



Quality indicators for endoscopic retrograde cholangiopancreatography

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INTRODUCTION

ERCP is the primary therapeutic intervention for biliary and pancreatic diseases, with more than 600,000 performed annually in the United States.¹ ERCP is a complex procedure that is highly operator-dependent with multiple associated and sometimes significant adverse events, including pancreatitis, bleeding, and cholangitis.¹ In the United States, ERCP procedures are performed by providers and in facilities of varying experience and volume. Numerous studies have shown that ERCP quality varies significantly between providers and centers,²⁻⁴ and existing data suggest that procedure success and adverse event rates are closely associated with unit and endoscopist volume.^{1,3,5} Because ERCP outcomes have significant downstream implications on health, resource use, and costs to the patient, institutions, payors, and society, there remains a critical focus on improving the quality of this procedure in clinical practice.

The American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG)—the 2 cosponsors of this series—remain committed to delivering high-quality endoscopic care. This commitment is reflected, in part, by quality indicator documents, which aim to provide endoscopists and health systems with a framework through which quality improvement efforts can be operationalized. This document presents the quality indicators for ERCP (Table 1).

Quality can be measured at various levels, including that of the individual provider, group of providers, or across a health care system. Measuring and monitoring quality indicators at these various levels will have different but related implications. Assessment of quality indicators of an individual provider will inform the need for remediation and/or additional training, whereas measurement of

quality indicators at the group or system level may reveal the need for improvement in processes, personnel, facility structure, or workflow. The quality indicators for ERCP in this document were designed primarily for application at the provider level but may serve to inform quality improvement efforts at all levels.

METHODOLOGY

This work represents the third iteration of the ASGE/ACG quality indicators document pertaining to ERCP. The ASGE/ACG Task Force published the first version of this document in 2006 and revised it in 2015.^{6,7} The current revision integrates new data relevant to existing quality indicators and introduces new indicators as appropriate on the basis of interval progress in the field. This document focuses on ERCP; the indicators that are common to all GI endoscopic procedures, including ERCP, are presented in detail in a separate article (Table 2).⁸ The Task Force addressed common indicators only when modification was necessary specifically for ERCP.

As in preceding versions, we prioritized indicators with wide-ranging clinical implications associated with variation in practice and outcomes and validated in clinical studies. When supportive data were absent, indicators of clinical importance were chosen by expert consensus. Substantial progress has been made in the last decade in our ability to measure performance. However, feasibility and efficiency challenges still need to be addressed. Nevertheless, the Task Force elected to include a limited number of highly relevant but not yet easily measurable indicators to promote their eventual adoption.

Quality indicators are divided into 3 time periods: preprocedure, intraprocedure, and postprocedure. In addition, each quality indicator is classified as an outcome or process measure. Although outcome measures generally are considered more impactful toward improving quality of care, some can be difficult or impossible to measure in routine clinical practice because of the need for large amounts of data and/or long-term follow-up and because other factors may

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TABLE 1. ERCP quality indicators with associated performance targets

Quality indicator	Strength of recommendation	Measure type	Performance target, %
Preprocedure			
1. Frequency with which ERCP is performed for an accepted indication and that indication is documented (priority indicator)	1C+	Process	>98
2. Frequency with which informed consent is obtained, including a specific discussion of risks associated with ERCP, and the consent is documented	3	Process	>98
3. Frequency with which prophylactic antibiotics are administered for appropriate indications	2B	Process	>98
Intraprocedure			
4. Frequency with which deep cannulation of the duct of interest in patients with native papillae is achieved (priority indicator)	1C	Outcome	>90
5. Frequency with which radiation exposure is documented and measures are used to reduce exposure to patients and staff	1C	Process	>98
6. Frequency with which extrahepatic bile duct stones in patients with normal biliary anatomy are extracted successfully and documented (priority indicator)	1B	Outcome	>90
7. Frequency with which rectal indomethacin or diclofenac is administered in patients with an intact papilla (priority indicator)	1A	Process	>90
8. Frequency with which the use of prophylactic pancreatic stent placement for prevention of post-ERCP pancreatitis in high-risk cases is documented and tracked	1A	Process	>98
Postprocedure			
9. Frequency with which an unplanned hospital visit within 30 days of ERCP occurs (priority indicator)	1C	Outcome	<15
10. Frequency with which an unplanned biliary intervention (eg, salvage percutaneous transhepatic biliary drainage or repeat ERCP) within 30 days of ERCP occurs	1C	Outcome	<15
11. Frequency with which post-ERCP pancreatitis rate is documented and tracked	3	Process	>95
12. Frequency with which clinically significant hemorrhage after sphincterotomy or sphincteroplasty is documented and tracked	3	Process	>95
13. Frequency with which cholangitis within 30 days of ERCP is documented and tracked	3	Process	>95

Clinical implications of each strength of recommendation are as follows: 1A, strong recommendation, can be applied to most clinical settings; 1B, strong recommendation, likely to apply to most practice settings; 1Cp, strong recommendation, can apply to most practice settings in most situations; 1C, intermediate-strength recommendation, may change when stronger evidence is available; 2A, intermediate-strength recommendation, best action may differ depending on circumstances or patients or societal values; 2B, weak recommendation, alternative approaches may be better under some circumstances; 2C, very weak recommendation, alternative approaches are likely to be better under some circumstances; 3, weak recommendation, likely to change as data become available.

confound their measurement or interpretation. In such cases, process indicators are provided as surrogate measures of high-quality endoscopic practice. The relative value of a process indicator hinges on the evidence that supports its association with a clinically relevant outcome, and such process measures were emphasized. The measures in this document pertain directly to endoscopic care. Of course, the quality of care delivered to patients is influenced by additional factors, including those related to the facilities where endoscopy is performed. These structural measures are covered in a separate document dedicated to unit-level quality.⁹ The process and outcome measures included in this document are attached to a performance target and, therefore, each measure is considered a quality indicator. The Task Force selected performance targets on the basis of published benchmarking data informed by a literature review.

For this revision, the Task Force critically appraised existing quality indicators and determined whether to maintain or remove them by consensus on the basis of several factors,

including ongoing relevance and strength of evidence. In addition, the Task Force members proposed new quality indicators and, if appropriate, adopted these by consensus on the basis of similar considerations. For each indicator, the authors identified relevant articles through a systematic search of PubMed (U.S. National Library of Medicine, National Institutes of Health) from January 2014—the date of the last update of this document—through February 2025. The search strategies for each indicator included a combination of subject headings (Medical Subject Headings in PubMed) and pertinent keywords. English-language restrictions were applied. To identify additional articles, the authors reviewed PubMed’s “similar articles” and manually searched reference lists of relevant papers. Search strategies for the selected indicators were facilitated by health science librarians with expertise in systematic review. Searches that were judged to be incomplete after librarian assessment were repeated. On the basis of this revised literature review, the strength of evidence for each indicator was evaluated

TABLE 2. Quality indicators common to all endoscopic procedures with associated performance targets

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

according to a previously used framework (Table 3). Within this framework, the strength of each quality indicator is divided across a spectrum from “1A,” denoting a strong quality indicator that can be applied to most clinical settings, to “3,” denoting a weak quality indicator because of the absence of evidence requiring reliance on expert opinion only. The strength of the evidence grade for each indicator was established by author consensus.

It is important to emphasize that the included quality indicators and associated performance targets do not necessarily reflect the standard of care, credentialing requirements, or training standards, and the use of any of the quality indicators in this document as such is a misuse. Instead, the quality indicators are designed to serve as a framework for quality improvement efforts. To guide continual improvement for endoscopists and units in varying phases of their quality journey, the Task Force again recognized a subset of indicators deemed

“priority indicators,” on the basis of 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). We believe that quality improvement efforts should initially focus on the priority indicators and then progress to include other indicators once it is ascertained that endoscopists perform above the recommended thresholds, either at baseline or after corrective interventions.

PREPROCEDURE QUALITY INDICATORS

1. *Frequency with which ERCP is performed for an accepted indication and that indication is documented (priority indicator)*

TABLE 3. Strength of recommendation

Strength of recommendation	Clarity of benefit	Methodologic strength supporting evidence	Implications
1A	Clear	Randomized trials without important limitations	Strong recommendation; can be applied to most clinical settings
1B	Clear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Strong recommendation; likely to apply to most practice settings
1C+	Clear	Overwhelming evidence from observational studies	Strong recommendation; can apply to most practice settings in most situations
1C	Clear	Observational studies	Intermediate-strength recommendation; may change when stronger evidence is available
2A	Unclear	Randomized trials without important limitations	Intermediate-strength recommendation; best action may differ depending on circumstances or patients' or societal values
2B	Unclear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Weak recommendation; alternative approaches may be better under some circumstances
2C	Unclear	Observational studies	Very weak recommendation; alternative approaches are likely to be better under some circumstances
3	Unclear	Expert opinion only	Weak recommendation; likely to change as data 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*. AMA Press; 2002:599-608.

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Level of evidence: 1C+

Performance target: >98%

Type of measure: Process

ERCP is one of the greatest risk procedures performed by GI endoscopists and should be performed for an appropriate indication in essentially all cases.

Discussion. Since ERCP was first performed more than 50 years ago, ERCP indications have evolved from mostly diagnostic to largely therapeutic. Indeed, given the widespread availability of diagnostically equivalent but much safer alternatives, such as magnetic resonance cholangiopancreatography (MRCP) and EUS, ERCP has become a near-exclusively therapeutic procedure. Table 4 lists the commonly accepted indications for ERCP, updated from the previous version to reflect current evidence and practice.⁷ This list is not exhaustive, and the Task Force recognizes that ERCP may be indicated and beneficial in other scenarios for which the risk–benefit ratio is considered favorable.

Limitations of ERCP in current practice: suspected choledocholithiasis

Choledocholithiasis is the most common indication for ERCP. If a stone is visible on imaging tests such as transabdominal ultrasound, MRCP, or EUS, then ERCP is indicated for its removal in most patients. However, in some patients with suspected choledocholithiasis and less concrete evidence of a stone, ERCP can be negative because the stone has spontaneously passed into the intestine before the time of

TABLE 4. Common indications for ERCP*

Biliary indications
Choledocholithiasis
Cholangitis
Bile leak
Biliary stricture (malignant or benign)
Obstructive jaundice
Placement of transpapillary gallbladder stent
Ampullary mass
Biliary obstruction due to papillary stenosis
Exchange or removal of a stent for an accepted biliary indication
Pancreatic indications
Therapy of symptomatic pancreatic duct stone
Pancreatic duct leak
Recurrent acute pancreatitis with suspected papillary stenosis
Adjunctive management of pancreas fluid collections
Investigation of intraductal papillary mucinous neoplasm
Exchange or removal of a stent for an accepted pancreatic indication

*This is not an inclusive list, and ERCP may be performed for other indications in the appropriate clinical setting.

the procedure. In such cases, proceeding with ERCP might lead to a purely diagnostic procedure with minimal benefit and considerable risk. To more accurately determine whether a bile duct stone persists, on the basis of previous prospective surgical series and endoscopic cohort studies,

the ASGE developed a framework for predicting ongoing choledocholithiasis.¹ These ASGE guidelines, which are based on a combination of clinical, laboratory, and imaging parameters, allow clinicians to categorize patients into high, intermediate, and low probability categories for ongoing choledocholithiasis. However, studies evaluating the original 2010 version of these guidelines found that they had a positive predictive value of just 62%, resulting in unnecessary ERCP in up to 30% of cases.¹⁰⁻¹² In 1 retrospective study, patients in the high-risk category had choledocholithiasis only 73.6% of the time.¹³

On this basis, the ASGE guidelines were updated in 2019 to be more stringent about placing patients in the high-risk category.¹ An analysis of the revised algorithm found that the high-risk category had a sensitivity and positive predictive value for stones of 96.87% (95% CI, 95.37-97.98) and 89.57% (95% CI, 85.20-92.75), respectively, demonstrating meaningful improvement in our ability to select appropriate patients for ERCP, in whom the risk-benefit ratio is most favorable.¹⁴

Despite this improvement, however, existing criteria for the prediction of choledocholithiasis have limitations. In clinical practice, the use of guidelines alone to guide performance of ERCP may still lead to some diagnostic-only ERCP. The best way to ensure that diagnostic-only ERCP is minimized is through definitive visualization of a stone on transabdominal ultrasound, intraoperative cholangiogram, MRCP, or EUS. The use of antecedent EUS before any ERCP for which a stone has not confidently been identified on prior imaging is likely to reduce the rate of diagnostic ERCP,¹⁵ but the lack of local EUS availability may limit this practice. A systematic approach to limiting unnecessary ERCP for suspected choledocholithiasis represents a valuable quality improvement goal for any unit performing this procedure.

Common controversial indications for ERCP

Suspected sphincter of Oddi disorder. ERCP is not indicated for patients with biliary-type pain but no objective evidence of obstruction (eg, possessing a nondilated bile duct and normal liver enzymes). A randomized sham-controlled trial published in 2014 definitively ended the controversy regarding these patients, who were previously suspected to have sphincter of Oddi dysfunction type III or postcholecystectomy pain syndrome.¹⁶ The Evaluating Predictors and Interventions in Sphincter of Oddi Dysfunction (EPISOD) trial randomized 214 patients with biliary-type pain after cholecystectomy, normal liver enzymes, and a nondilated bile duct (defined as sphincter of Oddi dysfunction type III) to sphincterotomy compared with sham; all received manometry. Patients in the sham group reported greater relief of pain and disability at the 1-year mark compared with those who actually underwent sphincterotomy (37% vs 23%, $P = .01$). Results were similar at the 5-year mark.¹⁷ In this trial, manometry was not reproducible or predictive of any outcome.¹⁸

Although the EPISOD trial ended any controversy surrounding the utility of sphincterotomy for what is now considered a disorder of gut-brain interaction (previously functional GI disorder), there is utility in ERCP for some patients with biliary-type pain and elevated liver enzymes or dilated bile duct. In these patients, papillary stenosis obstructing the bile duct outlet may be considered an indication for biliary sphincterotomy. Care must be taken, however, in judiciously evaluating these patients before ERCP, because there are many other, more common reasons for elevated liver function tests, and the bile duct often dilates without obstructive pathology with increasing age, cholecystectomy, and use of opioids.

Recurrent acute pancreatitis. The use of ERCP with sphincterotomy to prevent further attacks of recurrent unexplained pancreatitis in patients with normal pancreatic ductal anatomy remains controversial. Open-label trials, which have included different interventions such as pancreatic stent placement (PSP), biliary sphincterotomy alone, pancreatic sphincterotomy alone, or dual pancreaticobiliary sphincterotomies, have shown mixed results. Because of varying interventions and inconsistent outcome measures, clear benefit is difficult to ascertain. A small randomized trial initially demonstrated a reduction in recurrent pancreatitis by pancreatic duct stent placement compared with medical therapy alone (11% vs 53%; $P < .02$).¹⁹ A subsequent observational study with 10-year follow-up also suggested a benefit associated with ERCP and sphincterotomy.²⁰ Conversely, a retrospective study with a median follow-up of 7 years demonstrated that endoscopic sphincterotomy did not reduce the rate of recurrent attacks of pancreatitis in this population.²¹ As evidence evolves, ERCP for this indication should only be considered after the findings of other evaluations have been negative and only after a thorough discussion regarding the potential lack of benefit and the risk of severe adverse events.²²

In patients with recurrent pancreatitis and pancreas divisum, endoscopic therapy via minor papilla stent placement or minor papillotomy is intended to improve drainage, reduce intraductal hypertension, and avert future attacks. Robust data evaluating the efficacy of minor papilla interventions are lacking. Systematic reviews of observational data suggest >70% benefit but are limited by heterogeneity in study subjects and endoscopic interventions.²³ A single randomized controlled trial (RCT) of 19 patients found a significant reduction in future episodes of pancreatitis with pancreatic duct stenting alone compared with no therapy (10% vs 67%; $P < .05$).²⁴ In a recent large-scale, multicenter randomized sham-controlled trial²⁵—presented in abstract form at Digestive Disease Week 2025—the authors concluded that minor papilla sphincterotomy did not significantly reduce the recurrence of acute pancreatitis episodes in patients with pancreas divisum compared with sham intervention. These findings challenge the longstanding practice of empiric minor papilla sphincterotomy in this population.

Preoperative drainage of malignant biliary obstruction. The endoscopic management of biliary

malignancy before surgical resection continues to evolve. Randomized trials and meta-analyses have shown that preoperative endobiliary stent placement in patients with obstructive jaundice attributable to resectable pancreatic cancer or extrahepatic cholangiocarcinoma places these patients at greater risk for adverse events (mostly cholangitis) compared with those who go directly to surgery.²⁶ However, preoperative neoadjuvant chemoradiotherapy, even in patients with resectable malignancies, has been shown in some studies to confer greater margin-negative resection rates and improved disease-free survival²⁷ and has accordingly become standard practice in many settings. Normalization of the bilirubin via ERCP with stenting is a prerequisite for the administration of chemotherapy. In the context of neoadjuvant therapy, a meta-analysis has shown that placement of a metallic stent at index ERCP reduces the rate of stent-related adverse events and unplanned reinterventions compared to plastic stents.²⁸ If an uncovered metal stent is used for drainage, it is imperative to confirm malignancy before placement because of the inability to reliably remove it in the case of unexpected benign stricture.²⁹

In comparison with extrahepatic obstruction, the preoperative management of malignant hilar obstruction is even more complicated, with less evidence to guide decision-making, although ERCP with stent placement is used in this context to improve surgical outcomes in patients in whom the remnant liver will be <50% of the original volume.³⁰ Regardless of the location of obstruction, ERCP should be performed for a clear clinical purpose, not simply because obstructive jaundice exists.

Primary sclerosing cholangitis. Primary sclerosing cholangitis (PSC) is a chronic cholestatic liver disease of unknown etiology characterized by inflammation and stricturing of the intrahepatic and extrahepatic bile ducts. Because of the increased risk of colorectal cancer and cholangiocarcinoma in patients with PSC, and to maximize effective management of biliary obstruction in this population, an accurate diagnosis is critical for appropriate patient management. In the past, cholangiography via ERCP was the preferred diagnostic modality. However, ERCP in patients with PSC carries a greater risk of adverse events, primarily cholangitis due to impaired drainage of the biliary tree. Moreover, magnetic resonance imaging with MRCP has high sensitivity (86%) and specificity (94%)³¹ and similar diagnostic accuracy compared to ERCP (83% vs 85%, $P = \text{not significant}$).³² On the basis of its noninvasive nature and favorable performance characteristics compared with ERCP, MRCP has become the guideline-recommended diagnostic approach for PSC.³³⁻³⁵ An international study group comprising hepatologists and radiologists has established standards for performance and interpretation of MRCP for the diagnosis of PSC.³⁶ ERCP should be reserved as a primarily therapeutic modality in symptomatic patients and/or patients with cholestasis or for the evaluation of malignancy in patients with dominant and/or indeterminate-appearing strictures on MRCP. Rarely, when there is high clinical suspicion for PSC

with a negative or equivocal MRCP and an unrevealing liver biopsy, ERCP may be justifiable for diagnostic purposes.³⁵

2. *Frequency with which informed consent is obtained, including a specific discussion of risks associated with ERCP, and the consent is documented*

Level of evidence: 3

Performance target: >98%

Type of measure: Process

In addition to the risks associated with endoscopy in general, the informed consent for ERCP should address the salient and substantial adverse events pertaining specifically to ERCP. Consent for ERCP should emphasize at least 5 possible adverse outcomes: (1) pancreatitis, (2) hemorrhage, (3) infection (both procedure- and duodenoscopy-related), (4) perforation, and (5) cardiopulmonary events. The patient should be informed that adverse events could be severe in nature. It is also advisable that patients be informed of the possibility that the ERCP may not be successful, and additional procedures may be necessary; in some cases, such as in the setting of a bile leak for which a temporary stent is placed, a second ERCP is not due to failure of the index procedure but is required to remove the stent.

Discussion. Some adverse events related to ERCP are unique and others are either more common or more potentially severe than those resulting from standard luminal endoscopy. A review of the adverse events of ERCP and their management has been published previously.³⁷ The expected rate of post-ERCP pancreatitis (PEP) is generally between 1% and 7% for average-risk patients.^{37,38} Particularly, high-risk patient populations include those undergoing ERCP for suspected sphincter of Oddi disorder, recurrent idiopathic acute pancreatitis, and patients with a history of PEP. Adverse events in such patients may be as high as 30%, with severe pancreatitis being more common as well.³⁹ Cholangitis occurs in <1% of patients after ERCP, and cholecystitis complicates 0.2% to 0.5% of ERCPs.^{37,38} Infections with carbapenem-resistant *Escherichia coli* organisms are rare but have been reported in the context of previous hospital outbreaks.⁴⁰ Hemorrhage is most often an adverse event of endoscopic sphincterotomy 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%.^{37,38} The general risks that are associated with ERCP as well as those unique or increased to a particular case should be communicated specifically to the patient during the informed consent process.^{41,42}

3. *Frequency with which prophylactic antibiotics are administered for appropriate indications*

Level of evidence: 2B

Performance target: >98%

Type of measure: Process

Prophylactic antibiotics for ERCP should be administered when existing evidence suggests they will be beneficial.

Discussion. Detailed guidelines for the administration of antibiotics before and during ERCP have been published previously.^{38,43} The role of routine prophylactic antibiotics for all patients undergoing ERCP remains controversial^{44,45}; however, published literature most strongly supports the use of prophylactic antibiotics in the following 3 scenarios: (1) patients in whom complete relief of biliary obstruction is not anticipated (eg, PSC or biliary cyst) or is not achieved, (2) patients undergoing cholangioscopy,⁴⁶⁻⁴⁹ and (3) those who have undergone an orthotopic liver transplantation. At present, there are no data to support the routine use of antibiotic prophylaxis for pancreatoscopy. Until such evidence becomes available, the decision should be individualized, taking into account patient-specific risk factors and the nature of the interventions performed.

Generally speaking, the aforementioned 3 situations should serve as the denominator for this indicator. More recent data, however, have demonstrated low rates of ERCP-associated infections in patients postliver transplant.⁵⁰ In response, ASGE has adjusted the recommendation from universal administration of antibiotics for all postliver transplant ERCP to a conditional recommendation wherein antibiotics are given for anticipated incomplete drainage (ie, ischemic cholangiopathy, multiple intrahepatic strictures, contrast injection without stent placement).⁵¹

The use of antibiotics also may be worthwhile in situations in which extraluminal contamination is suspected during the conduct of ERCP, such as when there is concern about an intraprocedural perforation or bile duct injury. Equally important to the administration of antibiotics for appropriate indications is the avoidance of antibiotics in settings in which clinical benefit is not likely. Use of antibiotics in inappropriate situations contributes to antibiotic resistance and antibiotic-related adverse events.

INTRAPROCEDURE QUALITY INDICATORS

4. *Frequency with which deep cannulation of the duct of interest in patients with native papillae is achieved in patients with standard foregut anatomy (priority indicator)*

Level of evidence: 1C

Performance target: >90%

Type of measure: Outcome

Achieving deep cannulation of the duct of interest is the essential first step of any ERCP, allowing the performance of necessary diagnostic and therapeutic interventions. However, variability in physician cannulation rates is closely associated with patient morbidity and mortality.

Discussion. Successful cannulation of the native papilla—one without previous biliary or pancreatic sphincterotomy—

depends on various factors related to the patient and the provider. Papilla morphology, including its relationship to diverticula, surgical alterations, and procedure indication, is among the factors associated with decreased cannulation rates.^{52,53} However, the primary factor that influences the variation in success of deep cannulation is the skill and experience of the provider.^{43,45} Considering that ERCP failure is associated with worse clinical outcomes and increased cost,^{6,46} successful cannulation is fundamental to high-quality ERCP.

In the United States, there are few data on ERCP cannulation rates outside of a registry of 85 high-volume endoscopists who anonymously self-reported ERCP outcomes over a 4-year period. In this cohort, the overall cannulation rate was >80%, and 83.5% of participants had a success rate >90%.⁵⁴ In more recent work, 22 recently graduated trainees reported ERCP performance after the completion of an advanced endoscopy trainee program.⁵⁵ For the entire cohort, native papilla cannulation success rate was 93.1%. However, only 77.3% of the independent endoscopists achieved a native papilla cannulation success rate of >90%. There are no other high-quality longitudinal data on ERCP performance after the completion of training.

Outside of the United States, the most robust data come from the Netherlands, where participation in an ERCP registry is mandatory. The registry identified an overall native papilla cannulation success rate of 90.7%.⁵⁶ However, many endoscopists had a cannulation success rate of <90%, with several endoscopists reporting a success rate of <85%. The lowest cannulation success rates were among providers with lower ERCP volume, consistent with previous work showing a strong volume-to-outcomes relationship in ERCP.³ There is no agreed-upon definition of a low-volume ERCP operator. In a large meta-analysis of 13 studies, volumes of between <25 annual and <156 annual ERCPs have been used as thresholds to define “low volume.”³

Thus, available data demonstrate that high native papilla cannulation rates are achievable but are not consistently attained by all endoscopists, underscoring the importance of quality improvement initiatives aiming to address this variability in clinical practice. What remains unknown, however, is when persistence to achieve deep cannulation may cause more harm than benefit. Although >90% is a desired target for all endoscopists, it is likely that at some point, overambitious efforts to achieve deep cannulation will unacceptably increase pancreatitis, perforation, and/or sedation-related risks. Moreover, returning on a different day after ampullary edema has resolved is associated with a high cannulation success rate.⁵⁷ Thus, persistence at the index ERCP to primarily avoid “failure” and achieve the proposed performance target may be detrimental due to an increased adverse event rate. The optimal time to pivot to an alternative cannulation strategy and the length of time to persist during a difficult case require further study.

There are numerous advanced ERCP techniques to improve biliary cannulation rates such as double-

guidewire technique, cannulation over a pancreas stent, needle-knife sphincterotomy, and fistulotomy. It is recommended that endoscopists performing ERCP become familiar with one or more of these techniques to improve success rates.⁵⁸ Use of an advanced technique to achieve deep cannulation of the duct of interest would be counted as a successful procedure as part of this quality indicator. However, there is growing evidence that EUS-guided biliary drainage (EUS-BD) is an efficacious and safe alternative to ERCP in patients with malignant biliary obstruction. EUS-BD has been used both as primary^{59,60} and salvage therapy. Although the use of EUS-BD after failed cannulation achieves palliation of obstruction, the Task Force felt that this should represent an unsuccessful ERCP. Thus, patients who require EUS-BD after attempted ERCP would be represented in the denominator (but not the numerator) of this quality indicator. Patients with duodenal obstruction (preventing access to the papilla) would be considered a “failure” of ERCP. Although the Task Force recognizes that an unsuccessful ERCP due to duodenal obstruction generally does not reflect the technical skill of the endoscopist, this more rigid definition was kept to better standardize the measurement. In contrast, patients with modified upper GI anatomy (eg, Roux-en-Y gastric bypass or Billroth II anatomy) would not be included as ERCP is often significantly more challenging in this setting.

5. *Frequency with which radiation exposure is documented and measures are used to reduce exposure to patients and staff*

Level of evidence: 1C

Performance target: >98%

Type of measure: Process

Radiation dose or an accepted equivalent should be measured and recorded for all ERCPs. This is the first step in a comprehensive plan to systematically minimize radiation exposure to the patient and medical staff.

Discussion. The vast majority of ERCPs use fluoroscopy to define pathology and guide therapy, although ERCP without fluoroscopy has been described in restrictive settings such as during pregnancy.⁶¹ Fluoroscopy carries risks to both patients and staff as excess radiation exposure can predispose to subsequent cancer through DNA damage and, in extreme situations, can cause cutaneous injury to the patient.⁶² As a result, guidelines from radiology societies recommend that all procedures using fluoroscopy be performed in compliance with ALARA (as low as reasonably achievable) principles.⁶³⁻⁶⁶ Central to achieving ALARA is consistent measurement of radiation exposure and the implementation of measures that are known to reduce dose to both the patient and staff.

Precise measurements of radiation exposure are expressed as “dose area product” and “dose at reference point.” Because of the needed infrastructure and technology to directly measure exposure, fluoroscopy time often

is tracked instead as a surrogate measure of the overall radiation dose. However, studies suggest that fluoroscopy time may not correlate well with overall radiation exposure, especially in the setting of prolonged and complex cases.^{67,68} On this basis, primary measurement of radiation exposure is encouraged as a quality improvement goal, but if this is not possible, fluoroscopy time at the very least should be tracked. Because case indications and complexity vary more so by center than by provider, comparison of radiation exposure (including fluoroscopy time) among providers within a particular institution will likely provide more useful targets for quality improvement than absolute fluoroscopy time/exposure.

Best practices to reduce radiation exposure include reducing the pulse rate (frames per second), using a “save last image” function rather than static image acquisition, keeping the radiation source distant from the patient and the detector close to the patient, routine collimation, and the uniform use of personal protective equipment, including leaded eye protection, and proper shielding.⁶⁷ These and other principles for optimizing safe, effective fluoroscopy use in GI procedures were outlined in a recent international consensus statement.⁶⁹ All potentially helpful interventions should be considered and implemented as part of a comprehensive plan (including ongoing radiation exposure monitoring for all ERCP personnel) that balances the optimal delivery of endoscopic care with the safety of all those involved in the ERCP practice. All involved health care professionals (physicians or radiology technicians) should undergo radiation safety training to ensure proper usage.

6. *Frequency with which extrahepatic bile duct stones in patients with normal biliary anatomy are extracted successfully and documented (priority indicator)*

Level of evidence: 1B

Performance target: >90%

Type of measure: Outcome

Extraction of extrahepatic bile duct stones is the most common indication for ERCP in the United States, and routine success in this endeavor is central to a high-quality ERCP practice. For this reason, the ability to completely clear the extrahepatic duct of stones at the index procedure is a priority indicator for ERCP. The performance target for this indicator assumes that biliary cannulation has been successfully achieved.

Discussion. Most stones found during ERCP are smaller than 10 mm in diameter and can be removed using conventional methods such as sphincterotomy and balloon extraction. However, certain factors may make it difficult to clear the stones, such as stones located above the biliary confluence, stones retained in the cystic duct, and the need for needle knife sphincterotomy to obtain access.⁷⁰ Stones larger than 10 mm, multiple stacked stones, impacted stones, and stones in patients with a nondilated or tapered distal duct can also increase the difficulty of

complete clearance. Still, such situations are less common, occurring in less than 20% of ERCPs. In these cases, nonconventional approaches such as transpapillary large balloon dilation, mechanical lithotripsy, or single-operator cholangioscopy with electrohydraulic lithotripsy (EHL) or laser lithotripsy may be required. In a rigorous systematic review and meta-analysis, complete clearance of large (>10 mm) stones was achieved at first ERCP using sphincterotomy plus transpapillary balloon dilation in 85% of cases.¹ In cases requiring EHL or laser lithotripsy, complete clearance was achieved in 75% of cases. In a second systematic review and meta-analysis of 19 RCTs (2752 patients) comparing 5 approaches for the treatment of CBD stones >10 mm, clearance rates ranged from 100% for single-operator cholangioscopy to 57% for mechanical lithotripsy.⁷¹

Prospective data on individual provider clearance rates for choledocholithiasis are limited because most studies report aggregate outcomes (ie, according to center with multiple providers or entire study cohort). In 1 prospective study using self-reported anonymized data, 63 endoscopists reported outcomes in 18,182 ERCPs.⁷² The overall technical success rate for the extraction of biliary stones smaller than 10 mm was nearly 100% across both academic and community practices. On a per-provider basis, technical success was still quite high at >92%. These results must be viewed with the potential bias of self-reporting. Indeed, a prospective study using data from a nationwide registry in the Netherlands showed that the success rate for ERCP (without regard to indication) entered into the registry was 85.8% compared to only 76.0% for ERCPs not reported ($P < .001$).⁷³ In addition, in 1 study using independent verified hospital episode statistics data from 37,468 patients undergoing a first ERCP for biliary stones, only two-thirds of patients had complete clearance.⁶ Despite this limitation, available data in aggregate suggest that routine stone extraction cases can (and should) be associated with a greater than 90% success rate.

When the indication for ERCP is choledocholithiasis, the endoscopist should use maneuvers, such as occlusion cholangiogram and balloon sweeps, to ensure stone clearance and document whether complete stone extraction is achieved. The documentation should also include sufficient information about the size and location of the stone(s), the presence of strictures, and the presence of postsurgical anatomy to allow proper comparisons in subsequent benchmarking efforts. Provider-specific stone extraction rates should approximate benchmark rates for patients with similar circumstances and stone characteristics. An important difference between this indicator and the previous (2015) version is that this version is not restricted to stones less than 1 cm. Given the lower incidence of larger stones and the expectation that high-quality ERCP entails proficiency with at least some advanced extraction techniques, the denominator for this indicator is all stones in the extrahepatic bile duct after successful cannulation of the bile duct is achieved.

7. Frequency with which rectal indomethacin or diclofenac is administered in patients with an intact papilla (priority indicator)

Level of evidence: 1A

Performance target: >90%

Type of measure: Process

Robust clinical trial data demonstrate that nonsteroidal anti-inflammatory drugs (NSAIDs) administered rectally around the time of ERCP are effective in preventing PEP.⁷⁴ On this basis, the administration of rectal indomethacin or diclofenac is guideline-recommended for PEP prevention by the ASGE and other professional societies.⁷⁵⁻⁷⁷

Discussion. Both rectally delivered diclofenac and indomethacin have been shown in clinical trials to reduce the risk of PEP. Meta-analyses suggest that the associated risk reduction is in the range of 50%.^{74,78,79} A high-profile trial published in 2012 enrolled patients at elevated risk for PEP, leading to the perception that rectal NSAIDs are only effective in high-risk cases.⁸⁰ Furthering this notion was another RCT of largely average-risk patients undergoing ERCP at a single center that showed no benefit associated with rectal indomethacin.⁸¹ However, the overall body of evidence does indicate that NSAIDs are effective in all patients. A large-scale RCT comparing >2000 average-risk participants showed a 54% relative risk reduction associated with the administration of rectal indomethacin compared to no intervention,⁸² and meta-analyses restricted to studies enrolling average-risk cases have consistently demonstrated benefit.⁸³⁻⁸⁵ In addition, 2 real-world clinical effectiveness studies appear to affirm benefit in all-comers.^{86,87} On the basis of these data, the most recent ASGE guidelines on PEP prevention recommend rectal NSAIDs administration in unselected patients undergoing ERCP after having restricted this recommendation to high-risk cases in prior versions of the guideline.⁷⁵ Evidence suggests that rectal NSAIDs are effective when given before or after ERCP; however, the aforementioned large RCT showed benefit associated with systematic administration of the drug before the procedure.⁷⁶

Some patients undergoing ERCP are at negligible risk for PEP and thus do not require prophylaxis. The largest such group of patients is those with a preexisting biliary sphincterotomy undergoing repeat biliary intervention (eg, routine biliary stent exchange or removal). Therefore, toward the goal of a highly feasible and easily calculable measure, the denominator in this quality indicator is the number of patients with an intact papilla undergoing ERCP. This captures the large majority of patients who would benefit from rectal NSAIDs while minimizing drug exposure to patients at negligible risk. Endoscopists should not, however, refrain from administering rectal NSAIDs to patients with a preexisting sphincterotomy who are at risk for PEP and would likely benefit (eg, patients with prior biliary sphincterotomy undergoing pancreatic endotherapy).

The performance target for this quality indicator was set at 90% to account for patients with contraindications to rectal NSAIDs, including those with allergies and renal dysfunction, as well as those at very low risk who are unlikely to benefit.^{88,89} Since existing evidence suggests that NSAIDs are given to well less than 50% of patients undergoing ERCP, quality improvement efforts that aim to increase this rate to 90% would have a highly favorable impact.⁹⁰

8. *Frequency with which the use or nonuse of prophylactic PSP for the prevention of PEP in high-risk cases is documented and tracked*

Level of evidence: 1A

Performance target: >98%

Type of measure: Process

On the basis of randomized controlled trial data,^{74,91} prophylactic PSP is strongly recommended by the ASGE and other professional societies to prevent pancreatitis in high-risk cases.^{38,75,77} A recent large-scale, methodologically rigorous, multicenter RCT that was conducted across 20 centers in the United States and Canada affirmed the benefit of PSP in patients at elevated risk.⁹² In this trial, the combination of rectal indomethacin plus a prophylactic stent was more effective than indomethacin alone, reducing PEP by more than 30%, and resulting in numerically fewer cases of severe pancreatitis and pancreatitis-related death. The benefit was most pronounced in patients at greatest risk for PEP. The risk of PEP is determined according to widely published pre- and intraprocedure independent risk factors for PEP, including but not limited to clinical suspicion of biliary or pancreatic sphincter of Oddi dysfunction, ampullectomy, difficult cannulation, double-wire cannulation technique, pancreatic sphincterotomy, and pancreatic endotherapy.

Discussion. Despite the strength of evidence, PSP has been difficult to operationalize as a quality indicator because of the complexity of the intervention and its associated decision-making. PSP requires a high level of training and technical proficiency and can contribute to the very harm that it aims to prevent because each step in the process could theoretically injure the pancreas, especially if achieved traumatically. In addition, an unsuccessful attempt at stent placement may increase the risk of PEP above baseline.^{93,94} Thus, the primary concern with PSP as a quality indicator is that it may encourage overambitious efforts to place a stent among practitioners aiming to satisfy performance targets, ultimately leading to more harm than good. However, despite this potential concern and other known disadvantages, such as cost and inconvenience for patients, existing evidence is clear that high-quality ERCP requires the use of PSP in appropriate scenarios.

The decision to perform PSP depends on several factors, the most important of which are the patient's risk of PEP and the anticipated level of difficulty in stent placement. For example, PSP is clearly advisable when pancre-

atic duct access is already achieved (eg, inadvertent pancreatic wire passage during biliary ERCP). In contrast, the risk-benefit equation is not as clear when the risk of PEP is only modestly elevated, but PSP is anticipated to be challenging because of suboptimal cannulation alignment or a pancreatic ansa loop. Other factors, such as the patient's ability to undergo follow-up abdominal radiography (which is mandatory after placement of an unflanged stent to ensure that prolonged retention does not occur) as well as the endoscopist's comfort level with PSP also influence decision-making.

The many potential variations in the risk-benefit ratio of PSP underscore the challenge in attaching a performance target to how often this intervention should be attempted. Therefore, until more robust benchmarking data are available according to clinical and procedural scenario and practice setting, documenting and tracking PSP use is the most cogent quality improvement activity, aiming to reinforce the importance of this prophylactic intervention among endoscopists and to generate outcomes data that will inform future versions of this quality indicator. Because prophylactic stent placement appears to have decreased substantially in the last decade,^{95,96} with some data suggesting use in less than 5% of high-risk cases,⁹⁰ the recommitment to documenting and tracking PSP is anticipated to have a favorable impact over time.

PSP is a technically challenging and potentially dangerous intervention that has been performed much less commonly in recent years. On this basis, it is important for practitioners, particularly those without training and/or experience in this maneuver, to remain responsible in their approach. Those without experience in performing PSP should refer anticipated high-risk cases—the patients who are most likely to require PSP—to referral centers and consider engaging in postgraduate training pathways to gain proficiency. Those with expertise should not feel compelled, on the basis of this quality indicator or in general, to engage in overly aggressive efforts to place a stent in challenging cases because there will be scenarios in which the risk-benefit ratio of ongoing attempts becomes unfavorable. Most importantly, with recent renewed emphasis on PSP, fellowship programs must recommit to high-quality training in this complicated but salutary intervention.

Whether a prophylactic stent was placed should be documented in patients at high risk for PEP undergoing ERCP. Thus, for this quality indicator, the denominator is the number of high-risk ERCPs performed and the numerator is the number of these cases for which the use or nonuse of PSP is clearly documented.

POSTPROCEDURE INDICATORS

9. *Frequency with which an unplanned hospital visit within 30 days of ERCP occurs (priority indicator)*

Level of evidence: 1C

Performance target: <15%

Type of measure: Outcome

Unplanned or prolonged hospitalization because of ERCP-associated morbidity encompasses physician-defined adverse events and other unspecified morbidity from the patient's perspective.

Discussion. Physician-defined adverse events such as PEP, postsphincterotomy bleeding, and cholangitis do not fully encapsulate the morbidity associated with ERCP.⁹⁷ A discrete sequela of postprocedural morbidity is an unplanned hospital visit specifically attributable to the procedure. In fact, hospitalization should encompass all of the ERCP-specific adverse events detailed in other quality indicators that follow within this document, additional physician-defined adverse events, and other morbidity (eg, postprocedure pain or nausea). The rate of unplanned hospital visits is widely incorporated into other quality measures, including those proffered by the Centers for Medicare and Medicaid Services for Ambulatory Surgical Centers (eg, the rate after outpatient colonoscopy) and even after hospital discharge (ie, the hospital readmission rate, <https://data.cms.gov/provider-data/topics/hospitals/unplanned-hospital-visits>). Compared with peers, greater rates of unplanned or prolonged hospitalization after procedures are likely to reflect one or more of the following: (1) suboptimal preprocedure evaluation (ie, case selection or optimization), (2) technical performance factors that may lead to higher rates of morbidity (eg, abdominal pain, PEP, nausea, or other), and (3) having an adequate ambulatory infrastructure to support patients in the recovery period. More or longer hospital time means more disruption for patients and greater costs per ERCP.

There are undoubtedly patient factors that influence the rate of unplanned hospitalizations and that are independent of the quality of the procedure, such as procedure indication, baseline comorbidity, and patient support structure.⁹⁸ There is also potential bias in defining hospitalization related to ERCP morbidity as opposed to underlying disease. Nevertheless, substantial deviations from local, regional, and national rates may reflect suboptimal case selection, procedural performance, or periprocedure management, especially when an individual provider's spectrum of indications and patient cohort is comparable with their peers. Therein lies the importance of documenting the need for hospitalization after ERCP. In the United States and other Western countries, reported rates of unplanned hospitalization, using state cohorts or multistate cohorts, encompassing the most common ERCP indications are typically <15%.^{2,99-106}

10. *Frequency with which an unplanned biliary intervention (eg, salvage percutaneous transhepatic biliary drainage or repeat ERCP) within 30 days of ERCP occurs*

Level of evidence: 1C

Performance target: <15%

Type of measure: Outcome

An unplanned biliary intervention shortly after ERCP is often the result of a technically unsuccessful ERCP. The

frequent occurrence of such events indicates suboptimal quality of care and should prompt the implementation of quality improvement efforts.

Discussion. There is no universally accepted definition for a successful ERCP. However, there are few clinical scenarios in which a patient needs to undergo a second ERCP or pivot to an alternative biliary drainage procedure such as percutaneous transhepatic cholangiography within 30 days of the index procedure.^{2,3,107} It is more likely that such an event represents an unplanned intervention, indicating that a procedure was required based on technical (eg, failed cannulation¹⁰⁸) or clinical failure (eg, insufficient or improper biliary drainage).^{107,109} As opposed to cannulation and stone extraction (discussed elsewhere in this document), this quality indicator incorporates both technical and clinical success in a metric that is discrete and measurable. For the purposes of this indicator, unplanned denotes an event that was not anticipated before the index ERCP (eg, placing a stent in a patient with acute suppurative cholangitis who is not safe to undergo stone extraction during the index procedure would represent a "planned" future event). Instead, an early unplanned intervention may include repeat ERCP or pivot to an alternative technique for biliary drainage such as EUS-guided direct biliary drainage (during a subsequent procedure) or percutaneous transhepatic biliary drainage.

Rates of successful ERCP vary widely. A systematic review identified studies reporting success rates ranging from 76% to 99%, although with varying definitions, methodology, and enrollment criteria.³ Documenting the frequency of early repeat ERCP or related interventions such as percutaneous transhepatic drainage and EUS-guided drainage¹¹⁰ is important, because deviations from peers may indicate lower quality (ie, value) service.¹¹¹

There was disagreement among the Task Force members about the timeline for this indicator. Rates of repeat intervention at any time after the ERCP would capture both unsuccessful procedures and excess ERCP use, a classic example of which is excess rates of stent placement when ERCP is performed for choledocholithiasis, indicating suboptimal technical proficiency or clinical judgment.^{112,113} However, there is complexity in interpreting an individual's repeat ERCP rate related to their patient population; for example, certain indications for ERCP such as benign bile duct stricture require at least 2 ERCPs per patient. Consistent with providing high-value care, providers should strive to minimize their rate of additional interventions after the index ERCP.

It is important to consider that a rescue intervention (eg, EUS-BD for unsuccessful ERCP cannulation) would not be registered as an unplanned intervention if performed at the time of the index ERCP but would be an unplanned intervention if performed a few days later. Nevertheless, clinicians are encouraged to always use their best judgment regarding the risk-benefit ratio of

deploying the rescue intervention at the same time as the index ERCP, as there are situations for which a delay might be most prudent. The performance target of <15% is intended to account for intentional delays that are judged to be in the best interest of the patient.

Because estimates of success rates across various health systems and providers are imprecise, documentation of unplanned interventions within 30 days of the initial ERCP will be informative to providers when these data are reported in reference to their peers with similar case mixes and indications and will refine appropriate targets for unplanned interventions as an outcome quality metric in the future.

11. *Frequency with which PEP rate is documented and tracked*

Level of evidence: 3

Performance target: >95%

Type of measure: Process

PEP remains the most frequent and potentially dangerous adverse event of ERCP, with stable incidence but increasing mortality.^{114,115} Preventing PEP should be a major priority for every endoscopist and unit that performs ERCP.

Discussion. Given the importance of reducing PEP as a quality improvement goal, the rate of this adverse event would ideally be benchmarked as an outcome measure. However, between-provider and between-center comparisons of PEP rates are not reliable because of the subjective nature of the most commonly used (consensus) definition.¹¹⁶ The consensus definition of PEP is all of the following: abdominal pain consistent with pancreatitis, serum amylase or lipase greater than 3 times the upper limit of normal measured more than 24 hours after ERCP, and either the need for admission or requiring prolongation of admission of at least 2 days. The interpretation of post-ERCP pain and the decision to hospitalize a patient after the procedure—both central to this consensus diagnosis of PEP—are nonobjective and variable across practice styles and settings. Indeed, practitioners with a low threshold to hospitalize patients after ERCP may observe a higher rate of PEP, and vice versa. Moreover, varying clinical scenarios, especially in patients with preexisting chronic pain, that partially satisfy the criteria for this diagnosis are subject to biased interpretation depending on multiple factors, including attitudes toward iatrogenesis. In addition, patient selection and case-mix have a major impact on PEP rates. A referral center that cares for patients with previous unsuccessful ERCP and recurrent acute pancreatitis may observe a greater rate of PEP than a center that primarily treats choledocholithiasis and pancreatic cancer.

For these reasons, defining a precise, widely applicable performance target for PEP rate as an outcome measure is problematic. Instead, concerted efforts to reduce the incidence of this adverse event relative to one's past perfor-

mance (or maintain high-quality performance) represent the current mainstay of maximizing quality around this adverse event. Such longitudinal comparisons mandate consistent capture, documentation, and tracking of PEP events.

Widespread adoption and reporting of this quality indicator will eventually lead to the collection of sufficient data to inform the development of performance targets that more precisely apply to varying practice settings (eg, high-complexity or high-risk case mix vs routine ERCP) and may be used by comparable providers and units for meaningful benchmarking. In addition, research aiming to identify an accurate biomarker for PEP will be critical toward translating PEP rate into an objective and actionable outcome measure.

12. *Frequency with which clinically significant hemorrhage after sphincterotomy or sphincteroplasty is documented and tracked*

Level of evidence: 3

Performance target: >95%

Type of measure: Process

Clinically significant bleeding is a serious adverse event that usually occurs after endoscopic sphincterotomy or sphincteroplasty.

Discussion. There are variable definitions for clinically significant bleeding, but most definitions require a notable decrease in hemoglobin (at least 2-3 g) with melena, hematemesis, or other signs of GI hemorrhage.^{37,117} The Task Force deliberated retaining this as an outcome indicator, striving for a rate <1% as in the previous document, but there was agreement that an individual provider's rate of post-ERCP bleeding is dependent upon other factors pertaining to case selection such as the rate of ERCPs with a sphincterotomy and the proportion of patients with underlying coagulopathy (innate and medication-induced).^{118,119} This latter factor may vary according to practice setting, and since ERCP with sphincterotomy—most index ERCP cases—is considered “high-risk” for bleeding adverse events according to ASGE guidelines, it is an important determinant of this outcome.¹²⁰ In addition, bleeding after ERCP is not entirely preventable, but the rate should be low (<1%-2% of all procedures).

Ideally, the rate of post-ERCP bleeding is calculated using the subgroup of cases without a history of previous sphincterotomy since practices with an inordinately high volume of patients undergoing repeat ERCPs with stent exchanges for benign bile or pancreatic duct disease could skew this rate lower. The Task Force also agreed that excess use of precut sphincterotomy, a probable technical risk factor for post-ERCP bleeding, would reflect in a substantially greater rate of post-ERCP bleeding.

Nevertheless, documentation of clinically significant post-ERCP bleeding remains an important process

measure and is the only means by which an endoscopist can compare their rate to prior performance and to their peers.

13. *Frequency with which cholangitis and cholecystitis within 30 days of ERCP is documented and tracked*

Level of evidence: 3

Performance target: >95%

Type of measure: Process

Clinically significant cholangitis (and cholecystitis) is a serious adverse event that may occur after instrumentation of the bile duct.

Discussion. Just as post-ERCP hemorrhage is closely linked with the performance of sphincterotomy, the risk of post-ERCP cholangitis or cholecystitis is associated with procedure indications as well as the effectiveness of the intervention (eg, achieving adequate drainage of obstructed liver segments). Rates vary from 1% to 8% in reported cohorts, with PSC representing the highest risk indication.^{121,122} Since incomplete biliary drainage is another important risk factor for post-ERCP cholangitis, documenting the incidence of this adverse event will permit endoscopists to compare their rate with peers. Rates exceeding the published range may indicate a need to compare the spectrum of indications (eg, proportion of cases performed for hepatic confluence strictures and PSC) and related (or potentially related) maneuvers such as performance of cholangioscopy and mechanical lithotripsy.³⁸

The Task Force recognizes the recent literature detailing duodenoscope-associated infections and contamination of duodenoscopes after reprocessing. However, this was not incorporated into this infection-specific quality indicator (or other quality indicators) because the measurable event rate of duodenoscope-associated infections is low and the clinical significance of duodenoscope contamination identified by endoscope culture remains unclear.¹²³⁻¹²⁶

CONCLUSIONS

ERCP, despite its frequent application across practice settings, is a highly complex procedure associated with significant morbidity and costs. Because of this, measures to improve the quality of ERCP performance will benefit patients and health care systems both directly and indirectly. Although quality improvement efforts aiming to improve outcome measures are associated with the greatest impact, these are often influenced by an individual provider or center's case mix with varying indications and comorbidities. In some situations (eg, rate of PEP), quality indicators may be subject to interpretation and reporting bias. Therefore, designating a single benchmark that is fair and applicable to all endoscopists performing ERCP may not be feasible or justified. Instead, in these areas,

the Task Force has chosen to use process measures, such as complete tracking and documentation of the event in question, with the expectation that the associated clinical outcomes would be benchmarked within groups having similar case mixes.

Important changes to this revision of the ERCP quality indicators document include a more restrictive approach to ERCP indications and a clear endorsement of rectal NSAIDs in average-risk patients with intact ampullary sphincters undergoing ERCP. Moreover, because recent data have confirmed the role of prophylactic pancreatic stents in patients at high risk for PEP, we have introduced the tracking of this intervention as a new quality indicator. The area of PEP prevention will continue to evolve with emerging evidence about these and other prophylactic interventions.

We have also placed significant emphasis on the tracking of unplanned events such as the need for early biliary reintervention and unexpected hospitalization. These indicators were felt to measure comprehensive aspects of quality as it pertains specifically to ERCP, are believed to be associated with significant variability, and are perhaps more reliably defined than other potential ERCP-related outcome measures. Therefore, the associated quality indicators (regarding unplanned biliary interventions and unplanned hospitalization) are highlighted in this revision as postprocedure outcome measures.

As discussed herein, it is not the intention of this document that providers and centers track all of the proposed quality indicators. Rather, each provider and/or center should select the most likely indicators to improve clinical care delivery in their practice. High-quality ERCP requires improvement in all the proposed areas, and we hope that this document will serve as a sequential guide along the quality journey.

DISCLOSURE

All authors disclosed no financial relationships.

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Abbreviations: ACG, American College of Gastroenterology; ALARA, as low as reasonably achievable; ASGE, American Society for Gastrointestinal Endoscopy; EHL, electrohydraulic lithotripsy; EPISOD, Evaluating Predictors and Interventions in Sphincter of Oddi Dysfunction; EUS-BD, EUS-guided biliary drainage; MRCP, magnetic resonance cholangiopancreatography; NSAID, nonsteroidal anti-inflammatory drug; PEP, post-ERCP pancreatitis; PSC, primary sclerosing cholangitis; PSP, pancreatic stent placement; RCT, randomized controlled trial.

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