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

Authors
Dirk Domagk1, Kofi W. Oppong2,3, Lars Aabakken4,5, Laszlo Czakó6, Tibor Gyökeres7, Gianpiero Manes8, Peter Meier9, Jan-Werner Poley16, Thierry Ponchon11, Andrea Tringali12,13, Cristina Bellisario14, Silvia Minozzi1, Carlo Senore14, Cathy Bennett15, Michael Bretthauer16, Cesare Hassan17, Michał F. Kaminski18,19,20, Mario Dinis-Ribeiro21, Colin J. Rees22, Cristiano Spada12,23, Roland Valori24, Raf Bisschops25, Matthew D. Rutter22,26

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, DIAOVERE Henriitenstift, 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, AOI Città della Salute e della Scienza, Turin, Italy
15 Office of Research and Innovation, Royal College of Surgeons in Ireland Colaiste Riogá na Mánleá in Erinn, 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 Sklodowska-Curie Memorial Cancer Center and Institute of Oncology, Warsaw, Poland
20 Department of Health Management and Health Economics, University of Oslo, Norway
21 Servicio 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: 0.0.2018 | 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 pancreateobiliary 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.

<table>
<thead>
<tr>
<th>Domains</th>
<th>Pre-procedure</th>
<th>Completeness of procedure</th>
<th>Identification of pathology</th>
<th>Management of pathology</th>
<th>Complications</th>
<th>Patient experience</th>
<th>Post-procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key performance measures</td>
<td>Adequate antibiotic prophylaxis before ERCP (≥ 90%)</td>
<td>Bile duct cannulation rate (≥ 90%)</td>
<td>Tissue sampling during EUS-FNA (≥ 85%)</td>
<td>Clearance of common bile duct stones (≥ 90%)</td>
<td>Safety of ERCP (PEP rate &lt;10%)</td>
<td>N/A</td>
<td>Being covered by Endoscopy Services Working Group</td>
</tr>
<tr>
<td>Minor performance measures</td>
<td>Adequate antibiotic prophylaxis before EUS (≥ 95%)</td>
<td>Stent placement in case of biliary obstruction (≥ 95%)</td>
<td>Documentation of EUS landmarks (≥ 90%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

▶ Fig. 1 The domains and performance measures chosen by the pancreateobiliary working group. EUS-FNA, endoscopic ultrasound-fine needle aspiration; ERCP, endoscopic retrograde cholangiopancreatography; PEP, post-ERCP pancreatitis; N/A, not available.
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** | **Denominator:** Patients with indication for antibiotic prophylaxis  
**Numerator:** Patients receiving antibiotics  
**Exclusions:** Patients who are on ongoing antibiotic treatment
**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%
**Consensus agreement for performance measure** | 100%
**PICO number (see Supporting information)** | 3.1
**Evidence grading** | Low quality evidence

### Antibiotic prophylaxis before EUS-guided puncture of cystic lesions

<table>
<thead>
<tr>
<th>Key performance measure</th>
<th>Description</th>
<th>Domain</th>
<th>Category</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Antibiotic prophylaxis before EUS-guided puncture of cystic lesions</strong></td>
<td>The percentage of patients with prophylactic antibiotics before EUS-guided puncture of cystic lesions</td>
<td>Pre-procedure</td>
<td>Process</td>
<td>Patient safety, reduction of infection following EUS-fine needle aspiration (EUS-FNA)</td>
</tr>
</tbody>
</table>
| **Denominator:** Patients undergoing EUS-FNA in cystic lesions  
**Numerator:** Patients in denominator receiving antibiotics  
**Exclusions:** Patients who are on ongoing antibiotic treatment  
**Calculation:** Proportion (%)  
**Level of analysis:** Service and, if necessary, endoscopist level  
**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.
**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:

- 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.

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

<table>
<thead>
<tr>
<th>Key performance measure</th>
<th>Bile duct cannulation rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>The percentage of successful bile duct cannulations in patients with normal anatomy (and native papilla)</td>
</tr>
<tr>
<td>Domain</td>
<td>Completeness of procedure</td>
</tr>
<tr>
<td>Category</td>
<td>Process</td>
</tr>
<tr>
<td>Rationale</td>
<td>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 inconveniences as the examination has to be repeated or recourse made to alternative therapeutic techniques.</td>
</tr>
</tbody>
</table>

Construct

| Denominator | All procedures in patients with normal anatomy |
| Numerator   | Procedures that document successful biliary cannulation (report and fluoroscopy) |
| Exclusions  | Procedures with no indication for biliary cannulation. Previous biliary sphincterotomy |

Calculation: Proportion (%)
Level of analysis: Service and endoscopist level
Frequency: Yearly audit of a sample of 100 consecutive cases
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.

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 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

<table>
<thead>
<tr>
<th>Key performance measure</th>
<th>Tissue sampling during EUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>Frequency of obtaining a diagnostic tissue sample in EUS-FNA or EUS-fine needle biopsy (FNB) of solid lesions</td>
</tr>
<tr>
<td>Domain</td>
<td>Procedure</td>
</tr>
<tr>
<td>Category</td>
<td>Process</td>
</tr>
<tr>
<td>Rationale</td>
<td>Improve technical success of EUS-FNA/FNB of solid lesions</td>
</tr>
</tbody>
</table>

Construct

| Denominator | All EUS-FNAs of solid lesions performed |
| Numerator   | Successful acquisition of diagnostic tissue of solid lesions during EUS |
| Exclusions  | Patients with post-surgery altered anatomy |

Calculation: Proportion (%)
Level of analysis: Service and endoscopist level
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.
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 ≥ 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.

### Tissue sampling during EUS

<table>
<thead>
<tr>
<th>Standards</th>
<th>Minimum standard: 85% Target standard: 90%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consensus agreement for performance measure</td>
<td>90%</td>
</tr>
<tr>
<td>PICO number (see Supporting Information)</td>
<td>1.21</td>
</tr>
<tr>
<td>Evidence grading</td>
<td>Very low quality of evidence</td>
</tr>
</tbody>
</table>

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...
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

<table>
<thead>
<tr>
<th>Indication for EUS</th>
<th>Relevant landmarks for visualization and documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mediastinal lesion/Esophageal cancer</td>
<td>Mass/tumor, Mediastinum (lymph nodes), Gastroesophageal junction, Celiac axis (lymph nodes), Left lobe of the liver (to rule out metastatic disease)</td>
</tr>
<tr>
<td>Subepithelial tumor</td>
<td>Subepithelial mass including the affected wall layers, Regional lymph nodes, Vascular infiltration, Infiltration of surrounding organs (e.g., liver, pancreas)</td>
</tr>
<tr>
<td>Pancreatobiliary cancer</td>
<td>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</td>
</tr>
<tr>
<td>Rectal cancer</td>
<td>Tumor including its location, expansion, infiltration of surrounding structures, Surrounding structures: genitourinary structures, iliac vessels, sphincter apparatus, lymph nodes</td>
</tr>
</tbody>
</table>

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

- After successful cannulation, stent placement should be achieved in at least 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.

<table>
<thead>
<tr>
<th>Key performance measure</th>
<th>Appropriate stent placement in patients with biliary obstruction below the hilum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Construct</td>
<td>Denominator: All ERCPs in patients with subhilar biliary strictures requiring stent placement, after successful cannulation</td>
</tr>
<tr>
<td></td>
<td>Numerator: Successful stent placement</td>
</tr>
<tr>
<td>Calculation:</td>
<td>Proportion (%)</td>
</tr>
<tr>
<td>Level of analysis:</td>
<td>Service and endoscopist level</td>
</tr>
<tr>
<td>Frequency:</td>
<td>Yearly audit</td>
</tr>
<tr>
<td>Standards</td>
<td>Minimum standard: 95%</td>
</tr>
<tr>
<td>Target standard:</td>
<td>95%</td>
</tr>
</tbody>
</table>

Consensus agreement for performance measure: 90%

PICO number (see Supporting Information): 1.19

Evidence grading: Low quality evidence

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

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 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.

Domagk Dirk et al. Performance measures for ERCP and EUS... Endoscopy 2018, 50
Supporting information

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

online content viewable at:

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 Hamilton Services for project administrative support; the Scott-

tish and running of the web platform; Iwona Escreet and all at

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 Hamilton Services for project administrative support; the Scott-

tish and running of the web platform; Iwona Escreet and all at

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 (2011–2014); speaker’s fee and re- 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 Medtronics (2014–2017) for a comparative study; together with C. Belissario and S. Minozzi he received a consultancy fee from ESGE to provide method- ological expertise (PICOs 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. Czakó, 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


Domagk Dirk et al. Performance measures for ERCP and EUS … Endoscopy 2018; 50

Domagk Dirk et al. Performance measures for ERCP and EUS... Endoscopy 2018; 50