, and sedation-related complications.<sup>10</sup>

**Discussion.** Obtaining informed consent has several patient benefits. It ensures 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 to proceed with a given course of action. Finally, it provides the patient the opportunity to ask questions, increasing patient understanding and confidence in the health care team. The informed consent process should include a discussion of the risks of any therapeutic procedures that exceed general precautions.

3. Preprocedure history and directed physical examination. Before the use of moderate or deep sedation, a directed preprocedure history and physical examination should be documented.<sup>11,12</sup>

**Discussion.** Both the ASGE and the American Society of Anesthesiologists (ASA) recommend a preprocedure assessment that includes a health history and directed physical examination.<sup>11,12</sup> The history should focus on the indications for the procedure and on conditions that might affect the performance of the endoscopy (eg, prior gastrointestinal surgery) or safety of therapeutic procedures (eg, implanted defibrillators). The history should also focus on aspects that might affect the administration of sedation or anesthesia, such as (1) abnormalities of the major organ systems, (2) previous adverse experience with sedation/analgesia as well as regional and general anesthesia, (3) drug allergies, current medications, and potential drug interactions, (4) time and nature of last oral intake, and (5) history of tobacco, alcohol, or substance use or abuse. Patients should undergo a focused physical examination including vital signs, auscultation of the heart and lungs, and evaluation of the airway. Documentation of a “current” patient history and physical examination is needed. Some accrediting organizations may not allow this documentation to be solely on the endoscopy report, and separate documentation may be required. Current requirements may vary from locale to locale, but each institution must develop and follow its own policies. These need to follow accreditation requirements and local regulations.

4. Risk stratification. Before sedation is begun, a risk assessment is performed to stratify patients into higher- or lower-risk-for-complications groups (particularly as pertains to sedation). The physician/nurse team should document the risk assessment.

**Discussion.** The task force recommends that facilities wishing to use this quality indicator adopt a system for stratifying risk. Several risk stratification systems exist. The ones used most commonly before endoscopic procedures are the ASA score and the Mallampati score. The ASA score primarily considers comorbid conditions and ranks patients on a 1 to 5 scale (1, completely healthy, to 5, critically ill and not expected to survive). Large endoscopic database studies have shown that the ASA score correlates with complications during endoscopy, primarily sedation-related complications.<sup>13,14</sup> The Mallampati score uses a visual analog scale to assess the upper airway. The Mallampati score correlates with difficulty encountered in

**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 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, Jaeschke R, Schunemann H, Pauker S. Moving from evidence to action: grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, eds. *Users' guides to the medical literature*. Chicago: AMA Press; 2002. p. 599-608.

intubating patients.<sup>15</sup> It has not been assessed as a risk stratification tool for endoscopic procedures.

5. Prophylactic antibiotics are administered to high-risk patients undergoing high-risk procedures.<sup>16</sup>

**Discussion.** The ASGE guidelines recommend prophylactic antibiotics for high-risk patients undergoing high-risk procedures. High-risk patients are those with underlying cardiovascular abnormalities placing them at increased risk for bacterial endocarditis or intravascular infection. These patients include those with a prosthetic valve, a history of endocarditis, a systemic pulmonary shunt, a synthetic vascular graft less than 1 year old, or complex cyanotic congenital heart disease. High-risk procedures are those that carry an increased risk of bacteremia and include stricture dilation, variceal sclerotherapy, and ERCP in an obstructed bile duct. These patients should receive antibiotic prophylaxis. Additionally, well-done controlled studies in patients undergoing percutaneous endoscopic gastrostomy (PEG) demonstrate the efficacy of prophylactic antibiotics in preventing skin infections. Antibiotics should also be given to patients with cirrhosis and acute gastrointestinal bleeding before endoscopy.

6. Timeliness. Endoscopic procedures should be performed in a timely manner. The time interval between

the decision to perform endoscopy and performance of the procedure should be recorded.

**Discussion.** Delays in care may be harmful in some clinical situations and can be frustrating to the patient and referring provider. The expeditious provision of endoscopic procedures is consistent with recommendations by the Institute of Medicine and the American Gastroenterological Association (AGA).<sup>17,18</sup> What represents acceptable timeliness depends on the indication, procedure performed, and patient preferences. Although optimal or acceptable intervals cannot be recommended, the task force concluded that measuring these intervals would be useful to the quality improvement process.

7. Sedation plan. Before the administration of any sedatives, the intended level of sedation is specified: minimal, moderate, deep, general anesthesia.

**Discussion.** The cardiorespiratory risks of sedation correlate with the depth of sedation. The ASA and ASGE specify that training standards and monitoring differ depending on the intended depth of sedation, with more rigorous standards applying to the deeper levels.<sup>11,12</sup>

8. Anticoagulation. Whether the patient is currently using anticoagulants or antiplatelet medications is recorded.

**TABLE 3. General indications and contraindications for gastrointestinal endoscopy**

GI endoscopy is generally indicated	<ol style="list-style-type: none"> <li>1. If a change in management is probable on the basis of results of endoscopy</li> <li>2. After an empiric trial of therapy for a suspected benign digestive disorder has been unsuccessful</li> <li>3. As the initial method of evaluation as an alternative to radiographic studies</li> <li>4. When a primary therapeutic procedure is contemplated</li> </ol>
GI endoscopy is generally not indicated	<ol style="list-style-type: none"> <li>1. When the results will not contribute to a management choice</li> <li>2. For periodic follow-up of healed benign disease unless surveillance of a premalignant condition is warranted</li> </ol>
GI endoscopy is generally contraindicated	<ol style="list-style-type: none"> <li>1. When the risks to patient health or life are judged to outweigh the most favorable benefits of the procedure</li> <li>2. When adequate patient cooperation or consent cannot be obtained</li> <li>3. When a perforated viscus is known or suspected</li> </ol>

GI, Gastrointestinal.

**Discussion.** ASGE guidelines have been published regarding anticoagulants and antiplatelet medications.<sup>19,20</sup>

In general, anticoagulants should be stopped in patients undergoing high-risk procedures such as polypectomy of large polyps, sphincterotomy, and esophageal dilation. Patients who are at high risk for a serious thromboembolic event should receive bridging therapy with standard heparin or low-molecular-weight heparin. Most endoscopic procedures can be performed with the patient who is taking aspirin. The endoscopic risks of dopedogrel and ticlopidine are uncertain.<sup>19</sup> A plan to manage anticoagulants should be made at the time the procedure is scheduled.

9. Team pause. Before the institution of sedation or insertion of an endoscope, a pause is documented during which correct patient and proper procedure is confirmed.

**Discussion.** Many institutions have now adopted the concept of a team pause before initiation of procedures requiring sedation or anesthesia. The purpose of this pause is to ensure that the correct patient is undergoing the correct indicated procedure. The pause also allows a reassessment of any history, laboratory, or radiologic data that may affect the conduct of the endoscopic procedure. Although there are no data supporting the efficacy of the team pause for endoscopy, it was felt by the task

force to represent best current practice and was therefore recommended.

### Research questions

- How often are procedures performed for valid indications in clinical practice?
- Does this differ in different settings (eg, open access) or by different types of practitioners (eg, nongastroenterologists)?
- Do the current guidelines as to the appropriate use of endoscopy accurately reflect best clinical practice?
- What is the best setting for obtaining informed consents from patients?
- Who should obtain this consent?
- Do tools such as pamphlets and videos aid in the consent process?
- Which aspects of the history and physical examination actually have an impact on subsequent patient management?
- Which system, ASA, Mallampati, or other, best predicts risks for complications associated with endoscopic procedures?
- Does the use of risk scores alter clinical practice and result in an improved outcome?
- How often are prophylactic antibiotics given inappropriately (ie, when they are not indicated)?
- Does provision of time interval data result in changes in practice achieving a shortened interval?
- Do shorter intervals improve patient satisfaction or improve outcome?
- How often is the intended level of sedation the level actually achieved in clinical practice?
- What is the most cost-effective way to manage patients taking chronic warfarin?
- What are the risks of endoscopic procedures in patients with newer antiplatelet agents such as clopidogrel?
- What proportion of examinations are cancelled or delayed because of anticoagulation issues?
- How often does the team pause result in a change in the endoscopic plan?

### INTRAPROCEDURE

The intraprocedure period extends from the administration of sedation or insertion of the endoscope to removal of the endoscope. This period includes all the technical aspects of the procedure, including completion of the examination and of any therapeutic maneuvers. Common to the majority of endoscopic procedures is the provision of sedation and the need for patient monitoring.

10. Photo documentation. Major abnormalities are photo documented.

**Discussion.** It is the opinion of the task force that high-quality endoscopy includes the use of photo

documentation. Although the cost-effectiveness of endoscopic photography may never be shown, its use reflects current best practice and should be encouraged.

11. Patient monitoring. 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.** Although adequate patient monitoring should theoretically improve safety, in fact none of the proposed monitoring parameters have been shown in well-designed studies to improve outcome. Nonetheless, these recommendations are consistent with guidelines published by the ASGE and the ASA<sup>11,12</sup> and provide a means to detect potentially dangerous changes in a patient's status during sedation.

12. Documentation of medications. Doses and routes of administration of all medications used during the procedure are documented.

13. Reversal agents. The use of reversal agents (eg, flumazenil, naloxone) or the need to discontinue propofol because of excessive sedation is recorded.

**Discussion.** Some health care institutions have chosen to use the administration of reversal agents as a surrogate marker for an adverse event or unsafe procedure. The task force feels this use of data to be of concern in that it may intentionally or unintentionally penalize physicians for use of these potentially life-saving medications. The task force strongly recommends that any use of this end point be done in a nonpenalizing manner so as not to discourage the use of this class of medications.

### Research questions

- Do extended monitoring techniques such as capnography improve detection of sedation-related complications and have an impact on outcome?
- Will monitoring reversal agent use inhibit practitioners from using them and thereby increase risk to patients?

### POSTPROCEDURE

The postprocedure period extends from the completion of the procedure to subsequent follow-up. Postprocedure activities include providing instructions to the patient, documentation of the procedure, recognition and documentation of complications, follow-up of pathologic conditions, and assessing patient satisfaction.

14. Discharge from the endoscopy unit. Documentation that the patient has met predetermined discharge criteria before discharge from the endoscopy unit.

**Discussion.** Each endoscopy unit should have a written policy as to what criteria the patient must meet before discharge from the unit.<sup>11</sup> That the patient has achieved these criteria should be documented before discharge.

15. Patient instructions. Written instructions should be provided to the patient before discharge.<sup>11</sup> These instructions should address diet restrictions, resumption of usual medications, and return to activities, especially driving. Procedure-specific information regarding potential delayed complications should also be provided. They should also provide a contact telephone number in the event of emergencies or should questions arise.

**Discussion.** Written discharge instruction should be provided in compliance with ASGE guidelines.<sup>11</sup>

16. Pathology follow-up. In cases where biopsy specimens have been obtained, the plan for patient notification is documented.

**Discussion.** The pathology results from biopsy specimens frequently alter or determine subsequent management plans (eg, timing of surveillance colonoscopy, need for *Helicobacter pylori* treatment). Integration of pathology results into care plans requires patient notification of the findings and their implications. Patients may be notified by letter, phone call, or subsequent follow-up visit (with the endoscopist or other provider), but the plan should be documented. With the development of integrated electronic medical records, specific pathology follow-up as a quality indicator may be practical in the future.

17. Procedure report. Immediately after the procedure, a procedure report is prepared.

**Discussion.** Quality assurance (QA) and pay-for-performance (P4P) programs critically depend on the collection of reliable data. Electronic medical records and computerized endoscopic reporting systems greatly aid in this task. It is likely that endoscopists participating in P4P or other QA programs will be required to use an electronic medical record (EMR) program for recording endoscopic procedure reports. Therefore, the next generation of report generators will need to comply with the Centers for Medicare and Medicaid Services (CMS) and other payer's requirements.

Although there is practice variation as to the what endoscopic procedure reports contain, ASGE guidelines<sup>21</sup> recommend that the procedure report contain the following elements:

- date of procedure
- patient identification data
- endoscopist(s)
- assistant(s)
- documentation of relevant patient history and physical examination
- indication of informed consent
- endoscopic procedure
- indication(s)
- type of endoscopic instrument
- medication (anesthesia, analgesia, sedation)
- anatomic extent of examination
- limitation(s) of examination

- tissue or fluid samples obtained
  - findings
  - diagnostic impression
  - results of therapeutic intervention (if any)
  - complications (if any)
  - disposition
  - recommendations for subsequent care
18. Reporting of complications. Each endoscopy unit will have a protocol for the reporting of adverse events or unplanned interventions and these will be reported according to this protocol.

**Discussion.** Improving the safety of endoscopy is a major goal of the ACG and ASGE<sup>21</sup> and is consistent with efforts spearheaded by the Institute of Medicine.<sup>22</sup> To this end, the ASGE and ACG support collecting complication data so that processes may be put in place to reduce these risks. See the accompanying articles regarding collection of procedure-specific delayed complication data.

19. Patient satisfaction. Information on patient satisfaction will be collected by use of a validated and standardized questionnaire.<sup>21</sup>

**Discussion.** The ASGE in its publications "Quality and outcomes assessment in gastrointestinal endoscopy" recommended the use of a validated questionnaire of patient satisfaction (GHAA 9) modified for use after endoscopic procedures.<sup>23-25</sup> 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 in the continuous quality improvement (CQI) process.

20. Communication with referring providers. Documentation that the results of the endoscopic procedure and any therapeutic and follow-up recommendations have been given to the referring provider or primary care physician.

**Discussion.** Lack of communication of endoscopic results with other care providers may result in patient mismanagement. It is the responsibility of the endoscopist and endoscopy unit to make certain that results, and recommendations as to therapy, further diagnostic testing, and follow-up, are communicated to the referring physician, primary provider, or other relevant health care providers. This may be done by letter, fax, phone call, or e-mail. In particular, patients with suspected malignancies need documentation of plans for further follow-up, staging, and treatment.

21. Anticoagulation plan. Plan regarding postprocedure resumption of anticoagulants or antiplatelet medications is recorded.

**Discussion.** In the majority of nontherapeutic procedures, anticoagulant and antiplatelet medications may be immediately resumed. 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 indication for the anticoagulant or antiplatelet agent.<sup>19,20</sup>

## Research questions

- How often do patients actually comply with instructions about resumption of driving after sedation?
- Do computerized report generators improve documentation?
- Are the data obtained from these generators adequately reliable and robust to be used for QA programs?
- What are the complication rates for endoscopic procedures in clinical practice and do these rates vary over time?
- Does reporting and provision of feedback result in practice changes leading to a reduction in the number of procedure-related complications?
- Which clinical, demographic, and procedural variables are associated with higher levels of patient satisfaction?
- What are the relative risks of immediate versus delayed resumption of anticoagulants or antiplatelet medications?

## CONCLUSIONS

QA and P4P programs will rely on validated, useful quality indicators. P4P programs are rapidly being developed and in some areas already being used. It is of paramount importance that endoscopists themselves be involved in the development of these quality indicators lest those outside the endoscopic community make them for us.

It is our purpose that these proposed end points be used to create rational quality indicators that any well-trained endoscopist who is committed to patient care would exceed. These will also be useful in identifying poorly trained individuals providing a disservice to their patients and the medical profession.

In this introduction and in the articles that follow dealing with the specific endoscopic procedures, we have proposed a large number of potential end points (Table 4). Before their adoption as quality indicators, these end points should be studied and validated as to which are most useful and feasible for widespread use. The task force has attempted to create a comprehensive list of potential quality indicators. We recognize that not every indicator will be applicable to every practice setting. Facilities should select the subset most appropriate to their individual needs.

## General research questions

- For each of the proposed quality indicators, what are the current compliance rates in clinical practice?
- Does a high level of compliance correlate with better outcomes?
- Does provision of quality data to endoscopists and endoscopy units result in changes leading to higher compliance rates or improved outcomes?
- Does compliance with credentialing guidelines correlate with other measures of quality?

**TABLE 4. Summary of proposed quality indicators for endoscopic procedures\***

Quality indicator	Grade of recommendation
1. Proper indication	1C+
2. Informed consent	3
3. History and physical examination	3
4. Risk stratification	1C
5. Prophylactic antibiotics	2C
6. Timeliness recorded	3
7. Sedation plan recorded	3
8. Anticoagulants recorded	3
9. Team pause	3
10. Photo documentation of major abnormalities	3
11. Patient monitoring	3
12. Medications are documented	3
13. Reversal agents	3
14. Discharge criteria	3
15. Discharge instructions	3
16. Pathology follow-up	3
17. Procedure report	3
18. Reporting of complications	3
19. Patient satisfaction	3
20. Communication with referring provider(s)	3
21. Plan for postprocedure resumption of anticoagulants	3

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

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# Quality indicators for esophagogastroduodenoscopy

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Esophagogastroduodenoscopy (EGD) is one of the most commonly performed endoscopic procedures. Properly performed, it provides valuable information in patients with upper gastrointestinal (GI) conditions. Additionally, therapeutic EGD forms the mainstay of treatment for upper GI bleeding and for dilation or stenting of benign and malignant strictures. In this article, the task force has identified a set of quality indicators that are particular to diagnostic EGD and to therapeutic maneuvers that may be carried out during this procedure. The levels of evidence supporting these quality indicators were graded according to Table 1.

## PREPROCEDURE QUALITY INDICATORS

The preprocedure period includes all contacts between the endoscopist, the endoscopy nurse, and the unit staff with the patient before administration of sedation or insertion of the endoscope. Common issues for all endoscopic procedures during this period include proper indication, patient consent for the procedure, patient clinical status and risk assessment, steps to reduce risk such as through the use of prophylactic antibiotics, management of anticoagulants, and timeliness in the performance of the procedure.

Preprocedure indicators and discussion specific to the performance of EGD include the following:

1. Accepted indication(s) are provided before performance of EGD.

**Discussion.** The indications for EGD are covered in detail in a separate publication (Table 2).<sup>1</sup> It has been demonstrated that there is a statistically higher rate of significant pathologic findings when GI endoscopy is performed for indications listed in the American Society for Gastrointestinal Endoscopy (ASGE) guidelines for GI endoscopy.<sup>2,3</sup>

2. Informed consent is obtained, including specific discussions of risks associated with EGD.

**Discussion.** As with all other endoscopic procedures, consent must be obtained before the procedure from the patient or guardian on the same day (or as required by local law or per policy of the institution) as the procedure. Consent

may be obtained in the procedure room. It must include a discussion of the risks, benefits, and alternatives to the procedure. The risks of endoscopy include bleeding, perforation, infection, sedation adverse events, missed diagnosis, missed lesions, and intravenous site complications. In upper endoscopy, specific risks include chest pains, sore throat, aspiration, and reaction to local anesthetic spray.<sup>4</sup>

3. Prophylactic antibiotics are given to patients with cirrhosis with acute upper GI bleeding who undergo EGD.

**Discussion.** Outcomes studies have shown both a decreased infection rate and a decreased mortality rate when prophylactic antibiotics are given to cirrhotic patients with GI bleeding.<sup>5</sup>

4. Prophylactic antibiotics are given before placement of a percutaneous endoscopically placed gastrostomy (PEG).

**Discussion.** Several well-designed randomized controlled trials have demonstrated decreased local skin infections when appropriate prophylactic antibiotics are administered (eg, first-generation cephalosporin). For this reason, antibiotics are recommended before PEG placement.<sup>5</sup>

## Research questions

- What proportion of EGD procedures are performed for indications apart from those specified in published guidelines?
- Do existing guidelines concerning indications for EGD represent best clinical practice?
- What proportion of patients with cirrhosis undergoing EGD for upper GI bleeding receives indicated antibiotics?

## INTRAPROCEDURE QUALITY INDICATORS

The intraprocedure interval begins with the administration of sedation and ends with removal of the endoscope. This period includes all the technical aspects of the procedure, including completion of the examination and of any therapeutic maneuvers. Minimum performance elements that are generic to all GI procedures performed with the patient sedated include attention to patient monitoring, medication administration, reversal or resuscitative efforts, and photo documentation of pertinent landmarks or pathologic conditions. Both procedures and disease-specific quality indicators can be proposed for EGD practice, as follows:

5. Complete examination of the esophagus, stomach and duodenum, including retroflexion in the stomach.

**TABLE 1. Grades of recommendation\***

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

\*Adapted from Guyatt G, Sinclair J, Cook D, Jaeschke R, Schunemann H, Pauker S. 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.

**Discussion.** Except in cases of esophageal or gastric outlet obstruction, every EGD should include a complete visualization of all the organs of interest from the upper esophageal sphincter to the second portion of the duodenum. This may entail efforts to clear material from the fundus, as in assessment for the source of upper GI hemorrhage. Written documentation should confirm the extent of the examination. If an abnormality is encountered, photo documentation is necessary. In studies of the learning curve of EGD, more than 90% of trainees successfully perform technically complete EGD after 100 cases.<sup>6</sup> It is reasonable to expect that any practicing endoscopist be capable of visualizing the organs of interest with rare exception. This should include retroflexion in the stomach in all cases.

6. Biopsy specimens are taken of gastric ulcers.

**Discussion.** Careful attention to the presence of mucosal abnormalities during EGD is crucial. Adequate and appropriate samples demonstrate an understanding of the importance of a complete and thorough examination. Biopsy specimens from gastric ulcers are required to assess for the possibility of malignancy. The optimal number and type (maximum capacity vs standard) has not been determined. In the setting of acute GI bleeding, it is acceptable not to perform biopsy of the ulcer provided that a subsequent repeat endoscopy is planned.

7. Barrett's esophagus is measured when present; with the location of the gastroesophageal junction and

squamocolumnar junction in centimeters from the incisors being documented.

**Discussion.** Barrett's esophagus may be present in up to 5% of high-risk patients with gastroesophageal reflux disease (eg, older white men) undergoing upper endoscopy. The risk of progression to dysplasia or cancer may be related to the length of Barrett's epithelium.<sup>7</sup> Therefore, it is important to characterize and document the length and location of the salmon-colored mucosa during EGD. On the other hand, intestinal metaplasia of the Z line may occur in up to 18% of individuals without sufficient evidence that this significantly increases the risk of cancer to warrant surveillance programs when this is diagnosed. Accordingly, it is important that, when the presence of Barrett's tissue is suspected, these landmarks are clearly documented.<sup>8</sup>

8. Biopsy specimens are obtained in all cases of suspected Barrett's esophagus.

**Discussion.** The diagnosis of Barrett's esophagus requires demonstration of specialized intestinal metaplasia (SIM) on a biopsy specimen. Only those with SIM are at increased risk for development of adenocarcinoma and are candidates for surveillance protocols. Although the endoscopic appearance may suggest Barrett's esophagus, a definitive diagnosis cannot be made without pathologic confirmation. For patients with known Barrett's esophagus undergoing EGD, an adequate number of biopsy specimens should be obtained to exclude dysplasia.<sup>9</sup>

**TABLE 2. Indications and contraindications for EGD**

EGD is generally indicated for evaluating	<ul style="list-style-type: none"> <li>A. Upper abdominal symptoms that persist despite an appropriate trial of therapy</li> <li>B. Upper abdominal symptoms associated with other symptoms or signs suggesting serious organic disease (eg, anorexia and weight loss) or in patients &gt;45 years old</li> <li>C. Dysphagia or odynophagia</li> <li>D. Esophageal reflux symptoms that are persistent or recurrent despite appropriate therapy</li> <li>E. Persistent vomiting of unknown cause</li> <li>F. Other diseases in which the presence of upper GI pathologic conditions might modify other planned management (examples include patients who have a history of ulcer or GI bleeding who are scheduled for organ transplantation, long-term anticoagulation, or long-term nonsteroidal anti-inflammatory drug therapy for arthritis, and those with cancer of the head and neck)</li> <li>G. Familial adenomatous polyposis syndromes</li> <li>H. For confirmation and specific histologic diagnosis of radiologically demonstrated lesions               <ul style="list-style-type: none"> <li>1. Suspected neoplastic lesion</li> <li>2. Gastric or esophageal ulcer</li> <li>3. Upper tract stricture or obstruction</li> </ul> </li> <li>I. GI bleeding               <ul style="list-style-type: none"> <li>1. In patients with active or recent bleeding</li> <li>2. For presumed chronic blood loss and for iron deficiency anemia when the clinical situation suggests an upper GI source or when colonoscopy results are negative</li> </ul> </li> <li>J. When sampling of tissue or fluid is indicated</li> <li>K. In patients with suspected portal hypertension to document or treat esophageal varices</li> <li>L. To assess acute injury after caustic ingestion</li> <li>M. Treatment of bleeding lesions such as ulcers, tumors, vascular abnormalities (eg, electrocoagulation, heater probe, laser photocoagulation, or injection therapy)</li> <li>N. Banding or sclerotherapy of varices</li> <li>O. Removal of foreign bodies</li> <li>P. Removal of selected polypoid lesions</li> <li>Q. Placement of feeding or drainage tubes (peroral, percutaneous endoscopic gastrostomy, percutaneous endoscopic jejunostomy)</li> <li>R. Dilation of stenotic lesions (eg, with transendoscopic balloon dilators or dilation systems using guidewires)</li> <li>S. Management of achalasia (eg, botulinum toxin, balloon dilation)</li> <li>T. Palliative treatment of stenosing neoplasms (eg, laser, multipolar electrocoagulation, stent placement)</li> </ul>
EGD is generally not indicated for evaluating	<ul style="list-style-type: none"> <li>A. Symptoms that are considered functional in origin (there are exceptions in which an endoscopic examination may be done once to rule out organic disease, especially if symptoms are unresponsive to therapy)</li> <li>B. Metastatic adenocarcinoma of unknown primary site when the results will not alter management</li> <li>C. Radiographic findings of               <ul style="list-style-type: none"> <li>1. Asymptomatic or uncomplicated sliding hiatal hernia</li> <li>2. Uncomplicated duodenal ulcer that has responded to therapy</li> <li>3. Deformed duodenal bulb when symptoms are absent or respond adequately to ulcer therapy</li> </ul> </li> </ul>
Sequential or periodic EGD may be indicated	<ul style="list-style-type: none"> <li>A. Surveillance for malignancy in patients with premalignant conditions (ie, Barrett's esophagus)</li> </ul>
Sequential or periodic EGD is generally not indicated for	<ul style="list-style-type: none"> <li>A. Surveillance for malignancy in patients with gastric atrophy, pernicious anemia, or prior gastric operations for benign disease</li> <li>B. Surveillance of healed benign disease such as esophagitis or gastric or duodenal ulcer</li> <li>C. Surveillance during repeated dilations of benign strictures unless there is a change in status</li> </ul>

9. Type of upper GI bleeding lesion is described and location is documented.

**Discussion.** For peptic ulcers, at least one of the following stigmata is noted: active bleeding, nonbleeding visible vessels (pigmented protuberance), adherent clot, flat spot, clean based.

10. Unless contraindicated, endoscopic treatment is given to ulcers with active bleeding or with nonbleeding visible vessels.

**Discussion.** A basic characteristic of a quality endoscopy is the completion of therapeutic procedures. It is impossible to define prospectively all potential thera-

peutic maneuvers in upper endoscopy for the purpose of quality monitoring. Nonetheless, given the clinical importance of the management of GI bleeding, monitoring these issues ought to be representative of the mastery of endoscopic therapy and overall clinical care. In general, practitioners performing EGD to diagnose the source of upper GI bleeding should be trained, equipped, and prepared to therapeutically manage the bleeding source when it is found.

The first function of the therapeutic endoscopist is to find and define the location of the bleeding site. The site's description should be detailed enough to allow

a subsequent endoscopist to find the site. A detailed description of the lesion is also necessary, including documentation of stigmata associated with different risks of rebleeding.<sup>10-13</sup>

This requires knowledge of not only the stigmata but also of their different rates of rebleeding in various clinical scenarios. The cause for failure to identify the bleeding site should be clearly stated, if this occurs.

11. In cases of attempted hemostasis of upper GI bleeding lesions, whether hemostasis has been achieved is clearly documented.

**Discussion.** In many prospective series evaluating various modalities for managing actively bleeding upper GI bleeding lesions, immediate hemostasis rates from 90% to 100% have been achieved.<sup>14</sup> To gauge and track successful hemostasis, it will be necessary for endoscopists to clearly record whether their efforts to stop actively bleeding lesions are successful.

12. When epinephrine injection is used to treat nonvariceal upper GI bleeding or nonbleeding visible vessels, a second treatment modality is used (eg, coagulation or clipping).

**Discussion.** Multiple treatment modalities may be used in the treatment of nonvariceal GI bleeding. Current practices include the use of injection in conjunction with multipolar coagulation, heater probe thermal coagulation, endoscopic clipping, argon plasma coagulator, or various laser therapies in the exceptional case. The success or failure of such treatments should be photo documented when practical or clearly described. Epinephrine injection alone should not be considered adequate because studies have documented the superiority of combined modality therapy over epinephrine alone.<sup>15</sup> In general, immediate hemostasis should be achieved in more than 90% of cases.<sup>16</sup>

Treating these lesions has been shown to significantly reduce rebleeding rates and should therefore be attempted in most instances. There are good supportive data for the endoscopic removal of adherent clots and subsequent treatment of underlying stigmata.<sup>17-20</sup> However, because this is not yet standard practice, it would be premature at this time to include attempts to remove and treat clots in this quality measure.

13. For the endoscopic treatment of esophageal varices, variceal ligation is used as the preferred modality in the majority of cases.

**Discussion.** In bleeding from esophageal varices, banding is preferred over sclerotherapy for safety and efficacy.<sup>21,22</sup> Medical treatment with octreotide or  $\beta$ -blockers should be considered.<sup>23,24</sup> After the initial treatment, follow-up plans should include a short interval, repeat endoscopy, and repeated treatment until varices are eradicated. Postprocedure plans should also include some recommendation concerning the use of  $\beta$ -blockers for prevention of recurrent bleeding or a statement about why they are contraindicated.<sup>25</sup>

## Research questions

- Do endoscopists in all specialties who perform EGD document a complete examination of all organs with retroflexion in the stomach with similar frequency?
- What is the frequency of Barrett's diagnosis on EGD performed by different groups of providers?
- What is the mean number of biopsy specimens taken in clinical practice to investigate for celiac disease? For *Helicobacter pylori*? For Barrett's esophagus? And for exclusion of malignancy in gastric ulcers?
- How often do endoscopists perform hemostasis procedures and does case volume affect immediate hemostasis or delayed rebleeding rates?

## POSTPROCEDURE QUALITY INDICATORS

Minimum postprocedure performance elements common to all procedures include completion of a procedure report, provision of patient instructions, plans for pathology follow-up, determination of patient satisfaction, and communication to other care providers. Postprocedure quality indicators specific to performance of EGD include the following:

14. Written instructions provided to the patient on discharge include particular signs and symptoms relevant to EGD.

**Discussion.** In upper endoscopy, patients should be informed to contact the physician if abdominal or chest pain, fever, chills, abdominal distention, or signs of gastrointestinal bleeding such as vomiting blood or passage of black, tarry, or bloody stools develops. Patients should also be notified about how they will be informed of any biopsy results.

15. In patients undergoing dilation for peptic esophageal strictures, proton pump inhibitor (PPI) therapy is recommended.

16. Patients diagnosed with gastric or duodenal ulcers are instructed to take PPI medication or an H<sub>2</sub> antagonist.

**Discussion.** PPIs, when used in patients who have had peptic strictures, reduce the need for future dilations.<sup>26,27</sup> Patients diagnosed with gastric or duodenal ulcers are instructed to take PPI medication or an H<sub>2</sub> antagonist.

17. Patients diagnosed with gastric or duodenal ulcers have documented plans to test for the presence of *H pylori* infection.

**Discussion.** *H pylori* is a common cause of gastric and duodenal ulcer disease. Successful eradication of this organism results in dramatically reduced rates of ulcer recurrence.<sup>28</sup> Patients will only benefit from this therapy if a diagnosis of *H pylori* infection is made. Although nonsteroidal anti-inflammatory drugs (NSAIDs) may also cause ulcerations, it is not possible on the basis of clinical and endoscopic criteria alone to distinguish NSAID- from *H pylori*-caused ulcers.<sup>29</sup> Therefore, all patients with gastric or duodenal ulcers should be assessed for this infection. Testing may include gastric biopsy for rapid urease

**TABLE 3. Summary of proposed quality indicators for EGD\***

Quality indicator	Grade of recommendation
1. Accepted indication(s) is provided before performance of EGD.	1C+
2. Informed consent is obtained, including specific discussion of risks associated with EGD.	3
3. Prophylactic antibiotics are given in patients with cirrhosis with acute upper GI bleeding who undergo EGD.	1A
4. Prophylactic antibiotics are given before placement of a PEG.	1A
5. Complete examination of the esophagus stomach and duodenum, including retroflexion in the stomach.	2C
6. Biopsy specimens are taken of gastric ulcers.	1C
7. Barrett's esophagus is measured when present, with the location of the gastroesophageal junction and squamocolumnar junction in centimeters from the incisors being documented.	3
8. Biopsy specimens are obtained in all cases of suspected Barrett's esophagus.	3
9. Type of upper GI bleeding lesion is described and location is documented. For peptic ulcers, at least one of the following stigmata is noted: active bleeding, nonbleeding, nonbleeding visible vessels (pigmented protuberance), adherent clot, flat spot, cleaned based.	3
10. Unless contraindicated, endoscopic treatment is given to ulcers with active bleeding or with nonbleeding visible vessels.	1A
11. In cases of attempted hemostasis of upper GI bleeding lesions, whether hemostasis has been achieved is clearly documented.	3
12. When epinephrine injection is used to treat nonvariceal upper GI bleeding or nonbleeding visible vessels, a second treatment modality is used (eg, coagulation or clipping).	1A
13. Variceal ligation is used for endoscopic treatment of esophageal varices.	1A
14. Written instructions, which include particular signs and symptoms to watch for after EGD, are provided to the patient on discharge.	3
15. In patients undergoing dilation for peptic esophageal strictures, PPI therapy is recommended.	1A
16. Patients diagnosed with gastric or duodenal ulcers are instructed to take PPI medication or an H <sub>2</sub> antagonist.	1A
17. Patients diagnosed with gastric or duodenal ulcers have documented plans to test for the presence of <i>H pylori</i> infection.	1A
18. Rebleeding rates after endoscopic hemostasis are measured.	1C+

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

testing or histologic examination, culture, urea breath test, or stool testing.

18. Efforts to track rebleeding rates after hemostasis are included in endoscopy unit protocol for the reporting of adverse events.

**Discussion.** Beyond the usual tracking of postprocedure data recommended for all endoscopic procedures, it is particularly important to ascertain the rates of rebleeding when the quality of endoscopy performed to diagnose and treat upper GI hemorrhage is assessed.

### Research questions

- How often do patient instructions specify symptoms after an EGD that should prompt an immediate call to the physician for evaluation?

- What are the observed clinically important aspiration rates after EGD in practice?
- Do instructions to follow up with the endoscopist lead to differences in outcome (recurrent bleeding, *H pylori* eradication rates, Barrett's surveillance intervals) compared with instructions for follow-up of results with the referring physician alone?

### CONCLUSION

To define what constitutes a high-quality EGD, this article first identified the key components of the examination, including preprocedural, intraprocedural, and postprocedure metrics (Table 3). Those quality indicators important for EGD but applicable to all endoscopic procedures

appear in an accompanying article.<sup>30</sup> The task force has attempted to create a comprehensive list of potential quality indicators. We recognize that not every indicator will be applicable to every practice setting. Facilities should select the subset most appropriate to their individual needs.

More prospective performance data will be required to validate the indicators outlined in this article. Further, we have identified a few specific areas for future investigation to ensure that adherence to these benchmarks leads to safe, effective, and well-indicated procedures with high patient satisfaction. We hope that, by establishing these guidelines and by urging practitioners to track their performance with these measures, this effort will promote excellence among endoscopists and enable them to provide the highest possible quality of patient care.

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# Quality indicators for colonoscopy

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Colonoscopy is widely used for the diagnosis and treatment of colonic disorders. Properly performed, colonoscopy is generally safe, accurate, and well tolerated by most patients. Visualization of the mucosa of the entire large intestine and distal terminal ileum is usually possible at colonoscopy. In patients with chronic diarrhea, biopsy specimens can help diagnose the underlying condition. Polyps can be identified and removed during colonoscopy, thereby reducing the risk of colon cancer. Colonoscopy is the preferred method to evaluate the colon in most adult patients with bowel symptoms, iron deficiency anemia, abnormal radiographic studies of the colon, positive colorectal cancer screening tests, postpolypectomy and post-cancer resection surveillance, surveillance in inflammatory bowel disease, and in those with suspected masses.

The use of colonoscopy has become accepted as the most effective method of screening the colon for neoplasia in patients over the age of 50 years and in younger patients at increased risk.<sup>1</sup> The effectiveness of colonoscopy in reducing colon cancer incidence depends on adequate visualization of the entire colon, diligence in examining the mucosa, and patient acceptance of the procedure. Preparation quality affects the ability to perform a complete examination, the duration the procedure, and the need to cancel or reschedule procedures.<sup>2,3</sup> Ineffective preparation is a major contributor to costs.<sup>4</sup> Longer withdrawal times have been demonstrated to improve polyp detection rates,<sup>5-7</sup> and conversely, rapid withdrawal may miss lesions and reduce the effectiveness of colon cancer prevention by colonoscopy. The miss rates of colonoscopy for large ( $\geq 1$  cm) adenomas may be higher than previously thought.<sup>8,9</sup> Thus, careful examinations are necessary to optimize the effectiveness of recommended intervals between screening and surveillance examinations. Finally, technical expertise will help prevent complications that can offset any cost-benefit ratio gained by removing neoplastic lesions.

The following quality indicators have been selected to establish competence in performing colonoscopy and help define areas for continuous quality improvement. The levels of evidence supporting these quality indicators were graded according to Table 1.

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## PREPROCEDURE

The preprocedure period encompasses the time from first contact by the patient until administration of sedation or instrument insertion. The aspects of patient care addressed in prior documents apply here as well, including timely scheduling, patient preparation, identification, history and physical examination, appropriate choice of sedation and analgesia, evaluation of bleeding risk, etc. Because many examinations are currently being performed for colon cancer screening and are elective, care must be taken to be certain that all potential risks have been reduced to as low as practically achievable.

The American Society for Gastrointestinal Endoscopy (ASGE)<sup>10</sup> and the U.S. Multi-Society Task Force on Colon Cancer have published appropriate indications for colonoscopy<sup>11</sup> (Tables 2 and 3).

## Specific quality indicators

1. Appropriate indication. The ASGE and the U.S. Multi-Society Task Force on Colon Cancer have published appropriate indications for colonoscopy (Tables 2 and 3). An indication should be documented for each procedure, and when it is a nonstandard indication it should be justified in the documentation.

**Discussion.** The ASGE in 2000 published a list of accepted indications for endoscopic procedures.<sup>10</sup> This list was determined by a review of published literature and expert consensus. Studies have shown that when esophago-gastroduodenoscopy and colonoscopy are done for appropriate reasons significantly more clinically relevant diagnoses are made.<sup>12-14</sup> In these studies, which divided indications into appropriate, uncertain, and inappropriate, and looked at high-volume European centers, 21% to 39% were classified as inappropriate. It is likely that this can be improved to less than a 20% inappropriate rate.<sup>15</sup> The European Panel of Appropriateness of Gastrointestinal Endoscopy (EPAGE) Internet guideline is a useful decision support tool for determining the appropriateness of colonoscopy.<sup>15</sup> The goal is to minimize as much as possible the number of inappropriate procedures.<sup>16-19</sup>

In the average-risk population, colonoscopic screening is recommended in all current guidelines at 10-year intervals.<sup>20-22</sup> Direct observational data to support this interval are lacking. However, in a cohort of average-risk persons who underwent an initial colonoscopy

**TABLE 1. Grades of recommendation\***

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

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

with negative results, a repeat colonoscopy 5 years later had a very low yield.<sup>23</sup> Two studies of flexible sigmoidoscopy showed that the protective effect of endoscopy with polypectomy was present for intervals of 10 years and 16 years and could not exclude longer durations of effect.<sup>24,25</sup> Thus, although colonoscopy is not perfectly protective, its protective effect is prolonged. These data support the continued use of the 10-year interval.

2. Informed consent is obtained, including specific discussions of risks associated with colonoscopy.

**Discussion.** As with all other endoscopic procedures, consent must be obtained before the procedure from the patient or guardian on the same day (or as required by local law or per policy of the institution) as the procedure. Consent may be obtained in the procedure room. It must include a discussion of the risks, benefits, and alternatives to the procedure. The risks of endoscopy include bleeding, perforation, infection, sedation adverse events, missed diagnosis, missed lesions, and intravenous site complications.

3. Use of recommended postpolypectomy and post-cancer resection surveillance intervals (Tables 2 and 3).

**Discussion.** For colonoscopy to be both effective and cost-effective and to minimize risk, the intervals between examinations should be optimized. Intervals between examinations can only be effective in prevention of incident colorectal cancer when the colon is effectively cleared

of neoplasia. Therefore, detailed and effective examination of the colon, as discussed below, is critical to the effectiveness of recommended intervals between colonoscopies. The recommended intervals assume cecal intubation, adequate bowel preparation, and careful examination.

Colonoscopy, even when performed carefully, is not expected to prevent all incident colorectal cancers. Some colorectal cancers arise because of genetic factors that make the adenoma-to-carcinoma sequence faster.<sup>26</sup> In addition, in some instances, colonoscopic polypectomy may not be effective in eradicating polyps.<sup>27</sup> Because colonoscopy can be an expensive procedure and is associated with a low risk of serious consequences, intervals between examinations are recommended on the basis of the best available evidence and experience that indicates a balance between the protective effect of high-quality clearing colonoscopy with the risks and cost of colonoscopy.

Recent evidence from 4 surveys indicated that postpolypectomy surveillance colonoscopy in the United States is frequently performed at intervals that are shorter than those recommended in guidelines.<sup>28-31</sup> These surveys underscore the importance of measuring intervals between examinations in continuous quality improvement programs. Some endoscopists in these studies performed colonoscopy in patients with only small hyperplastic polyps or a single tubular adenoma at 1 year, an interval abandoned in guidelines after publication of the National Polyp

**TABLE 2. Colonoscopy indications\***

- A. Evaluation on barium enema or other imaging study of an abnormality that is likely to be clinically significant, such as a filling defect or stricture
- B. Evaluation of unexplained gastrointestinal bleeding
  - 1. Hematochezia
  - 2. Melena after an upper gastrointestinal source has been excluded
  - 3. Presence of fecal occult blood
- C. Unexplained iron deficiency anemia
- D. Screening and surveillance for colonic neoplasia
  - 1. Screening of asymptomatic, average-risk patients for colonic neoplasia
  - 2. Examination to evaluate the entire colon for synchronous cancer or neoplastic polyps in a patient with treatable cancer or neoplastic polyp
  - 3. Colonoscopy to remove synchronous neoplastic lesions at or around time of curative resection of cancer followed by colonoscopy at 3 years and 3-5 years thereafter to detect metachronous cancer
  - 4. After adequate clearance of neoplastic polyp(s) survey at 3- to 5-year intervals
  - 5. Patients with significant family history
    - a. Hereditary nonpolyposis colorectal cancer: colonoscopy every 2 years beginning at the earlier of age 25 years or 5 years younger than the earliest age of diagnosis of colorectal cancer. Annual colonoscopy should begin at age 40 years.
    - b. Sporadic colorectal cancer before age 60 years: colonoscopy every 5 years beginning at age 10 years earlier than the affected relative or every 3 years if adenoma is found
  - 6. In patients with ulcerative or Crohn's pancolitis 8 or more years' duration or left-sided colitis 15 or more years' duration every 1-2 years with systematic biopsies to detect dysplasia
- E. Chronic inflammatory bowel disease of the colon if more precise diagnosis or determination of the extent of activity of disease will influence immediate management
- F. Clinically significant diarrhea of unexplained origin
- G. Intraoperative identification of a lesion not apparent at surgery (eg, polypectomy site, location of a bleeding site)
- H. Treatment of bleeding from such lesions as vascular malformation, ulceration, neoplasia, and polypectomy site (eg, electrocoagulation, heater probe, laser or injection therapy)
- I. Foreign body removal
- J. Excision of colonic polyp
- K. Decompression of acute nontoxic megacolon or sigmoid volvulus
- L. Balloon dilation of stenotic lesions (eg, anastomotic strictures)
- M. Palliative treatment of stenosing or bleeding neoplasms (eg, laser, electrocoagulation, stenting)
- N. Marking a neoplasm for localization

\*ASGE. Appropriate use of gastrointestinal endoscopy. *Gastrointest Endosc* 2000;52:831-7.

Study randomized trial in 1993.<sup>32</sup> Surgeons were more likely than gastroenterologists to use short intervals.<sup>28</sup> These data underscore the need for endoscopic leaders to promote continuous quality improvement among all specialties practicing colonoscopy in a given community.

Diminutive hyperplastic polyps, when found only in the rectosigmoid colon, can be considered normal. The presence of small distal hyperplastic polyps only should not alter the recommended interval for surveillance. Appropriate intervals in patients with large hyperplastic

**TABLE 3. Indications for colonoscopy and appropriate intervals\***

Indication	Interval*
<b>Bleeding</b>	
Positive FOBT	NR
Hematochezia	NR
Iron deficiency anemia	NR
Melena with negative esophagogastroduodenoscopy	NR
<b>Screening</b>	
Average risk	10 y (begin at age 50 y)
Single FDR with cancer (or adenomas) at age $\geq 60$ y	10 y (begin at age 40 y)
$\geq 2$ FDRs with cancer (or adenomas) or 1 FDR diagnosed at age $< 60$ y	5 y (begin at age 40 y or 10 y younger, whichever is earlier)
Prior endometrial or ovarian cancer diagnosed at age $< 50$ y	5 y
HNPCC (begin age 20-25 y)	1-2 y
Abdominal pain, altered bowel habit†	
Positive sigmoidoscopy (large polyp or polyp of $< 1$ cm shown to be an adenoma)‡	
<b>Postadenoma resection</b>	
1-2 tubular adenomas of $< 1$ cm	5-10 y
3-10 adenomas or adenoma with villous features, $\geq 1$ cm or with HGD	3 y
$> 10$ adenomas	$< 3$ y
Sessile adenoma of $\geq 2$ cm, removed piecemeal§	2-6 m
<b>Postcancer resection</b>	
	Clear colon, then in 1 y, then 3 y, then 5 y
Ulcerative colitis, Crohn's colitis surveillance after 8 y of pancolitis or 15 y of left-sided colitis	2-3 y until 20 y after onset of symptoms, then 1 y

FOBT, Fecal occult blood test; NR, interval not recommended; FDR, first-degree relative; HNPCC, hereditary nonpolyposis colorectal cancer; HGD, high-grade dysplasia.

\*From: Rex DK, Bond JH, Winawer S, et al. Quality in the technical performance of colonoscopy and the continuous quality improvement process for colonoscopy: recommendations of the U.S. Multi-Society Task Force on Colorectal Cancer. *Am J Gastroenterol* 2002;97:1296-308. Updated based on guideline revisions in press. Used with permission.

†If colonoscopy has negative results and symptoms are stable, repeat examination should be done according to screening recommendations.

‡See postadenoma resection recommendation.

§The goal is to reexamine the site for residual polyp; repeating a flexible sigmoidoscopy is adequate for a distal polyp.

polyps located in the proximal colon, or in patients who have many hyperplastic polyps (30 or more) are not yet established, but close follow-up may be appropriate.<sup>33,34</sup>

Patients who have evidence of colonic bleeding that occurs after a colonoscopy with negative results may need repeat examinations at intervals shorter than those recommended in Tables 2 and 3. However, the use of fecal occult blood testing for the first 5 years after a colonoscopy is discouraged because the positive predictive value of

guaiac-based fecal occult blood testing during that interval is extremely low.<sup>35</sup> Additional study of fecal immunochemical testing for blood in this setting as an adjunct to colonoscopy is warranted.<sup>36</sup>

4. The use of recommended ulcerative colitis and Crohn's colitis surveillance.

**Discussion.** In ulcerative colitis and Crohn's colitis, surveillance refers to interval examinations of patients with long-standing disease who have undergone an initial

examination in which dysplasia is not detected. The term is also used when patients who are asymptomatic are prospectively entered into interval colonoscopy programs on the basis of their duration of disease. Surveillance does not refer to diagnostic examinations or examinations in previously diagnosed patients to assess symptoms. Both ulcerative colitis and Crohn's colitis of long duration are associated with an increased risk of colorectal cancer.<sup>37,38</sup> There are no randomized trials to support the effectiveness of surveillance colonoscopy in ulcerative colitis or Crohn's colitis, but case control studies in ulcerative colitis suggest a survival benefit for patients who participate in surveillance.<sup>39,40</sup> Surveys of practitioners in the United States<sup>41</sup> and the United Kingdom<sup>42</sup> demonstrate that many practitioners are not familiar with surveillance recommendations, have a poor understanding of dysplasia, and make inappropriate recommendations in response to findings of dysplasia.<sup>41,42</sup>

Patients should be encouraged to undergo surveillance colonoscopy, and surveillance has emerged as a standard of medical care in the United States. The onset of disease is timed to the onset of symptoms for the purpose of timing the initiation of surveillance in both ulcerative colitis and Crohn's colitis. Because the yield of ulcerative colitis in surveillance for cancer and severe dysplasia is relatively low,<sup>43,44</sup> it is important to not overuse surveillance colonoscopy during the first 20 years because overuse is not cost-effective.<sup>45</sup> Shorter intervals between examinations are indicated for patients with long-duration disease and may be initiated earlier in the course of disease in patients with established risk modifiers, such as a family history of colorectal cancer or a personal history of primary sclerosing cholangitis.<sup>46,47</sup> Persons with primary sclerosing cholangitis who are discovered to have asymptomatic ulcerative colitis should begin surveillance at the time ulcerative colitis is diagnosed.

5. Preparation: in every case the procedure note should document the quality of preparation.

**Discussion.** In each colonoscopy, the colonoscopist should document the quality of the bowel preparation. In clinical trials of bowel preparation, terms used to commonly characterize bowel preparation include "excellent," "good," "fair," and "poor." In clinical practice, these terms do not have standardized definitions. In clinical trials on the effectiveness of various laxative regimens for bowel preparation, excellent is typically defined as no or minimal solid stool and only small amounts of clear fluid requiring suctioning. "Good" is typically no or minimal solid stool with large amounts of clear fluid requiring suctioning. "Fair" refers to collections of semisolid debris that are cleared with difficulty. "Poor" refers to solid or semisolid debris that cannot be effectively cleared. These terms can be interpreted as having more to do with retained intraluminal contents that often can be removed by suctioning rather than the quality of inspection allowed after suctionable material has been fully removed;

however, these terms are probably reasonable guides to the appropriate use of bowel descriptors.

Poor bowel preparation is a major impediment to the effectiveness of colonoscopy. Poor preparation prolongs cecal intubation time and withdrawal time and reduces detection of both small<sup>2</sup> and large<sup>2,3</sup> polyps. In every colonoscopic practice, some colonoscopies must be repeated at intervals shorter than those recommended in Table 3 because of inadequate preparation. The task force recommends that the procedure be considered adequate if it allows (within the technical limitations of the procedure) detection of polyps 5 mm or larger.<sup>11</sup> The economic burden of repeating examinations because of inadequate bowel preparation is substantial.<sup>4</sup> No thresholds are recommended by the committee for the percentage of examinations that are repeated for poor preparation because the percentage of patients requiring repeat examination may depend mostly on patient population characteristics.<sup>4</sup> However, measurement of individual practitioners' percentage of examinations requiring repeat because of preparation is recommended. Individual endoscopists may compare their percentages to others within the same practice or to other endoscopists practicing in the same hospital. This can allow identification of outliers within that hospital for whom corrective measures should be taken.

### Preprocedure research questions

- What are the most effective methods to disseminate guidelines and educate physicians on quality recommendations?
- Why do physicians fail to follow recommended guidelines for screening and surveillance intervals? Do they know the guidelines? Are they concerned about missed lesions?
- Which hyperplastic polyps in the proximal colon are clinically important? What are cost-effective intervals for follow-up after removal of large hyperplastic polyps?
- What is the current understanding among clinicians of surveillance guidelines for ulcerative colitis and Crohn's colitis?
- Can patients with ulcerative colitis be triaged on the basis of endoscopic findings into low- and high-risk groups for surveillance intervals?
- What method would allow same-day bowel preparation in the endoscopy unit in patients with poor preparation? Would this prevent patients with poor preparation from being lost to follow-up?
- What bowel preparation is the best combination of safety, effectiveness, and tolerability?

### INTRAPROCEDURE

Quality evaluation of the colon consists of intubation of the entire colon and a detailed mucosal inspection. Cecal intubation improves sensitivity and reduces costs by

eliminating the need for radiographic procedures or repeat colonoscopy to complete examination. Careful mucosal inspection is essential to effective colorectal cancer prevention and reduction of cancer mortality. The detection of neoplastic lesions is the primary goal of most colonoscopic examinations.

Cost-benefit analyses of colonoscopy for the detection of neoplastic lesions are well within acceptable rates (approximately \$20,000 per year of life saved).<sup>20-22</sup> However, complications, repeat procedures, and inappropriate surgical intervention for endoscopically removable polyps can significantly reduce this benefit. It is incumbent on endoscopists to evaluate their practices and seek to make improvements wherever possible to reduce the costs associated with neoplasia detection.

6. Cecal intubation rates: visualization of the cecum by notation of landmarks and photodocumentation of landmarks should be documented in every procedure.

**Discussion.** In the United States, colonoscopy is generally undertaken with the intent to intubate the cecum. Cecal intubation is defined as passage of the colonoscope tip to a point proximal to the ileocecal valve so that the entire cecal caput, including the medial wall of the cecum between the ileocecal valve and appendiceal orifice, is visible. The need for cecal intubation is based on the persistent finding that a substantial fraction of colorectal neoplasms are located in the proximal colon, including the cecum.<sup>48</sup> Techniques of cecal intubation are discussed elsewhere.<sup>49</sup> Cecal intubation should be documented by naming the identified cecal landmarks. Most important, these include the appendiceal orifice and the ileocecal valve. In cases where there is uncertainty as to whether the cecum has been entered, visualization of the lips of the ileocecal valve (ie, the orifice) or intubation of the terminal ileum will be needed. Experienced colonoscopists can verify cecal intubation in real time in 100% of cases,<sup>50</sup> because there is no other portion of the gastrointestinal tract with a similar appearance. It can be helpful to document other landmarks, such as the cecal sling fold or intubation of the terminal ileum.

Photography of the cecum is also recommended. Still photography of the cecum may not be convincing in all cases because of variations in cecal anatomy.<sup>50</sup> Thus, the ileocecal valve may not be notched or may not have a lipomatous appearance; however, still photography is convincing in a substantial majority of cases, and its use allows verification of cecal intubation rates of individual endoscopists in the continuous quality improvement program. The best photographs of the cecum to prove intubation are of the appendiceal orifice, taken from a distance sufficiently far away that the cecal strap fold is visible around the appendix, and a photograph of the cecum taken from distal to the ileocecal valve.<sup>50</sup> Photographs of the terminal ileum are sometimes convincing if they show villi, circular valvulae connivente, and lymphoid hyperplasia, but they are less likely to be effective compared with the

above-mentioned photographs.<sup>50</sup> Videotaping of the cecum is not necessary in clinical practice because its feasibility remains low at this time; however, the appearance of the cecum is unmistakable in real time and videotaping of the cecum can be a very effective way of documenting cecal intubation for an examiner whose rates of cecal intubation require verification.<sup>50</sup>

Effective colonoscopists should be able to intubate the cecum in  $\geq 90\%$  of all cases<sup>51</sup> and in  $\geq 95\%$  of cases when the indication is screening in a healthy adult.<sup>52-61</sup> All colonoscopy studies done for screening have reported cecal intubation rates of 97% or higher.<sup>52-61</sup> Cases in which procedures are aborted because of poor preparation or severe colitis need not be counted in determining cecal intubation rates. It is also not necessary to count cases in which the initial intent of the procedure is colonoscopic treatment of a benign or malignant stricture or a large polyp (provided that complete colonic imaging by some method has been previously performed). All other colonoscopies, including those in which a previously unknown benign or malignant stricture is encountered, should be counted.

7. Detection of adenomas in asymptomatic individuals (screening).

**Discussion.** Among healthy asymptomatic patients undergoing screening colonoscopy, adenomas should be detected in  $\geq 25\%$  of men and  $\geq 15\%$  women more than 50 years old. Measuring adenoma detection rates of individual colonoscopists is a priority in the quality improvement process for colonoscopy for multiple reasons. First, the fundamental goal of colonoscopy for most indications is detection of neoplastic lesions in the colon. Second, although early studies in the 1990s indicated that colonoscopy and polypectomy prevented 76% to 90% of incident cancers and provided an even higher level of mortality reduction,<sup>62-64</sup> recent studies of adenoma cohorts have demonstrated incident cancer rates after clearing colonoscopy that are substantially higher than those identified in the earlier studies<sup>65-67</sup> and suggest that colonoscopy may provide a lower protection level against incident cancers. Analysis of individual cases in one of these trials suggested that at least a portion of the incident cancers were related to missed lesions.<sup>27</sup> Third, recent data from two U.S. practice groups, one in private practice<sup>6</sup> and one in academia,<sup>68</sup> have indicated large disparities between practicing gastroenterologists in their rates of detection of both small and large adenomas. Thus, suboptimal performance of colonoscopy by some practitioners, as evidenced by variable performance, may be a fundamental obstacle to colonoscopy's ability to provide near-complete protection against incident colorectal cancers.

The evolution of evidence regarding missed lesions during colonoscopy is as follows. First, tandem colonoscopy studies in the mid 1990s demonstrated miss rates during colonoscopy for adenomas  $\geq 1$  cm of 0% to 6%, 12% to 13% for adenomas 6 to 9 mm in size, and 15% to 27% for adenomas  $\leq 5$  mm in size.<sup>69,70</sup> A tandem study

that used flexible sigmoidoscopy confirmed these findings.<sup>71</sup> Subsequently, citing the obvious defect of studies using colonoscopy as its own gold standard,<sup>8,9</sup> centers of excellence in computed tomography (CT)-colonography measured miss rates of conventional colonoscopy of adenomas  $\geq 1$  cm in size of 12%<sup>8</sup> and 17%.<sup>9</sup> In these studies, conventional colonoscopy comparisons used the technique of "segmental unblinding."<sup>72</sup> CT-colonography thus far is not usable as a method of measuring miss rates for conventional colonoscopy for adenomas  $< 1$  cm in size because the sensitivity of CT-colonography is falling more precipitously for polyps  $< 1$  cm than is that of conventional colonoscopy; however, the results of these CT-colonography studies<sup>8,9</sup> indicate that miss rates calculated by tandem endoscopic studies probably substantially underestimate the miss rates of colonoscopy and sigmoidoscopy for polyps of all sizes. In addition, miss rates of colonoscopy for colorectal cancer have also been identified in two large studies as 5%<sup>73</sup> and 4%.<sup>74</sup>

Studies demonstrating variable sensitivity among endoscopists constitute the evidence indicating suboptimal performance as an important factor in the failure of colonoscopy to identify and prevent colorectal cancers. With regard to cancer detection, one study demonstrated miss rates of 3% for gastroenterologists versus 13% for nongastroenterologists; however, miss rates for cancer were 5% for one group of gastroenterologists compared with 1% for all other gastroenterologists studied.<sup>73</sup> In a recent study in Canada, higher miss rates for cancer were associated with lesions in the right colon and were higher when colonoscopy was performed by internists or family physicians and when colonoscopy was performed in an office setting.<sup>75</sup>

With regard to variable detection of adenomas, a large tandem colonoscopy study involving 26 colonoscopists demonstrated a range of miss rates from 17% to 48%.<sup>69</sup> A comparison of withdrawal techniques between the two examiners in this study at the extremes of adenoma detection showed that higher sensitivity was associated with longer examinations, superior examination of mucosa proximal to folds and flexures, better colonic distention, and better cleaning of debris and fluid from the colon.<sup>5</sup> A flexible sigmoidoscopy screening study involving 12 endoscopists in the United Kingdom demonstrated a range of detection of adenomas from 21 per 100 examinations to 11 per 100 examinations.<sup>76</sup> A private practice group of 12 gastroenterologists in the United States performing screening colonoscopy in adults aged 50 years and older described a range of adenoma detection from  $> 100$  adenomas per 100 colonoscopies for the highest performer to  $< 10\%$  this rate for the lowest performer.<sup>6</sup> Detection of small adenomas correlated with detection of large adenomas. Persons who spent longer than 6 minutes of withdrawal time had a detection rate of adenomas  $\geq 1$  cm of 6.6% compared with 3% for persons who averaged less than 6 minutes of withdrawal time. A group of 9 academic

gastroenterologists in the United States were shown to have detection rates of adenomas during colonoscopy in persons aged 50 years and older that ranged from 86 adenomas per 100 colonoscopies to 21 adenomas per 100 colonoscopies, and a range of prevalences of adenomas  $\geq 1$  cm of 5.5% to 1.5%.<sup>68</sup>

There is a strong interaction between the quality with which the colon is cleared of neoplasia and the effectiveness of recommended intervals for surveillance. Thus, suboptimal performers with low detection rates for large adenomas and for multiple adenomas have recently been demonstrated.<sup>6,68</sup> These individuals will recommend that fewer persons undergo surveillance colonoscopy at 3 years, rather than at 5-year intervals, on the basis of large adenomas or the presence of 3 or more adenomas, although these same colonoscopists have been less effective at clearing the colon of neoplasia. Recommended intervals for surveillance and screening can only have adequate effectiveness when the current disparities between examiners in clearing the colon of neoplasia are improved.

The principal demographic features that predict adenomas at colonoscopy are age and sex and, to a lesser extent, family history of colorectal neoplasia. The indication for the procedure is not a strong predictor of the presence of adenomas.<sup>43</sup> Screening colonoscopy studies in the United States have identified adenomas in 25% to 40% of patients more than 50 years old.<sup>52-61</sup> The best established neoplasia-related quality indicator is the actual prevalence of adenomas detected. Prevalence rates of adenomas in colonoscopy screening studies have been consistently over 25% in men and 15% in women more than 50 years old.<sup>52-61</sup> Although detection of overall numbers of adenomas per colonoscopy could prove to be the ideal measure of adenoma detection, there are currently insufficient data to establish acceptable compliance rates for this threshold. Overall adenoma prevalence rates correlate with detection rates of large adenomas,<sup>6,68</sup> are easier to measure and have better established thresholds for acceptable compliance rates. Individuals who reach the primary goals for prevalence rates of adenomas are likely to have a satisfactory withdrawal technique. For these examiners, secondary measures, such as the time taken for withdrawal (see below), are of less importance.

8. Withdrawal times: studies have demonstrated increased detection of significant neoplastic lesions in colonoscopic examinations where the withdrawal time is 6 minutes or more. Mean withdrawal time should be  $\geq 6$  minutes in colonoscopies with normal results performed in patients with intact colons.

**Discussion.** In instances of low detection rates of adenomas, measurement of withdrawal time is appropriate as a quality indicator. To measure withdrawal time, the time at which the cecum is reached and the time at which the scope is withdrawn from the anus must be noted. Some electronic report-generating systems allow the

time to be noted electronically when cecal photographs are taken. On the basis of the mean withdrawal times of an examiner with very low miss rates<sup>5</sup> and previously cited evidence that the detection rate of large adenomas was greater for examiners who took longer than 6 minutes for withdrawal during screening colonoscopy,<sup>6</sup> it is recommended that the withdrawal phase of colonoscopy in patients without previous surgical resection should last at least 6 minutes on average. Application of this standard to an individual case is not appropriate because colons differ in length and in some instances a very well prepared colon of relatively short length and with nonprominent haustral markings can be carefully examined in less than 6 minutes. Further, recent evidence suggests that colonoscopes with a wide angle of view allow quicker examination without increasing miss rates for polyps.<sup>77</sup>

9. Biopsy specimens should be obtained from the colon in patients with chronic diarrhea.

**Discussion.** Patients with microscopic colitis (collagenous and lymphocytic colitis) may have normal-appearing mucosa at colonoscopy. The diagnosis requires biopsy of otherwise unremarkable-appearing colon. All patients undergoing colonoscopy for the evaluation of chronic diarrhea should have biopsy specimens obtained. The optimal number and location of biopsy specimens is not established. Inclusion of samples from the proximal colon improves the sensitivity for collagenous colitis.<sup>78,79</sup>

10. Number and distribution of biopsy samples in ulcerative colitis and Crohn's colitis surveillance. Goal: 4 per 10-cm section of involved colon or approximately 32 biopsy specimens in cases of panulcerative colitis.

**Discussion.** Systematic biopsy of the colon and terminal ileum can assist in establishing the extent of ulcerative colitis and Crohn's disease and in differentiating ulcerative colitis from Crohn's disease. During surveillance, a systematic biopsy protocol is needed to maximize the sensitivity of surveillance for dysplasia.<sup>80</sup> The recommended protocol includes biopsies in all 4 quadrants from each 10 cm of the colon. This typically results in 28 to 32 biopsy samples as a minimum. The procedure report in ulcerative colitis surveillance examinations should note the number and locations of specimens from flat mucosa and the location and endoscopic appearance of any mass or suspicious polypoid lesions that were sampled or removed.

Recent studies have reported that patients with endoscopically abnormal colons (eg, endoscopic scarring, pseudopolyp formation, or cobblestoning) are at increased risk for development of cancer compared with those with colons that are endoscopically normal.<sup>81</sup> Thus, patients with endoscopically normal colons might be triaged to longer intervals of surveillance than those with scarred or endoscopically abnormal colons.<sup>81</sup> Recent studies have reported that panchromoscopy of the colon and targeted biopsies results in a higher yield of dysplasia than systematic 4-quadrant biopsies in non-dye-sprayed

colons.<sup>82,83</sup> This intriguing observation deserves additional consideration and evaluation.

11. Mucosally based pedunculated polyps and sessile polyps <2 cm in size should not be sent for surgical resection without an attempt at endoscopic resection or documentation of endoscopic inaccessibility.

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

Patients with sessile polyps <2 cm in size should seldom be referred for surgical resection because these polyps are readily resectable in most cases by competent colonoscopists. Consistent referral of sessile polyps <2 cm in size for surgical resection is inappropriate. In some cases, these polyps may be difficult to access or properly position for polypectomy, and referral to a more experienced endoscopist may be appropriate.

Certainly endoscopists should not attempt removal of polyps they consider beyond their skill or comfort level, and they should feel comfortable in referring such polyps to other endoscopists for a second opinion (eg, review of photographs) or endoscopic resection. Many sessile polyps >2 cm in size are also removable endoscopically, depending on their location within the colon, their size, and the ability to access them endoscopically. Essentially all mucosally based pedunculated polyps can be removed endoscopically. All polyps referred for surgical resection should be photographed to document the need for surgical resection in the continuous quality improvement process. Review of photographs by a second, more experienced endoscopist can be useful to ensure the appropriateness of surgical referral. When surgical referral is pursued, correlation of photographs and endoscopic and pathologic measurements of polyp size should be undertaken to confirm the appropriateness of surgical referral.

### Intraprocedure research questions

- Can electronic report generating systems automate collection of intraprocedural quality indicator data?
- What technical improvements could improve the ease, speed, and safety of colonoscopy?
- Can physicians already in practice with low cecal intubation rates improve? What are effective measures and teaching methods that produce improvement?
- Can physicians with low adenoma detection rates improve? What is needed to produce improvement (ie, Is slowing down enough? Is additional training needed?)
- What are the key elements of examination by endoscopists with high adenoma detection rates? How can these

elements be taught to other colonoscopists? Can such information improve suboptimal performance?

- What technical improvements in colonoscopy can reduce variation between endoscopists in adenoma detection rates (eg, chromoendoscopy? autofluorescence? narrow-band imaging)?
- What is the optimal duration of the withdrawal phase with white-light colonoscopy (ie, at what duration does detection of clinically significant neoplasms plateau)?
- What technical advances would allow reliable and efficient detection of flat dysplastic tissue without chromoscopy or other practices that reduce efficiency?
- How is dysplasia in flat mucosa, dysplasia associated lesion or mass (DALM), and sporadic adenoma managed in community practice?
- What is the degree of adherence to recommended biopsy protocols for irritable bowel disease in community practice?
- How are large (> 2 cm) colon polyps managed in community practice, and does this management differ among colonoscopists in different specialties (eg, gastroenterologists vs surgeons)?
- What is the success rate of endoscopic resection of large sessile polyps (> 2 cm) in community practice?
- What is the optimal biopsy protocol for detection of microscopic colitis?

## POSTPROCEDURE

The aspects of postprocedure care that have been discussed in previous sections also apply here. A complete and accurate report, describing the procedure and findings, must be completed immediately after the procedure. The report should include photo documentation of abnormalities and identification of any biopsy specimens obtained. Expectations for follow-up care and determination of who will provide the follow-up should be specified.

The postprocedure interval also provides an opportunity to determine the safety of the procedure as performed by any given endoscopist. Although some complications are discovered immediately, each practitioner should establish a system to contact patients after a period of time to determine whether any delayed complications have occurred. Methods to report and evaluate these complications should be in place so that systematic errors can be discovered and corrected.

12. Incidence of perforation by procedure type (all indications vs screening) is measured.

**Discussion.** Perforation is the most serious complication in the short term during or after colonoscopy. About 5% of colonoscopic perforations are fatal.<sup>84-86</sup> The rates of colonoscopic perforation vary widely in the medical literature. One study from an established endoscopic center reported an overall perforation rate of 1 in 500 in the

1990s.<sup>87</sup> A population-based study of Medicare patients reported an overall risk of perforation of 1 in 500 but a risk of less than 1 in 1,000 screening patients.<sup>88</sup> A review of screening colonoscopy studies revealed no perforations in the first 6,000 reported cases.<sup>11</sup> Expected perforation rates in screening patients are lower because the patients are generally healthy and tend not to have associated colonic conditions that have been associated with perforation, including pseudoobstruction, ischemia, severe colitis, radiation-induced changes, stricture formation, bulky colorectal cancers, more severe forms of diverticular disease, and chronic corticosteroid therapy.

Considering all the available data, perforation rates greater than 1 in 500 overall or greater than 1 in 1,000 in screening patients should raise concerns as to whether inappropriate practices are the cause of the perforations.

Perforations are of two general types. Diagnostic perforations occur as a result of insertion of the colonoscope. They are most commonly mechanical and caused by rupture of the side of the instrument through the rectosigmoid region. They typically result in large rents in the colon that may be recognized during the procedure. Mechanical perforations can also result from barotraumas.<sup>89</sup> Barotrauma perforations are the result of pneumatic pressures in the cecum that exceed its bursting pressure. They are most likely to occur when the colonoscope has passed either a stricture or severe diverticular disease and the patient has an ileocecal valve that is competent to air. Barotrauma perforations can probably be avoided in most cases by judicious use of air during insufflation, particularly after passing strictures, perhaps by insufflation of carbon dioxide rather than air, and by ensuring that the air pump and the light source will not continue to insufflate air when intraluminal pressures exceed the bursting pressure of the colon.<sup>89</sup> Mechanical perforations can also occur during attempts to pass benign or malignant strictures.

Perforations may also result from polypectomy. In virtually every case, they are the result of the electrocautery burn. The risk of perforation is greatest with large polyps in the proximal colon. Submucosal saline solution injection polypectomy is now frequently used by gastroenterologists,<sup>90</sup> although no standardized guidelines regarding the size and location of polyps that require submucosal saline solution injection have been developed. In experimental models, injection reduces the chance of electrocautery damage to the muscularis propria,<sup>91</sup> but no randomized controlled clinical trial has been performed that demonstrates reduction of risk of perforation or postpolypectomy syndrome by injection. Therefore, colonoscopists should be familiar with and comfortable with the technique of submucosal saline solution injection, but clinical judgment is necessary in determining which polyps should undergo submucosal injection.

Anecdotal reports have suggested an increased risk of complications associated with the use of hot biopsy

**TABLE 4. Summary of proposed quality indicators for colonoscopy\***

Quality indicator	Grade of recommendation
1. Appropriate indication	1C+
2. Informed consent is obtained, including specific discussion of risks associated with colonoscopy	3
3. Use of recommended postpolypectomy and postcancer resection surveillance intervals	1A
4. Use of recommended ulcerative colitis/Crohn's disease surveillance intervals	2C
5. Documentation in the procedure note of the quality of the preparation	2C
6. Cecal intubation rates (visualization of the cecum by notation of landmarks and photo documentation of landmarks should be present in every procedure)	1C
7. Detection of adenomas in asymptomatic individuals (screening)	1C
8. Withdrawal time: mean withdrawal time should be $\geq 6$ minutes in colonoscopies with normal results performed in patients with intact anatomy	2C
9. Biopsy specimens obtained in patients with chronic diarrhea	2C
10. Number and distribution of biopsy samples in ulcerative colitis and Crohn's colitis surveillance. Goal: 4 per 10-cm section of involved colon or approximately 32 specimens per case of pancolitis	1C
11. Mucosally based pedunculated polyps and sessile polyps <2 cm in size should be endoscopically resected or documentation of unresectability obtained	3
12. Incidence of perforation by procedure type (all indications vs screening) is measured	2C
13. Incidence of postpolypectomy bleeding is measured	2C
14. Postpolypectomy bleeding managed nonoperatively	1C

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

forceps,<sup>92</sup> and forceps removal of small polyps reduces the chance of complete removal.<sup>93</sup> Cold snaring is attractive for the removal of small polyps because it effectively removes small polyps and has been associated with exceedingly low risks of complications.<sup>94-96</sup> Cold snaring often results in immediate bleeding that is of no clinical significance and allows effective retrieval of polyps.<sup>96</sup>

13. Incidence of postpolypectomy bleeding is measured.

**Discussion.** Bleeding is the most common complication of polypectomy.<sup>84-86,97,98</sup> Bleeding can be either immediate (during the procedure) or delayed. In general, the use of blended or cutting current is associated with an increased risk of immediate bleeding, whereas pure low-power coagulation is associated with a greater risk of delayed bleeding.<sup>99,100</sup> In clinical practice, the use of pure low-power coagulation or blended current is common, and the use of pure cutting current for polypectomy is rare.<sup>90</sup>

Endoscopic series suggests that the overall risk for postpolypectomy bleeding should be less than 1%.<sup>84-86,97,98</sup> Overall, bleeding rates for polypectomy that exceed this rate should prompt review by experts from within or outside the institution regarding whether polypectomy practices are appropriate. In general, the risk of bleeding increases with the size of the polyps and with a more proximal colonic location. For polyps larger than 2 cm,

particularly in the proximal colon, bleeding rates may exceed 10%.<sup>97,98,101,102</sup>

Inclusion of epinephrine in submucosal injection fluid has been shown to reduce the risk of immediate bleeding<sup>103,104</sup> but not delayed bleeding. Because the overall risk of immediate bleeding with pure low-power coagulation current is low and immediate bleeding can generally be treated successfully by experienced endoscopists, there is no mandate to include epinephrine in injection fluid. Many experts prefer pretreatment of pedunculated polyps with thick stalks by epinephrine injection or placement of detachable snares. Two trials have demonstrated benefit from the use of detachable snares.<sup>104,105</sup> However, the clinical benefit may be marginally significant, and therefore the use of detachable snares in clinical practice for pedunculated polyps is not mandated.

14. Postpolypectomy bleeding should be managed nonoperatively. In the presence of continuous bleeding, repeat colon examination and endoscopic treatment of polypectomy sites results in successful hemostasis.

**Discussion.** In general, >90% of postpolypectomy bleeding can be managed nonoperatively. Immediate postpolypectomy bleeding can generally be treated effectively by endoscopic means and should seldom require operative treatment. After transection, immediate bleeding

from the stalk of the pedunculated polyp can be treated by regrasping the stalk and holding it for 10 to 15 minutes. This causes spasm in the bleeding artery. Immediate bleeding can also be treated by application of clips<sup>106</sup> or by injection of epinephrine, followed by application of multipolar cautery.<sup>107</sup>

Delayed bleeding frequently stops spontaneously.<sup>107</sup> In-hospital observation may be appropriate if the patient has comorbidities or lives far from the treating physician. Repeat colonoscopy in patients who have stopped bleeding is optional and should be performed at the discretion of the colonoscopist. Patients seen for delayed bleeding who are continuing to pass bright red blood are usually having an arterial hemorrhage. Prompt repeat colonoscopy, which may be performed without bowel preparation,<sup>107</sup> is warranted. Treatment can be either by application of clips<sup>106</sup> or by injection in combination with multipolar cautery.<sup>107</sup> Multipolar cautery is generally applied at low power, without forceful tamponade (especially in the proximal colon), and continued until there is subjective cessation of bleeding. Findings in the base of the bleeding polypectomy site can include an actively bleeding visible vessel, a non-bleeding visible vessel, an apparent clot without bleeding, or an apparent clot with bleeding. Rebleeding seldom occurs after postpolypectomy bleeding has either stopped spontaneously or from endoscopic therapy.

### Postprocedure research questions

- What are the causes of colonoscopic perforations in population-based studies? How many perforations are avoidable by improved training, altered technique, or new or improved techniques?
- Do perforation rates vary in clinical practice by specialty or by extent of training or duration of experience?
- Can efficient methods for endoscopic removal of large sessile polyps be developed that substantially reduce or eliminate the risk of bleeding or perforation?
- Does cold resection definitely reduce small polypectomy complications?
- Does submucosal injection definitely reduce large sessile polyp perforation rates?

### CONCLUSION

Reduction in variation of quality has emerged as an important priority for colonoscopy practice. The continuous quality improvement process should be instituted and embraced in all colonoscopy practices. This article summarizes current evidence and expert consensus on quality indicators to be used in this process (Table 4). The task force has attempted to create a comprehensive list of potential quality indicators. We recognize that not every indicator will be applicable to every practice setting. Facilities should select the subset most appropriate to their individual needs.

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# Quality indicators for endoscopic retrograde cholangiopancreatography

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ASGE/ACG Taskforce on Quality in Endoscopy

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Endoscopic retrograde cholangiopancreatography (ERCP) is one of the most technically demanding and highest-risk procedures performed by gastrointestinal endoscopists. Hence, it requires significant focused training and experience to maximize success and safety.<sup>1,2</sup> ERCP has evolved from a purely diagnostic to a predominately therapeutic procedure.<sup>3</sup> ERCP and ancillary interventions are effective in the nonsurgical management of a variety of pancreaticobiliary disorders, most commonly removal of bile duct stones and relief of malignant obstructive jaundice.<sup>4</sup> The American Society for Gastrointestinal Endoscopy (ASGE) has published specific criteria for the training and granting of clinical privileges for ERCP.<sup>5,6</sup> The ASGE/American College of Gastroenterology task force has established the following indicators to aid in the recognition of ERCP examinations of high quality. The levels of evidence supporting these quality indicators were graded according to Table 1. Such indicators would permit the development of quality assurance programs and enable endoscopists who perform ERCP to share their personal quality measures with patients and other interested parties.

## PREPROCEDURE QUALITY INDICATORS

The generic preprocedure quality indicators discussed in the accompanying article<sup>7</sup> also pertain to performance of ERCP. Specific preprocedure indicators and discussion pertinent to the performance of ERCP include the following points:

1. Appropriate indication. ERCP should be performed for an appropriate indication as defined in a previously published guideline.<sup>8,9</sup> An indication should be documented for each procedure, and when it is a non-standard indication it should be justified in the documentation.

**Discussion.** The indications for ERCP are covered in detail in a separate publication<sup>9</sup> and are summarized in Table 2. Clinical settings in which ERCP is generally *not* indicated include the following: (1) Abdominal pain without

objective evidence of pancreaticobiliary disease by laboratory or noninvasive imaging studies.<sup>10</sup> In this setting the yield is very low, yet the risk of complications is significant.<sup>11</sup> When considered in this patient group, ERCP should only be undertaken in a setting capable of performing sphincter of Oddi manometry.<sup>12</sup> (2) As a routine before cholecystectomy. Preoperative ERCP should be reserved for patients with cholangitis or a significant likelihood of biliary obstruction or duct stones by clinical criteria<sup>13</sup> or imaging studies. (3) As a routine for relief of biliary obstruction in patients with potentially resectable malignant distal bile duct obstruction. Preoperative biliary decompression has not been shown to improve postoperative outcomes, yet it may result in both preoperative and postoperative complications.<sup>14</sup> Preoperative relief of biliary obstruction is recommended in patients with acute cholangitis and those with intense pruritus in whom operation may be delayed.

2. Informed consent. Informed consent for ERCP should focus on 5 possible adverse outcomes: (1) pancreatitis, (2) postsphincterotomy hemorrhage, (3) infectious complications, usually cholangitis but also cholecystitis and infection of pancreatic fluid collections, (4) adverse cardiopulmonary reactions, usually related to sedation, and (5) perforation. The patient should be informed of the probable need for hospitalization (if outpatient) should complications occur and the possible need for surgical repair if perforation occurs.

**Discussion.** Some complications of ERCP are unique from those that occur with standard endoscopy. A review of the complications specific to ERCP has been published previously.<sup>15</sup> Some endoscopists include in the informed consent process a variety of other possible outcomes (eg, possible need for emergency radiologic procedures, blood transfusion, etc). Patterns of practice indicate that an informed consent can be obtained on the day of the procedure, even in open access practices. The expected rate of ERCP-induced pancreatitis is generally between 1% and 7%, although there are several situations in which this rate may be significantly higher. Numerous factors, both patient- and procedure-related, may influence the risk for post-ERCP pancreatitis and need to be taken into account when planning for the procedure and obtaining informed consent. Cholangitis occurs in 1% or less and cholecystitis complicates 0.2% to 0.5% of ERCPs.

**TABLE 1. Grades of recommendation\***

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

\*Adapted from Guyatt G, Sinclair J, Cook D, Jaeschke R, Schunemann H, Pauker S. 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.

Hemorrhage is most commonly a complication of endoscopic sphincterotomy and has been reported to occur in 0.8% to 2% of cases. Perforations may be guidewire induced, sphincterotomy induced, and endoscope induced at a site remote from the papilla. The overall incidence of perforation during ERCP has been reported to be 0.3% to 0.6%.

3. Assessment of procedural difficulty. Identify ERCP grade of difficulty preprocedurally.

**Discussion.** The degree of difficulty of ERCP has been suggested as way of assessing outcomes on the basis of procedural difficulty (Table 3).<sup>16</sup> Although it has not been prospectively validated, there is a general assumption that higher degrees of difficulty are associated with lower success rates and higher complication rates. In general, for all indications, competent ERCP endoscopists should expect to succeed in 80% to 90% of ERCP cases with a difficulty grade of 1. It has also been suggested that those ERCP endoscopists with lower levels of expertise should not attempt ERCP cases with a difficulty grade 2 or 3.<sup>16</sup>

4. Prophylactic antibiotics. Preprocedure antibiotics should be administered according to published guidelines.<sup>17</sup>

**Discussion.** Detailed guidelines for the administration of antibiotics before ERCP have been previously pub-

lished. In brief, patients with known or suspected biliary obstruction, including primary sclerosing cholangitis, biliary or pancreatic leaks, and pancreatic pseudocysts or pancreatic necrosis, are at increased risk for procedure-related infections and should receive antibiotic prophylaxis.

### Proposed research questions

- How often is ERCP performed outside accepted clinical indications?
- How often is purely diagnostic ERCP performed in general clinical practice?
- How often are prophylactic antibiotics administered appropriately for ERCP?
- What are the rates of complications of ERCP in general practice?

### INTRAPROCEDURE QUALITY INDICATORS

The intraprocedure interval begins with the administration of sedation and ends with removal of the endoscope. Minimum performance elements that are generic to all sedated gastrointestinal procedures include attention to patient monitoring, medication administration, reversal

or resuscitative efforts, and photo documentation of pertinent landmarks or pathologic conditions. Both procedure-specific and disease-specific quality indicators can be proposed for ERCP practice, as follows.

5. Cannulation rates. Cannulation of the duct of interest with a high success rate and with an associated low complication rate is achieved by experts in ERCP and requires adequate training and continued experience in ERCP.

**Discussion.** Cannulation of the desired duct of interest is the foundation for successful diagnostic and therapeutic ERCP. Deep cannulation is achieved when the tip of the catheter is passed beyond the papilla into the desired duct. This allows effective installation of contrast to visualize the entire ductal system of interest and the introduction of instruments to perform therapeutic maneuvers. Successful cannulation may avoid the need for a second ERCP or percutaneous transhepatic cholangiography (PTC) to complete the study. Reports from the 1990s indicate that successful cannulation rates at or above 95% are consistently achieved by experienced endoscopists<sup>18</sup> and rates at or above 80% are a goal of training programs in ERCP.<sup>19</sup> Thus, although  $\geq 90\%$  is an overall appropriate target for successful cannulation, rates of  $\geq 85\%$  should be achievable for most endoscopists performing ERCP. When cannulation rates are calculated, failed examinations because of inadequate sedation or prior abdominal surgery such as pancreaticoduodenectomy (Whipple operation), Billroth II anatomy, prior gastrojejunostomy and hepaticojejunostomy, and obstruction to the duodenum should be excluded. Additionally, procedures that are aborted because of a high volume of retained gastric contents or inability to achieve adequate sedation should be excluded.

The procedure report should document whether deep cannulation was achieved and should in all cases specify the types of accessories used to achieve cannulation. One or more fluoroscopic images should be included. Photo documentation of endoscopically identified abnormalities is considered advisable by the task force.

Successful cannulation of the desired duct may be achieved by precut sphincterotomy when standard techniques fail. Precut sphincterotomy has an associated learning curve<sup>20</sup> and may increase the risk of post-ERCP procedural complications.<sup>21</sup> Most experienced endoscopists do not rely on precut methods in more than 10% to 15% of cases<sup>20,22</sup> and they should not be used as an alternative to proper cannulation techniques.

Technical success of ERCP is not only dependent on successful cannulation. Once cannulation is achieved, other maneuvers are required to achieve complete technical success, including traversing of a stricture, extraction of stones, and successful stent placement, to name a few. Technical success for the most commonly performed procedures (stone extraction, relief of biliary ob-

**TABLE 2. Indications for ERCP**

- A. Jaundice thought to be the result of biliary obstruction
- B. Clinical and biochemical or imaging data suggestive of pancreatic or biliary tract disease
- C. Signs or symptoms suggesting pancreatic malignancy when direct imaging results are equivocal or normal
- D. Pancreatitis of unknown etiology
- E. Preoperative evaluation of chronic pancreatitis or pancreatic pseudocyst
- F. Sphincter of Oddi manometry
- G. Endoscopic sphincterotomy
  - 1. Choledocholithiasis
  - 2. Papillary stenosis or sphincter of Oddi dysfunction causing disability
  - 3. Facilitate biliary stent placement or balloon dilatation
  - 4. Sump syndrome
  - 5. Choledochocele
  - 6. Ampullary carcinoma in poor surgical candidates
  - 7. Access to pancreatic duct
- H. Stent placement across benign or malignant strictures, fistulae, postoperative bile leak, or large common bile duct stones
- I. Balloon dilatation of ductal strictures
- J. Nasobiliary drain placement
- K. Pseudocyst drainage in appropriate cases
- L. Tissue sampling from pancreatic or bile ducts
- M. Pancreatic therapeutics

struction, stent placement for bile leaks) should be achievable in  $\geq 85\%$  of cases. Technically failed ERCP may result in complications (cholangitis, pancreatitis), need for additional procedures (PTC, surgery, additional ERCP), and their associated costs. Although little is known about the technical failures of ERCP and their impact on cost, preliminary studies have suggested that the cost of failed ERCP is substantial.<sup>23</sup>

6. Extraction of common bile duct stones. Choledocholithiasis is one of the most common indications for ERCP. Acute cholangitis and severe acute gallstone pancreatitis require rapid and effective relief of biliary obstruction and duct clearance.

**Discussion.** Some expert endoscopy centers can achieve a greater than 99% bile duct clearance rate for all bile duct stones.<sup>24</sup> However, it should now be expected that competent ERCP endoscopists can clear the duct of common bile duct stones in  $>85\%$  of cases by use of

TABLE 3. ERCP degrees of difficulty

	Diagnostic	Therapeutic
Grade 1: standard	Selective deep cannulation, diagnostic sampling	Biliary sphincterotomy, stones <10 mm, stents for leaks and low tumors
Grade 2: advanced	Billroth II diagnostics, minor papilla cannulation	Stones >10 mm, hilar tumor stent placement, benign biliary strictures
Grade 3: tertiary	Manometry, Whipple, Roux-en-Y, intraductal endoscopy	Billroth II therapeutics, intrahepatic stones, pancreatic therapies

sphincterotomy and balloon or basket stone extraction. When standard techniques fail, mechanical lithotripsy will increase the success rate to more than 90%, leaving a small number of patients requiring more advanced procedures such as electrohydraulic, laser, or extracorporeal shockwave lithotripsy, which will increase the success rate further to almost 100%.

7. Stent placement for biliary obstruction below the bifurcation. Indications for placement of a biliary stent to treat an obstruction below the bifurcation include pancreatic cancer, nonextractable or large common bile duct stones, and benign strictures (chronic pancreatitis, postbiliary surgery).

**Discussion.** Relief of obstructive jaundice from pancreatic cancer is a common indication for ERCP. Relief of biliary obstruction is mandatory in those with cholangitis and in any patient with clinical jaundice whose biliary tree has been instrumented and contrast introduced. Obstructive processes below the bifurcation are technically easier to achieve than hilar obstruction. Competent ERCP endoscopists should be able to place a biliary stent for relief of nonhilar biliary obstruction in >80% to 90% of patients.<sup>16</sup>

### Research questions

- What is the optimal training curriculum to be technically proficient in ERCP?
- What technical improvements could improve the ease, speed, and safety of ERCP?
- What is the cost to the health care system of failed ERCP?
- What is the overall technical success rate of ERCP in the community setting?
- What is the utilization rate of precut sphincterotomy in the community setting?

### POSTPROCEDURE QUALITY INDICATORS

The postprocedure interval extends from withdrawal of the endoscope to patient dismissal and, for certain elements, beyond this until appropriate communication is completed. Minimum performance elements common to

all procedures include attention to procedure report, patient instructions, pathology follow-up, determination of patient satisfaction, and communication to other care providers, among others. Postprocedure quality indicators specific to performance of ERCP include the following:

8. Completeness of documentation. Endoscopic reports should document successful cannulation, correlative fluoroscopic images, and endoscopic photo documentation should be obtained, when appropriate.

**Discussion.** Documentation of ERCP with representative radiographic images and endoscopic photos is the only way to provide evidence of what was performed during the procedure. Proper documentation has medicolegal ramifications. Additionally, documentation of these findings allows clinicians that are directly involved with the patients' medical care to make appropriate decisions on patient management.

9. Complication rates. The rates of ERCP-associated pancreatitis, bleeding, perforation, and cholangitis should be measured.

**Discussion.** The current rate of pancreatitis in clinical practice is variable. Reports suggest that in academic centers the rate of pancreatitis varies from between 1% to 30% of procedures.<sup>25</sup> This wide variation is due to the varying frequency of follow-up, definition used, and factors relating to patient susceptibility, case mix, types of maneuvers performed, and the endoscopist.<sup>25</sup> Rates of pancreatitis are commonly 1% to 7%. The endoscopist should inform the patient that pancreatitis may be severe and could result in prolonged hospitalization, need for surgery, or death.<sup>25</sup>

In patients undergoing ERCP who have normal anatomy, the expected perforation rate is less than 1%. Perforation may result from mechanical rupture of the esophagus, stomach, or duodenum from instrument passage, from sphincterotomy or passage of guidewires, or from other therapeutic procedures. Patients with surgically altered anatomy (Billroth II) are at higher risk of perforation while the endoscope is being manipulated through the afferent limb during ERCP. Such perforations are intraperitoneal and require surgical intervention.<sup>26</sup>

The expected rate of major postsphincterotomy bleeding is approximately 2%.<sup>21</sup> Risk factors that increase the

risk of postsphincterotomy bleeding include the presence of coagulopathy or active cholangitis before the procedure, anticoagulant therapy within 3 days after the procedure, and low endoscopist case volume (<1 per week).<sup>21</sup> However, the risk of postprocedural bleeding is higher when other therapeutic maneuvers are performed, such as ampullectomy<sup>27</sup> and transmural pseudocyst drainage.<sup>28</sup> The risk of major bleeding from a diagnostic ERCP or therapeutic ERCP without sphincterotomy or transmural puncture (eg, stent placement alone) is near 0, even in patients who are therapeutically anticoagulated.

Cardiopulmonary events account for adverse events during ERCP, some of which are related to sedation. The risk of adverse events is associated with higher American Society of Anesthesiologists (ASA) class, and the ASA class should therefore be systematically identified before ERCP. Endoscopists performing ERCP should be prepared to manage adverse cardiopulmonary events. Recommendations for monitoring during sedation have been previously published.<sup>29</sup> The most commonly used sedation in the United States is a combination of benzodiazepines and narcotics. Propofol has been given safely by endoscopists<sup>30</sup> and by use of patient-controlled analgesia.<sup>31</sup> However, local rules or state laws in the United States usually prevent its independent administration by gastroenterologists at this time. The cost-effectiveness of administration of sedation by an anesthesia specialist for routine cases has not been evaluated.

### Key research questions

- What are the incidences of pancreatitis, bleeding, and perforation in community practices?
- When is it cost-effective to routinely use anesthesia support during ERCP?

### CONCLUSIONS AND FINAL RECOMMENDATIONS

The effectiveness of ERCP depends on both high success and low complication rates. Competency in ERCP can improve the effectiveness of ERCP. Evidence for variable performance of ERCP indicates that patient outcomes could be improved by a constructive process of continuous quality improvement that educates endoscopists in optimal ERCP techniques to reduce complications. Thus, continuous quality improvement is an integral part of an ERCP program. The recommendations and rationale for continuous quality improvement made in this document are evidence or consensus based (Table 4). The task force has attempted to create a comprehensive list of potential quality indicators. We recognize that not every indicator will be applicable to every practice setting. Facilities should select the subset most appropriate to their individual needs.

The task force recommends that these targets be periodically reviewed in continuous quality improvement pro-

**TABLE 4. Summary of proposed quality indicators for ERCP\***

Quality indicator	Grade of recommendation
1. Appropriate indication	3
2. Informed consent	3
3. Assessment of procedural difficulty	3
4. Prophylactic antibiotics	2B
5. Cannulation rates	
Desired duct	1C
Use of precut	2C
6. Extraction of common bile duct stones	1C
7. Biliary stent placement	1C
8. Complete documentation	3
9. Complication rates: pancreatitis, bleeding, perforation, and cholangitis	1C

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

grams. Findings of deficient performance can be used to educate endoscopists, and additional monitoring can be undertaken to document improvement in performance. Further, we recommend that both academic and community-based endoscopy programs report in the medical literature the results of their reviews of adherence to these continuous quality improvement measures in their programs. This information will help validate the appropriateness and feasibility of the performance goals recommended in this article. We expect these recommendations to be updated as new information appears regarding optimal technical performance of ERCP.

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# Quality indicators for endoscopic ultrasonography

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Endoscopic ultrasonography (EUS) has become integral to the diagnosis and staging of gastrointestinal (GI) and mediastinal mass lesions. EUS-guided fine-needle aspiration (FNA) allows the endoscopist to obtain tissue or fluid for cytologic and chemical analysis, adding to the procedure's utility. Furthermore, the recent development of EUS guided tru-cut biopsy techniques enable histologic sampling in selected cases. The clinical effectiveness of EUS and EUS-FNA depends on the judicious use of these techniques and the skill of the endosonographer. Requiring both advanced endoscopic ability and radiologic interpretation, sufficient training in EUS is generally beyond the realm of a standard GI fellowship. Recognizing the specialized nature of EUS and EUS-FNA, the American Society for Gastrointestinal Endoscopy (ASGE) has published specific criteria for the training of, and the granting of clinical privileges for, individuals who want to perform these procedures.<sup>1,2</sup> The American College of Gastroenterology (ACG)/ASGE task force has also established the following indicators to aid in the recognition of high-quality EUS examinations. The levels of evidence supporting these quality indicators were graded according to Table 1. Such indicators would permit the development of quality assurance programs and enable endosonographers to share their personal quality measures with patients and other interested parties.

## PREPROCEDURE QUALITY INDICATORS

1. Proper indication. EUS should be performed for an acceptable indication as defined by the ASGE. Acceptable indications have been published previously.<sup>3</sup>

**Discussion.** Although there are many instances in which EUS *can* be performed, the necessity of the procedure in the care of any particular patient depends on its impact on management and the superiority of EUS over other available imaging or surgical procedures. This implies a certain degree of clinical judgment in choosing if and when to perform EUS in relation to other procedures, making rigid indications inadvisable. That being said, expert opinion has identified specific clinical situations for

which EUS is deemed an appropriate diagnostic or therapeutic procedure (Table 2).<sup>5</sup> It is fully expected that certain indications may change with time. In addition, the appropriate use of EUS also depends in part upon the availability of other imaging methods because not all patients will have reasonable access to alternatives to EUS.

It is also recognized that there may be unforeseen circumstances in which EUS can provide clinically useful information. For this reason, 100% compliance with predetermined indications is considered restrictive. However, the inclusion of an indication in the procedure documentation for all cases is considered a useful quality measure for 2 reasons. First, it provides a justification for the procedure and serves as a means of tracking compliance with accepted indications. In addition, the indication places the remainder of the procedure report in a specific context wherein certain endosonographic landmarks and finding characteristics should logically follow. For example, detailed descriptions of the pancreas may not be necessary when the indication for EUS is esophageal cancer staging. However, once esophageal cancer staging is provided as the indication, certain components of the examination, such as T and N staging, including celiac axis visualization barring nontraversibility, are expected and their subsequent inclusion would reflect a thorough EUS.

2. Proper consent. Consent should be obtained and documented for every procedure. In addition to the risks associated with all endoscopic procedures, the consent should address the relevant and substantial complications pertaining to each specific EUS procedure.

**Discussion.** EUS and EUS-FNA present some unique complication risks beyond those associated with standard endoscopy. A review of the complications specific to EUS have been published previously.<sup>4</sup> In some instances, EUS requires passage of large echoendoscopes or endoscopes with relatively rigid portions. This has been associated with an increased risk of perforation. Perforation risk may also be higher when staging esophageal cancer, particularly in the setting of pre-EUS dilation of an obstructing malignancy. FNA introduces an increased risk of infection and hemorrhage, as well as pancreatitis when FNA of a pancreatic lesion is performed. Finally, a risk of tumor seeding along the FNA tract has been reported in very rare circumstances.<sup>5,6</sup> Celiac plexus neurolysis or celiac plexus block (CPN or CPB) carry unique risks of hypotension and diarrhea, in addition to the standard risks.

**TABLE 1. Grades of recommendation\***

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

\*Adapted from Guyatt G, Sinclair J, Cook D, Jaeschke R, Schunemann H, Pauker S. 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.

3. Prophylactic antibiotics. Antibiotics should be administered in the setting of FNA of cystic lesions.

**Discussion.** There have been no randomized trials conducted to determine the need for prophylactic antibiotics in the setting of EUS-FNA of cystic lesions. One study examining the efficacy of EUS-FNA found no clinically significant bacteremia resulting from FNA of solid lesions.<sup>7</sup> However, a subgroup analysis of patients with cysts undergoing FNA demonstrated a 14% risk of infectious complications.<sup>8</sup> There have also been reports of mediastinitis complicating FNA and tru-cut needle biopsy of bronchogenic cysts.<sup>9,10</sup> This has led to the ASGE recommendation that prophylactic antibiotics be administered to all patients undergoing EUS-FNA of pancreatic cystic lesions.<sup>11</sup>

### Proposed research questions

- Does EUS have an impact on patient management for each specific indication?
- Does EUS improve patient outcomes for each specific indication?
- What are the rates of complications of EUS in general practice?
- What is the absolute impact of prophylactic antibiotics on the risk of infection after FNA of cystic lesions?

### INTRAPROCEDURE

4. Visualization of structures of interest. There should be documentation of the appearance of relevant structures, specific to the indication for the EUS. Specific quality indicators identified are as follows:

- A. In the setting of esophageal cancer staging without obstruction, celiac axis visualization should be documented.
- B. In the setting of evaluating for the presence of pancreatic disease, visualization of the entire pancreas should be documented.

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

5. Description of abnormalities.

- A. All gastrointestinal cancers are staged with the American Joint Commission for Cancer (AJCC)/Union Internationale Contre le Cancer (UICC) TNM staging system.<sup>12,13</sup>
- B. Pancreatic mass measurements are documented.

C. The EUS wall layers involved by subepithelial masses are documented.

**Discussion.** A diagnosis based on EUS findings, with or without cytologic examination from FNA, requires not only an accurate localization and description of sonographic findings, but also an accurate interpretation of these findings within the individual patient's clinical context. Currently the AJCC/UICC TNM systems are the most widely used methods for staging gastrointestinal malignancies. Therefore, to maximize the utility of EUS in the setting of cancer staging, the elements necessary to assign both T and N stages should be obtained during the procedure and documented in writing and with saved images. This includes measurements of pancreatic masses because T staging may depend on tumor size.

In the setting of subepithelial lesions, the differential diagnosis is based on wall layer of origin, echo characteristics, and size of lesion. Therefore, these findings should be documented in every report.

6. Appropriate use of biopsy. EUS-guided FNA is performed of celiac axis lymph nodes discovered at EUS staging of thoracic esophageal cancer.

**Discussion.** The additional clinical information obtained from FNA can increase the diagnostic accuracy of EUS significantly by confirming a pathologic diagnosis, obtaining more accurate nodal staging in malignancy, and yielding fluid for various analyses, including chemical analyses, tumor markers, and bacterial/fungal stains or culture. It is also recognized that FNA is not feasible or appropriate in all conditions. For example, it is acknowledged that FNA through a tumor to obtain tissue from an adjacent lymph node may yield a false-positive result. It therefore becomes impossible to suggest a fixed percentage of EUS cases in which FNA should be done. However, when FNA is appropriate, the endosonographer should make every effort to incorporate this step into the EUS.

In the setting of esophageal cancer in the thoracic esophagus, malignant celiac axis lymph nodes confer M1a status and alter patient management. It has also been shown that echo characteristics alone are not sufficiently accurate in predicting metastatic involvement of lymph nodes.<sup>14-16</sup> The involvement of an on-site cytopathologist during EUS-FNA may help limit the number of FNA passes taken or increase the overall diagnostic accuracy of the procedure.<sup>17</sup> However, it is recognized that not all endosonographers will have access to this degree of service. Therefore, in situations where a cytopathologist or cytotechnologist is not available, several FNA passes should be made to maximize sensitivity. For lymph nodes, prospective studies have suggested that 3 to 5 passes are adequate to maximize sensitivity.<sup>18,19</sup>

### Proposed research questions

- Under what circumstances does FNA change patient management?

**TABLE 2. Acceptable indications for EUS according to the ASGE**

1. Staging of tumors of the GI tract, pancreas, bile ducts, and mediastinum
2. Evaluating abnormalities of the GI tract wall or adjacent structures
3. Tissue sampling of lesions within, or adjacent to, the wall of the gastrointestinal tract
4. Evaluation of abnormalities of the pancreas, including masses, pseudocysts, and chronic pancreatitis
5. Evaluation of abnormalities of the biliary tree
6. Providing endoscopic therapy under ultrasonographic guidance

- What is the cost-efficacy of having immediate cytologic interpretation in the EUS suite during EUS-FNA?
- What is the best method for processing FNA samples for subsequent interpretation when a cytopathologist is not on site?

### POSTPROCEDURE

7. Complication rates. The incidence of pancreatitis after EUS-FNA of the pancreas is measured.

**Discussion.** Patients undergoing EUS-FNA of the pancreas are at risk for development of pancreatitis, likely as a result of direct tissue injury as the needle traverses pancreatic tissue. The incidence of pancreatitis in this setting, including data from prospective series, has ranged between 0% and 2%.<sup>20-25</sup>

### Proposed research questions

- Are there risk factors (FNA technique, needle size, lesion type, etc) that predict the development of pancreatitis with EUS-FNA of the pancreas?
- What is the risk of tumor seeding after EUS-FNA?
- What are the complications of EUS guided tru-cut biopsies?

### CONCLUSION

The quality indicators proposed in this article were selected in part because of their ease of implementation, monitoring, and reporting (Table 3). The task force has attempted to create a comprehensive list of potential quality indicators. We recognize that not every indicator will be applicable to every practice setting. Facilities should select the subset most appropriate to their individual needs.

We recognize that the field of EUS continues to expand, with the possible appearance of new indications and complications. Therefore, these quality indicators should be

**TABLE 3. Summary of proposed quality indicators for endoscopic ultrasound\***

Quality indicator	Grade of recommendation
1. Proper indication	3
2. Proper consent	3
3. Prophylactic antibiotics	2C
4. Visualization of structures	3
A. In EUS for nonobstructing esophageal cancer, visualization of the celiac axis	
B. In EUS for evaluation of suspected pancreatic disease, visualization of the entire pancreas	
5. Description of abnormalities	3
A. Gastrointestinal cancers should be staged with the TNM staging system.	
B. Pancreatic mass measurements should be documented.	
C. The wall layers involved by subepithelial masses should be documented.	
6. When celiac axis lymph nodes are seen during EUS staging of a thoracic esophageal cancer, FNA is performed.	2C
7. The incidence of pancreatitis after EUS-FNA of the pancreas.	1C

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

updated as the need arises. With the increasing demand for EUS, the number of physicians performing this complex procedure will continue to grow. It is the hope of the ACG and ASGE that these measures will also be incorporated into the training of new endosonographers to ensure that all patients receive the highest quality care possible.

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