Quality Indicators for ERCP

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

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

METHODOLOGY

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

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

The quality indicators for this update were written in a manner that lends them to be developed as measures. Although they remain quality indicators and not measures, this document also contains a list of performance targets for each quality indicator. The task force selected performance targets from benchmarking data in the literature when available. When no data was available to support establishing a performance target level, "N/A" (not available) was listed. However, when expert consensus considered failure to perform a given quality indicator a 'never event,' such as monitoring

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Table 1. Grades of recommendation[a] (12)

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

[a]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.

vital signs during sedation, then the performance target was listed as >98%. It is important to emphasize that the performance targets listed do not necessarily reflect the standard of care but rather serve as specific goals to direct quality improvement efforts.

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

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

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

Preprocedure quality indicators

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

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

Level of evidence: 1C+

Performance target: >90%

Type of measure: process

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

Discussion: The indications for ERCP are covered in detail in separate publications (13,14). **Table 3** contains a list of the vast majority of acceptable indications for ERCP (15). **Table 4** contains a list of all proposed quality indicators for ERCP. The task force selected a higher performance target for ERCP (>90%) as opposed to other endoscopic procedures (>80%) to reflect the higher incidence of serious adverse events after ERCP. Clinical settings in which ERCP is generally *not* indicated include the following:

Abdominal pain without objective evidence of pancrea-ticobiliary disease by laboratory or noninvasive imaging studies (16,17). In this setting, the yield of ERCP is low, the risk of adverse events is

Table 2. Summary of proposed quality indicators common to all endoscopic procedures[a] (12)

Quality indicator	Grade of recommendation	Measure type	Performance target (%)
Preprocedure			
1. Frequency with which endoscopy is performed for an indication that is included in a published standard list of appropriate indications, and the indication is documented (priority indicator)	1C+	Process	>80
2. Frequency with which informed consent is obtained and fully documented	3	Process	>98
3. Frequency with which preprocedure history and directed physical examination are performed and documented	3	Process	>98
4. Frequency with which risk for adverse events is assessed and documented before sedation is started	3	Process	>98
5. Frequency with which prophylactic antibiotics are administered only for selected settings in which they are indicated (priority indicator)	Varies	Process	>98
6. Frequency with which a sedation plan is documented	Varies	Process	>98
7. Frequency with which management of antithrombotic therapy is formulated and documented in print before the procedure (priority indicator)	3	Process	N/A
8. Frequency with which a team pause is conducted and documented	3	Process	>98
9. Frequency with which endoscopy is performed by an individual who is fully trained and credentialed to perform that particular procedure	3	Process	>98
Intraprocedure			
10. Frequency with which photodocumentation is performed	3	Process	N/A
11. Frequency with which patient monitoring among patients receiving sedation is performed and documented	3	Process	>98
12. Frequency with which the doses and routes of administration of all medications used during the procedure are documented	3	Process	>98
13. Frequency with which use of reversal agents is documented	3	Process	>98
14. Frequency with which procedure interruption and premature termination because of oversedation or airway management issues is documented	3	Process	>98
Postprocedure			
15. Frequency with which discharge from the endoscopy unit according to predetermined discharge criteria is documented	3	Process	>98
16. Frequency with which patient instructions are provided	3	Process	>98
17. Frequency with which the plan for pathology follow-up is specified and documented	3	Process	>98
18. Frequency with which a complete procedure report is created	3	Process	>98
19. Frequency with which immediate adverse events requiring interventions are documented	3	Process	>98
20. Frequency with which immediate adverse events requiring interventions including hospitalization occur	3	Outcome	N/A
21. Frequency with which delayed adverse events leading to hospitalization or additional procedures or medical interventions occur within 14 days	3	Outcome	N/A
22. Frequency with which patient satisfaction data are obtained	3	Process	N/A
23. Frequency with which communication with referring providers is documented	3	Process	N/A

N/A, not available.

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

significant, and those adverse events are disproportionately severe (18). When considered in this patient group, ERCP should be undertaken only after appropriate patient consultation and consent. If the diagnosis of sphincter of Oddi dysfunction is being considered, ERCP generally should be performed in a setting capable of performing sphincter of Oddi manometry and placing prophylactic pancreatic stents, although the efficacy of manometry in this setting has not been estab-lished (19,20). A recent, randomized, controlled, multicenter, clinical trial (EPISOD) presented in abstract form suggested that ERCP is not likely to be efficacious

Table 3. Appropriate indications for ERCP (15)

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

in sphincter of Oddi type III in which there are no objective measures of pancreaticobiliary pathology (21).

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

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

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

Level of evidence: 1C

Performance target: >98%

Type of measure: process

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

Discussion: Some ERCP adverse events are unique from those that occur with standard luminal endoscopy. A review of the adverse events specific to ERCP has been published previously (26). The expected rate of post-ERCP pancreatitis is generally between 1 and 7% for most average-risk patients (27–30). There are several situations in which this rate may be

Table 4. Summary of proposed quality indicators for ERCP[a]

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

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

significantly higher, most notably in patients with known or suspected sphincter of Oddi dysfunction. Adverse events in these patients can approach 20 to 30%, with severe pancreatitis also being more likely (31).

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

3. Frequency with which appropriate antibiotics for ERCP are administered for settings in which they are indicated

Level of evidence: 2B

Performance target: >98%

Type of measure: process

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

Discussion: Detailed guidelines for the administration of antibiotics before ERCP have been published previously. In brief, preprocedure antibiotics for ERCP should be considered in patients with known or suspected biliary obstruction in which complete relief of the obstruction is not anticipated (such as with primary sclerosing cholangitis) or in patients undergoing immunosuppression

after liver transplantation, patients with active bacterial cholangitis, patients with pancreatic pseudocysts, and in other clinical sit-uations (35). Antibiotics should be considered in patients who pose any additional concerns about the risk of infection.

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

Level of evidence: 3

Performance target: >98%

Type of measure: process

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

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

Level of evidence: 1C

Performance target: >98%

Type of measure: process

Discussion: Individual endoscopist ERCP case volume has been associated with variance in both procedure success rates and adverse event rates and, accordingly, should be recorded. An Austrian group showed that endoscopists with <50 annual ERCPs had lower success rates and more adverse events during ERCP than physicians performing higher procedure volumes (37). Similarly, investigation has shown that endoscopists who performed at least one sphincterotomy per week had significantly fewer ERCP-related adverse events. When compared with those who performed fewer ERCP procedures, endoscopists who performed >1 sphincterotomy per week (which can be viewed as a surrogate for performing more ERCP procedures overall) had lower rates of all adverse events (8.4 vs. 11.1%; P=0.03) and severe adverse events (0.9 vs. 2.3%; P=0.01) (38). Although the actual procedure success rates and adverse event rates are more direct measures of an individual endoscopist's quality in ERCP, this and other ERCP benchmarking data suggest that individual case volume may predict such outcomes and, therefore, should be tracked (39).

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

Preprocedure research questions

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

Intraprocedure quality indicators

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

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

Level of evidence: 1C

Performance target: >98%

Type of measure: process

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

Level of evidence: 1C

Performance target: >90%

Type of measure: process

Discussion: Cannulation of the desired duct is the foundation of successful ERCP. The achievement (or lack thereof) of cannulation of the desired duct should be recorded in all cases. Actual cannulation rates should approximate benchmark cannulation rates for patients presenting with similar indications. Cannulation of the duct of interest with a high success rate and with associated low adverse event rate is achieved by experts in ERCP and requires adequate training and continued experience in ERCP. Deep cannulation is achieved when the tip of the catheter, usually over a guidewire, is passed beyond the papilla into the desired duct. This allows effective injection of contrast material to visualize the duct system of interest and the introduction of instruments to perform diagnostic and therapeutic maneuvers. Successful cannulation may avoid the need for a second ERCP or percutaneous transhepatic cholangiography to complete the study, with resultant avoidance of morbidity. Reports from the 1990 s indicate that successful cannulation rates ≥95% are consistently achieved by experienced endoscopists, and rates ≥80% are a goal of training programs in ERCP, although these data include patients who have undergone prior biliary sphincterotomy and are of limited applicability (40,41). More recent data demonstrate that tracking deep biliary cannula-tion success rates in patients with native papillary anatomy only is a better assay of competency and the ability to perform ERCP independently after training (42). Thus, although ≥90% is an overall appropriate target for successful cannulation, no consensus has yet been reached as to the benchmark in cannulation success rates necessary to become a quality ERCP

performer. A recent meta-analysis with a random-effects model suggests that cannulation rates in practice, even at tertiary-care centers, may be <90% (in the mid 80% range) and also suggests significant variability in cannulation rates across the developed world (43). Nevertheless, the expert consensus of the ASGE/ACG task force on this topic and review of the aforementioned literature published before mid-2013 suggest that physicians with consistently suboptimal cannulation rates (<80% success) should consider undergoing further training or discontinuing their ERCP practices.

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

In general, for all indications, competent ERCP endoscopists should expect to cannulate the duct of interest in >90% of ERCP procedures of mild-to-moderate difficulty. Some investigators have attempted to stratify ERCP based on perceived difficulty. In the future, such stratification by difficulty may help standardize quality assurance programs in ERCP across varying patient populations (19,44–46).

It has been suggested that ERCP endoscopists with lower levels of expertise should not attempt complex or difficult ERCP cases without the assistance of a more experienced endoscopist, but this approach has not been validated (47).

7. Frequency with which fluoroscopy time and radiation dose are measured and documented

Level of evidence: 2C

Performance target: >98%

Type of measure: process

Fluoroscopy time or dose should be recorded for all ERCPs.

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

8. Frequency with which common bile duct stones <1 cm in patients with normal bile duct anatomy are extracted successfully and documented (priority indicator)

Level of evidence: 1C

Performance target: ≥90%

Type of measure: outcome

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

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

9. Frequency with which stent placement for biliary obstruction in patients with normal anatomy whose obstruction is below the bifurcation is successfully achieved and documented (priority indicator)

Level of evidence: 1C

Performance target: ≥90%

Type of measure: outcome

Discussion: Indications for placement of a biliary stent to treat an obstruction most commonly include malignancy, non-extractable or large common bile duct stones, and benign strictures (chronic pancreatitis, post-biliary surgery). Relief of obstructive jaundice from pancreatic cancer or other causes of biliary obstruction remains a common indication for ERCP. Relief of biliary obstruction is mandatory in those with cholangitis and in any patient with clinical jaundice whose biliary tree has undergone instrumentation and introduction of contrast material. For cases of intended

stent placement, the endoscopist should document whether or not successful stent placement is achieved. The documentation should include sufficient information about indication, stricture location, stent size and type, and the presence of post-surgical anatomy to allow proper comparisons in subsequent benchmarking efforts.

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

Intraprocedure research questions

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

Postprocedure quality indicators

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

10. Frequency with which a complete ERCP report that details the specific techniques performed, particular accessories used, and all intended outcomes is prepared

Level of evidence: 3
Performance target: >98%
Type of indicator: process

ERCP reports should document successful cannulation and, if feasible, correlative fluoroscopic images. Photo-documentation of key aspects of the procedure should be included. Whether or not the primary goal of the procedure was achieved also should be documented. The report should clearly convey the events and overall outcome of the procedure.

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

11. Frequency with which acute adverse events and hospital transfers are documented

Level of evidence: 3
Performance target: >98%
Type of measure: process

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

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

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

Level of evidence: 1C
Performance target: N/A
Type of measure: outcome

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

Discussion: Post-ERCP pancreatitis rates are dependent on the type of ERCP performed. Endoscopists who perform sphincter of Oddi manometry are likely to have higher rates of post-ERCP pancreatitis compared with those of endo-scopists who do not. The current rate of ERCP-induced pancreatitis in clinical practice is variable and affected by operator skill and experience as well as the type of ERCP procedures being undertaken, and, for that reason, it is difficult to set a single performance target for all ERCPs for this indicator. Post-ERCP pancreatitis is defined as abdominal pain after ERCP consistent with pancreatitis, with a concurrent serum amylase and lipase level of ≥3 times the upper limit of normal (52). Typical rates of post-ERCP pancreatitis are commonly

1 to 7%, excluding certain high-risk patient subsets such as those with known or suspected sphincter of Oddi dysfunction and those undergoing pancreatic endotherapy, who may warrant special prophylaxis for post-ERCP pancreatitis including pancreatic stent placement or prophylactic use of nonsteroidal anti-inflammatory drugs (16,18,27,53,54). It should be noted that the value of this agent in patients with normal sphincter of Oddi function is not firmly established. Nonetheless, if available, the use of rectal indomethacin should be considered. It is unclear at this time whether rectal indomethacin should be used in all or just selected patients.

13. Rate and type of perforation

Level of evidence: 2C

Performance target: ≤0.2%

Type of measure: outcome

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

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

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

Level of evidence: 1C

Performance target: ≤1%

Type of measure: outcome

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

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

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

Level of evidence: 3

Performance target: >90%

Type of indicator: process

Efforts to contact patients within 14 days should help identify any adverse events and will help with overall data tracking.

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

Postprocedure research questions

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

Table 5. Priority quality indicators for ERCP[a]

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

[a]See text for specific targets and discussion.

Priority indicators for ERCP

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

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

CONCLUSION

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

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

ABBREVIATIONS

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

CONFLICT OF INTEREST

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