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Quality Indicators for Gastrointestinal Endoscopic Procedures: An Introduction

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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) (1).

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 (2). 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

Table 1. Composition of the Task Force

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the patient and is not indicated when the information or therapy will not have an impact on clinical decision making or outcome (Table 3) (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 (2). This list was determined by a review of published literature and 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 (4–9). 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 (10).

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

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. pp. 599–608.

Table 3. General Indications and Contraindications for Gastrointestinal Endoscopy

GI endoscopy is generally indicated	1. If a change in management is probable on the basis of results of endoscopy 2. After an empiric trial of therapy for a suspected benign digestive disorder has been unsuccessful 3. As the initial method of evaluation as an alternative to radiographic studies 4. When a primary therapeutic procedure is contemplated
GI endoscopy is generally not indicated	1. When the results will not contribute to a management choice 2. For periodic follow-up of healed benign disease unless surveillance of a premalignant condition is warranted
GI endoscopy is generally contraindicated	1. When the risks to patient health or life are judged to outweigh the most favorable benefits of the procedure 2. When adequate patient cooperation or consent cannot be obtained 3. When a perforated viscus is known or suspected

GI = Gastrointestinal.

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 examinationshould be documented. (11, 12).

Discussion. Both the ASGE and the American Society of Anesthesiologists (ASA) recommend a preprocedure assessment that includes a health history and directed physical examination (11, 12). The history should focus on the indications for the procedure and on conditions that might affect the performance of the endoscopy (e.g., prior gastrointestinal surgery) or safety of therapeutic procedures (e.g., 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 aspertains to sedation). The physician/nurse teamshould 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 (13, 14). The Mallampati scoreuses a visual analog scale to assess the upper airway. TheMallampati score correlates with difficulty encountered in incubating patients (15). It has not been assessed as a risk stratification tool for endoscopic procedures.

5. Prophylactic antibiotics are administered to high-riskpatients undergoing high-risk procedures (16).

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 cya-notic 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) (17, 18). 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 (11, 12).

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

Discussion. ASGE guidelines have been published regarding anticoagulants and antiplatelet medications (19, 20). 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 hep-arin or low-molecular-weight heparin. Most endoscopic procedures can be performed with the patient who is taking aspirin. The endoscopic risks of dopidogrel and ticlo-pidine are uncertain (19) 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 (e.g., open access)or by different types of practitioners (e.g., 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 (i.e., 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 inthe 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, andblood pressure. Blood pressure and pulse rate shouldbe 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 (11, 12) 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 (e.g., 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. Documentationthat 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 (11). That the patient has achieved these criteria should be documented before discharge.

15. Patient instructions. Written instructions should beprovided to the patient before discharge (11). Theseinstructions should address diet restrictions, resumption of usual medications, and return to activities,especially driving. Procedure-specific information regarding potential delayed complications should alsobe provided. They should also provide a contact telephone number in the event of emergencies or shouldquestions arise.

Discussion. Written discharge instruction should be provided in compliance with ASGE guidelines (11).

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 (e.g., 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 (21) 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 (21) and is consistent with efforts spearheaded by the Institute of Medicine (22). 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(21).

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 (23–25). 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 primarycare 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 postprocedureresumption 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 (19, 20).

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 adequatelyreliable and robust to be used for QA programs?
- What are the complication rates for endoscopic procedures in clinical practice and do these rates vary overtime?
- Does reporting and provision of feedback result inpractice changes leading to a reduction in the numberof procedure-related complications?
- Which clinical, demographic, and procedural variablesare associated with higher levels of patient satisfaction?
- What are the relative risks of immediate versus delayed resumption of anticoagulants or antiplateletmedications?

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

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.

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?

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