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Guideline

Performance measures for upper gastrointestinal endoscopy: a European Society of Gastrointestinal Endoscopy (ESGE) Quality Improvement Initiative

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In brief

This is the first in a series of five articles describing performance measures developed within the ESGE quality improvement committee during the last three years with the support of UEG. The upper GI working group proposes 11 performance measures to assess and audit quality of upper gastrointestinal endoscopy.

Introduction

The European Society of Gastrointestinal Endoscopy (ESGE) and United European Gastroenterology (UEG) have identified quality of endoscopy as a major priority and we described our rationale for this in a first manuscript that also addressed the methodology of the quality initiative process [1].

The identification of upper gastrointestinal (UGI) performance measures presents a considerable challenge, in contrast to the situation with colonoscopy for instance, where several performance measures (inspection time, adenoma detection rate, and interval cancers, among others) have been identified over the last decade [2,3]. Following the Quality in UGI Endoscopy meeting held in Lisbon in 2013, it was clear that there was a need to identify performance measures for the UGI tract, and that quality standards could be identified although there is a paucity of evidence. This lack of evidence helps however to identify research priorities for the development of clinical trials that will further validate and substantiate the implementation of performance measures.

The aim therefore of the UGI working group was twofold: (1) to identify performance measures for UGI endoscopy; (2) to identify the evidence or absence of evidence that would develop the research priorities in this field.

We used an innovative methodology to facilitate the quality initiative process, which combined a thorough search and standardized evaluation of the available evidence for each clinical question, followed by a Delphi process (http://is.njit.edu/pubs/delphibook/delphibook.pdf. Accessed: July 2016) using an online platform [4,5]. This online platform permitted iterative rounds of modification and comment by all members of the UGI working group until agreement was reached

on the performance measure. We now report these newly identified performance measures.

Abbreviations

CI	confidence interval
EAC	early adenocarcinoma
EMR	endoscopic mucosal resection
ENT	ear, nose, and throat
ESGE	European Society of Gastrointestinal Endoscopy
FAP	familial adenomatous polyposis
GAVE	gastric antral vascular ectasia
HGD	high grade dysplasia
LGD	low grade dysplasia
MAPS	Management of precancerous conditions and lesions in the stomach
OLGA	Operative Link for Gastritis Assessment
OLGIM	Operative Link on Gastric Intestinal Metaplasia
OR	odds ratio
PEG	percutaneous endoscopic gastrostomy
PICO	population/patient; intervention/indicator; comparator/control; outcome
PPI	proton pump inhibitor
QIC	Quality improvement committee
SCC	squamous cell cancer

UEG United European Gastroenterology

UGI upper gastrointestinal tract

Methodology

We previously described the multistep process for the methodology to develop performance measures [1]. Briefly, following the Lisbon meeting in 2013, a list of 56 possible performance measures was distributed to all of the working group members for comments, suggestions, and shortcomings in September 2014. Every participant was required to comment on all of the proposed performance measures during teleconferences that took place between October 1st and December 18th 2014.

All possible performance measures that were identified by this process were structured using the PICO framework (where P stands for Population/Patient; I for Intervention/Indicator; C for Comparator/Control; and O for Outcome) to inform searches for available evidence to support the performance measures. This process resulted in 67 possible performance measures and 108 PICOs.

Because of the timeframe for this first initiative and the wide range of pathology in the UGI tract, the working group had to prioritize general UGI endoscopy topics within the abundance of proposed performance measures and PICOs. As part of this prioritization, PICOs that were concerned with areas where guidelines were already available or under development were omitted. We also excluded PICOs that focused on: the assessment of effectiveness, or comparative effectiveness, of specific treatments (e.g. administration of proton pump inhibitors [PPIs] before endoscopy for acute bleeding, percentage of patients undergoing endoscopic resection in Barrett's esophagus with high grade dysplasia [HGD] before ablation); legal or local regulation (informed consent); histopathology (e.g. the need for confirmation/revision of a

diagnosis of dysplasia by an independent pathologist); and service working group issues (e.g. adequate management of anticoagulants, sedation, etc.).

The initial priority list was developed during a face-to-face meeting on February 14th 2015. In total, 44 PICOs were retained as the basis for literature searches. Several disease-specific performance measures were also developed (Barrett's esophagus, intestinal metaplasia in the stomach, and squamous cell cancer [SCC] in the esophagus).

The PICOs and the clinical statements derived from these, which were organized into eight domains on the basis of their clinical applications, were adapted and/or excluded during the iterative rounds of comments and suggestions from the working group members during the Delphi process. The evolution and adaptation of the different PICOs and clinical statements during the Delphi process can be reviewed in **Appendix e1** (available online). In total, working group members participated in four rounds of voting to agree on the performance measures in predefined domains and their respective thresholds, which are discussed below. The agreement that is given for the different statements refers to the last voting round in the Delphi process. A statement was accepted if at least 80% agreement was reached after a minimum of two voting rounds.

The performance measures are displayed in boxes under the relevant domain. Each box describes the performance measure and the rationale behind its adoption, the agreement on acceptance during the modified Delphi process, and the grading of the available evidence, along with details of how the score should be measured and the desired threshold.

During the Delphi process, the Quality Improvement Committee (QIC) chairs distinguished key performance measures from minor performance measures to assist service providers with decisions about the implementation of performance measures in their endoscopy services. Reasons to qualify a performance measure as minor included the measure being very disease specific (e.g. detection of neoplasia during surveillance of Barrett's esophagus or gastric intestinal metaplasia) or that its implementation might be relatively difficult and dependent on the availability of adequate software for auditing of the performance measures. The division and allocation of performance measures to key and minor performance measures was agreed by the UGI working group in an additional face-to-face meeting in April 2016.

The number of cases that need to be audited to adequately assess if the threshold for a certain performance measure is reached can be calculated by estimating the 95% confidence intervals (CI) for a predefined threshold and variable sample size (see **Appendix e2**, **Table e1**, available online). For reasons of practicality and feasibility when implementing an audit, the working group agreed that 100 procedures (or all, if <100 procedures had been performed) should be measured to assess the performance measure. Ideally this should be done at an individual procedure level but, as this requires robust and sophisticated software, we suggest that the assessment is first performed at a service level. If problems are detected at a service level, further analysis at an individual level is then required to identify possible targets for improvement.

Performance measures for upper gastrointestinal endoscopy

In the first round of development, the working group accepted 11 performance measures in total, after a total of four voting rounds in the modified Delphi process. The evidence quality (assessed using the GRADE criteria [6]) for most of these

performance measures is low; however, this does not indicate that a performance measure is not important.

Taking into account both the feasibility of implementation and the possible impact on diagnostic quality and patient outcome, we identified six key and five minor performance measures (**Table 2**; **Fig. 1**). Nevertheless, all the performance measures were deemed valuable by the working group members and were obtained after a rigorous process, as described above. From a practical viewpoint, it may be desirable to implement the key performance measures first in those units that are not presently monitoring any performance measures. Once a culture of quality measurement is accepted and software is available, the minor performance measures may then further aid monitoring of the quality of UGI endoscopy.

All of the performance measures are described below, according to the domain to which they are attributed. The PICOs and statements that were used during the modified Delphi process to develop the performance measures can be found in **Appendix e1**. The statement numbers correspond to those used in **Appendix e1.**

1 Domain: Pre-procedure

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Key performance measure	**Fasting instructions**
Description	Percentage of patients receiving proper instructions for fasting prior to UGI endoscopy
Domain	Pre-procedure
Category	Process
Rationale	Patient safety and comfort Efficacy of UGI endoscopy
Construct	**Denominator:** Patients undergoing a UGI endoscopy (**note:** patients whose

	endoscopies are postponed because of lack of proper instructions should also be included in the calculation of the denominator) **Numerator:** Patients in the denominator who received proper instructions for fasting (2 hours for liquids and 6 hours for solids), as reported in the pre-assessment part of the endoscopy report **Exclusions:** Emergency endoscopies
	Calculation: Proportion (%) Level of analysis: Service level Frequency: Yearly for a sample of 100 consecutive UGI endoscopies on a service level
Standards	Minimum standard: 95% Target standard: 95%
	If the minimum standard is not reached, information channels to patients and healthcare providers should be reviewed and revised on a service level After evaluation and adjustment, close monitoring should be performed with a further audit within 6 months
Consensus agreement for performance measure	91%
PICO number (see **Appendix 3**)	1
Evidence grading	Very low quality

</PerfM>

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

• Patients referred for scheduled UGI endoscopy should be fasting. (Statement number N1.1 [see **Appendix e1]**) Agreement: 100%

• Patients referred for UGI endoscopy should be fasting for solids for at least 6 hours prior to the procedure. (N1.2) Agreement: 91%

• Patients referred for UGI endoscopy are allowed to take in water until 2 hours prior to the procedure. (N1.3) Agreement: 100%

Two studies were found that addressed these instructions and the duration of fasting prior to a scheduled UGI endoscopy [7,8]. In both studies, the authors mainly assessed the fasting time for liquids. The fasting time for solids was at least 6 hours prior to the endoscopy in both studies, with a good effect on visibility during endoscopy.

In the study by Koeppe et al. [7], general discomfort was reported less frequently by patients who had a drink of water (200 mL) 2 hours before the procedure than in those who were fasting for solids and liquids for a full 8 hours (18% vs. 42%; $P = 0.010$). Even though the endoscopists subjectively observed more liquid in the stomach of the former group, no cases of aspiration were observed in the sample of 50 lightly sedated patients.

De Silva et al. [8] also reported lower discomfort scores when water ad libitum was allowed until 1 hour before the procedure (recorded volumes drunk were 200–410 mL) compared with no water being allowed during a 6-hour pre-endoscopy fast (5.6 vs. 9.7; $P < 0.0001$). No significant differences were found for complications and safety outcomes, apart from a significant difference in the volume of retained fluid in the gastric fundus, this being more when water was drunk until 1 hour prior to the procedure, which was performed without sedation. Again no cases of aspiration were observed.

The outcome “incomplete examination” was not reported in the retrieved studies. The outcome “good or normal visibility of gastric mucosa” could be used as an indirect

outcome for the evaluation of incomplete examination. This outcome was consistently high after both 2 hours/1 hour minimum of no fluids and nil by mouth for at least 6 hours (96% vs. 98% [7] and 93% vs.100% [8], respectively).

Although no data from the two available studies directly assessed the duration of fasting for solids, it appears that an interval of at least 6 hours is safe and effective for UGI endoscopy in patients without any history or predisposing factors for delayed gastric emptying. For endoscopies that are planned to be performed in the afternoon, patient satisfaction may be increased if a small breakfast is allowed.

Unlike with colonoscopy, we do not have a standardized scale to measure "gastric preparation" for UGI endoscopy. We advise that the contents of the stomach, such as food residues, blood, bile, or the presence of bubbles, should be reported, along with information on whether a waterjet system was used to improve mucosal visualization. Just recording this as a surrogate performance measure may however omit patients that are sent home again because they did not receive fasting instructions. Recording that proper instructions were given should therefore be done prior to the endoscopy itself and this could be included in the pre-assessment part of the endoscopy report (together with, for instance, the informed consent). This would mean that patients who show up for endoscopy having not received proper instructions and therefore have their endoscopy cancelled should be included in any audits of this performance measure.

2 Domain: Completeness of procedure

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Key performance measure	**Documentation of procedure duration**

Description	Percentage of endoscopy reports that record the duration of the procedure from intubation to extubation
Domain	Completeness of procedure
Category	Process
Rationale	Completeness of UGI endoscopy cannot be defined only by the duodenum having been reached A longer inspection time reflects a more complete examination and is related to higher diagnostic yield during UGI endoscopy
Construct	Record the time from intubation to extubation **Denominator:** All UGI endoscopies **Numerator:** Procedures in the denominator that report the time of the procedure from intubation to extubation **Exclusions:** None Calculation: Proportion (%) Level of analysis: Service and, if necessary, individual level Frequency: Yearly for a sample of 100 consecutive UGI endoscopies. If the minimum standard is not reached, analysis on an individual level should be performed
Standards	Minimum standard: 90% Target standard: 90% Recording the duration of an examination should be attempted and should mostly be possible If the threshold is not reached on a service level, the service should assess whether technical support is sufficient to accurately record the procedure time If the threshold is not reached for an individual endoscopist, feedback should be provided, followed by close monitoring for 3 months to assess the performance of the individual endoscopist After evaluation and adjustment, close monitoring should be performed with a further audit within 6 months

Consensus agreement for performance measure	82%
PICO numbers (see **Appendix 3**)	2,3
Evidence grading	Very low quality

</PerfM>

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

• A UGI endoscopy in a patient who has not undergone a previous gastroscopy within the last 3 years should include inspection of the esophagus, stomach, and duodenum, and should last for at least 7 minutes from intubation to extubation. (N2.2) Agreement: 80%

• Although the evidence to support this is of very low quality, the major duodenal papilla should be visualized and photographed in all UGI endoscopies in patients with normal anatomy when a full examination is intended. (N2.1) Agreement: 73%

In contrast to colonoscopy, there is a paucity of data on the assessment of a complete procedure. As a definition, "reaching the duodenum" seems too trivial: it does not really reflect endoscopic competence as it is easy to achieve; there is no data comparable to cecal intubation rate in the colon that supports its relationship to better disease detection.

During the discussions of the working group, there was a strong emphasis on trying to define this performance measure and searching the literature for an anatomical landmark or finding that might be related to disease detection. We formulated several PICOs to assess whether reaching any specific anatomical landmark yielded a better rate of diagnosis. One may speculate whether documentation that the major papilla

has been visualized can serve as an auditable performance measure for completeness of the procedure in a patient referred for a complete UGI endoscopy. Analogous to cecal intubation, it cannot be achieved in all endoscopies and is less trivial than reaching the second portion of the duodenum. In the absence however of any data to support this, no consensus was reached on this statement (only 73% agreement) and the working group therefore formulated this as one of the research priorities (**Table 3**).

We did however find one study that aimed to evaluate whether the length of time spent on UGI endoscopy improved the diagnostic yield. This was a retrospective cohort study by Teh et al. [9] that aimed to determine the diagnostic yield for early neoplastic lesions in the stomach. The study included 837 symptomatic patients with no history of gastric cancer who underwent a first diagnostic endoscopy by one of 16 endoscopists. The mean examination time for the 224 examinations without any abnormal findings or biopsies taken was 6.6 minutes, which allowed the definition of a cut-off time of ≥7 minutes to distinguish between "slow" versus "fast" procedures. Afterwards, in a retrospective evaluation of the 837 endoscopies, they concluded that a "slow" endoscopist (who took on average at least 7 minutes to perform a normal endoscopy) was twice as likely to detect high risk gastric lesions, defined as biopsy evidence of intestinal metaplasia, gastric atrophy, gastric dysplasia, or cancer (odds ratio [OR] 2.50, 95%CI 1.52–4.12) and three times as likely to detect a case of dysplasia or cancer (OR 3.42, 95%CI 1.25–10.38) than a "fast" endoscopist (who took fewer than 7 minutes on average).

A similar concept of measuring length of time for inspection, but in the specific context of Barrett's esophagus, has shown increased detection of dysplasia with an inspection time of 1 minute per cm of Barrett's esophagus [10].

Only one study has evaluated the correlation between increased detection of gastric dysplasia or gastric cancer and other UGI endoscopic diagnoses [11]. Park et al. retrospectively analyzed 54 889 records of patients who underwent a screening UGI endoscopy, performed by 66 experienced endoscopists, from 2006 to 2013 in a single center in Korea. Any diagnoses of reflux esophagitis, Barrett's esophagus, atrophic gastritis, intestinal metaplasia, erosion, ulceration, polyps, subepithelial lesions, xanthoma, angiodysplasia, or a diverticulum were recorded and the relevant records were re-evaluated with respect to increased detection of early gastric neoplasia. In multivariate analysis, the detection rates of gastric subepithelial lesions and gastric diverticula were independently associated with the detection rate of early gastric neoplasms.

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Key performance measure	**Accurate photodocumentation**
Description	Percentage of endoscopy reports with accurate photodocumentation of anatomical landmarks and all abnormal findings
Domain	Completeness of procedure
Category	Process
Rationale	Photodocumentation of all anatomical landmarks is an indicator of a complete examination Accurate photodocumentation of abnormal findings allows for better communication and follow-up
Construct	Accurate photodocumentation includes at least one representative picture of each of the following anatomical landmarks: duodenum, major papilla, antrum, angulus, corpus, retroflex of the fundus, diaphragmatic indentation, upper end of the gastric folds, squamocolumnar junction, distal and proximal esophagus (i.e. at least 10 images in total)

	There should be pictures of all abnormal findings mentioned in the report
	Denominator: All diagnostic UGI endoscopies
	Numerator: Procedures in the denominator that contain accurate photodocumentation, as detailed above
	Exclusions:
	– Therapeutic procedures
	– Follow-up endoscopies performed within 12 months of a previous endoscopy and for a previously diagnosed disease or condition (coeliac disease, varices, ulcers, cancer after any treatment, dysplastic Barrett's esophagus, gastric dysplasia, duodenal polyps, infections, inflammation, bleeding, or endoscopic treatment of any of the aforementioned)
	– Emergency endoscopy
	– Endoscopy with a specific diagnostic purpose without the need for a full evaluation: evaluation of a fistula or perforation
	– Early termination of endoscopy due to patient intolerance or for reasons of safety
	Calculation: Proportion (%)
	Level of analysis: Service and, if necessary, individual level
	Frequency: Yearly for a sample of 100 consecutive UGI endoscopies. If the minimum standard is not reached, analysis on an individual level should be performed
Standards	Minimum standard: 90%
	Target standard: 90%
	If the threshold is not reached on a service level, the service should assess whether technical support is sufficient for image acquisition and integration into the report
	If the threshold is not reached for an individual endoscopist, feedback should be provided, followed by close monitoring for 3 months to assess the performance of the individual endoscopist
	After evaluation and adjustment, close monitoring should be performed with a

	further audit within 6 months Factors such as whether the examination is diagnostic or therapeutic should be recorded to allow subgroup analysis and future adaptation of the performance measure
Consensus agreement for performance measure	91%
PICO numbers (see **Appendix 3**)	4,5
Evidence grading	Very low quality

</PerfM>

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

• High quality reporting includes photodocumentation of all normal anatomical landmarks and abnormal findings. (N3.1) Agreement: 100%

• An accurate endoscopy report for reflux disease includes documentation of the anatomical hallmarks (diaphragm indentation, top of gastric folds). (N4.1) Agreement: 100%

• An accurate endoscopy report for reflux disease includes application of the Los Angeles classification. (N4.2) Agreement: 100%

• An accurate endoscopy report for Barrett's esophagus includes documentation of the anatomical landmarks (diaphragm indentation, top of gastric folds). (N4.3) Agreement: 100%

• The Prague criteria should be used to report the results of endoscopic examination of Barrett's esophagus. (N4.4) Agreement: 100%

No data exist to support that photodocumentation of all normal anatomical landmarks and abnormal findings will improve diagnostic yield. However, photodocumentation should be considered a general quality improvement in comparison with previous reports that were made before dedicated reporting software was available. Most endoscopic systems now enable digital picture acquisition, therefore the working group strongly agreed on the inclusion of digital photography in reports. This measure is supported by endoscopic societies and experts suggest it might be an indirect quality indicator for careful inspection of the digestive lumen [12–14].

The minimum number of pictures to be collected, combining relevance and applicability, in a normal endoscopic examination should be 10, namely: proximal esophagus, distal esophagus, Z line and diaphragm indentation, cardia and fundus in inversion, corpus in forward view including lesser curvature, corpus in retroflex view including greater curvature, angulus in partial inversion, antrum, duodenal bulb, and second part of duodenum. The working group suggested that it may be desirable to document more extensively in specific surveillance examinations, such as for Barrett's esophagus (e.g. one picture per cm of Barrett's esophagus) [10], or where there are extensive gastric premalignant conditions (e.g. 21 pictures of the stomach) [13].

In addition, several validated classifications have been developed for specific pathologies. The working group agreed that the use of these classifications in conjunction with photodocumentation improves comparability and accurate information exchange among gastroenterologists, both in the clinical setting and for investigational purposes. In the UGI tract, this is especially true for the Los Angeles classification for the reporting of reflux esophagitis and the Prague classification for Barrett's esophagus [15–18].

Implementation of this performance measure is inevitably dependent on the availability of image acquisition and software to incorporate images into the report. Because this performance measure simplifies and improves communication between different endoscopists, implementation of appropriate software should be prioritized by hospital policy makers. The working group recognizes that gastroenterologists performing procedures mainly in their own surgeries will often struggle to find a reasonable way to be reimbursed for the considerable cost of this software.

3 Domain: Identification of pathology

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Minor performance measure	**Inspection time in the stomach**
Description	Percentage of first-time gastroscopies and follow-up gastroscopies for gastric intestinal metaplasia lasting more than 7 minutes from intubation to extubation
Domain	Identification of pathology
Category	Process
Rationale	Longer inspection times allow the detection of more lesions in the stomach
Construct	Record time from intubation to extubation of the endoscope
	Denominator: First-time diagnostic UGI endoscopies or follow-up gastroscopies for gastric intestinal metaplasia
	Numerator: Procedures in the denominator with the duration of the procedure documented as being at least 7 minutes from intubation to extubation (**note:** procedures without a recorded time should be regarded as fails)
	Exclusions:
	– Therapeutic procedures
	– Follow-up endoscopy within 36 months of a previous endoscopy for follow-up of gastric intestinal metaplasia

	– Emergency endoscopy – Endoscopy with a very specific diagnostic focus where there is no intent to detect stomach pathology: e.g. evaluation of a fistula, perforation – Early termination of endoscopy due to patient intolerance or for reasons of safety Calculation: Proportion (%) Level of analysis: Service and, if necessary, individual level Frequency: Yearly for a sample of 100 consecutive UGI endoscopies. If the minimum standard is not reached, analysis on an individual level should be performed
Standards	Minimum standard: 90% Target standard: 90% Recording the duration of an examination should be attempted and should mostly be possible If the threshold is not reached on a service level, the service should assess whether technical support is sufficient to accurately record the procedure time If the threshold is not reached for an individual endoscopist, feedback should be provided, followed by close monitoring for 3 months to assess the performance of the individual endoscopist After evaluation and adjustment, close monitoring should be performed with a further audit within 6 months
Consensus agreement for performance measure	82%
PICO number (see **Appendix 3**)	1
Evidence grading	Very low quality evidence

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

• The entire procedure for surveillance of intestinal metaplasia should last at least 7 minutes from scope intubation to scope extubation of the patient (N6.1). Agreement: 100%

• A UGI endoscopy in a patient who has not undergone a previous gastroscopy within the last 3 years should include inspection of the esophagus, stomach, and duodenum, and should last for at least 7 minutes from intubation to extubation. (N2.2) Agreement: 80%

The evidence for this performance measure is mainly derived from the study by Teh et al. [8]. By using a cut-off time of ≥7 minutes per endoscopy, from intubation to extubation, endoscopists performing above the cut-off (i.e. longer inspection times) detect two times as many high risk gastric lesions (intestinal metaplasia, gastric atrophy, gastric dysplasia, or cancer) and three times as many dysplastic lesions and gastric cancers. The study did not evaluate differing diagnostic yields in the esophagus or duodenum between endoscopists but it provides evidence for the stomach that is comparable to that for inspection times in the colon [18].

The interval of 3 years in the statement from the Delphi process stems from the suggestion of the European consensus on "Management of precancerous conditions and lesions in the stomach" (MAPS guideline) [19,20]. The 3-year interval was suggested among experts to be the best clinically applicable interval for endoscopic surveillance of extensive atrophy and/or extensive intestinal metaplasia. This 3-year interval strategy has been shown more recently, in a European population between 50 and 75 years of age, to be cost-effective as a surveillance strategy [21].

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Key performance	**Use of standardized terminology**

measure	
Description	Percentage of endoscopy reports with accurate application of standardized disease-related terminology
Domain	Identification of pathology
Category	Process
Rationale	Uniformity in communication
Construct	Record the use of the: – Los Angeles classification for erosive esophagitis – Zargar classification for caustic esophagitis – Prague classification for Barrett's esophagus – Forrest classification for bleeding ulcers – Spigelman classification for duodenal adenomas in patients with familial adenomatous polyposis (FAP) – Paris classification for visible lesions in the stomach and esophagus – Baveno classification for varices **Denominator:** All endoscopy reports addressing one or more of the aforementioned group of pathologies **Numerator:** Reports with appropriate use of all disease-related terminology The performance measure is only met when all applicable disease-related terminology is used in a report, so for instance in a patient with esophagitis and Barrett's esophagus both the Los Angeles and Prague classifications should be used **Exclusions:** None, but limited to the specified diseases Calculation: Proportion (%) Level of analysis: Service and, if necessary, individual level Frequency: Yearly for a sample of 100 consecutive UGI endoscopies. If the minimum standard is not reached, analysis on an individual level should be performed
Standards	Minimum standard: 95% Target standard: 95%

	Recording of the final diagnosis of the endoscopy is fundamental to allow the calculation of this performance measure and therefore its implementation may be more difficult If the threshold is not reached at a service level, the service should assess whether technical support is sufficient to make a search for auditable endoscopies feasible, based on software that allows the diagnosis on an endoscopy report to be searched If the threshold is not reached for an individual endoscopist, feedback should be provided, followed by close monitoring for 6 months to assess the performance of the individual endoscopist After evaluation and adjustment, close monitoring should be performed with a further audit within 6 months
Consensus agreement for performance measure	91%
PICO numbers (see **Appendix 3**)	6–13
Evidence grading	Very low quality

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

• Abnormal findings should be reported according to available internationally validated and standardized terminology. (N3.2) Agreement: 100%

• An accurate endoscopy report for reflux disease includes application or the Los Angeles classification. (N4.2) Agreement: 100%

• The Prague criteria should be used to report the results of endoscopic examination of Barrett's esophagus. (N4.4) Agreement: 100%

The quality of endoscopy is closely related to the quality of the report and the use of standardized terminology enables better communication between endoscopists and unequivocal discrimination of disease-related findings.

The working group considered accurate reporting as one of the main topics for quality assurance. Besides reporting and documentation of anatomical landmarks, the correct use of available and validated terminology for specific diseases was considered to be a cardinal point for quality improvement. It enables the gathering of sound epidemiological data and is a prerequisite for auditing the quality of endoscopic reports. Although the literature searches for the PICOs did not render any evidence in terms of higher diagnostic yield or proven efficacy for better physician interaction and communication, the statements on implementing standardized terminology as a quality measure for accurate reporting all reached 100% agreement.

The Paris classification is a uniform and relatively well established endoscopic classification for early neoplastic lesions [22,23], with clinical value in terms of the prediction of the risk of submucosal invasion and therefore eligibility for endoscopic treatment [23]; however, little is known about the interobserver agreement of this classification. Recently, the value of this classification system has been questioned in an interobserver study for polyp assessment in the colon, which showed a Kappa value of 0.42 and a mean pairwise agreement of 67% [24]. This study indicates that further research is clearly necessary to assess the applicability of the Paris classification or perhaps to simplify it.

The Los Angeles classification for erosive reflux disease was validated when it was introduced in 1996 [25] and demonstrated that interobserver agreement for the assessment of minimal changes, mucosal breaks, demarcated areas of slough or erythema, and complications was good. Because of the availability of interobserver

data and the fact that this classification is now used most widely, the working group opted to implement the Los Angeles classification as the standard for endoscopic assessment of reflux disease [25,26].

Similarly, the Prague classification is a relatively straightforward and reproducible score, which enables better communication between endoscopists. The score has been validated among experts [18] and in two additional studies among trainees and community-based endoscopists, strengthening the value of the Prague classification for the accurate description of Barrett's esophagus and the length of the hiatal hernia [27,28].

The ESGE guideline on the diagnosis and management of nonvariceal UGI bleeding has strongly recommended the uniform use of the Forrest classification, as used in several studies assessing the risk for peptic ulcer bleeding and rebleeding [29,30]. Therefore it is clinically important that this classification is used in the endoscopy report in order to ascertain the correct clinical management after endoscopy for UGI bleeds [31].

Other classification systems that should be implemented are the Zargar's classification for caustic esophagitis [32], the Baveno classification for grading of esophageal varices [33,34], and the Spigelman's classification for duodenal polyps in FAP syndrome [35,36]. Although there is less data available in terms of reproducibility, these scoring systems are relatively simple to apply and have an intrinsic clinical value in terms of patient management and follow-up.

The working group accepted that although agreement was reached about the use of the aforementioned standardized terminology in the modified Delphi process, its implementation may be not so easy. In particular, in order to provide data that will

enable this performance measure to be audited, there is a requirement for an adequate electronic reporting system that can match a diagnosis (e.g. bleeding duodenal ulcer) to the standardized terminology being used (Forrest classification). A prerequisite of such a reporting system is that it would permit automated queries to be run at regular intervals and feedback to be supplied to individual endoscopists. Outputs from such reporting systems can help to improve the performance for this measure: for instance, the system can be adapted to provide a reminder of the criteria of the relevant classification system and so that a report cannot be validated unless, when a particular diagnosis has been made, the corresponding terminology is used. If such a system is in place, systematic electronic reports are encouraged and the over-riding of this requirement by the endoscopist should be discouraged.

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Minor performance measure	**Inspection time of Barrett's esophagus**
Description	Percentage of routine Barrett's surveillance endoscopies with at least 1 minute of inspection time per cm of circumferential Barrett's epithelium
Domain	Identification of pathology
Category	Process
Rationale	Better detection of Barrett's neoplasia
Construct	Record inspection time of the esophagus Record the Prague classification Calculate the inspection time expressed as minutes/circumferential extent of Barrett's epithelium in cm **Denominator:** Barrett's surveillance endoscopies **Numerator:** Procedures in the denominator with an inspection time of >1 minute per cm of circumferential Barrett's epithelium **Exclusions:**

	– Presence of severe esophagitis defined as a Los Angeles classification of grade C or higher – Therapeutic procedures for treatment of Barrett's esophagus Calculation: Proportion (%) Level of analysis: Service and, if necessary, individual level Frequency: Yearly for a sample of 100 consecutive UGI endoscopies. If the minimum standard is not reached, analysis on an individual level should be performed
Standards	Minimum standard: 90% Target standard: 90%
	Recording of the diagnosis of an examination (Barrett's esophagus) and the extent of the Barrett's epithelium (Prague classification) are fundamental to allow the calculation of this performance measure. On a service level this is a prerequisite that, if not possible, may hamper implementation in the short term If on a service level this performance measure is not met, measures should be taken to implement software that will allow the performance measure to be audited If the threshold is not reached for an individual endoscopist, feedback should be provided, followed by close monitoring for the next 30 procedures or a period of 6 months to assess the performance of the individual endoscopist
Consensus agreement for performance measure	91%
PICO number (see **Appendix 3**)	14
Evidence grading	Very low quality evidence

</PerfM>

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

• Inspection time in the esophagus for surveillance of a Barrett's segment should be at least 1 minute/cm of circumferential extent of Barrett's epithelium. (N4.5) Agreement: 90%

No studies were found that have directly addressed the comparison between measuring or not measuring the inspection time. One study aiming to determine whether the inspection time in Barrett's esophagus correlated with the detection of endoscopically suspicious lesions and/or Barrett's esophagus-associated neoplasia, namely HGD or early adenocarcinoma (EAC), was considered partially relevant [10]. It was a cross-sectional post hoc analysis of data from a multicenter, prospective clinical trial of 112 patients that investigated the performance of novel imaging techniques for dysplasia detection during Barrett's esophagus surveillance. The study found that greater proportions of patients had an endoscopically suspicious lesion with increasing inspection times (≤2 minutes, 30%; 3–4 minutes, 35.5%; 5–6 minutes, 82.1%; ≥7 minutes, 84.6%; $P < 0.001$) and a greater proportion were found to have HGD/EAC (≤2 minutes, 15%; 3–4 minutes, 32.3%; 5–6 minutes, 46.4%; ≥7 minutes, 69.2%; $P = 0.001$). The study suggested that an inspection time of 1 minute per cm of Barrett's esophagus resulted in increased detection of neoplasia.

Although this study had certain limitations and did not reflect the real-life prevalence of Barrett's esophagus dysplasia in a community-based hospital, the working group members agreed to support this performance measure with a high degree of agreement. In contrast to the detection of colon polyps, where a solid scientific basis seems to exist with regard to the measurement of inspection time during withdrawal [3,19] as a performance measure, for UGI endoscopy there is a paucity of scientific data [9,10]. Nonetheless, it seems reasonable to assume that a lengthier inspection of Barrett's esophagus may result in better lesion detection.

The optimal inspection time also includes rinsing the esophagus sufficiently to improve visualization, proper sedation and patient tolerance, and the use of high definition endoscopy (i.e. high definition endoscopes connected to high definition monitors using a high definition signal). At this time, there are no data to support the systematic use of any advanced imaging technique, such as chromoendoscopy or electronically enhanced endoscopy [37,38], but neither is there harm in applying them when available. In the recent BOB CAT consensus, it was suggested that these techniques should be used in experienced hands only [4].

The implementation of this performance measure is again dependent on the availability and development of an electronic reporting system; however, once this is in place, it should be easy to comply with. One of the research priorities should be to elucidate whether there is a correlation between inspection time and increased neoplasia detection in Barrett's esophagus in a general secondary-care setting.

<PerfM>

Minor performance measure	**Use of Lugol chromoendoscopy in patients with an increased risk of SCC**
Description	Percentage of procedures with accurate application of chromoendoscopy in patients referred for screening for SCC after curative treatment of ear, nose, and throat (ENT) or lung cancers
Domain	Identification of pathology
Category	Process
Rationale	Better detection of early esophageal SCC in patients with an increased risk
Construct	Record the use of Lugol chromoendoscopy in patients with a history of ENT or lung cancer treated with a curative intent **Denominator:** All endoscopies performed for screening for a second primary tumor after curative treatment of ENT or lung cancer **Numerator:** Procedures in the denominator where Lugol chromoendoscopy

	is used **Exclusions:** – Allergy to iodine – Patients treated without curative intent – Patients older than 80 years – Patients with a life expectancy of less than 2 years
	Calculation: Proportion (%) Level of analysis: Service Frequency: Every 2 years for a sample of all or 100 eligible UGI endoscopies, whichever is the larger
Standards	Minimum standard: 90% Target standard: 90%
	Because this is a relatively rare indication that may be disseminated among the endoscopists within a service, as a first step, feedback on a service can be provided. If the threshold is not met, endoscopists need to be educated about the risk in these patients and the additional value of Lugol staining for the detection of early lesions
Consensus agreement for performance measure	82%
PICO number (see **Appendix 3**)	15
Evidence grading	Moderate quality

</PerfM>

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

• Accurate use of chromoendoscopy in patients with a history of ENT or lung tumors who are treated with curative intent results in a higher diagnostic yield for the detection of squamous dysplasia and SCC (N5.1). Agreement: 80%

Eight studies addressed this clinical question specifically in patients with a history of head and neck tumors by comparing conventional white-light endoscopy with Lugol chromoendoscopy [39–46]. Because this is a screening examination by a minimally invasive technique, from a clinical point of view it only makes sense to perform it in patients who have been previously treated with curative intent for their primary tumor. For the diagnosis of SCC, five of the studies showed improvements in the rates of diagnosis, mostly for early cancers, ranging from 20% to 100% of detected lesions [39,41,42,45,46], while all eight studies showed increased yield for dysplasia ranging from 33% to 100% of lesions. The overall incidence rates of lesions in this particular high risk group of patients were 2%–9% for dysplasia and 1%–5% for cancer after Lugol chromoendoscopy.

The usual technique in UGI endoscopy uses esophageal staining with 10–20 mL of a 2% Lugol dye solution applied by a spray catheter or directly by the biopsy channel of the endoscope, with the esophageal examination being repeated 2 minutes later. In view of the fact that Lugol chromoendoscopy is a cheap and relatively easily applied technique, for which the available evidence is of moderate quality, the working group reached a high degree of agreement on the acceptance of this performance measure.

4 Domain: Management of pathology
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Key performance measure	**Use of the Seattle protocol in Barrett's surveillance**

Description	Percentage of patients undergoing routine Barrett's surveillance with proper application of the Seattle protocol
Domain	Management of pathology
Category	Process
Rationale	Accurate surveillance with optimal detection of Barrett's neoplasia Allowing an interval between surveillance endoscopies that is according to the guidelines
Construct	Record the Prague classification Record the use of the Seattle protocol with four biopsies taken every 2 cm along the circumferential extent of the Barrett's epithelium. Biopsies should be collected in separate jars for targeted biopsies and per level for random biopsies For example, in a C4M5 Barrett's segment, at least 12 biopsies should be taken, i.e. four at levels 0, 2, and 4 cm, and these should be put into three different jars numbered according to the biopsy location **Denominator:** All Barrett's surveillance endoscopies **Numerator:** Procedures in the denominator where biopsies were taken in complete accordance with the extensive Seattle protocol, as described above **Exclusions:** – Presence of severe esophagitis defined as Los Angeles classification of grade C or higher – Therapeutic procedures for treatment of Barrett's esophagus – Work-up endoscopy for known Barrett's neoplasia when a visible lesion is present that is defined as a type IIa, IIc, Is, or a more advanced lesion according to the Paris classification – Patients with contraindications for biopsies, such as coagulopathy or the use of anticoagulants Calculation: Proportion (%) Level of analysis: Service and, if necessary, individual level Frequency: Yearly for a sample of 100 consecutive UGI endoscopies. If the minimum standard is not reached, analysis on an individual level should be

	performed
Standards	Minimum standard: 90% Target standard: 90%
	Recording of the diagnosis of Barrett's esophagus and the Prague classification are fundamental to allow the calculation of this performance measure. In addition, a link with a pathology database would be ideal to allow automatic audit If the threshold is not reached on a service level, the availability of registration of the parameters should first be facilitated; if this is available, awareness of the need for registration should be increased If the threshold is not reached for an individual endoscopist, feedback should be provided, followed by a close monitoring for the next 30 procedures or a period of 6 months to assess the performance of the individual endoscopist
Consensus agreement for performance measure	100%
PICO numbers (see **Appendix 3**)	16–18
Evidence grading	Very low quality of evidence

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

• In patients undergoing routine surveillance for non-dysplastic Barrett's esophagus, biopsies should be taken according to the Seattle protocol. (N4.6) Agreement: 100%

The Seattle protocol typically consists of targeted biopsies of any visible lesion, followed by four quadrant biopsies taken every 2 cm along the extent of the circumference of the Barrett's esophagus [47], all collected in different containers per level and per lesion. This is generally accepted in guidelines to be the standard method for Barrett's esophagus surveillance [37,38,48].

The acceptance of this protocol dates back to several observational – sometimes contradictory – studies, which were mainly performed in an era prior to advanced imaging, that suggested better detection of neoplasia and possibly a reduction in mortality. In a retrospective cohort study including 362 patients with ≥3 cm Barrett's esophagus undergoing endoscopic surveillance, 180 patients received a systematic Seattle biopsy protocol and 182 subjects received a non-systematic biopsy strategy [49]. The Seattle protocol detected significantly more low grade dysplasia (LGD; 18.9% vs. 1.6%; $P < 0.001$) and HGD (2.8% vs. 0%; $P = 0.03$). In the non-Seattle biopsy group, three patients died of invasive Barrett's esophagus adenocarcinoma, compared with none in the Seattle group. In concordance with this study, Peters et al. [50] reported a cohort of patients treated endoscopically for early Barrett's esophagus neoplasia and found that those without a prior diagnosis of dysplasia were more likely not to have undergone the Seattle biopsy protocol.

In the era prior to an established endoscopic treatment of early Barrett's esophagus neoplasia particularly, controversy existed as to whether an intensified protocol better predicted the presence of cancer in comparison to a less intensive protocol. Reid et al. [47] intensified the classical protocol to four quadrant biopsies every 1 cm for patients followed up after a diagnosis of HGD and suggested that a 2-cm biopsy protocol would miss 50% of the cancers. In contrast, Kariv et al. [51] found that a 2-cm interval for the biopsy protocol was sufficient to detect cancer prior to esophagectomy. Studies using advanced imaging techniques in experienced referral centers suggest that in the future there may be a role for new techniques to replace the Seattle protocol, but currently there are insufficient data to support this [38].

Because of the widespread acceptance of this protocol in all guidelines, the working group agreed fully that, despite the low quality evidence, adherence to the Seattle

protocol could serve as a valuable performance measure to monitor UGI endoscopy practice. It is important to emphasize that this parameter is only applicable in the surveillance setting.

From a practical viewpoint, containers should be labelled according to the level at which the biopsy was taken. The working group suggests a coding system that unequivocally allows a location to be allocated to each container using a two number combination "xxyy." In this "xx" refers to the distance from the incisors and "yy" to the location on a clock with the 3 o'clock position corresponding to the lesser curvature (scope in neutral position) and with 00 indicating random biopsies. For instance, 4000 would indicate random biopsies taken at 40 cm from the incisors, while 3805 stands for a targeted biopsy taken from a lesion at 38 cm from the incisors and in the 5 o'clock position.

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Minor performance measure	**Identification of patients at risk for gastric cancer**
Description	Percentage of patients in which MAPS guidelines are followed when applicable
Domain	Management of pathology
Category	Process
Rationale	Accurate application of the MAPS guidelines identifies patients at risk for gastric cancer
	Adequate surveillance allows the detection of gastric cancer at an early stage
Construct	Record the procedures in which gastritis is detected, and where screening for HP gastritis and intestinal metaplasia are performed
	Record if at least two biopsies from the antrum and two biopsies from the corpus were taken and placed into two different jars for histology (MAPS guidelines)

	Denominator: All endoscopic examinations where assessment of the gastric cancer risk is considered clinically relevant (see exclusion criteria) **Numerator:** Procedures in the denominator in which at least two biopsies from the antrum and two biopsies from the corpus were taken and placed into two different jars **Exclusions:** – Therapeutic procedures – UGI with normal gastric findings – Gastric findings that do not need the application of guidelines – Follow-up of intestinal metaplasia – Work-up endoscopy for known gastric dysplasia
	Calculation: Proportion (%) Level of analysis: Service Frequency: Every 2 years for a sample of 100 eligible UGI endoscopies
Standards	Minimum standard: 90% Target standard: 90%
	Recording the diagnosis of an examination is fundamental to allow further assessment of the gastric cancer risk and calculation of this performance measure. Implementation may therefore be difficult and depend largely on the availability of applicable software on a service level If the threshold is not reached on a service level, the availability of registration for the parameters should be facilitated. If this is in place, awareness of the need to follow the MAPS guidelines should be raised
Consensus agreement for performance measure	91%
PICO number (see **Appendix 3**)	19
Evidence grading	Very low quality of evidence

</PerfM>

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

• For the diagnosis of intestinal metaplasia and *Helicobacter pylori*, at least two biopsies of the antrum and two biopsies of the corpus should be taken. (N6.2) Agreement: 80%

• In addition to two biopsies of the antrum and two biopsies of the corpus, a biopsy in the incisura is demanded for both the Operative Link for Gastritis Assessment (OLGA) and Operative Link on Gastric Intestinal Metaplasia (OLGIM) classifications. (N6.3) Agreement: 80%

The MAPS guideline recommends that for the assessment of extension of gastric atrophy and intestinal metaplasia, beyond performing the best available endoscopy in terms of technology and the time for inspection, at least two biopsies must be taken from the antrum and two from the body of the stomach, and these must be placed into separate containers [20]. This recommendation is in concordance with the minimum standards for pathology as described in the OLGA or OLGIM grading systems for gastritis [52,53]. These grading systems require an additional separate biopsy from the incisura. However, several studies have addressed the issue of the number of biopsies and inconsistency exists regarding the incisura biopsy in terms of increased diagnostic yield [54–59].

De Vries et al. [54] in a prospective cohort study comparing different numbers of non-targeted biopsies (five, seven, or nine) to the 12-biopsy scheme (used as the reference) found that, in a population with a low gastric cancer risk, at least nine non-targeted biopsies should be taken from the cardia, lesser curvature of the corpus, angulus, and antrum to achieve the best diagnostic yield. Guarner et al. [55] compared protocols of

three, five, and seven biopsies and found that the five-biopsy protocol reached 100% sensitivity for *H. pylori*, 96% for atrophy, and 95% for metaplasia and dysplasia.

Eriksson et al. [56], in consecutive patients from a similar low risk population, took six biopsies (two from the antrum, two from incisura, and two from corpus). While no patients showed dysplasia in their incisura biopsies, these biopsies were the only ones to show intestinal metaplasia but, as this was seen in 3.3% of cases only, they concluded that routine biopsy of the incisura would provide little additional information. El-Zimaity et al. [57] also found that intestinal metaplasia was missed in more than 50% of cases, and that this was independent of the site of biopsy and that no set or site of biopsy specimens, including the incisura, could reliably exclude the presence of intestinal metaplasia.

On the other hand, Isajevs et al. [58] assessed the relevance of the incisura biopsy and concluded that, if the incisura biopsy was excluded, down-staging would occur in 18% of cases for the OLGA classification and 4% for the OLGIM, resulting in a 30%–35% downgrading from high risk to low risk in terms of the OLGA/OLGIM stages. Finally, Stolte et al. [59], using the same five-biopsy protocol, concluded that the presence of antral mucosa at the incisura was associated with considerably more severe gastritis (14% atrophy and 20% intestinal metaplasia in the antrum) than the presence of corpus mucosa at the incisura (only 2% atrophy and 6% intestinal metaplasia).

From a practical and clinical point of view, five non-targeted biopsies overall, comprising two from the antrum, one from the incisura, and two from the corpus, seems to provide the most relevant information without compromising clinical applicability.

We do realize that the MAPS guidelines address more than just taking biopsies to assess the extent of atrophy or metaplasia. However, the emphasis of this performance measure lies in identifying patients at risk that should be followed up. It is obvious that the MAPS guidelines remain applicable independent of the proposed performance measures. Furthermore, depending on the prevalence of a certain disease, the attention that is given to the corresponding performance measure may vary geographically throughout Europe. For instance, follow-up and adequate diagnosis of Barrett's esophagus will be more important in Western Europe, whereas intestinal metaplasia of the stomach may carry a higher interest in Eastern and Southern Europe.

5 Domain: Complications

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Key performance measure	**Monitoring complications after therapeutic endoscopy**
Description	Percentage of patients monitored for complications (adverse events) after therapeutic UGI endoscopy
Domain	Complications
Category	Outcome/process
Rationale	Monitoring of the incidence of complications after therapeutic endoscopy is important to assess the safety of procedures, to identify possible targets for improvement, and to allow patients to be accurately consented for procedures
Construct	Record therapeutic procedures including: – Savary dilation – Pneumatic dilation – Endoscopic resection of lesions in the esophagus, stomach, and duodenum – Percutaneous endoscopic gastrostomy (PEG) insertions – Stent placement – Varices band ligation

	– Endoscopic hemostasis – Endoscopic ablation (Barrett's epithelium; gastric antral vascular ectasia [GAVE]; squamous epithelium, duodenal mucosa) Record the following parameters: – Immediate complications – Delayed complications: record if patient was contacted between 7 and 14 days after the procedure to assess post-procedural complications ideally the patient should have been notified beforehand that this contact would be made **Denominator:** All applicable therapeutic procedures **Numerator:** Number of applicable therapeutic procedures with accurate registration of complications **Exclusions:** – Emergency procedures – Patients who refuse to be contacted Calculation: Proportion (%) Level of analysis: Service Frequency: Yearly on an audit sample of 100 random eligible endoscopy reports
Standards	Minimum standard: 95% Target standard: 95%
	Implementation of these performance measures is mainly situated on a service level. Because of the lack of standardized grading of complications into major or minor, a description of the action related to the complication should be given (e.g. need for transfusion or hospitalization, prolonged hospitalization, surgery, death, need for dilation, need for endoscopic re-intervention), along with the time from the endoscopic procedure to onset of the complication Recording of the type of therapeutic procedure should be detailed enough to allow subgroup analysis

	Endoscopic reporting systems should allow the reporting of complications, including the absence of immediate complications, and the type of complication (hemorrhage, perforation, or anesthesia-related) Ideally the 30-day complication rate should also be calculated but this can be implemented at a later stage once a system to record complications systematically is in place
Consensus agreement for performance measure	91%
PICO numbers (see **Appendix 3**)	20–25
Evidence grading	Very low quality of evidence

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

• The perforation rate following polypectomy or endoscopic mucosal resection (EMR) in the esophagus, stomach, or duodenum should not exceed 2%. (N9.1) Agreement: 54%

• The rate of clinically significant bleeding following polypectomy or EMR in the esophagus, stomach, or duodenum should not exceed 10% (N9.2) Agreement: 64%

• The perforation rate following pneumatic or Savary dilation in the esophagus should not exceed 1%. (N9.3) Agreement: 73%

For this domain, we specifically addressed adverse events and harms for procedures that are generally and frequently carried out in all endoscopic units. We focused on the perforation and bleeding rate after Savary or pneumatic dilation and endoscopic resections in the UGI tract.

A total of 37 studies were included for complications after dilation [60–87]. They generally seemed to have prospectively recruited patients, but the information was often not very clear. Overall 3263 patients were included, of which 2202 were adults and 1061 children. Overall 8524 Savary and 5491 balloon dilations were performed. None of the studies reported cases of serious bleeding, but the majority of the studies did not assess this outcome. Perforations occurred in 0.98% of cases of balloon dilation and in 0.68% of cases of Savary dilation. Similarly, for adverse events after endoscopic resection, 38 papers were included [88–118]. The perforation rates were 1.6%, 0.98%, and 1.61% in the esophagus, stomach, and duodenum, respectively, with bleeding rates of 4%, 6.9%, and 9.2%, respectively.

Although the literature search yielded the highest number of included papers for these PICOs, including several systematic reviews, the working group could not agree on a predefined maximal allowance for these post-procedural adverse events. This was attributed to the fact that the overall quality of the evidence was graded as very low, being retrospective in nature and with it not always being clear if patients had been consecutively included in the studies. For these indications, the data were therefore not sufficiently adequate to decide on a threshold that would be used to audit an endoscopy service. Indeed, the final result would to a large extent be determined by the denominator, and it is therefore not clear what the incidence of adverse events would be in individual centers with lower numbers.

The working group did however reach agreement on the fact that patients should be monitored for adverse events or harms after therapeutic interventions. This monitoring will generate more realistic numbers, which in turn can be used to determine a minimum number of procedures per service or operator for these interventions (see below).

6 Domain: Procedure numbers

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Performance measure	**No current standard defined**

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In the absence of any evidence regarding the number of procedures needed for an individual to be certified to perform UGI endoscopy, we were not able to set any minimum numbers.

Any recommendation in terms of the minimum annual number of procedures per endoscopist that are required to maintain adequate levels of quality would need to be based on an established strong association of poor quality with a minimum threshold number of procedures performed per year; however, such data are unavailable. The working group anticipates that, with application of the present performance measures, information will come to light to clarify whether such a concept does apply to diagnostic and/or therapeutic UGI endoscopy.

7 Domain: Patient experience

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Performance measure	**No current standard defined**

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Patient experience and satisfaction are important outcome measures of endoscopy in general. The UGI working group concluded that this should be measured after any endoscopic procedure. In general, there is lack of evidence assessing the effect of certain logistic or procedural aspects on patient's satisfaction and experience.

The working group members concluded that this is a domain for research and, because it applies to all forms of endoscopy within an endoscopy service, it was

suggested that this particular domain resides more under the service working group. Undoubtedly, several measures can be undertaken to improve patient's experience. For instance, providing an information brochure on UGI endoscopy at least 1 day prior to the procedure has been shown to result in less anxiety beforehand and greater satisfaction after the procedure [119].

8 Domain: Post-Procedure

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Minor performance measure	**Barrett's patient registry**
Description	Percentage of patients with a confirmed diagnosis of Barrett's esophagus that are entered into a registry to monitor the incidence of dysplasia
Domain	Post-procedure
Category	Process/structural
Rationale	Better follow-up of Barrett's patients helps to identify risk factors, and helps with an accurate incidence of neoplasia and adherence to surveillance guidelines
Construct	Record all patients with a diagnosis of Barrett's esophagus Cross-match with registration in a Barrett's registry **Denominator:** All patients with a diagnosis of Barrett's esophagus of at least 1 cm circumferential extent and histologically confirmed specialized intestinal metaplasia **Numerator:** Patients in the denominator who are registered in a Barrett's surveillance database **Exclusions:** – Absence of intestinal metaplasia in the biopsies – All patients with suspected Barrett's esophagus that is less than C1M1 according to the Prague classification – Patients older than 75 years

	– Patient's with contraindications for biopsies
	Calculation: Proportion (%) Level of analysis: Service Frequency: Every 2 years for a sample of 100 eligible/applicable UGI endoscopies
Standards	Minimum standard: 85% Target standard: 85%
	Implementation of the measurement of this performance measure on a service level is challenging. Implementation of performance measures 5, 6, and 8 is a prerequisite. Therefore this is a regarded as a minor performance measure, mainly focusing on the real incidence and prevalence of the disease as an important research question
Consensus agreement for performance measure	82%
PICO (see **Appendix 3**)	26
Evidence grading	Very low quality of evidence

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

• In a Barrett's surveillance program, the incidence of dysplasia should be monitored. (N4.7) Agreement: 80%

• The incidence of HGD in a Barrett's surveillance program, when diagnosed by at least two specialist gastrointestinal pathologists, should not be lower than 0.1% per year. (N4.8) Agreement: 70%

As with the colonic adenoma detection rate that is used as a performance measure for colonoscopy, it would seem appropriate for UGI endoscopy to use a minimum detection rate for dysplasia in the surveillance of Barrett's esophagus. From the PICO search, 28 studies with 49 815 patients were finally included [49,120–146]. All of the studies included patients with a diagnosis of Barrett's esophagus who underwent regular surveillance. Of the 28 studies, 17 were retrospective or prospective studies assessing prevalence of LGD and HGD at baseline and the incidence of LGD and HGD during follow-up. The length of follow-up ranged from 1.6 to 6 years, with a median of 4 years. The remaining studies were cross-sectional studies that reported prevalence data, although often they had objectives other than the assessment of prevalence. These cross-sectional studies had, on average, smaller samples sizes ranging from 30 to 295 patients, with a median of 80 patients included. Sample sizes of the cohort studies ranged from 121 to 42 207 included patients, with a median of 277 patients.

Although the quality of the evidence was rated as moderate, because of inconsistency in the data, no agreement was achieved in the Delphi process on a specific cut-off for the detection of dysplasia. Indeed, the prevalence of LGD ranged from 0.6% to 33.3% in the cross-sectional studies and from 0 to 37.2% in the cohort studies, with the prevalence of HGD ranging from 0 to 14.6% and 0 to 23.9%, respectively. The incidence of LGD and HGD ranged from 2% to 34.5% and from 0% to 5.8%, with median values of 14.7% and 2%, respectively.

Although no agreement was obtained on the cut-off for dysplasia detection, the working group members agreed on the fact that the incidence of dysplasia in a Barrett's esophagus surveillance program should be monitored in order to obtain more consistent and accurate epidemiological data. When these data become available, a

more realistic cut-off value may be determined, taking into account geographical differences and other risk factors of progression.

General conclusions, research priorities, and future prospects

This paper describes the first performance measures generated by evidence-based consensus that can be used for UGI endoscopy. We used a systematic and scientifically sound methodology to substantiate the proposed measures with available evidence where possible. As this is a largely unexplored field, most of the generated evidence is, as expected, graded as low quality. This in itself generates an important research priority, which is merely to measure the proposed performance measures and to evaluate whether they do in fact influence health outcome.

The working group identified several additional research priorities. These are listed in **Table 3** and will be addressed in an additional manuscript from the ESGE research committee.

The first step now is to implement these new performance measures into endoscopy practice over Europe. This is the only way forward that can evaluate the actual value of the performance measures and allow their adaptation in future. The working group members emphasize that all performance measures were perceived as important but, in order to facilitate their implementation, we made a distinction between key performance measures and minor performance measures. Although this distinction is somewhat arbitrary, attention was paid especially to patient safety, patient service (increasing diagnostic yield), and the feasibility of implementation. Indeed, some of the performance measures may be more difficult than others to implement or, because of geographical differences in disease prevalence, may be less relevant in certain centers.

The implementation of performance measures is important to identify services and individual endoscopists with lower levels of performance. We encourage individual endoscopists, as well as heads of endoscopy units, to start the implementation of these performance measures without delay. At a unit level, this may well mean investing in hardware to accommodate a more efficient auditing process.

Through individual feedback, measures can be taken to improve quality to rise above the proposed minimum thresholds. This should not be regarded as a "big brother" strategy with the goal of penalizing specific endoscopists, but rather as a tool to improve the quality of endoscopy in general, improve patient outcomes, and provide training and assistance where needed.

A second barrier may be the financial repercussions of implementing a quality control system. We want to encourage hospital management to support the implementation of these performance measures in their endoscopy services. We think that in an era where general hospital accreditation is becoming more and 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.

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Fig. 1 The domains and performance measures chosen by the working group (MAPS, management of precancerous conditions and lesions in the stomach; SCC, squamous cell carcinoma).

Table e1 Confidence intervals (CI) with varying thresholds and sample sizes.

Threshold	*P*	1-*P*	n	SE	Lower 95% CI	Higher 95% CI
0.85	0.85	0.15	100	0.03571	0.78	0.92
0.85	0.85	0.15	200	0.02525	0.80	0.90
0.85	***0.85***	***0.15***	***250***	***0.02258***	***0.81***	***0.89***
0.85	0.85	0.15	300	0.02062	0.81	0.89
0.85	0.85	0.15	400	0.01785	0.82	0.88
0.85	0.85	0.15	500	0.01597	0.82	0.88
0.85	0.85	0.15	1000	0.01129	0.83	0.87
0.90	0.9	0.1	100	0.03000	0.84	0.96
0.90	0.9	0.1	200	0.02121	0.86	0.94
0.90	0.9	0.1	250	0.01897	0.86	0.94
0.90	***0.9***	***0.1***	***300***	***0.01732***	***0.87***	***0.93***
0.90	0.9	0.1	400	0.01500	0.87	0.93
0.90	0.9	0.1	500	0.01342	0.87	0.93
0.90	0.9	0.1	1000	0.00949	0.88	0.92
0.95	0.95	0.05	100	0.02179	0.91	0.99
0.95	0.95	0.05	200	0.01541	0.92	0.98
0.95	0.95	0.05	250	0.01378	0.92	0.98
0.95	***0.95***	***0.05***	***300***	***0.01258***	***0.93***	***0.97***
0.95	0.95	0.05	400	0.01090	0.93	0.97
0.95	0.95	0.05	500	0.00975	0.93	0.97
0.95	0.95	0.05	1000	0.00689	0.94	0.96

SE, standard error

Table 2 Description of the different performance measures.

Key performance measures	Minor performance measures
Fasting instructions prior to UGI endoscopy	Minimum 7-minute procedure time for first diagnostic UGI endoscopy and follow-up of gastric intestinal metaplasia
Documentation of procedure duration	Minimum 1-minute inspection time per cm circumferential Barrett's epithelium
Accurate photodocumentation of anatomical landmarks and abnormal findings	Use of Lugol chromoendoscopy in patients with a curatively treated ENT or lung cancer to exclude a second primary esophageal cancer
Accurate application of standardized disease-related terminology	Application of validated biopsy protocol to detect gastric intestinal metaplasia (MAPS guidelines)
Application of Seattle protocol in Barrett's surveillance	Prospective registration of Barrett's patients
Accurate registration of complications after therapeutic UGI endoscopy	

UGI, upper gastrointestinal; ENT, ear, nose, and throat; MAPS, management of patients with precancerous conditions and lesions of the stomach.

Table 3 Research priorities identified by the working group.

What is the percentage detection of dysplasia in a Barrett's surveillance program in a general endoscopy practice?
What is the percentage of intestinal metaplasia in the stomach throughout Europe in a general endoscopy practice?
Could visualization of the papilla of Vater be used as a measure for a complete and high quality endoscopy? Does the percentage of endoscopies where the papilla is visualized correlate with a higher general diagnostic yield during UGI endoscopy?
What is the relationship between inspection time during UGI endoscopy and diagnostic yield?
The role of endoscopy in redefining diseases of the UGI tract
Endoscopy with or without biopsies Do biopsies alter the management of patients with Barrett's esophagus or eosinophilic esophagitis? What is the role of advanced imaging in a general endoscopy practice for dysplasia detection in: Barrett's esophagus Squamous cancer detection in high risk patients Intestinal metaplasia in the stomach? Can automated image analysis remove the need for biopsies and guide the management of patients with: Barrett's esophagus Intestinal metaplasia of the stomach Celiac disease? What is the role of teaching modules in training endoscopists in image interpretation and lesion recognition?

UGI, upper gastrointestinal.

Appendix e1 Excel file for Delphi voting process.

Appendix e2

The number of procedures that need to be used when auditing a particular performance measure to obtain an accurate estimate for performance is shown in

Table e1. For performance measures with a threshold of 85%, the number is 250; for performance measures with a threshold of 90% or 95%, the number is 300. Furthermore, as indicated in the table, the additional benefit in terms of narrowing of the 95% confidence interval (CI) is negligible for bigger sample sizes. The most significant gain in accuracy is achieved by increasing the sample from 100 to 200.

Appendix 3 The list of specific PICOs that were used for the final performance measures.

	Patients	Intervention	Comparison	Outcome
1	Patients undergoing UGI endoscopy	Time spent in the stomach	None	Higher overall diagnostic yield in the stomach
2	Patients undergoing UGI endoscopy	Time spent in the stomach	None	Higher overall diagnostic yield in the stomach
3	Patients undergoing UGI endoscopy	Visualizing a specific structure/disease	Not visualizing a specific structure/disease	Higher overall diagnostic yield in the stomach
4	Patients undergoing UGI endoscopy	Picture of anatomical landmarks	No picture documentation	Higher overall diagnostic yield
5	Patients undergoing UGI endoscopy	Picture of abnormal findings	No picture documentation	Higher overall diagnostic yield
6	Patients with reflux undergoing UGI endoscopy	Endoscopy report documenting Z line morphology	Endoscopy report not documenting Z line morphology	Higher diagnostic accuracy to diagnose reflux esophagitis
7	Patients with reflux undergoing UGI endoscopy	Documentation of Los Angeles classification	No documentation of Los Angeles classification	Diagnosis of erosive esophagitis
8	Patients undergoing UGI endoscopy	Standardized reporting system	No standardized reporting system	Higher overall diagnostic yield
9	Patients undergoing Barrett's surveillance endoscopy	Classification as per Prague criteria	No mention of Prague criteria	Accurate diagnosis of Barrett's
10	Patients with Barrett's and visible lesions	Reporting on visible lesions according to the Paris classification	No mention of visible lesion morphology and location	Accurate documentation of visible lesions in Barrett's / Better communication among physicians

11	Patients with Barrett's and visible lesions	Reporting on visible lesions according to the Paris classification	No mention of visible lesion morphology and location	Higher diagnostic yield for Barrett’s dysplasia.
12	Patients with a history of squamous cell ear, nose and throat tumors, treated with curative intent, referred for screening chromoendoscopy for squamous dysplasia or cancer with a visible lesion	Systematic use of standardized reporting of lesions found according to the Paris classification	No systematic report	Need to repeat the endoscopy for accurate diagnosis
13	Patients referred for gastroscopy	Systematic standardized reporting of visible lesions according to Paris classification	No systematic standardized reporting of visible lesions	Increased detection of intestinal metaplasia, dysplasia and gastric cancer
14	Barrett's patients undergoing surveillance endoscopy	Measuring the Barrett's inspection time	No measurement of inspection time	Increased dysplasia detection
15	Patients with a history of squamous cell ear, nose and throat tumors, treated with curative intent, referred for screening for squamous dysplasia or cancer	Screen by chromoendoscopy with Lugol	No screening with chromoendoscopy	Increased detection of squamous dysplasia and cancer in the esophagus
16	Barrett's patients undergoing surveillance endoscopy	Systematic biopsy as per Seattle protocol	Non systematic biopsy protocol followed	Early detection of neoplasia

17	Barrett's patients undergoing surveillance endoscopy	Systematic biopsy as per Seattle protocol	Non-systematic biopsy protocol followed	Decreased mortality from adenocarcinoma of the esophagus
18	Barrett's patients undergoing surveillance endoscopy	Systematic biopsy as per Seattle protocol	Non-systematic biopsy protocol followed	Detection of dysplasia or cancer at an early stage (could be searched as “need for esophagectomy” or treatment by “endoscopic resection” or “radiofrequency ablation”)
19	Patients referred for gastroscopy	Systematic biopsies of antrum, corpus, and angulus	No systematic biopsies	Increased detection of intestinal metaplasia, dysplasia, and gastric cancer
20	Patients with a benign or malignant stricture in the esophagus (achalasia excluded)	Savary dilation	None	Percentage of patients with perforation
21	Patients with a benign or malignant stricture in the esophagus (achalasia excluded)	Savary dilation	None	Percentage of patients with bleeding
22	Patients with a benign or malignant stricture in the esophagus (achalasia excluded)	Pneumatic dilation	None	Percentage of patients with perforation

23	Patients with a benign or malignant stricture in the esophagus (achalasia excluded)	Pneumatic dilation	None	Percentage of patients with bleeding
24	Patients with a benign or malignant lesion in the esophagus, stomach, or duodenum (SCC, HGD, LGD, adenoma, papilloma, stomach cancer, adenocarcinoma)	Endoscopic resection (EMR or polypectomy in esophagus, stomach or duodenum)	None	Percentage of patients with perforation
25	Patients with a benign or malignant lesion in the esophagus, stomach, or duodenum (SCC, HGD, LGD, adenoma, papilloma, stomach cancer, adenocarcinoma)	Endoscopic resection (EMR or polypectomy in esophagus, stomach, or duodenum)	None	Percentage of patients with bleeding
26	Patients undergoing Barrett's surveillance endoscopy	UGI endoscopy with dysplasia in biopsy	UGI endoscopy without dysplasia in biopsy	Percentage of patients diagnosed with HGD

UGI, upper gastrointestinal endoscopy; SCC, squamous cell cancer; HGD, high grade dysplasia; LGD, low grade dysplasia; EMR, endoscopic mucosal resection.

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