

Performance measures for ERCP and endoscopic ultrasound: a European Society of Gastrointestinal Endoscopy (ESGE) Quality Improvement Initiative



Authors

Dirk Domagk¹, Kofi W. Oppong^{2,3}, Lars Aabakken^{4,5}, Laszlo Czakó⁶, Tibor Gyökeres⁷, Gianpiero Manes⁸, Peter Meier⁹, Jan-Werner Poley¹⁰, Thierry Ponchon¹¹, Andrea Tringali^{12,13}, Cristina Bellisario¹⁴, Silvia Minozzi¹, Carlo Senore¹⁴, Cathy Bennett¹⁵, Michael Bretthauer¹⁶, Cesare Hassan¹⁷, Michal F. Kaminski^{18,19,20}, Mario Dinis-Ribeiro²¹, Colin J. Rees²², Cristiano Spada^{12,23}, Roland Valori²⁴, Raf Bisschops²⁵, Matthew D. Rutter^{22,26}

Institutions

- 1 Department of Medicine I, Josephs Hospital Warendorf, Academic Teaching Hospital, University of Muenster, Warendorf, Germany
- 2 HPB Unit, Freeman Hospital, Newcastle upon Tyne, United Kingdom
- 3 Institute of Cellular Medicine, Newcastle University, Newcastle, United Kingdom
- 4 Faculty of Medicine, University of Oslo, Oslo, Norway
- 5 Department of Transplantation Medicine, Oslo University Hospital, Oslo Norway
- 6 First Department of Medicine, University of Szeged, Szeged, Hungary
- 7 Department of Gastroenterology, Medical Center Hungarian Defence Forces, Budapest, Hungary
- 8 Department of Gastroenterology, ASST Rhodense, Rho, and Garbagnate Milanese Hospitals, Milan, Italy
- 9 Med. Klinik II, DIAKOVERE Henriettenstift, Klinik für Enterologie, Hannover, Germany
- 10 Department of Gastroenterology and Hepatology, Erasmus MC, University Medical Center Rotterdam, The Netherlands
- 11 Department of Endoscopy and Gastroenterology, Edouard Herriot Hospital, Lyon, France
- 12 Digestive Endoscopy Unit, Fondazione Policlinico Universitario Agostino Gemelli – IRCCS, Catholic University, Rome, Italy.
- 13 CERTT, Center for Endoscopic Research, Therapeutics and Training – Catholic University, Rome, Italy
- 14 CPO Piemonte, AOU Città della Salute e della Scienza, Turin, Italy
- 15 Office of Research and Innovation, Royal College of Surgeons in Ireland Coláiste Ríoga na Máinleá in Éirinn, Dublin, Ireland.
- 16 Clinical Effectiveness Research Group, University of Oslo and Oslo University Hospital, Oslo, Norway
- 17 Endoscopy Unit, Nuovo Regina Margherita Hospital, Rome, Italy
- 18 Department of Gastroenterology, Hepatology and Oncology, Medical Center for Postgraduate Education, Warsaw, Poland
- 19 Department of Gastroenterological Oncology and Department of Cancer Prevention, The Maria Skłodowska-Curie Memorial Cancer Center and Institute of Oncology, Warsaw, Poland
- 20 Department of Health Management and Health Economics, University of Oslo, Norway
- 21 Serviço de Gastroenterologia, Instituto Portugues de Oncologia Francisco Gentil, Porto, Portugal
- 22 Northern Institute for Cancer Research, Newcastle University, Newcastle, United Kingdom
- 23 Digestive Endoscopy and Gastroenterology Unit, Poliambulanza Foundation, Brescia, Italy
- 24 Department of Gastroenterology, Gloucestershire Hospitals NHS Foundation Trust, Gloucestershire, United Kingdom
- 25 Department of Gastroenterology and Hepatology, University Hospital Leuven, Leuven, Belgium
- 26 Department of Gastroenterology, University Hospital of North Tees, Stockton-on-Tees, Cleveland, UK

Bibliography

DOI <https://doi.org/10.1055/a-0749-8767>

Published online: 19.10.2018 | Endoscopy 2018; 50: 1116–1127

© Georg Thieme Verlag KG Stuttgart · New York
ISSN 0013-726X

Corresponding author

Dirk Domagk MD, Department of Medicine I, Josephs-Hospital Warendorf, Academic Teaching Hospital, University of Muenster, Am Krankenhaus 2, 48231 Warendorf, Germany
Fax: +49-2581-201402
domagkd@uni-muenster.de

ABSTRACT

The European Society of Gastrointestinal Endoscopy and United European Gastroenterology present a short list of key performance measures for endoscopic ultrasound (EUS) and endoscopic retrograde cholangiopancreatography (ERCP). We recommend that endoscopy services across Europe adopt the following seven key and one minor performance measures for EUS and ERCP, for measurement and evaluation in daily practice at center and endoscopist level:

1 Adequate antibiotic prophylaxis before ERCP (key performance measure, at least 90%); 2 Antibiotic prophylaxis before EUS-guided puncture of cystic lesions (key performance measure, at least 95%); 3 Bile duct cannulation rate (key performance measure, at least 90%); 4 Tissue sampling during EUS (key performance measure, at least 85%);

5 Appropriate stent placement in patients with biliary obstruction below the hilum (key performance measure, at least 95%); 6 Bile duct stone extraction (key performance measure, at least 90%); 7 Post-ERCP pancreatitis (key performance measure, less than 10%). 8 Adequate documentation of EUS landmarks (minor performance measure, at least 90%).

This present list of quality performance measures for ERCP and EUS recommended by ESGE should not be considered to be exhaustive: it might be extended in future to address further clinical and scientific issues.

PUBLICATION INFORMATION

This article is being published jointly in *United European Gastroenterology Journal* and *Endoscopy*.

Copyright © 2018 by United European Gastroenterology and Georg Thieme Verlag KG

ABBREVIATIONS

ACG	American College of Gastroenterology
ASGE	American Society for Gastrointestinal Endoscopy
CI	confidence interval
ERCP	endoscopic retrograde cholangiopancreatography
ESGE	European Society of Gastrointestinal Endoscopy
EUS	endoscopic ultrasound
EUS-FNA	endoscopic ultrasound-guided fine needle aspiration
FNB	fine needle biopsy
GI	gastrointestinal
GRADE	Grading of Recommendations Assessment, Development and Evaluation
ISFU	Importance, Scientific acceptability, Feasibility, Usability
N/A	not available
NSAID	nonsteroidal anti-inflammatory drug
PEP	post-ERCP pancreatitis
PICO	Population/Patient; Intervention/Indicator; Comparator/Control; Outcome
PSC	primary sclerosing cholangitis
PTCD	percutaneous transhepatic choledochal drainage
RCT	randomized controlled trial
QIC	Quality Improvement Committee
UEG	United European Gastroenterology

Introduction

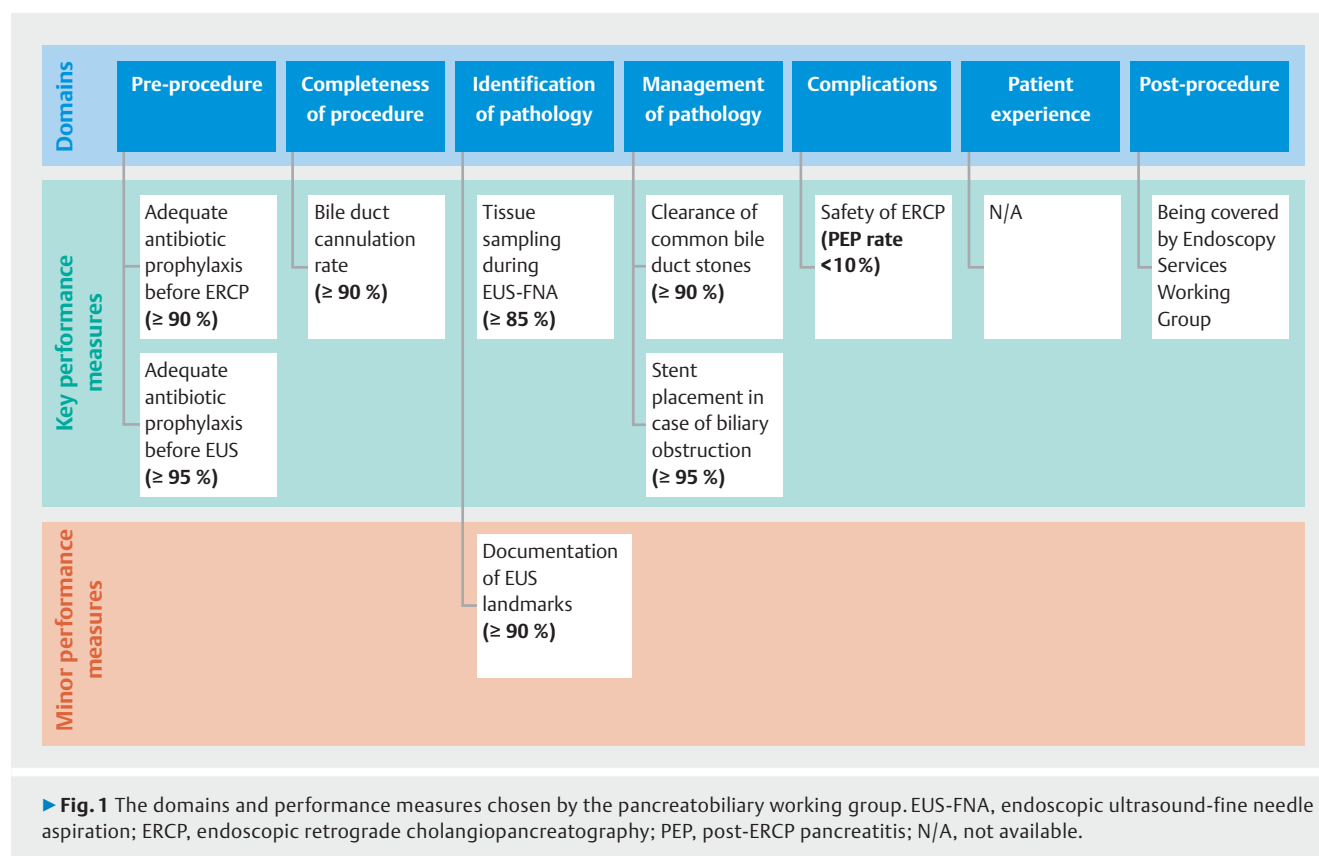
The European Society of Gastrointestinal Endoscopy (ESGE) and United European Gastroenterology (UEG) have identified quality of endoscopy as a major priority. The rationale for this priority and the methodology of the quality initiative process have been described elsewhere [1]. The aim of the ESGE pancreatobiliary endoscopy working group was to identify a list of key performance measures for EUS and ERCP that would be universally applicable. As with previous ESGE performance measures [2,3] the focus was on metrics that met the following requirements: proven impact on clinically relevant outcomes or quality of life; well-defined, and amenable to simple and robust measurement; and applicability to all levels of endoscopy services. This paper describes the methodological process utilized [1] and reports the agreed list of key performance measures for pancreatobiliary endoscopy.

Methodology

The multistep process of the methodology for developing performance measures has been described previously [1]. During initial meetings of the working group, a PICO approach (where P stands for Population/Patient; I for Intervention/Indicator; C for Comparator/Control; and O for Outcome) was used to define clinically relevant questions. Systematic literature searches were then performed by an expert team of methodologists. This in turn led to the development of performance measures in a consensus process.

The PICOs and the clinical statements derived from these were modified or excluded during iterative rounds of discussion of the working group members during a Delphi process [4]

In total, working group members participated in two rounds of voting to agree on performance measures in predefined domains and on their respective thresholds, discussed below. Statements were modified during the process and ultimately discarded if agreement was not reached after two voting



rounds. The agreement that is given for the different statements refers to the last voting round in the Delphi process. The threshold for agreement was set at 80% throughout the process. The key performance measures were distinguished from minor performance measures on the basis of the ISFU criteria [1] (Importance, Scientific acceptability, Feasibility, Usability, and comparison with competing measures), and expressed by mean voting scores. We used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system to assess the quality of the available evidence [5].

Performance measures for pancreatobiliary endoscopy

Using the evidence derived by the literature search group and input from the working group members, a total of 10 clinical statements addressing 8 potential performance measures grouped into five of the seven predefined quality domains were formulated. Over the course of two voting rounds, a consensus agreement was reached for 8 statements regarding 8 performance measures; 7 are considered to be key performance measures and one a minor performance measure. The development process for performance measures can be reviewed in the Supporting information (available online).

We used the highest mean voting scores to identify 7 key performance measures for five of the seven quality domains (► **Fig. 1**). As mentioned above, the remaining performance

measure was considered to be a minor performance measure. The pre-procedure domain and management of pathology domain each had 2 performance measures. All performance measures were deemed valuable by the working group members and were obtained after a rigorous process as described above. The use of appropriate endoscopy reporting systems is crucial for facilitating data retrieval on identified performance measures [6].

All the performance measures are presented below, according to domain, using the descriptive framework developed by the quality improvement committee (QIC) and with a short summary of evidence for the ISFU criteria. Each table describes a performance measure, the level of agreement during the modified Delphi process (scores), how the performance measure should be calculated, and recommendations supporting its adoption. The tables also note the desired thresholds.

The minimum number needed to assess whether the threshold for a certain performance measure has been reached can be calculated by estimating the 95% confidence intervals (CI) around the predefined threshold for different sample sizes [3, 7]. As with previous ESGE performance measures, for issues of practicality and to simplify implementation and auditing, we suggest that at least 100 consecutive procedures (or all of them if fewer than 100 procedures are performed) should be measured to assess a performance measure. Continuous monitoring is however the preferred method of measurement.

1 Domain: Pre-procedure

Key performance measure	Adequate antibiotic prophylaxis before ERCP
Description	The percentage of patients with adequate administration of prophylactic antibiotics before ERCP.
Domain	Pre-procedure
Category	Process
Rationale	Reduction of infection, prevention of inappropriate antibiotic use
Construct	<p>Denominator: Patients with indication for antibiotic prophylaxis</p> <p>Numerator: Patients receiving antibiotics</p> <p>Exclusions: Patients who are on ongoing antibiotic treatment</p> <p>Calculation: Proportion (%)</p> <p>Level of analysis: Service and endoscopist level</p> <p>Frequency: Yearly audit of a sample of 100 consecutive cases</p>
Standards	Minimum standard: 90 % Target standard: 95 %
Consensus agreement for performance measure	100 %
PICO number (see Supporting information)	3.1
Evidence grading	Low quality evidence

The acceptance of this performance measure is based on agreement with the following statement:

- Routine antibiotic prophylaxis is not recommended for ERCP in unselected patients. Antibiotic prophylaxis should be given before ERCP for the subgroup of patients with predicted incomplete biliary drainage, e.g. those with primary sclerosing cholangitis (PSC) and hilar tumors; to immunocompromised individuals and to patients with pancreatic pseudocysts communicating with the pancreatic duct. (Statement number 7.2)

Adherence to recommendations on prophylactic antibiotics before ERCP [8] should be monitored and reasons for deviation documented. The indication for antibiotic prophylaxis should be recorded in the endoscopy report.

Routine antibiotic prophylaxis is not recommended for ERCP in unselected patients as prophylactic antibiotics do not significantly reduce cholangitis in this setting. A systematic review of RCTs [9] reported that antibiotics did not significantly prevent cholangitis in unselected patients.

A Cochrane systematic review of RCTs [10] concluded that prophylactic antibiotics reduced cholangitis; however, in patients in whom biliary obstruction was relieved there was no benefit in using prophylactic antibiotics.

Key performance measure	Antibiotic prophylaxis before EUS-guided puncture of cystic lesions
Description	The percentage of patients with prophylactic antibiotics before EUS-guided puncture of cystic lesions
Domain	Pre-procedure
Category	Process
Rationale	Patient safety, reduction of infection following EUS-fine needle aspiration (EUS-FNA)
Construct	<p>Denominator: Patients undergoing EUS-FNA in cystic lesions</p> <p>Numerator: Patients in denominator receiving antibiotics</p> <p>Exclusions: Patients who are on ongoing antibiotic treatment</p> <p>Calculation: Proportion (%)</p> <p>Level of analysis: Service and, if necessary, endoscopist level</p> <p>Frequency: Yearly, for a sample of 50 consecutive EUS-FNAs. If the minimum standard is not reached, analysis on an individual level should be performed.</p>
Standards	Minimum standard: 95 % Target standard: 95 %
Consensus agreement for performance measure	90 %
PICO number (see Supporting information)	3.2
Evidence grading	Very low quality of evidence

The acceptance of this performance measure is based on agreement with the following statement:

- Prophylactic antibiotic administration should be performed before EUS-guided puncture of cystic lesions in ≥95 % of cases. (Statement number 8.1)

The percentage of patients with administration of prophylactic antibiotics before EUS-guided puncture of cystic lesions should be at least 95 % (minimum standard). In general, antibiotic prophylaxis should be used; the reason for any deviation (patient intolerance, patient preference etc.) should be reported.

The rate of infectious complications following EUS-guided puncture of cystic lesions is low [11, 12]. There are no systematic reviews or RCTs comparing antibiotics with no antibiotics before EUS-guided puncture of cystic lesions although one study compared two regimens of antibiotics [13], and two retrospective cohort studies [14, 15] focused exclusively on pancreatic cystic lesions. The study by Kwok and colleagues [13], in which 117 patients were screened over an 11-month period, lacked statistical significance however, since only 22 % of screened patients could be enrolled. The observed rate of cyst infection was zero. An adequately powered study to test non-inferiority of withholding antibiotics in this setting would likely

be logistically challenging since the authors calculated that inclusion of between 614 and 2450 patients would be needed. Current ESGE [16] and American Society for Gastrointestinal Endoscopy (ASGE) [8] guidelines recommend the use of prophylactic antibiotics for the EUS-guided puncture of cystic lesions although data are equivocal [14]. In addition, the use of prophylactic antibiotics might not be free of adverse events.

2 Domain: Completeness of procedure

Key performance measure	Bile duct cannulation rate
Description	The percentage of successful bile duct cannulations in patients with normal anatomy (and native papilla)
Domain	Completeness of procedure
Category	Process
Rationale	Successful biliary ERCP requires deep cannulation of the common bile duct via the major duodenal papilla. A low bile duct cannulation rate is associated with a delay in definitive therapy and increased risk of adverse events, and leads to increased costs and inconvenience as the examination has to be repeated or recourse made to alternative therapeutic techniques
Construct	<p>Denominator: All procedures in patients with normal anatomy</p> <p>Numerator: Procedures that document successful biliary cannulation (report and fluoroscopy)</p> <p>Exclusions: Procedures with no indication for biliary cannulation. Previous biliary sphincterotomy</p> <p>Calculation: Proportion (%)</p> <p>Level of analysis: Service and endoscopist level</p> <p>Frequency: Yearly audit of a sample of 100 consecutive cases</p> <p>Successful bile duct cannulation, meaning deep cannulation of the common bile duct via the major duodenal papilla, should be documented in a written report as well as in fluoroscopy documentation</p>
Standards	Minimum standard: 90 % Target standard: 95 % (in expert centers)
Consensus agreement for performance measure	100 %
PICO number (see Supporting Information)	1.17
Evidence grading	Low quality evidence

The acceptance of this performance measure is based on agreement with the following statement:

- In patients with normal anatomy and native papilla, bile duct cannulation should be achieved in at least 90 % of cases using all available techniques. (Statement number 1.1)

Technical success at biliary ERCP is predicated on successful deep cannulation of the desired duct. Success or failure of cannulation should be documented in the post-procedure report for all cases. In certain clinical scenarios, e.g. pyloric or duodenal stenosis and post-surgical altered anatomy, conventional ERCP may be impossible and such cases are not included in this performance measure. In addition, patients with prior sphincterotomy should not be included in the calculation of cannulation rate. There are a number of potential determinants of successful cannulation of a native papilla, including endoscopist experience and case mix. The literature predominantly reports outcomes from academic centers, where case mix and experience may differ from other settings. The included studies reported cannulation rates from 70.5 % to 100 % [17–43] with a median of 96 % and mean of 91.4 %. The consensus of the working party was that a competent ERCP practitioner should achieve a cannulation rate in excess of 90 % with a target standard of 95 % at expert centers. ESGE guidance on different techniques is available [44].

During the voting process (second voting round), members of the pancreatobiliary working group discussed whether this performance measure (bile duct cannulation rate) should be extended and be adopted to both duct systems in the pancreatobiliary system – the common bile duct and the pancreatic duct – by stating “cannulation rate of desired duct.” However, to our knowledge, there are no data which would support adopting such a performance measure.

3 Domain: Identification of pathology

Key performance measure	Tissue sampling during EUS
Description	Frequency of obtaining a diagnostic tissue sample in EUS-FNA or EUS-fine needle biopsy (FNB) of solid lesions
Domain	Procedure
Category	Process
Rationale	Improve technical success of EUS-FNA/FNB of solid lesions
Construct	<p>Denominator: All EUS-FNAs of solid lesions performed</p> <p>Numerator: Successful acquisition of diagnostic tissue of solid lesions during EUS</p> <p>Exclusions: Patients with post-surgery altered anatomy</p> <p>Calculation: Proportion (%)</p> <p>Level of analysis: Service and endoscopist level</p> <p>Frequency: Yearly, for a sample of 50 consecutive EUS-FNAs. If the minimum standard is not reached, analysis on an individual level should be performed</p>

Key performance measure	Tissue sampling during EUS
Standards	Minimum standard: 85 % Target standard: 90 %
Consensus agreement for performance measure	90 %
PICO number (see Supporting Information)	1.21
Evidence grading	Very low quality of evidence

The acceptance of this performance measure is based on agreement with the following statement:

- In patients with solid lesions undergoing EUS-FNA, the frequency of obtaining a full diagnostic tissue sample should be $\geq 85\%$. (Statement number 5.1)

The percentage of patients in which a full diagnostic tissue sample, meaning a tissue sample allowing an accurate diagnosis, is obtained in EUS-FNA of solid lesions should be documented. The frequency of successful EUS-FNA of a solid lesion should be at least 85 % (minimum standard); ESGE proposes a target standard of 90 %.

Since the evidence is of very low quality, this recommendation is to be considered as expert opinion. Although the evidence is scarce as regards the available literature [45–56], we consider the clinical issue of successful tissue sampling to be a major element in EUS. Based on the impact of EUS-fine needle puncture, whether performed as aspiration (FNA) or biopsy (FNB), we feel that this clinical quality indicator must be used as a key performance measure.

Minor performance measure	Adequate documentation of EUS landmarks
Description	Percentage of EUS reports that contain appropriate documentation of relevant landmarks
Domain	Identification of pathology
Category	Process
Rationale	Ensure comprehensive identification of pathology
Construct	<p>Denominator: All EUS procedures Numerator: EUS procedures where the landmark documentation is adequate Exclusions: EUS-guided therapy. Sampling of well-defined lesions where further anatomical overview is irrelevant</p> <p>Calculation: Proportion (%) Level of analysis: Service and, if necessary, individual Frequency: Yearly, for a sample of 50 consecutive EUS procedures. If the minimum standard is not reached, analysis on an individual level should be performed</p>

Minor performance measure	Adequate documentation of EUS landmarks
Standards	Minimum standard: 90 % Target standard: 90 %
Consensus agreement for performance measure	100 %
PICO numbers (see Supporting Information)	2.1–2.4
Evidence grading	Very low quality of evidence (expert opinion)

The acceptance of this performance measure is based on agreement with the following statement:

- Appropriate landmarks should be documented in $\geq 90\%$ of cases in patients undergoing EUS. (Statement 6.1)

The components of a complete EUS investigation will vary depending on the indications for the procedure. In many cases, however, the visualization and documentation of standardized landmarks give a measure of the quality of the procedure. Documentation of the appropriate landmarks includes detailed description in the patient record of the endosonographic findings of the EUS procedure, and ideally, procedure quality will be enhanced by image documentation of normal or diseased landmarks. Such reporting forms the basis of the quality indicator. Although EUS is not indicated for staging of metastatic tumors, which might have been previously documented by other imaging modalities, there are clinical settings in which EUS may be indicated nevertheless, for example if therapeutic decision making is based on EUS findings, or if EUS-FNA is used to obtain a full diagnostic tissue sample (see domain above, Identification of pathology) which may change the further management of the patient.

There are few data supporting the specification of the landmarks required for a high quality report, but the selection of landmarks surely relates to the indication for the procedure. The QIC working group agreed that, depending on the indication for EUS, the landmarks shown in ► **Table 1** should be evaluated during the EUS procedure and the assessment recorded afterwards. This includes a written report and documentation of the relevant images.

In 2015, an ASGE–American College of Gastroenterology (ACG) task force published a work on quality indicators for EUS [58]. The authors stated that inclusion of the indication for EUS in the procedural documentation for all cases is a useful quality measure for two reasons. First, it may provide a justification for the procedure, serving as a means of tracking compliance with accepted indications. Second, the indication puts the procedure report into a context wherein reporting of certain EUS landmarks and finding characteristics should logically follow. For example, a detailed description of the pancreatobiliary system may not be necessary when the indication for EUS is staging of esophageal cancer. If the indication for the EUS examination is

► **Table 1** Landmarks to be assessed at endoscopic ultrasound (EUS) according to the indication for the procedure.

Indication for EUS	Relevant landmarks for visualization and documentation
Mediastinal lesion/ Esophageal cancer	Mass/tumor Mediastinum (lymph nodes) Gastroesophageal junction Celiac axis (lymph nodes) Left lobe of the liver (to rule out metastatic disease)
Subepithelial tumor	Subepithelial mass including the affected wall layers Regional lymph nodes Vascular infiltration Infiltration of surrounding organs (e. g. liver, pancreas)
Pancreatobiliary cancer	Entire pancreas including pancreatic mass (tumor, cancer) Biliary tract (common bile duct, cystic duct, gallbladder) Local lymph nodes (peripancreatic) Celiac axis (lymph nodes) Left lobe of the liver and visible parts of the right lobe (to rule out metastatic disease) Vascular infiltration: superior mesenteric artery, superior mesenteric vein, portal vein Infiltration of other peripancreatic organs
Rectal cancer	Tumor including its location, expansion, infiltration of surrounding structures Surrounding structures: genitourinary structures, iliac vessels, sphincter apparatus, lymph nodes

staging of esophageal cancer, certain landmarks should be included (uT-stage and uN-stage, including celiac axis visualization). The exception to this is in the case of failed passage of a stenosed stricture when the tumor cannot be safely passed.

4 Domain: Management of pathology

Key performance measure	Appropriate stent placement in patients with biliary obstruction below the hilum
Description	Percentage of successful stent placements in cases of strictures located below the liver hilum, after successful cannulation
Domain	Completeness of procedure
Category	Process
Rationale	Unsuccessful stent placement is associated with an increased risk of cholangitis and entails further health care costs and potential hospitalization.

Key performance measure	Appropriate stent placement in patients with biliary obstruction below the hilum
Construct	Denominator: All ERCPs in patients with subhilar biliary strictures requiring stent placement, after successful cannulation Numerator: Successful stent placement Calculation: Proportion (%) Level of analysis: Service and endoscopist level Frequency: Yearly audit
Standards	Minimum standard: 95 % Target standard: 95 %
Consensus agreement for performance measure	90 %
PICO number (see Supporting Information)	1.19
Evidence grading	Low quality evidence

The acceptance of this performance measure is based on agreement with the following statement:

- After successful cannulation, stent placement should be achieved in $\geq 95\%$ of cases in patients with biliary obstruction below the hilum. (Statement number 3.1)

This statement refers to placement of plastic or metal stents. Subhilar strictures are the type most commonly encountered in daily practice. Stent placement in patients with obstruction below the hilum is technically less challenging than placement for obstruction at or above the hilum, with high success rates reported [59,60].

Indications include failure to clear bile duct stones, and the presence of biliary strictures of benign or malignant origin. Competent ERCP practitioners should achieve successful subhilar stent placement in at least 95 % of cases.

Key performance measure	Bile duct stone extraction
Description	Adequate removal of bile duct stones (< 10 mm) utilizing a retrieval balloon or basket
Domain	Management of pathology
Category	Process
Rationale	Incomplete stone extraction increases the risk of cholangitis and entails further health care costs and potential hospitalization.

Key performance measure	Bile duct stone extraction
Construct	Denominator: All ERCPs for patients with bile duct stones of <10 mm in diameter (after successful cannulation of the common bile duct) Numerator: Successful stones removal Calculation: Proportion (%) Level of analysis: Service and endoscopist level Frequency: Yearly audit of a sample of 100 consecutive cases
Standards	Minimum standard: 90 % Target standard: 95 % (in expert centers)
Consensus agreement for performance measure	90 %
PICO number (see Supporting Information)	1.18
Evidence grading	Low quality evidence

The acceptance of this performance measure is based on agreement with the following statement:

- After successful cannulation, clearance of bile duct stones <10 mm should be achieved in at least 90 % of cases. (Statement number 2.1)

The endoscopy report should provide details about size, number, and position of stones in the bile duct, and whether they were successfully cleared from the duct. All relevant findings, such as the presence of a stricture, should also be recorded.

A range of techniques and devices, including balloon/basket extraction, balloon dilation of the ampulla, and mechanical lithotripsy, are available for clearance of stones from the bile duct with high success rates reported for stones smaller than 10 mm in size [61,62]. Competent ERCP practitioners should be able to achieve a duct clearance rate in excess of 90 %.

5 Domain: Adverse events and harms

Key performance measure	Post-ERCP pancreatitis (PEP)
Description	Rate of PEP diagnosed according to consensus definition [63]
Domain	Procedure
Category	Process
Rationale	Pancreatitis is the most frequent complication of ERCP and potentially life-threatening. The rate of PEP is a surrogate quality indicator for performance of ERCP

Key performance measure	Post-ERCP pancreatitis (PEP)
Construct	Denominator: All procedures Numerator: Cases in which acute pancreatitis develops Exclusions: Patients with post-surgical altered anatomy Calculation: Proportion (%) Level of analysis: Service and endoscopist level Frequency: Yearly audit of a sample of 100 consecutive cases. Rate of pancreatitis should be evaluated according to the case mix
Standards	Minimum standard: <10 % Target standard: <5 %
Consensus agreement for performance measure	100 %
PICO number (see Supporting Information)	1.7
Evidence grading	Low quality evidence

The acceptance of this performance measure is based on agreement with the following statement:

- The rate of post-ERCP pancreatitis should be less than 10 %. (Statement number 4.1)

Post-ERCP pancreatitis (PEP) is the most common adverse event following ERCP and is therefore the most appropriate indicator of adverse event rate. There are a number of well-recognized risk factors, including female sex, normal bilirubin, and previous PEP. A recent systematic review of randomized controlled trials documented an overall PEP rate of 9.7 % with a rate of 14.7 % in high risk patients [64]. Large observational studies have reported rates of between 2.7 % and 5.1 % [65–68]. A minimum standard of <10 % adverse event rate (pancreatitis) is therefore recommended, with a target standard of 5 %. At audit, the rate of pancreatitis should be evaluated in terms of case mix. ESGE recommends PEP prophylaxis using rectal non-steroidal anti-inflammatory drug (NSAID) administration for all patients in whom a contraindication does not exist, and consideration of placement of pancreatic duct stents in high risk cases [69]. The working group suggests the documentation of use of rectal NSAIDs and prophylactic pancreatic duct stenting, to facilitate root cause analysis in severe cases of pancreatitis and to investigate reasons why this performance measure might not be reached.

General conclusions, research priorities, and future prospects

These performance measures, generated by evidence-based consensus, can be used for pancreatobiliary endoscopy, including ERCP and EUS (in general, as applied for large parts of the GI tract). We used a systematic and scientifically based methodology to substantiate the proposed measures with available evidence where possible. As this is a largely unexplored field, most of the evidence found was, as expected, graded as low quality. This generated important research priorities, primarily to audit the proposed performance measures and to evaluate whether they do in fact influence health outcome. Service providers would then be responsive to the findings and change practice. Furthermore, the working group identified several additional research priorities; these are listed in ► **Table 2** (ERCP) and ► **Table 3** (EUS) and will be addressed in a paper from the ESGE Research Committee.

This manuscript, like the other ESGE quality improvement papers, is a working document that will be used, it is hoped, by national member societies to determine which performance measures can feasibly be monitored in the setting of their countries and which measures are relevant. The first task now is to implement these new performance measures into endoscopy practice throughout Europe on a national basis. This is in order to determine the value of setting performance measures, to allow audit against such measures, and, in the light of audit findings, to permit responsive adaptation of performance measures in the future.

The implementation of performance measures is important to identify services and individual endoscopists with lower performance levels. Obviously, there are no legal implications associated with the ESGE QIC Initiative since these documents are not guidelines but are rather guidance on how quality can be monitored for all aspects of GI endoscopy.

The aim of setting performance measures is to improve the quality of endoscopy, and we encourage individual endoscopists, as well as heads of endoscopy units, to implement these performance measures without delay. Since the techniques of ERCP and EUS, belong to the most sophisticated endoscopic examinations, with a flat learning curve, performance measures should be put in place as soon as possible to monitor endoscopist and endoscopy unit performance. At a unit level, this may mean investing in hardware to accommodate a more efficient auditing process.

Through such feedback, measures can be taken to improve quality, to rise above the proposed minimum thresholds. This should not be considered as a “1984”-like scenario with the goal of penalizing specific endoscopists, but rather as a tool to improve patient outcomes, and provide training and assistance to endoscopists where needed. A second barrier may be the perceived financial implications of establishing a quality control system. The aim is to encourage hospital management to support the implementation of these performance measures in endoscopy services. We think that in an era where hospital

► **Table 2** Research priorities identified by the pancreatobiliary working group for quality improvement performance measures: endoscopic retrograde cholangiopancreatography (ERCP).

Prophylaxis of post-ERCP pancreatitis: Value of pancreatic duct stenting vs. NSAIDs?
Where and when (early/late) is precut indicated and safe?
How to manage benign pancreatic strictures?
Is ERCP-radiofrequency ablation (RFA) safe and effective for palliative cancer treatment?
What is the optimal endoscopic approach to access the biliary tree in in patients with altered anatomy?

► **Table 3** Research priorities identified by the pancreatobiliary working group for quality improvement performance measures: endoscopic ultrasonography (EUS).

What are the thresholds for accurate T and N staging of GI malignancies?
How does the accurate description of landmarks influence quality of EUS staging?
How can the results of EUS-fine needle aspiration (FNA) (tissue sampling) and fine needle biopsy (FNB) be improved? <ul style="list-style-type: none"> Value of rapid on-site cytological evaluation (ROSE) Formal EUS-FNA teaching classes/curriculum Clinical cytology for endoscopists
Therapeutic EUS <ul style="list-style-type: none"> Management (ablation) of cystic neoplasias of the pancreas Endosonography-guided ablation therapy and implantation of diagnostic material (fiducial placement) Interventional endosonographic drainage procedures (e. g., randomized controlled trial on EUS-biliary drainage vs. percutaneous transhepatic choledochal drainage [PTCD]) Endosonography-guided therapy of acute cholecystitis
How do we improve noninvasive diagnostic methods (e. g. contrast-enhanced EUS, 3D-reconstruction) for differential diagnosis of pancreatic cancer and non-neoplastic diseases?
What is the optimal endoscopic approach to access the biliary tree in in patients with altered anatomy?
What are the roles of MRCP, ERCP, and EUS in purely diagnostic clinical questions?
MRCP, magnetic resonance cholangiopancreatography.

accreditation is becoming more important, hospital administrations will be more inclined to support such actions.

Moreover, we owe it to our patients to overcome individual or financial barriers to ensure that endoscopy services are of the highest quality, and to set research priorities to gather data that will inform the next generation of performance measures (► **Table 4**).

► **Table 4** Performance measures to be included in the future for quality improvement in endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasonography (EUS).

Application of NSAIDs for prevention of post-ERCP pancreatitis
Documentation of relevant structures specific to the indication for EUS examination
Completeness of ERCP documentation (endoscopic and radiological images)
Radiation exposure and protection (staff and patient)
Accuracy of T and N staging for cancer
Cost – effectiveness of diagnostic and therapeutic cholangioscopy (is there an overuse of cholangioscopy?)
Patient involvement in discussing performance measures
NSAIDs, nonsteroidal anti-inflammatory drugs

Supporting information

The detailed literature searches performed by an expert team of methodologists, as well as evolution and adaptation of the different PICO's and clinical statements during the Delphi voting process can be viewed in Supporting Information on the ESGE website.

online content viewable at:

<https://www.esge.com/performance-measures-for-ercp-and-eus.html>

Acknowledgments

The authors gratefully acknowledge the contributions from the following: Dr. Stuart Gittens, of ECD Solutions, for the development and running of the web platform; Iwona Escreet and all at Hamilton Services for project administrative support; the Scottish Intercollegiate Guidelines Network for hosting the critical appraisal module; and the Research Foundation-Flanders (FWO) for providing funding for Professor Raf Bisschops. UEG supplied co-funding and additional project governance to this endeavor.

Competing interests

C. Bennett owns and works for Systematic Research Ltd, and received a consultancy fee from ESGE to provide scientific, technical, and methodological expertise for the present project (2014–2018). **R. Bisschops** has received speaker's fees from Covidien (2009–2014) and Fujifilm (2013); speaker's fee and hands-on training sponsorship from Olympus Europe (2013–2014); speaker's fee and research support from Pentax Europe; and an editorial fee from Georg Thieme Verlag as co-editor of *Endoscopy*. **M. Bretthauer** receives fees as a member of the Norwegian Government colorectal cancer screening advisory group (2012 to present) and receives fees from the American College of Physicians for editorial work for *Annals of Internal Medicine*. **M. Dinis-Ribeiro** receives fees from Georg Thieme Verlag for editorial work for *Endoscopy*. **M. Kaminski** receives speaker's and teaching fees and travel support from Olympus Erbe.

T. Ponchon receives funds for clinical research from Boston Scientific and Fujifilm; and workshop fees from Olympus. **C. Senore's** department received PillCam2 Colon devices from Medtronic (2014–2017) for a comparative study; together with **C. Belissario** and **S. Minozzi** he received a consultancy fee from ESGE to provide methodological expertise (PICO's evaluation, literature searches, and evidence summaries) for the present project (2014–2017). **R. Valori** is a director of AnderVal Ltd, a company providing endoscopy skills training (2015 to present). **L. Aabakken**, **L. Czako**, **D. Domagk**, **T. Gyökeres**, **C. Hassan**, **G. Manes**, **P.N. Meier**, **K. Oppong**, **J.-W. Poley**, **C. J. Rees**, **M. Rutter**, **C. Spada**, and **A. Tringali** have no competing interests.

References

- [1] Rutter M, Senore C, Bisschops R et al. The European Society of Gastrointestinal Endoscopy Quality Improvement Initiative: developing performance measures. *Endoscopy* 2015; 48: 81–89
- [2] Kaminski M, Thomas-Gibson S, Bugajski M et al. Performance measures for lower gastrointestinal endoscopy: a European Society of Gastrointestinal Endoscopy (ESGE) Quality Improvement Initiative. *Endoscopy* 2017; 49: 378–397
- [3] Bisschops R, Areia M, Coron E et al. Performance measures for upper gastrointestinal endoscopy: a European Society of Gastrointestinal Endoscopy (ESGE) Quality Improvement Initiative. *Endoscopy* 2016; 48: 843–864
- [4] Linstone HA, Turoff M 2nd edition The Delphi method – Techniques and applications. 2002: doi:10.2307/1268751 <https://web.njit.edu/~turoff/pubs/delphibook/delphibook.pdf>
- [5] Guyatt GH, Oxman AD, Vist GE et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ* 2008; 336: 924–926
- [6] Bretthauer M, Aabakken L, Dekker E et al. Requirements and standards facilitating quality improvement for reporting systems in gastrointestinal endoscopy: European Society of Gastrointestinal Endoscopy (ESGE) Position statement. *Endoscopy* 2016; 48: 291–294
- [7] Do A, Weinberg J, Kakkar A et al. Reliability of adenoma detection rate is based on procedural volume. *Gastrointest Endosc* 2013; 77: 376–380
- [8] Khashab MA, Chithadi KV, Acosta RD et al. Antibiotic prophylaxis for GI endoscopy. *Gastrointest Endosc* 2015; 81: 81–89
- [9] Bai Y, Gao F, Gao J et al. Prophylactic antibiotics cannot prevent endoscopic retrograde cholangiopancreatography-induced cholangitis: a meta-analysis. *Pancreas* 2009; 38: 126–130
- [10] Brand M, Bizo D, O'Farrell PJ. Antibiotic prophylaxis for patients undergoing elective endoscopic retrograde cholangiopancreatography. *Cochrane Database Syst Rev* 2010: CD007345 doi:10.1002/14651858.CD007345.pub2
- [11] O'Toole D, Palazzo L, Arotçarena R et al. Assessment of complications of EUS-guided fine-needle aspiration. *Gastrointest Endosc* 2001; 53: 470–474
- [12] Lee LS, Saltzman JR, Bounds BC et al. EUS-guided fine needle aspiration of pancreatic cysts: a retrospective analysis of complications and their predictors. *Clin Gastroenterol Hepatol* 2005; 3: 231–236
- [13] Kwok K, Chang JC, Lim BS et al. Sa1419 A pilot study on the use of prophylactic antibiotics for EUS-guided pancreatic cyst aspiration. *Gastrointest Endosc* 2015; 81: AB207 doi:10.1016/j.gie.2015.03.190
- [14] Guarner-Argente C, Shah P, Buchner A et al. Use of antimicrobials for EUS-guided FNA of pancreatic cysts: a retrospective, comparative analysis. *Gastrointest Endosc* 2011; 74: 81–86
- [15] Rivera R, Ray A, Zacharia G. Endoscopic ultrasound-guided fine needle aspiration of pancreatic cysts with and without antibiotic prophylaxis. *Am J Gastroenterol* 2010; 105: S572–S509

- [16] Polkowski M, Jenssen C, Kaye P et al. Technical aspects of endoscopic ultrasound (EUS)-guided sampling in gastroenterology: European Society of Gastrointestinal Endoscopy (ESGE) Technical Guideline – March 2017. *Endoscopy* 2017; 49: 989–1006
- [17] Bailey A, Bourke M, Williams S et al. A prospective randomized trial of cannulation technique in ERCP: effects on technical success and post-ERCP pancreatitis. *Endoscopy* 2008; 40: 296–301
- [18] Coté GA, Ansstas M, Pawa R et al. Difficult biliary cannulation: use of physician-controlled wire-guided cannulation over a pancreatic duct stent to reduce the rate of precut sphincterotomy (with video). *Gastrointest Endosc* 2010; 71: 275–279
- [19] Kawakami H, Maguchi H, Mukai T et al. A multicenter, prospective, randomized study of selective bile duct cannulation performed by multiple endoscopists: the BIDMEN study. *Gastrointest Endosc* 2012; 75: 362–372
- [20] Kubota K, Sato T, Kato S et al. Needle-knife precut papillotomy with a small incision over a pancreatic stent improves the success rate and reduces the complication rate in difficult biliary cannulations. *J Hepatobiliary Pancreat Sci* 2013; 20: 382–388
- [21] Lopes L, Dinis-Ribeiro M, Rolanda C. Safety and efficacy of precut needle-knife fistulotomy. *Scand J Gastroenterol* 2014; 49: 759–765
- [22] Miao L, Li Q-P, Zhu M-H et al. Endoscopic transpancreatic septotomy as a precutting technique for difficult bile duct cannulation. *World J Gastroenterol* 2015; 21: 3978–3982
- [23] Nakai Y, Isayama H, Sasahira N et al. Risk factors for post-ERCP pancreatitis in wire-guided cannulation for therapeutic biliary ERCP. *Gastrointest Endosc* 2015; 81: 119–126
- [24] Panteris V, Vezakis A, Filippou G et al. Influence of juxtaepapillary diverticula on the success or difficulty of cannulation and complication rate. *Gastrointest Endosc* 2008; 68: 903–910
- [25] Park CS, Park CH, Koh HR et al. Needle-knife fistulotomy in patients with periampullary diverticula and difficult bile duct cannulation. *J Gastroenterol Hepatol* 2012; 27: 1480–1483
- [26] Parlak E, Suna N, Kuzu UB et al. Diverticulum with papillae: does position of papilla affect technical success? *Surg Laparosc Endosc Percutan Tech* 2015; 25: 395–398
- [27] Peng C, Nietert PJ, Cotton PB et al. Predicting native papilla biliary cannulation success using a multinational endoscopic retrograde cholangiopancreatography (ERCP) quality network. *BMC Gastroenterol* 2013; 13: 147
- [28] Rajnakova A, Goh PM, Ngoi SS et al. ERCP in patients with periampullary diverticulum. *Hepatogastroenterology* 2003; 50: 625–628
- [29] Fukatsu H, Kawamoto H, Kato H et al. Evaluation of needle-knife precut papillotomy after unsuccessful biliary cannulation, especially with regard to postoperative anatomic factors. *Surg Endosc* 2008; 22: 717–723
- [30] Ramesh J, Kim H, Reddy K et al. Impact of pancreatic stent caliber on post-endoscopic retrograde cholangiopancreatogram pancreatitis rates in patients with confirmed sphincter of Oddi dysfunction. *J Gastroenterol Hepatol* 2014; 29: 1563–1567
- [31] Sasahira N, Kawakami H, Isayama H et al. Early use of double-guide-wire technique to facilitate selective bile duct cannulation: the multicenter randomized controlled EDUCATION trial. *Endoscopy* 2015; 47: 421–429
- [32] Testoni PA, Giussani A, Vailati C et al. Precut sphincterotomy, repeated cannulation and post-ERCP pancreatitis in patients with bile duct stone disease. *Dig Liver Dis* 2011; 43: 792–796
- [33] Tham TC, Kelly M. Association of periampullary duodenal diverticula with bile duct stones and with technical success of endoscopic retrograde cholangiopancreatography. *Endoscopy* 2004; 36: 1050–1053
- [34] Tsuchiya T, Itoi T, Maetani I et al. Effectiveness of the J-tip guidewire for selective biliary cannulation compared to conventional guidewires (The JANGLE Study). *Dig Dis Sci* 2015; 60: 2502–2508
- [35] Vihervaara H, Grönroos JM. Feasibility of the novel 3-step protocol for biliary cannulation – a prospective analysis. *Surg Laparosc Endosc Percutan Tech* 2012; 22: 161–164
- [36] Zhang Q-S, Han B, Xu J-H et al. Needle-knife papillotomy and fistulotomy improved the treatment outcome of patients with difficult biliary cannulation. *Surg Endosc* 2016; 30: 5506–5512
- [37] Geraci G, Modica G, Sciumè C et al. Intradiverticular ampulla of Vater: personal experience at ERCP. *Diagn Ther Endosc* 2013; 2013: 1–4
- [38] Halttunen J, Kylänpää L. A prospective randomized study of thin versus regular-sized guide wire in wire-guided cannulation. *Surg Endosc* 2013; 27: 1662–1667
- [39] Halttunen J, Meisner S, Aabakken L et al. Difficult cannulation as defined by a prospective study of the Scandinavian Association for Digestive Endoscopy (SADE) in 907 ERCPs. *Scand J Gastroenterol* 2014; 49: 752–758
- [40] Holt BA, Hawes R, Hasan M et al. Biliary drainage: role of EUS guidance. *Gastrointest Endosc* 2016; 83: 160–165
- [41] Huang L, Yu Q, Zhang Q et al. Comparison between double-guidewire technique and transpancreatic sphincterotomy technique for difficult biliary cannulation. *Dig Endosc* 2015; 27: 381–387
- [42] Ito K, Horaguchi J, Fujita N et al. Clinical usefulness of double-guide-wire technique for difficult biliary cannulation in endoscopic retrograde cholangiopancreatography. *Dig Endosc* 2014; 26: 442–449
- [43] Katsinelos P, Paroutoglou G, Kountouras J et al. A comparative study of standard ERCP catheter and hydrophilic guide wire in the selective cannulation of the common bile duct. *Endoscopy* 2008; 40: 302–307
- [44] Testoni PA, Mariani A, Aabakken L et al. Papillary cannulation and sphincterotomy techniques at ERCP: European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline. *Endoscopy* 2016; 48: 657–683
- [45] Aithal GP, Anagnostopoulos GK, Tam W et al. EUS-guided tissue sampling: comparison of “dual sampling” (Trucut biopsy plus FNA) with “sequential sampling” (Trucut biopsy and then FNA as required). *Endoscopy* 2007; 39: 725–730
- [46] Ardengh JC, Lopes CV, de Lima LFP et al. Cell block technique and cytological smears for the differential diagnosis of pancreatic neoplasms after endosonography-guided fine-needle aspiration. *Acta Gastroenterol Latinoam* 2008; 38: 246–251
- [47] Iglesias-Garcia J, Dominguez-Munoz JE, Abdulkader I et al. Influence of on-site cytopathology evaluation on the diagnostic accuracy of endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) of solid pancreatic masses. *Am J Gastroenterol* 2011; 106: 1705–1710
- [48] Jhala NC, Jhala D, Eltoum I et al. Endoscopic ultrasound-guided fine-needle aspiration biopsy: a powerful tool to obtain samples from small lesions. *Cancer* 2004; 102: 239–246
- [49] Alatawi A, Beuvon F, Grabar S et al. Comparison of 22G reverse-beveled versus standard needle for endoscopic ultrasound-guided sampling of solid pancreatic lesions. *United Eur Gastroenterol J* 2015; 3: 343–352
- [50] Baek HW, Park MJ, Rhee Y-Y et al. Diagnostic accuracy of endoscopic ultrasound-guided fine needle aspiration cytology of pancreatic lesions. *J Pathol Transl Med* 2015; 49: 52–60
- [51] Carrara S, Anderloni A, Jovani M et al. A prospective randomized study comparing 25-G and 22-G needles of a new platform for endoscopic ultrasound-guided fine needle aspiration of solid masses. *Dig Liver Dis* 2016; 48: 49–54
- [52] Cleveland P, Gill KRS, Coe SG et al. An evaluation of risk factors for inadequate cytology in EUS-guided FNA of pancreatic tumors and lymph nodes. *Gastrointest Endosc* 2010; 71: 1194–1199
- [53] Eloubeidi MA, Jhala D, Chhieng DC et al. Yield of endoscopic ultrasound-guided fine-needle aspiration biopsy in patients with suspected pancreatic carcinoma. *Cancer* 2003; 99: 285–292

- [54] Fritscher-Ravens A, Sriram PVJ, Krause C et al. Detection of pancreatic metastases by EUS-guided fine-needle aspiration. *Gastrointest Endosc* 2001; 53: 65–70
- [55] Fritscher-Ravens A, Sriram PVJ, Bobrowski C et al. Mediastinal lymphadenopathy in patients with or without previous malignancy: EUS-FNA-based differential cytodiagnosis in 153 patients. *Am J Gastroenterol* 2000; 95: 2278–2284
- [56] Hucl T, Wee E, Anuradha S et al. Feasibility and efficiency of a new 22G core needle: a prospective comparison study. *Endoscopy* 2013; 45: 792–798
- [57] Iglesias-Garcia J, Dominguez-Munoz JE, Abdulkader I et al. Influence of on-site cytopathology evaluation on the diagnostic accuracy of endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) of solid pancreatic masses. *Am J Gastroenterol* 2011; 106: 1705–1710
- [58] Wani S, Wallace MB, Cohen J et al. Quality indicators for EUS. *Gastrointest Endosc* 2015; 81: 67–80
- [59] Miao L, Fan Z, Ji G et al. Endoscopic stent for palliating malignant and benign biliary obstruction. *Chinese J Cancer Res* 2004; 16: 118–122
- [60] van Berkel A-M, Huibregtse IL, Bergman JJ et al. A prospective randomized trial of Tannenbaum-type Teflon-coated stents versus polyethylene stents for distal malignant biliary obstruction. *Eur J Gastroenterol Hepatol* 2004; 16: 213–217
- [61] Kuo C-M, Chiu Y-C, Changchien C-S et al. Endoscopic papillary balloon dilation for removal of bile duct stones: evaluation of outcomes and complications in 298 patients. *J Clin Gastroenterol* 2012; 46: 860–864
- [62] Oppong KW, Romagnuolo J, Cotton PB. The ERCP quality network benchmarking project: A preliminary comparison of practice in UK and USA. *Front Gastroenterol* 2012; 3: 157–161
- [63] Cotton PB, Lehman G, Vennes J et al. Endoscopic sphincterotomy complications and their management: an attempt at consensus. *Gastrointest Endosc* 1990; 37: 383–393
- [64] Kochar B, Akshintala VS, Afghani E et al. Incidence, severity, and mortality of post-ERCP pancreatitis: a systematic review by using randomized, controlled trials. *Gastrointest Endosc* 2014; 81: 143–149.e9
- [65] Kapral C, Duller C, Wewalka F et al. Case volume and outcome of endoscopic retrograde cholangiopancreatography: results of a nationwide Austrian benchmarking project. *Endoscopy* 2008; 40: 625–630
- [66] Testoni PA, Mariani A, Giussani A et al. Risk factors for post-ERCP pancreatitis in high- and low-volume centers and among expert and non-expert operators: a prospective multicenter study. *Am J Gastroenterol* 2010; 105: 1753–1761
- [67] Enochsson L, Swahn F, Arnelo U et al. Nationwide, population-based data from 11,074 ERCP procedures from the Swedish Registry for Gallstone Surgery and ERCP. *Gastrointest Endosc* 2010; 72: 1175–1184
- [68] Glomsaker T, Hoff G, Kvaløy JT et al. Patterns and predictive factors of complications after endoscopic retrograde cholangiopancreatography. *Br J Surg* 2013; 100: 373–380
- [69] Dumonceau J-M, Andriulli A, Elmunzer BJ et al. Prophylaxis of post-ERCP pancreatitis: European Society of Gastrointestinal Endoscopy (ESGE) Guideline – updated June 2014. *Endoscopy* 2014; 46: 799–815