Performance measures for small-bowel endoscopy: a European Society of Gastrointestinal Endoscopy (ESGE) Quality Improvement Initiative – Update 2025

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ABSTRACT

Quality markers and patient experience are being implemented to ensure standardization of practice across gastrointestinal (GI) endoscopy procedures. The set benchmarks ensure high quality procedures are delivered and linked to measurable outcomes.

There has been an increase in the demand for small-bowel endoscopy. In 2019, the European Society of Gastrointestinal Endoscopy (ESGE) embarked on setting performance measures for small-bowel endoscopy. This included major (key) and minor performance indicators for both small-bowel capsule endoscopy (SBCE) and device-assisted enteroscopy (DAE). These suggested quality indicators cover all procedure domains, from patient selection and preparation, to intraprocedural aspects such as pathology identification, appropriate management, the patient experience, and post-procedure complications. Since 2019, there has been an increase in published studies looking at different aspects of small-bowel endoscopy, including real-world data. This paper provides an update on the 2019 performance measures, considering the latest literature.

ABBREVIATIONS

AE	adverse event
AI	artificial intelligence
ASGE	American Society for Gastrointestinal Endoscopy
CEST	Capsule Endoscopy Structured Terminology
CNN	convolutional neural networks
DAE	device-assisted enteroscopy
DBE	double-balloon enteroscopy
ERCP	endoscopic retrograde cholangiopancreatography
ESGE	European Society of Gastrointestinal Endoscopy
GI	gastrointestinal
KPI	key performance indicator
MDT	multidisciplinary team
PICO	Population/Patient, Intervention/Indicator, Comparator/Control, Outcome
SBCE	small-bowel capsule endoscopy
SBE	single-balloon enteroscopy

Introduction

The European Society of Gastrointestinal Endoscopy (ESGE) developed Quality Improvement groups for different gastrointestinal (GI) procedures to benchmark standards that all units should aim for, or adhere to, to ensure delivery of high quality endoscopy. Since the initiative, several countries have adopted widespread electronic reporting, which has allowed greater insight and accuracy in recording performance measures.

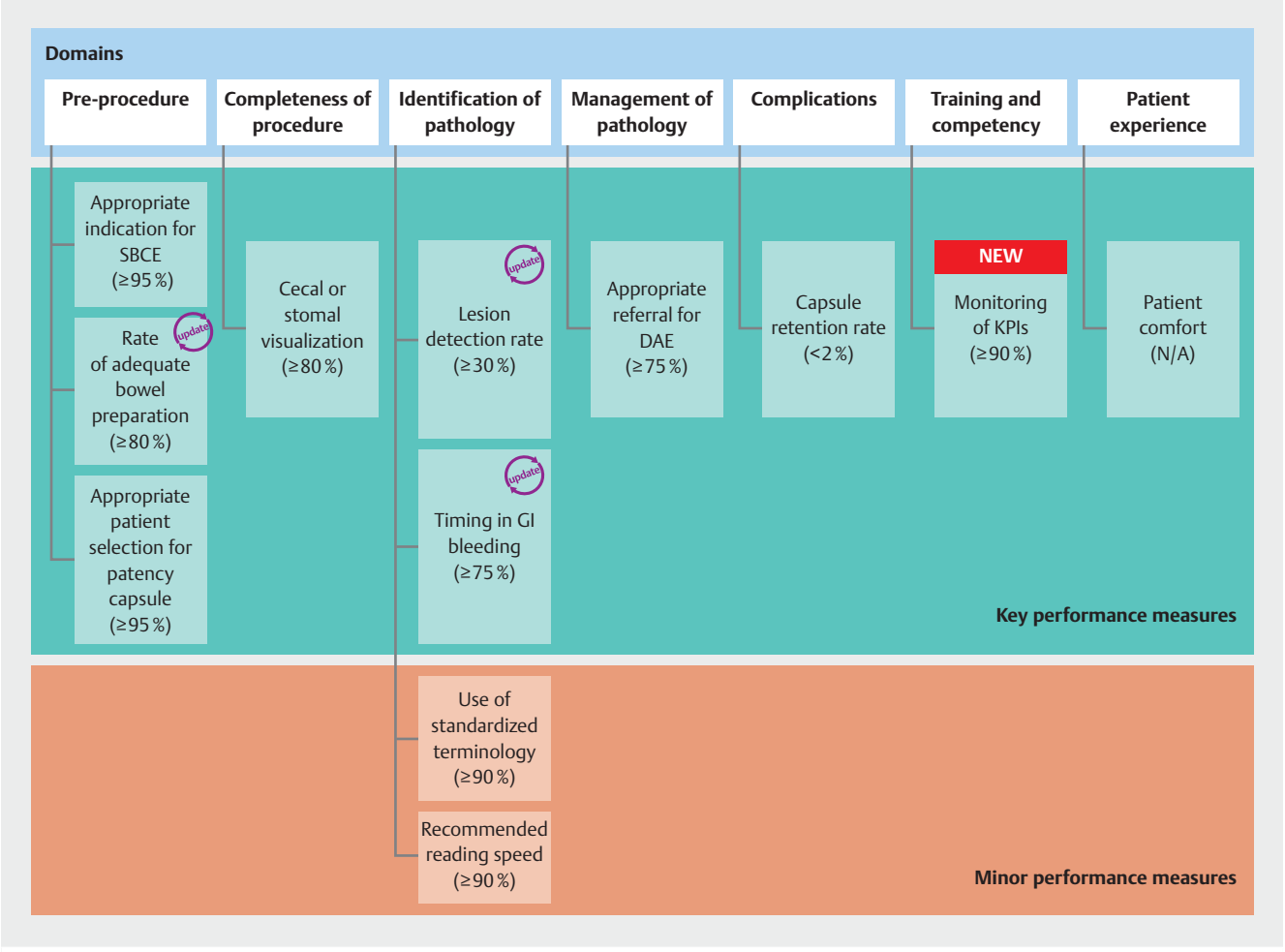
Small-bowel endoscopy encompasses two different modalities, namely small-bowel capsule endoscopy (SBCE) and device-assisted enteroscopy (DAE). SBCE and DAE target the same organ, but differ significantly in technique, procedure, process, and outcome. The latter had three subtypes – single-, double-balloon, and spiral enteroscopy – with comparative studies showing good diagnostic and therapeutic yields. Spiral enteroscopy, the latest invention in the field, which used a foot pedal for motorized scope advancement, showed promise in the initially published experience with rapid small-bowel intubation and correspondingly high diagnostic and therapeutic yield; however, a review of the minor and major complications resulted in this device being removed from the market. This highlights the importance of monitoring standards to ensure patient safety.

The ESGE Small-bowel Working Group aimed to review the 2019 list of performance measures for small-bowel endoscopy [1] and ensure that they remained applicable for small-bowel endoscopy services across Europe. Performance measures refer to specific issues identified for comparison and potential improvement, representing the minimum acceptable standard of care. Small-bowel investigation remains challenging owing to the lack of clear anatomical landmarks, apart from the duodenum and ileocecal valve. When the 2019 paper was published, there was an apparent lack of real-world data compared with other endoscopic modalities; however, the identified performance measures were well-defined, simple, and applicable worldwide. The key performance indicators (KPIs) have now been reviewed, with the updated literature incorporating real-world data, and some benchmarks have been redefined to ensure they continue to serve and be applicable to endoscopy services across Europe. This document supersedes the 2019 publication [1], providing updated standards for small-bowel endoscopy performance measures.

Methodology

The performance measures were updated using the multistep methodological process. For each identified domain within SBCE and DAE, ESGE Small-bowel Working Group members were invited to review the literature over the last 5 years in pairs.

The performance measures previously identified 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 any recent evidence to support and update these performance measures. The performance measures for the domains include pre-procedural and intraprocedural aspects such as procedure completion,



▶ **Fig. 1** Key performance measures for small-bowel capsule endoscopy (SBCE).
DAE, device-assisted enteroscopy; GI, gastrointestinal; KPI, key performance indicator.

identification, marking of pathology, appropriate management, patient experience, and post-procedure. The performance measures were divided into key performance measures and minor performance measures (▶ **Fig. 1** and ▶ **Fig. 2**).

Working group members were requested to provide a summary of the recent evidence to establish whether a particular performance measure required updating and whether the statement remained applicable. The assessment of the literature by the section members and the modification of the recommendations have been made based on expert consensus. The PICOs and the updated clinical statements derived from these were adapted or omitted during iterative rounds of comments and suggestions from the working group members during the Delphi voting process.

In total, working group members participated in two rounds of voting, followed by an extended consensus meeting to agree on performance measures in the predefined domains and their respective thresholds. A statement was accepted if at least 80 % agreement was reached after the two voting rounds. Statements not reaching agreement after the first round of voting were modified according to the comments made in the voting rounds. The agreement for the different statements refers to the last voting round in the Delphi process.

The performance measures (key and minor) are displayed in boxes under the relevant quality domain, and recommended thresholds are provided. The performance measures should be assessed at individual or service levels with regular audits of local practice. The use of digital endoscopy reporting systems would facilitate data collection and review of these performance measures.

Performance measures for small-bowel capsule endoscopy

1 Domain: Pre-procedure

Key performance measure	Indication for SBCE
Description	Percentage of patients undergoing SBCE in accordance with published recommendations
Domain	Pre-procedure
Category	Process
Rationale	SBCEs performed for an appropriate indication are associated with higher diagnostic yields for clinically significant lesions
Construct	**Denominator**: All SBCEs performed **Numerator**: SBCEs performed for an appropriate indication (according to the ESGE clinical guidelines for SBCE): obscure GI bleeding, iron deficiency anemia, Crohn's disease (known or suspected), small-bowel tumors, inherited polyposis syndromes, abnormal radiological imaging, and subgroups of patients with celiac disease (i. e. complicated and/or refractory celiac disease) **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service and individual level Frequency: Yearly and/or for a sample of at least 100 SBCEs
Standards	Minimum standard: ≥ 95 % Target standard: ≥ 95 % If the minimum standard is not reached, analysis of the appropriateness of the procedure should be performed at a service level and for each capsule reader After evaluation and adjustment, close monitoring should be performed with a further audit within 12 months and/or for a sample of 100 SBCEs
Consensus agreement	100 %
PICO number	1.1
Evidence grading	Moderate quality evidence

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

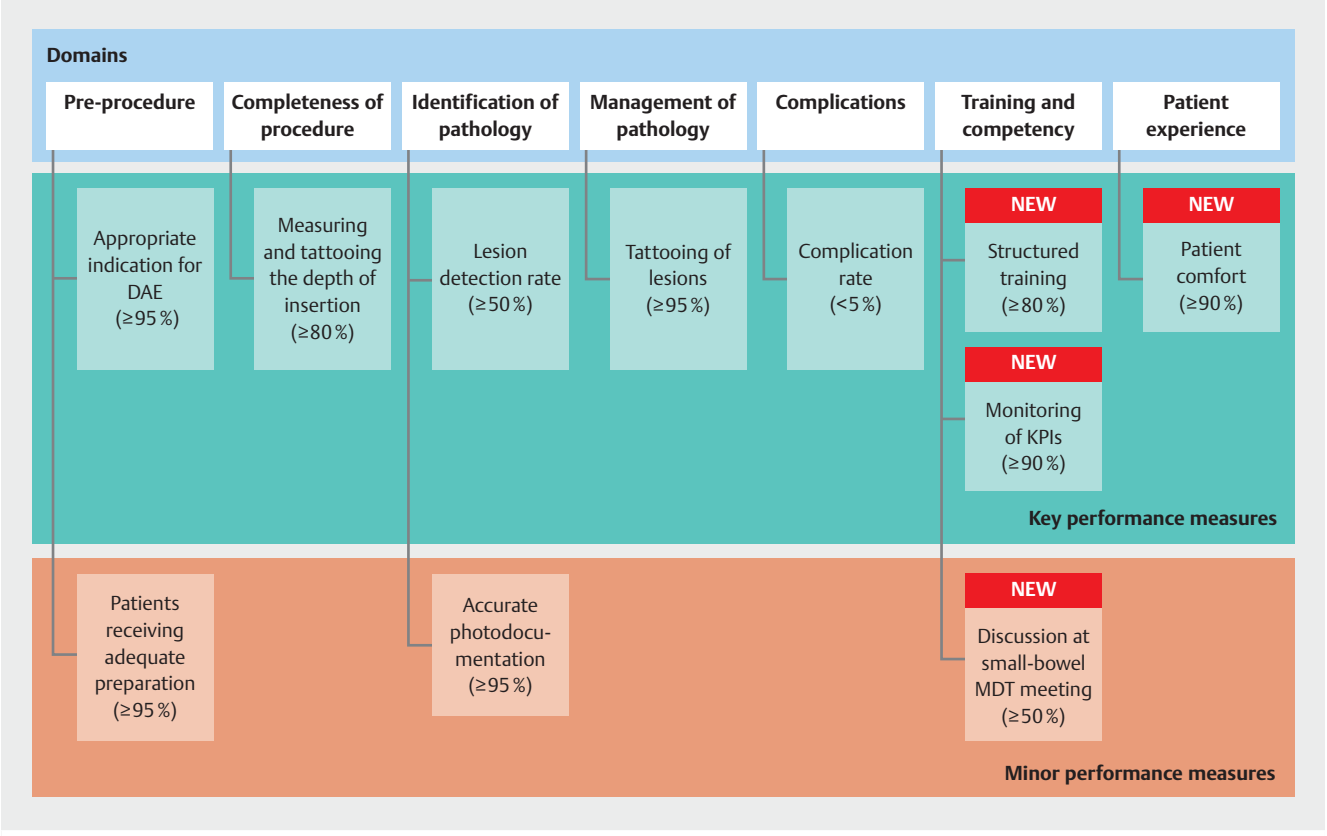
- The indications for SBCE should be guided by published recommendations (e. g. ESGE and American Society for Gastrointestinal Endoscopy [ASGE] guidelines). (Statement number 1.1a) Agreement: 100 %
- The percentage of SBCE procedures performed by indication should be audited. (Statement number 1.1b) Agreement: 95.2 %
- Studies performed for nonstandard indications (indications not approved by endoscopy organizations) should be regularly reviewed. (Statement number 1.1c) Agreement: 90.4 %

It is well established that the diagnostic yield of SBCE increases when employed for approved versus non-recommended indications, as described in both the European and American guidelines [2, 3]. Adherence to these recommended indications, for the majority of SBCE studies carried out, remains a key performance measure [4–8]. Reassuringly, across Europe, adoption of this performance measure appears high [9].

There is a growing body of research in which capsule endoscopy has been employed for other clinical indications, with evidence of efficacy for some indications, such as acute bleeding, graft-versus-host disease, and small-bowel enteropathy of unknown cause [5, 10–13], but limited evidence for others, such as Lynch syndrome surveillance [14]. There is also a recognition that SBCE technology and artificial intelligence (AI) may reduce the technical burden and cost of SBCE to providers. In addition, serious adverse event (AE) rates associated with SBCE procedures are falling with appropriate risk stratification and the use of patency capsules. As a result, access to SBCE as a noninvasive, accurate diagnostic clinical tool for small-bowel disease is likely to expand.

While the expansion of SBCE indications is expected to reduce the overall diagnostic yield, the clinical efficacy may increase when access, safety, timeliness, and cost are reduced, and the value of a negative diagnostic test, in some clinical situations, is considered. As such, the recommendation to audit and continually assess the performance of SBCE on an individual and unit basis by indication, when not performed for established indications, remains an important key performance measure. The use of appropriate and standardized endoscopy reporting systems with a drop-down menu for indication is critical to facilitating data acquisition for this performance measure [15].

Key performance measure	Rate of adequate bowel preparation
Description	Percentage of SBCEs with adequate or good mucosal visualization using acceptable bowel preparation methods
Domain	Pre-procedure
Category	Process
Rationale	Appropriate bowel preparation enhances small-bowel mucosal visualization. Inadequate bowel preparation results in increased costs and inconvenience as the examination may need to be repeated or an alternative investigation arranged
Construct	**Denominator**: Patients undergoing SBCE **Numerator**: Patients in the denominator with an adequate small-bowel cleansing level according to any published, validated cleansing scale (e. g. Brotz or Park scales) **Exclusions**: Emergency SBCE, patients with active bleeding, patients with previous small-bowel resections Calculation: Proportion (%) Level of analysis: Service and individual level Frequency: Yearly and/or for a sample of at least 100 SBCEs



▶ **Fig. 2** Key performance measures for small-bowel device-assisted enteroscopy (DAE).
KPI, key performance indicator; MDT, multidisciplinary team.

(Continuation)

Key performance measure	Rate of adequate bowel preparation
Standards	Minimum standard: ≥ 80 % Target standard: ≥ 80 % Bowel preparation quality should be included in the report If the minimum standard is not reached, analysis of the factors influencing bowel preparation (information given to patients, dietary restrictions, fasting, cleansing agents used, timing) should be performed on a service level After evaluation and adjustment, close monitoring should be performed with a further audit within 12 months
Consensus agreement	85.7 %
PICO number	1.2
Evidence grading	High quality evidence

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

- The mucosal visualization obtained for SBCE should be adequate or good in > 80 % of cases using accepted bowel preparation methods. (Statement number 1.2) Agreement: 85.7 %

As with all GI endoscopies, diagnostic accuracy for SBCE depends on adequate mucosal visualization; as such the pre-eminent performance measure relating to bowel cleansing is that 80 % of patients undergoing SBCE should have an adequately prepared small bowel.

The role of purgatives in SBCE has been debated widely. There is conflicting evidence, with some studies showing improved small-bowel visualization quality and a potential increase in diagnostic yield, but this needs to be weighed against the additional cost and patient reluctance toward purgative use. Meta-analyses published since the previous recommendations [1] have highlighted a lack of significant advantage in terms of diagnostic yield or completion rates with purgative use, and contradictory results for visualization quality [16–18]. A further meta-analysis has confirmed that simethicone as an adjunct reduces gas bubbling and improves small-bowel visualization quality [19]. Prokinetics have been shown to affect completion rates but not diagnostic yield [20]. What has changed is the growing recognition that both the type of bowel cleansing agent used (polyethylene glycol versus sodium phosphate) [17] and the timing of its administration (after versus before inges-

tion) [18] are important factors affecting procedure quality. Yet, no single accepted bowel cleansing regimen is recommended to achieve the desired performance measure. In addition, despite the availability of validated cleansing scales (**Tables 1 s** and **2 s**, see online-only Supplementary material), their use is not widespread nor embedded in most reading software packages [21, 22]. As such, the efficacy of any given cleansing regimen should be regularly audited. Individual clinicians are expected to judge whether any given study is adequate based on any validated scale that they are familiar with and confident in using.

Because there are limited data to set the minimum and target standards reliably, and bearing in mind the required preparation quality may vary by indication (emergency versus elective procedures, those with active bleeding, those with altered anatomy including Crohn's disease), the proposed value for the rate of adequate bowel preparation of ≥ 80 % was deemed to be a reasonable objective. This benchmark was also redefined based on the updated literature. Moreover, the adequate preparation performance parameter should be viewed in conjunction with other key indices of quality, particularly diagnostic yield and completion rates.

Key performance measure	Patient selection
Description	Percentage of patients at higher risk of capsule retention who are offered a patency capsule
Domain	Pre-procedure
Category	Process
Rationale	Patients at high risk of capsule retention should be identified before performing a capsule study and a patency capsule should be offered
Construct	**Denominator**: SBCEs performed in high risk patients (e. g. known Crohn's disease, symptoms of obstruction, long-term NSAID use, abdominopelvic radiation) **Numerator**: Number of patency capsules offered to high risk patients **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service and individual level Frequency: Yearly and/or for a sample of at least 100 SBCEs
Standards	Minimum standard: ≥ 95 % Target standard: ≥ 95 % The capsule report should include an explicit description of the risk of retention in high risk patients. Patients at high risk of capsule retention should be offered a patency capsule to reduce the incidence of retention If the minimum standard is not reached, analysis of the factors influencing proper patient selection should be performed at a service level and for each capsule endoscopist After evaluation and adjustment, close monitoring should be performed with a further audit within 12 months and/or for a sample of 100 SBCEs

(Continuation)

Key performance measure	Patient selection
Consensus agreement	100 %
PICO number	1.3
Evidence grading	Moderate quality evidence

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

- Certain groups of patients undergoing SBCE have a higher risk of capsule retention. (Statement number 1.3a) Agreement: 100 %
- The use of a patency capsule can reduce the incidence of capsule retention in patients at higher risk. (Statement number 1.3b) Agreement: 100 %

Capsule retention remains the most significant AE associated with capsule endoscopy and can be avoided in most patients. Risk factors for retention are known and widely accepted, such as chronic nonsteroidal anti-inflammatory drug (NSAID) use, established Crohn's disease, or previous abdominopelvic radiotherapy. All patients referred for SBCE who are at increased risk of retention should be identified and offered a patency capsule before undergoing the procedure. Two recent meta-analyses have shown that retention rates have decreased and that the appropriate use of a patency capsule reduced retention in all patients [22] and in high risk groups, such as those with established Crohn's disease [23].

The broader use of patency capsules may have reduced the false-negative rate previously recognized with cross-sectional imaging. Where patency capsules are unavailable, practitioners should remain aware of the risk of unidentified strictures with standard cross-sectional imaging and tailor their practice appropriately. While avoiding retention is laudable, it is well accepted that there is a need to adhere to the appropriate use of patency capsules to prevent the excessive exclusion of patients from undergoing capsule endoscopy [24]. While in the majority, patency capsule use is safe, there are reports of AEs, including transient obstructive symptoms and patency capsule retention [25].

This performance measure can and should be implemented at a service and individual endoscopist level. Variations from the expected capsule retention rates suggest suboptimal patient selection and procedure quality. There are insufficient data to set the minimum and target standards reliably, but the proposed values for proper selection of patients of ≥ 95 %, respectively, were deemed appropriate to ensure safer SBCE.

2 Domain: Completeness of procedure

Key performance measure	Complete cecal or stomal visualization
Description	The incomplete study rate (failure to reach the colon or stoma bag) should be < 20 %
Domain	Completeness of procedure
Category	Process
Rationale	Complete small-bowel visualization is a prerequisite for an adequate inspection of the mucosa in search of lesions
Construct	**Denominator**: All SBCEs performed **Numerator**: Procedures that report reaching the cecum/colon or stoma bag (in patients who have had ileocolonic resection or other relevant surgery) **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service and individual level Frequency: Yearly and/or for a sample of at least 100 SBCEs
Standards	Minimum standard: ≥ 80 % Target standard: ≥ 95 % Complete small-bowel visualization should be documented in a written report, including photodocumentation If the minimum standard is not reached, analysis of the factors influencing completion rate (selection of patients, cleansing agents used, timing) should be performed on a service level and for each individual capsule endoscopist After evaluation and adjustment, close monitoring should be performed with a further audit within 12 months and/or for a sample of 100 SBCEs
Consensus agreement	95.2 %
PICO number	1.4
Evidence grading	Low quality evidence

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

- The incomplete study rate (failure to reach the colon or stoma bag) should be < 20 %. (Statement number 1.4a) Agreement: 95.2 %
- In all cases of an incomplete study, the patient should be asked to confirm excretion. If excretion is not confirmed after 15 days, an abdominal radiograph should be obtained. (Statement number 1.4b) Agreement: 100 %

The basis for this recommendation remains unchanged in that a complete small-bowel examination, as defined by the capsule reaching the colon or stoma, is essential to ensure adequate pathology detection and to avoid the inconvenience and cost associated with repeat procedures. Incomplete transit, by its very definition, will miss pathology, and efforts to prevent such an outcome should be employed, including the appropriate use of preparation and real-time monitoring in at-risk patients, with administration of prokinetics if there is evidence of transit delay. Maintaining adequate rates of complete small-bowel transit, good mucosal visualization, and reading standards remain the best tools to ensure appropriate lesion detection for any given approved clinical indication.

3 Domain: Identification of pathology

Key performance measure	Lesion detection rate
Description	Percentage of SBCEs with clinically significant findings
Domain	Identification of pathology
Category	Process
Rationale	Lesion detection reflects adequate inspection of the small-bowel mucosa. Lesion detection rates predict quality in SBCE
Construct	**Denominator**: All SBCEs performed **Numerator**: SBCEs which provide a diagnosis or a finding considered clinically significant and related to the indication **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service and individual level Frequency: Yearly and/or for a sample of at least 100 SBCEs
Standards	Minimum standard: ≥ 30 % Target standard: ≥ 50 % A written description and photodocumentation of significant lesions should be included in the report Overall diagnostic yield and diagnostic yield per indication should be audited. Variations from expected rates raise the possibility of suboptimal patient selection, procedure quality, and/or reading, and reporting After evaluation and adjustment, close monitoring should be performed with a further audit
Consensus agreement	100 %
PICO number	2.1
Evidence grading	Moderate quality evidence

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

- The overall diagnostic yield of SBCE depends on the referral population and adherence to ESGE guidelines. (Statement number 2.1a) Agreement: 100 %
- The overall diagnostic yield for significant lesions on SBCE in clinical practice should be between ≥ 30 % and ≥ 50 %. (Statement number 2.1b) Agreement 80.9 %

Multiple studies have retrospectively collected data from a series of patients who have undergone SBCE in clinical practice

or from systematic registries of consecutive SBCE patients. In these studies, the overall diagnostic yield for mixed indications (all-comers) varied widely (27 %–77 %). A meta-analysis exploring indications, detection, completion, and retention rates of SBCE over the past two decades has recently been published [5]. This study encompassed 328 papers involving 86 930 patients undergoing SBCE. The spectrum of indications aligns with the guidelines set by the ESGE: SBCE was primarily employed for obscure GI bleeding (44 750 patients), Crohn's disease (11 299 patients), suspected neoplastic lesions (4989 patients), and celiac disease (947 patients). The overall diagnostic yield was 59.0 % (95 %CI 52 %–65 %). The corresponding detection rates for obscure GI bleeding, Crohn's disease, neoplastic lesions, and celiac disease were 55 % (95 %CI 44 %–66 %), 66 % (95 %CI 53 %–77 %), 63 % (95 %CI 52 %–66 %) and 52 % (95 %CI 40 %–64 %), respectively [5].

Despite the meta-analysis covering a wide period and including a considerable number of patients (who underwent capsule endoscopy with various capsule endoscopy devices), substantial variability in the overall and the per-indication diagnostic yield clearly emerged on analysis of the included papers. Several factors contributed to this variability. First, the methods used to assess diagnostic yield varied between studies: in some cases, all examinations that identified any finding were reported as positive, regardless of clinical relevance; in others, only clinically significant lesions were included. Additionally, the timing of the examinations varied greatly from one study to another. There was also a marked difference in the prevalence of various pathologies across different geographical regions. Lastly, there were significant differences in expertise and demographic characteristics among the various centers.

Consequently, it is challenging to establish a minimum threshold standard for the diagnostic yield for each indication; however, the working group considered a minimum standard of ≥ 30 % to be appropriate for overall SBCE diagnostic yield (considering clinically relevant findings only), especially when the overall spectrum of clinical indications aligns with those defined as being appropriate in the ESGE guidelines. Based on the published literature, the Small-bowel Working Group redefined this benchmark as the previously set threshold of 50 % was deemed too high and not reflective of real-world data.

Key performance measure	Timing of SBCE for overt bleeding
Description	Percentage of patients with overt suspected small-bowel bleeding in whom SBCE is performed in accordance with ESGE guidelines on timing
Domain	Identification of pathology
Category	Process
Rationale	In patients with overt small-bowel bleeding, the timing of the performance of SBCE is the major determinant of diagnostic yield. Earlier performance of SBCE achieves a higher diagnostic yield in this subgroup
Construct	**Denominator**: Proportion of SBCEs performed in the context of overt bleeding **Numerator**: SBCEs performed within the time threshold according to ESGE guidelines **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service and individual level Frequency: Yearly and/or for a sample of at least 100 SBCEs
Standards	Minimum standard: ≥ 75 % Target standard: ≥ 90 % The cutoff for timing varies among studies; however, earlier SBCE performance achieves a higher diagnostic yield for patients with overt small-bowel bleeding. Ideally, SBCE should be performed within 48 hours of the last bleeding episode. The interval from the last bleeding episode should be documented in a written report The timing of capsule endoscopy in patients with overt small-bowel bleeding should be audited. Variations from expected rates may suggest suboptimal timing After evaluation and adjustment, close monitoring should be performed with a further audit
Consensus agreement	95.2 %
PICO number	2.2
Evidence grading	High quality evidence

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

- In patients with overt suspected small-bowel bleeding, SBCE should be performed in accordance with ESGE guidelines on timing, as close to the bleeding episode as possible (ideally < 48 hours). (Statement number 2.2a) Agreement: 95.2 %
- In patients with occult suspected small-bowel bleeding, although a specific timing for SBCE could not be recommended at the present time, earlier procedures are associated with higher diagnostic yield. (Statement number 2.2b) Agreement: 95.2 %

The existing data on SBCE timing focuses primarily on patients undergoing the procedure for suspected small-bowel bleeding and, more specifically, on patients with overt small-bowel bleeding. Consistent findings suggest that diagnostic and therapeutic yield improves with earlier SBCE within this patient subset.

In the case of patients with overt bleeding, where it is easier to determine the time between clinical presentation and the diagnostic test, various studies have explored the diagnostic and therapeutic yield according to the time elapsed. Recently, two meta-analyses have reported that the diagnostic yield of SBCE remains high (around 80 %) when performed within 48 hours from the last bleeding episode. It significantly drops to approximately 60 % if SBCE is performed at ≥ 72 hours [26, 27]. Unfortunately, owing to the nature of the included studies, these meta-analyses do not provide detailed insights into the diagnostic yield trends over longer time intervals (e. g. 96 hours, 120 hours, etc.). Instead, they report diagnostic yield data only for examinations conducted after 14 days (with a diagnostic yield of about 40 %). Acknowledging the methodological limitations, the existing literature points toward a window of opportunity of 48 hours for maximization of the diagnostic yield of SBCE; however, this short timeframe poses practical and organizational challenges that may currently be unfeasible in all routine clinical settings. Given the practical organizational issues, the working group decided to accept a minimum standard of ≥ 75 %. The interval from the last bleeding episode should be documented in the written report, and the timing of SBCE in patients with overt small-bowel bleeding should be regularly audited. Variations from expected rates may suggest suboptimal timing of procedures.

The current literature does not specify a recommended timing for SBCE in patients with occult bleeding. In addition, it remains to be seen whether the ideal timing should be determined in relation to clinical evaluation or to the last of lower and/or upper GI endoscopic assessments. With these limitations in mind, while adhering to the general principle of "the sooner, the better," establishing a recommended definite timing for SBCE in patients with occult suspected small-bowel bleeding is currently not possible.

Minor performance measure	Use of standardized terminology
Description	Percentage of SBCE reports that adhere to structured and standardized reporting
Domain	Identification of pathology
Category	Process
Rationale	Uniformity in reporting and in communication
Construct	**Denominator**: SBCE reports produced per unit **Numerator**: SBCE reports in which both the following two conditions are met: ▪ includes > 95 % of the report fields outlined in the ESGE technical review (including patient demographics, details of capsule used, indication, examination characteristics, findings, recommendations, and complications, a detailed breakdown of descriptive methodology describing lumen, content, mucosal appearances, and any lesions identified) ▪ > 95 % of findings are described with appropriate scores/scales and nomenclature/semantic description **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service and individual level Frequency: Yearly and/or for a sample of at least 100 SBCEs
Standards	Minimum standard: ≥ 90 % Target standard: ≥ 95 % If the threshold is not reached at a service level, the service should verify whether technical support is needed to achieve the standard. If the threshold is not reached for an individual endoscopist, feedback should be provided, followed by close monitoring for 12 months to assess the individual endoscopist's performance After evaluation and adjustment, close monitoring should be performed with a yearly further audit
Consensus agreement	100 %
PICO number	3.1
Evidence grading	Very low quality evidence

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

- Structured and standardized reporting for SBCE improves the consistency of image interpretation, the description of findings, and patient management. It also facilitates audit and collation of study databases. (Statement number 3.1a) Agreement: 100 %
- A standardized report, including photodocumentation, should encompass > 95 % of the fields and items outlined in the ESGE technical review. (Statement number 3.1b) Agreement: 100 %

Within the published literature, no studies have evaluated the impact of using standardized terminology for reporting and its effect on image interpretation or diagnostic yield. Nonetheless, the development of minimum standard terminology for flexible endoscopy documentation has highlighted its value in retrieving information from databases for audits, and research, and enhancing education and training [28]. Similarly, the creation of the Capsule Endoscopy Structured Terminology (CEST) followed a comparable approach, structuring reports into two main components: structure and content [29]. The CEST framework standardizes documentation to include patient demographics, capsule endoscopy details, indication, examination characteristics, findings, recommendations, and complications. It provides a comprehensive descriptive methodology covering lumen, content, mucosal appearances, and any identified lesions. Validation criteria were defined by achieving 90% inclusion of all descriptors in any given section of historical cohort reports [30]. Studies have indicated moderate agreement in reporting using CEST, particularly among experts [31, 32]. More recently, international experts provided a standardized nomenclature and definitions for vascular, inflammatory, and atrophic lesions on SBCE [33–35].

Minor performance measure	Reading speed of SBCE
Description	Percentage of SBCEs read at the ESGE recommended reading speed
Domain	Identification of pathology
Category	Process
Rationale	SBCE reading reflects adequate inspection of the small-bowel mucosa and predicts the quality
Construct	**Denominator**: SBCEs performed in a unit **Numerator**: SBCEs where reading speed is up to 10 frames per second in single view or 20 frames per second in dual-/multiview **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service and individual level Frequency: Yearly and/or for a sample of at least 100 SBCEs
Standards	Minimum standard: ≥ 90% Target standard: ≥ 95% Reading speed should not compromise diagnostic yields. Where diagnostic yields are compromised, reading speed should be audited. Variations from expected rates of diagnostic yield might suggest a suboptimal reading speed After evaluation and adjustment, close monitoring should be performed with a yearly further audit
Consensus agreement	100%
PICO number	3.2
Evidence grading	Moderate quality evidence

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

- For all indications and in all cases, reading speed should be at a maximum of 10 frames per second in single-view mode and 20 frames per second in multiple-view mode. (Statement number 3.2a) Agreement: 90.4%
- Reading speed should be appropriate to ensure that lesion detection and diagnostic yields are not compromised, and regular audits to ensure indications and patient selection should demonstrate adherence to ESGE guidelines. (Statement number 3.2b) Agreement: 100%
- AI/machine-learning algorithms may be used as an adjunct to conventional capsule reading, where available. (Statement number 3.2c) Agreement: 80.9%

Lesion detection on SBCE is dependent on the speed of reading. Higher reading speeds may result in missed pathology [36]. The ESGE technical review recommends that SBCE videos should be reviewed at a maximum speed of 10 frames per second (single view) or 20 frames per second (for double- or multiple-view modes) [2]. It is also important to consider that, in the proximal small bowel, SBCE may progress more quickly because of vigorous peristalsis, with a higher risk of missed lesions [37]. Therefore, meticulous examination of this area is required. Virtual chromoendoscopy and "blue mode" imaging are not recommended for routine use, as they have not been demonstrated to improve diagnostic yield or enhance the detection or characterization of small-bowel mucosal pathology [37].

One of the main disadvantages of SBCE is the reading time, which is often between 40 and 60 minutes per procedure [38]. Moreover, the capsule reader must consistently focus when reading multiple videos in one session. A previous study has highlighted reader fatigue, including among experts, even after reading just one study [39].

AI algorithms, particularly deep convolutional neural networks (CNNs), are promising tools for reducing capsule reading times while maintaining diagnostic accuracy. CNNs can identify different pathological images, including ulcers, polyps, and vascular lesions, potentially outperforming human readers [40–42]. Several machine-learning algorithms have been developed in the past few years to improve the feasibility of SBCE and to ensure high diagnostic accuracy. To date, the evidence available in the literature mainly comes from proof-of-concept studies that have used altered images and/or video segments. Therefore, published results can be easily misinterpreted without a detailed understanding of the pitfalls, and real-world AI performance might not be replicated [43]. Trials using unaltered images and including comparison with standard care represent a clinical priority in confirmation of the reported expert-level performance of AI software.

Recently, two large studies that used unaltered images, potentially reflecting a real-world setting, have been published, suggesting that CNN-based algorithms are associated with an increased detection rate of findings on SBCE and reduced SBCE video reading time [40, 44]. Xie et al., in a retrospective multicenter trial, reported that AI-assisted reading resulted in a

higher per-patient detection rate for findings (79 %) compared with conventional reading (71 %; 95 %CI 69 %–72 %) [44]. The mean reading time with AI-assisted reading was shortened to 5.4 minutes compared with conventional reading (51.4 minutes), giving a mean reduction of 89.3 %. Similarly, Spada et al., in a prospective multicenter trial, showed that on per-patient analysis, the diagnostic yield of P1 and P2 lesions in AI-assisted reading (74 %) was noninferior (P < 0.001) and, in fact, superior (P = 0.02) to standard reading (62 %) [40]. Also, in this study, the mean small-bowel reading time was significantly shorter in AI-assisted reading (3.8 minutes) compared with standard reading (33.7 minutes) (P < 0.001).

Although additional trials are needed to confirm these preliminary results, the available evidence suggests that AI-assisted reading may assist physicians by providing more accurate and faster detection of clinically relevant small-bowel lesions than standard reading.

4 Domain: Management of pathology

Key performance measure	Appropriate referral for DAE
Description	Percentage of patients referred for DAE after positive SBCE
Domain	Management of pathology
Category	Process
Rationale	DAE is efficacious (diagnostic and therapeutic impact) when performed after SBCE. There are improved lesion detection rates/reduced miss rates when enteroscopy is performed after SBCE
Construct	**Denominator**: Positive SBCEs performed in a unit **Numerator**: Post-SBCE referral for DAE in accordance with the ESGE technical review DAE following SBCE is indicated in patients with: ▪ significant findings at capsule endoscopy (P1 and P2 lesions according to the Saurin classification for GI bleeding) ▪ a suspicion of Crohn's disease on SBCE (for biopsy) ▪ a suspicion of small-bowel tumor (for biopsy and/or tattooing) ▪ when a submucosal mass is detected by SBCE ▪ inherited polyposis syndromes when polypectomy is indicated ▪ nonresponsive or refractory celiac disease (for biopsy) **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service level Frequency: Yearly and/or for a sample of at least 100 SBCEs
Standards	Minimum standard: ≥ 75 % Target standard: ≥ 90 % If the minimum standard is not reached, the pre-procedure assessment for enteroscopy should be reviewed and revised at a service level After evaluation and adjustment, close monitoring should be performed with a further audit within 6 months
Consensus agreement	100 %
PICO number	3.3
Evidence grading	Very low quality evidence

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

- The use of SBCE prior to DAE improves diagnostic yield. Prior SBCE is associated with an increased diagnostic and therapeutic yield during DAE. (Statement number 3.3) Agreement: 100 %

When SBCE reveals pathological findings, these may warrant further investigation and potential treatment through DAE. In this setting, the reported findings from SBCE should guide the process. Providing a clear and detailed description of any lesion and its exact location, as recommended in the ESGE technical review [37], is essential as this information is crucial for the endoscopist in selecting the optimal route of approach (antegrade or retrograde) and planning any necessary endotherapy.

5 Domain: Complications

Key performance measure	Capsule retention rate
Description	Percentage of cases of capsule retention
Domain	Complications
Category	Process
Rationale	Monitoring of the incidence of capsule retention is important to assess the overall safety of the procedure, identify those patients at higher risk of complications, identify possible targets for improvement, and allow accurate informed consent of patients
Construct	**Denominator**: All SBCEs performed **Numerator**: Procedures in which the capsule was retained for > 14 days and/or required additional intervention **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service level and individual Frequency: Yearly and/or for a sample of at least 100 SBCEs

(Continuation)

Key performance measure	Capsule retention rate
Standards	Minimum standard: < 2 % Target standard: < 2 % Incomplete SBCE should be documented in a written report, as well as with photodocumentation of relevant lesions. If the minimum standard is not achieved, pre-procedure assessment for SBCE should be reviewed and revised on a service level and for individual endoscopists After evaluation and adjustment, close monitoring should be performed with a further audit within 12 months
Consensus agreement	100 %
PICO number	4
Evidence grading	Moderate quality evidence

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

- Retention rates should be regularly audited. Variations from the expected rates should prompt a review of patient selection and pre-procedure preparation. (Statement number 4) Agreement: 100 %

Capsule retention is defined as a capsule remaining in the GI tract for 15 days and/or requiring medical, endoscopic, or surgical intervention. Although rare, capsule retention is a significant potential complication of SBCE and should be assessed as a key performance measure for all centers and endoscopists. Proper patient selection and the use of a patency capsule, where indicated, are important in preventing retention and can influence retention rates, which vary by indication. Evidence suggests a target standard of 2 % for overall capsule retention, regardless of indication, with reported retention rates ranging from 0.3 % to 3 % [5].

In cases of capsule retention within the small bowel, a management plan should be developed with the patient to promote natural excretion or retrieval of the capsule, thereby avoiding complications such as perforation, obstruction, and bleeding. In asymptomatic patients, a "watch and wait" approach, potentially with laxatives, prokinetics, or disease-specific medical therapy, may be appropriate, as spontaneous capsule passage has been reported in up to 50 % of patients [45]. Patients who are symptomatic and those with significant small-bowel pathologies, such as tumors or tight stenosis, on cross-sectional imaging may benefit from early endoscopic or surgical intervention [46].

6 Domain: Training and competency

Key performance measure	Maintaining competency in SBCE
Description	Percentage of SBCE providers who monitor their KPIs to ensure ongoing competency in accordance with the ESGE curricula guidance
Domain	Training and competency
Category	Process
Rationale	Capsule endoscopy providers should ensure their competence in SBCE reading is kept up to date with a sufficient throughput of cases and by achieving adequate rates of lesion detection and complications
Construct	**Denominator**: All SBCE providers **Numerator**: SBCE providers with satisfactory KPIs **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service level and individual Frequency: Yearly and/or for a sample of at least 100 SBCEs
Standards	Minimum standard: ≥ 90 % Target standard: ≥ 90 %
Consensus agreement	100 %
PICO number	5
Evidence grading	Very low quality evidence

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

- SBCE providers should monitor their KPIs and ensure they maintain competency in accordance with the ESGE curricula guidance. (Statement number 4) Agreement: 100 %

Since the 2019 paper, the ESGE formulated a Small-bowel Curriculum Working Group who set competency levels for small-bowel endoscopy, similarly to other endoscopic procedures [47]. Within this document, recommendations are made on the training required, attendance at a capsule endoscopy course, and minimum thresholds for the number of procedures needed to gain competency. Experience in bidirectional endoscopy before learning capsule endoscopy is desirable, and it is envisaged that capsule endoscopy courses should have at least 50 % hands-on training covering indications, contraindications, and the use of standard terminology. Competence in capsule endoscopy can be assessed using direct observation of procedures and SBCE reporting, and centers providing training should be undertaking 75–100 procedures per annum.

While it is recognized that many European countries do not have a formal certification process in place yet for SBCE, the small-bowel curriculum was a first step to provide guidance and to ensure training in SBCE is streamlined, and training centers and trainers fulfil minimum criteria before offering train-

▶ **Table 1** List of statements for small-bowel capsule endoscopy (SBCE).

Domains	Statements
Pre-procedure	The indications for SBCE should be guided by published recommendations (e. g. ESGE and ASGE guidelines) The percentage of SBCE procedures performed by indication should be audited Studies performed for nonstandard indications (indications not approved by endoscopy organizations) should be regularly reviewed **The mucosal visualization obtained for SBCE should be adequate or good in > 80 % of cases using accepted bowel preparation methods** Certain groups of patients undergoing SBCE have a higher risk of capsule retention The use of a patency capsule can reduce the incidence of capsule retention in patients at higher risk
Completeness of procedure	The incomplete study rate (failure to reach the colon or stoma bag) should be < 20 % In all cases of an incomplete study, the patient should be asked to confirm excretion. If excretion is not confirmed after 15 days, an abdominal radiograph should be obtained
Identification of pathology	The overall diagnostic yield of SBCE depends on the referral population and adherence to ESGE guidelines **The overall diagnostic yield for significant lesions on SBCE in clinical practice should be between ≥ 30 % and ≥ 50 %** **In patients with overt suspected small-bowel bleeding, SBCE should be performed in accordance with ESGE guidelines on timing, as close to the bleeding episode as possible (ideally < 48 hours)** In patients with occult suspected small-bowel bleeding, although a specific timing for SBCE could not be recommended at the present time, earlier procedures are associated with higher diagnostic yield Structured and standardized reporting for SBCE improves the consistency of image interpretation, the description of findings, and patient management. It also facilitates audit and collation of study databases **A standardized report, including photodocumentation, should encompass > 95 % of the fields and items outlined in the ESGE technical review** For all indications and in all cases, reading speed should be at a maximum of 10 frames per second in a single-view mode and 20 frames per second in multiple-view mode Reading speed should be appropriate to ensure lesion detection and diagnostic yields are not compromised, and regular audits to ensure indications and patient selection should demonstrate adherence to ESGE guidelines **AI/machine-learning algorithms may be used as an adjunct to conventional capsule reading, when available**
Management of pathology	The use of SBCE prior to DAE improves diagnostic yield. Prior SBCE is associated with an increased diagnostic and therapeutic yield during DAE
Complications	Retention rates should be regularly audited. Variations from the expected rates should prompt a review of patient selection and pre-procedure preparation
Training and competency	**SBCE providers should monitor their KPIs and ensure they maintain competency in accordance with the ESGE curricula guidance**

AI, artificial intelligence; DAE, device-assisted enteroscopy; KPI, key performance indicator.

ing. Training and reporting in SBCE go beyond just reading and reporting the pathology seen on SBCE; they also ensure a clear plan for the management of small-bowel pathology. The ESGE small-bowel curriculum was provided to ensure high quality training, and that trainees are exposed to a variety and a good number of cases of SBCE [47].

For SBCE providers, ensuring a good throughput of cases per year is essential to maintaining their competence. The number of SBCE procedures per indication, detection rate, and complication rate should all be regularly audited for each SBCE reader and managed locally. This is analogous to other endoscopic procedures, such as colonoscopy, where competence is maintained with a high number of procedures per year and audit of the cecal intubation rate.

Summary of statements for SBCE

The final agreed statements relating to SBCE are shown in ▶ **Table 1**, with those that are new or have been updated displayed in bold text.

Performance measures for device-assisted enteroscopy

7 Domain: Pre-procedure

Key performance measure	Indication for DAE
Description	Percentage of DAE examinations performed for recognized indications, as published in international guidelines
Domain	Pre-procedure
Category	Process
Rationale	Adherence to appropriate indications for DAE (in accordance with ESGE guidance) ensures patient safety (by reducing the risks associated with unnecessary procedures), may improve diagnostic and therapeutic yield, and enhances efficiency regarding the appropriate allocation of limited resources

(Continuation)

Key performance measure	Indication for DAE
Construct	**Denominator**: DAE procedures performed **Numerator**: DAE procedures performed for an appropriate indication (see text for the list of appropriate indications) **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service level and individual Frequency: Yearly and/or for a sample of at least 50 DAEs
Standards	Minimum standard: ≥ 95 % Target standard: ≥ 95 % Regular audit should be encouraged to assess if procedures are being performed for recognized indications After evaluation and adjustment, close monitoring should be performed with a further audit within 12 months
Consensus agreement	100 %
PICO number	6.1
Evidence grading	Moderate quality evidence

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

- DAE examinations should be performed for recognized indications, as published in international guidelines. (Statement number 6.1a) Agreement: 100 %
- A "straight to DAE" approach should be reserved for emergencies, including active small-bowel bleeding, using the antegrade route first unless a distal lesion is known to be present. (Statement number 6.1b) Agreement: 95.2 %

In line with ESGE guidance [2, 37], the Small-bowel Working Group strongly recommends adherence to appropriate indications for DAE. The following are considered accepted indications for DAE:

- diagnosis of small-bowel bleeding (occult or overt) when SBCE is not available or is contraindicated
- endoscopic therapy of small-bowel bleeding
- in selected cases of ongoing overt obscure GI bleeding
- clarification of the diagnosis of jejunal or proximal ileal Crohn's disease, suspected on radiological imaging tests or SBCE
- endoscopic therapy of Crohn's disease, when indicated
- locating (tattooing) and biopsy sampling of uncertain diagnoses of small-bowel tumor on capsule endoscopy or imaging
- polypectomy in patients with inherited polyposis syndromes
- diagnosis and disease monitoring of refractory celiac disease
- foreign body retrieval
- DAE-assisted percutaneous endoscopic jejunostomy for enteral feeding
- DAE-guided endoscopic retrograde cholangiopancreatography (ERCP) in patients with altered anatomy.

SBCE and/or cross-sectional imaging should precede DAE to provide key information on the need for DAE and the choice of procedure (route and type of DAE). A "straight to DAE" approach should be reserved for emergency situations, including active small-bowel bleeding [48], using the antegrade route first unless a distal lesion is known to be present [37].

Minor performance measure	Adequate pre-procedure preparation
Description	Percentage of patients undergoing DAE who receive adequate pre-procedure preparation, including fasting for antegrade DAE and approved bowel preparation for retrograde DAE
Domain	Pre-procedure
Category	Process
Rationale	Adequate bowel preparation allows a greater diagnostic yield and a safer procedure. It also decreases the need for repeat DAE or an alternative investigation
Construct	**Denominator**: Patients undergoing DAE **Numerator**: Patients undergoing DAE with adequate bowel preparation **Exclusions**: Emergency DAE, patients with ongoing bleeding Calculation: Proportion (%) Level of analysis: Service level and individual level Frequency: Yearly and/or for a sample of at least 50 DAEs
Standards	Minimum standard: ≥ 95 % Target standard: ≥ 95 % If the minimum standard is not reached, analysis of the factors that influence proper information about bowel preparation (information given to patients, dietary restrictions, fasting, cleansing agents used, timing) should be performed on a service level After evaluation and adjustment, close monitoring should be performed with a further audit within 12 months
Consensus agreement	100 %
PICO number	6.2
Evidence grading	Low quality evidence

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

- All patients undergoing DAE should receive adequate pre-procedure preparation, including fasting for antegrade DAE and approved bowel preparation for retrograde DAE. (Statement number 6.2a) Agreement: 100 %

- All patients referred for antegrade DAE should be fasting for solids for at least 6 hours prior to the procedure. (Statement number 6.2b) Agreement: 100 %
- All patients referred for retrograde DAE should follow the same regimen for preparation as recommended by ESGE guidelines for colonoscopy. (Statement number 6.2c) Agreement: 100 %

In line with ESGE guidance [2, 37], the Small-bowel Working Group recognizes the need for adequate bowel preparation for DAE and strongly recommends adherence to appropriate preparation instructions for DAE. Adequate bowel preparation is crucial and necessary to achieve a higher diagnostic yield and a safer procedure. Poor bowel preparation can negatively impact the technical success of retrograde DAE [49, 50], as the presence of intraluminal debris may lead to excessive friction between the enteroscope and overtube, limiting the progress of the procedure. There are no comparative studies on preparation for antegrade DAE; however, a prolonged fast for solid foods at least 6 hours is usually sufficient. For clear liquids, a fasting period of 2 hours may be enough [51], depending on local guidelines. For retrograde DAE, the Small-bowel Working Group recommends the same preparation as per the local protocol for colonoscopy [52]. The presence or suspicion of stenosis may potentially increase the risk of residual intraluminal debris and, in such cases, more prolonged fasting (and careful additional preparation) may be required.

8 Domain: Completeness of procedure

Key performance measure	Measurement and marking of maximal insertion depth
Description	Percentage of DAE procedures where the maximal depth of insertion is measured and marked with a submucosal tattoo of sterile carbon particles when clinically indicated
Domain	Procedure
Category	Process
Rationale	Marking of the maximal insertion depth is considered relevant to clinical practice, particularly to guide further procedures, especially if the clinical scenario requires a completion panenteroscopy through the alternative route of approach. Recording of the estimated insertion depth is also considered to be clinically helpful
Construct	**Denominator**: Patients undergoing DAE **Numerator**: Patients in whom the extent of insertion has been marked with a tattoo on the initial DAE **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service level and individual level Frequency: Yearly and/or for a sample of at least 50 DAEs
Standards	Minimum standard: ≥ 80 % Target standard: ≥ 80 % Tattooing rates should be audited based on intention to treat. Tattooing should be performed in at least 80 % of cases

(Continuation)

Key performance measure	Measurement and marking of maximal insertion depth
Consensus agreement	100 %
PICO number	7.1
Evidence grading	Very low quality evidence

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

- The maximal depth of insertion should be measured and marked with a submucosal tattoo of sterile carbon particles in at least 80 % of cases when clinically indicated. (Statement number 7.1) Agreement: 85.7 %

Since the publication of the original ESGE performance measures for small-bowel endoscopy in 2019 [53], three series have evaluated the depth of insertion at DAE [49, 50, 54]. The largest series was the "DEEP UK," a multicenter retrospective quality evaluation from the UK involving 2005 DAE procedures. In this national project, the depth of insertion at DAE was measured in 73 % of cases and marked with a submucosal tattoo of sterile carbon particles in 35 % of cases [49]. Yin et al. reported on a series of 2134 single-center double-balloon enteroscopy (DBE) procedures and found that the estimated depth of insertion was recorded in 81 % of cases; this series did not report on marking of the insertion depth [50]. Another single-center series, including 460 DBE procedures, noted that estimation of insertion depth was routinely performed; however, this was marked in only 31 % of cases [54].

Although the estimation of insertion depth at DAE may be somewhat less accurate than actual direct measurement, the current Small-bowel Working Group tasked with updating these ESGE Performance measures for small-bowel endoscopy consider this estimate remains relevant and beneficial in clinical practice. Marking of the deepest point of insertion is considered helpful to guide further DAE procedures, particularly if a completion panenteroscopy (via the alternative route of insertion) is deemed clinically appropriate.

9 Domain: Identification of pathology

Key performance measure	Lesion detection rate
Description	Percentage of DAE procedures with clinically significant findings when DAE is used as a second-line diagnostic method after SBCE or magnetic resonance/computed tomography enterography, according to ESGE indications
Domain	Identification of pathology
Category	Process
Rationale	Careful preselection of patients undergoing DAE, according to appropriate recognized indications, which should be audited to address any deviations from recommended practice/guidance, should maximize the diagnostic yield of DAE
Construct	**Denominator**: Patients undergoing DAE **Numerator**: Patients undergoing DAE with positive findings **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service level and individual level Frequency: Yearly and/or for a sample of at least 50 DAEs
Standards	Minimum standard: ≥ 50 % Target standard: ≥ 70 % Universal recording of DAE indication should be assessed through an annual audit, with any deviations addressed and corrected
Consensus agreement	95.2 %
PICO number	7.2
Evidence grading	Moderate quality evidence

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

- The procedure intent and diagnostic yield of DAE should be ≥ 70 % if DAE is used as a second-line diagnostic method after SBCE or magnetic resonance/computed tomography enterography, according to ESGE indications. (Statement number 7.2) Agreement: 95.2 %
- Although the use of AI has shown promising results in helping with the delineation of lesions in DAE, there is not enough evidence to suggest its routine use. (Statement number 9.4) Agreement: 100 %

Since the original ESGE performance measures for small-bowel endoscopy were published in 2019 [1], seven more series have evaluated the diagnostic yield of DAE [49, 50, 53–57]. Four of these series reported a diagnostic yield of ≥ 70 % [49, 54–56]. Only one series of these seven had a diagnostic yield that was below 60 % [57]; however, this series was limited because several of the included DAEs were performed for unrecognized indications (e. g. abdominal pain). The remaining two series had diagnostic yields of 60 %–70 % [50, 53].

AI application in gastroenterology is growing exponentially in many areas, such as upper and lower GI endoscopy, whereas there is still a lack of evidence of its use during DAE. In recent years, several studies have focused on the development of CNN-based algorithms for the automated detection of small-bowel pathologies. Retrospective databases of images (after validation) were used to create a CNN that could detect intestinal erosions/ulcers, angioectasia, and protruding lesions [58–60]. These models showed very good performance in terms of sensitivity and specificity in all applications. The limitations of the studies were similar, in particular, their retrospective nature and monocentric validation, the small number of images, and the use of built frames instead of real-time videos. Only studies with real-time enteroscopy could reach definite conclusions regarding the clinical significance of AI assistance for DAE.

Minor performance measure	Accurate photodocumentation
Description	Percentage of cases with accurate photodocumentation of clinically relevant findings
Domain	Identification of pathology
Category	Process
Rationale	Photodocumentation of findings reflects good clinical practice and may serve to guide further care
Construct	**Denominator**: All patients undergoing DAE with pathology/lesions detected **Numerator**: Patients undergoing DAE with photodocumentation of identified pathology/lesions detected **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service level and individual level Frequency: Yearly and/or for a sample of at least 50 DAEs
Standards	Minimum standard: ≥ 95 % Target standard: ≥ 95 % Annual audit with correction of any deviations recommended
Consensus agreement	100 %
PICO number	7.3
Evidence grading	Very low quality evidence

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

- It is recommended to use photodocumentation as a record of findings in all cases. (Statement number 7.3) Agreement: 100 %

Image documentation of specific landmarks and pathology encountered during endoscopy has been accepted as an important measure of the quality of endoscopy and is part of routine clinical care. Regardless of the scarcity of evidence to support this performance measure, the current working group tasked with updating these ESGE quality parameters unanimously agreed that this remains a surrogate marker of a high quality DAE procedure that is strongly recommended. Despite the lack of anatomical landmarks in the small bowel (apart from the duodenum and the ileocecal valve), photodocumentation may serve to guide appropriate further endoscopic or surgical management and onward referral. Comparisons can also be made should follow-up procedures be required.

10 Domain: Management of pathology

Key performance measure	Lesion marking
Description	Percentage of DAE procedures where lesions/tumors are marked for subsequent therapeutic interventions
Domain	Management of pathology
Category	Process
Rationale	Marking of lesion location with a submucosal tattoo of sterile carbon particles facilitates further care and follow-up, and is recommended in clinical practice
Construct	**Denominator**: Patients undergoing DAE in whom a lesion is detected and surgical treatment or endoscopic resection is intended **Numerator**: Patients in the denominator with tattooing of the lesion **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service level and individual level Frequency: Yearly and/or for a sample of at least 50 DAEs
Standards	Minimum standard: ≥ 95 % Target standard: 100 % If the minimum standard is not reached, the reasons for this should be explored on a service level After evaluation and adjustment, close monitoring should be performed with a further audit within 12 months
Consensus agreement	100 %
PICO number	7.4
Evidence grading	Very low quality evidence

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

- It is recommended practice to mark a lesion/tumor that may later be a target for therapeutic intervention. (Statement 7.4) Agreement: 95.2 %

The "Deep UK" study reported that appropriate marking of lesions was performed in 78 % of cases [49]. The working group has retained this quality indicator unchanged, given its clinical impact in guiding optimal further management of identified pathology. In keeping with the ESGE guidelines for colorectal polypectomy [61], we recommend placing a single tattoo 3–5 cm away from the lesion or polypectomy site. The relationship between the tattoo and the lesion should be included in the report and clearly documented in writing and photographs.

Although not addressed directly as a performance measure, another accepted surrogate marker of the appropriate indication for DAE is the therapeutic yield (percentage of successful therapeutic DAE interventions/intended therapeutic DAE interventions). This quality indicator was also evaluated in the "Deep UK" study, which reported a high therapeutic success rate of 97 % [49].

11 Domain: Complications

Key performance measure	Rate of complications in diagnostic and therapeutic DAE
Description	The rate of complications (overall, including perforation, bleeding, and pancreatitis) resulting from diagnostic and therapeutic DAE in an unselected population
Domain	Complications
Category	Process
Rationale	Monitoring for complications is essential to ensure patient safety
Construct	**Denominator**: Patients undergoing DAE **Numerator**: Patients in the denominator experiencing a complication (perforation, bleeding, or pancreatitis) **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service level and individual level Frequency: Yearly and/or for a sample of at least 50 DAEs
Standards	Minimum standard: < 5 % Target standard: < 5 % If the minimum standard is not reached, analysis of the factors influencing the complication rate (including assessment of operator numbers, operator experience, case complexity, presence of previous small-bowel surgery, and underlying pathology) should be performed on an individual and service level After evaluation and adjustment, close monitoring should be performed with a further audit within 12 months
Consensus agreement	100 %
PICO number	8.1
Evidence grading	Moderate quality evidence

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

- The rate of severe complications (overall, including perforation, bleeding, and pancreatitis) resulting from diagnostic DAE should not exceed 1 % in an unselected population. (Statement 8.1a) Agreement: 100 %
- The rate of severe AEs (overall, including perforation, bleeding, and pancreatitis) resulting from therapeutic DAE should not exceed 5 % in an unselected population. (Statement number 8.1b) Agreement: 90.4 %
- AE rates by operator and indication should be audited for all DAE procedures against known rates of AEs. Reasons for variations from these rates should be examined. (Statement number 8.1c) Agreement: 80.9 %

As documented in the previous guidance [1], and based on all scientific evidence accumulated since then, DAE remains an overall safe procedure. A large retrospective cohort study across four US referral centers over a 5-year period reported four and eight complications in 391 single-balloon enteroscopies (SBEs; 1.0 %) and 1017 DBEs (0.8 %), respectively, and no deaths [56]. Complications rates were not statistically different between antegrade and retrograde examinations. A recent systematic review and meta-analysis incorporating 6036 procedures in 4592 patients from 54 articles showed severe AEs occurred in 26/4984 procedures (0.5 %), including 11 perforations and nine cases of acute pancreatitis, whereas the mild AE rate was 2.5 % (94/3728 procedures) [62].

In addition, a multicenter retrospective study has been conducted on 68 patients with surgically altered GI anatomy and non-ERCP indications for balloon-assisted enteroscopy. Data from 80 procedures (48 SBEs and 32 DBEs) were collected, and only one major complication was identified (one perforation; 1.2 %) [63].

For therapeutic DAE, two recent monocentric series in Peutz–Jegher's syndrome (mostly DBEs, with numerous polypectomies) have shown 8.5 % and 6 % complication rates (intraprocedural or delayed bleeding, pneumothorax, perforation, and pancreatitis) [64, 65]. Lastly, in a systematic review and meta-analysis that pooled data from 1189 procedures in 463 patients from 18 studies examining the outcome of small-bowel Crohn's disease stricture dilation during balloon-assisted enteroscopy, major complications (bleeding, perforation, or dilation-related surgery) were seen in 5.3 % of all procedures [66].

12 Domain: Training and competency

Key performance measure	Training in DAE
Description	Percentage of trainees undergoing structured training in DAE in accordance with the ESGE curricula guidance
Domain	Training and competency
Category	Process
Rationale	Structured training in DAE that meets standards may lead to better diagnostic and therapeutic yield in small-bowel endoscopy
Construct	**Denominator**: All DAEs performed **Numerator**: Number of retrograde DAEs and therapeutic DAEs performed **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service level and individual level Frequency: Yearly and/or for a sample of at least 100 DAEs
Standards	Minimum standard: ≥ 80 % Target standard: ≥ 90 % If the minimum standard is not reached, analysis of the number of DAEs carried out during training should be performed at a service level and for DAE trainees After evaluation and adjustment, close monitoring should be performed with a further audit within 12 months and/or for a sample of 50 DAEs
Consensus agreement	80.9 %
PICO number	9.1
Evidence grading	Very low quality evidence

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

- Training in DAE should be structured according to the ESGE curriculum, with a minimum of 75 procedures, including 35 retrograde DAEs, with therapeutic procedures undertaken in at least 50 % of the DAEs performed. (Statement number 9.1) Agreement: 80.9 %

An adequate number of DAEs ensures a varied caseload in centers offering training and that the quality of training is maintained [1]. This allows trainees to cover several indications for DAEs and develop skills to be able to delineate a number of pathologies [47]. Trainees will also be able to understand the varied complexity of DAE and become independent in endotherapy. Trainees are encouraged to keep a logbook of procedures they undertake during their training period to reflect the indications for DAE, procedure details, and further management of patients with small-bowel pathology. If a trainee does not reach the desired number of DAEs per year, a mentoring system among centers offering DAEs is encouraged to allow

trainees to train in centers with a higher workload of DAEs and gain independence in diagnostic DAE and endotherapy.

Key performance measure	Maintaining competence in DAE
Description	Percentage of endoscopists who monitor their KPIs to ensure ongoing competency, in accordance with the ESGE curricula guidance
Domain	Training and competency
Category	Process
Rationale	DAE endoscopists should ensure ongoing competency with an adequate number of cases per annum, and detection and complication rates as suggested within the curricula guidance
Construct	**Denominator**: All DAE endoscopists **Numerator**: DAE endoscopists with satisfactory KPIs **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service level and individual Frequency: Yearly and/or for a sample of at least 50 DAEs
Standards	Minimum standard: ≥ 90 % Target standard: ≥ 90 %
Consensus agreement	100 %
PICO number	10
Evidence grading	Very low quality evidence

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

- DAE endoscopists should monitor their KPIs and ensure they maintain competency, in accordance with the ESGE curricula guidance. (Statement number 10) Agreement: 100 %

The ESGE curricula guidance has set minimum standards for DAE endoscopists before offering training [47]. While there is no literature on the number of DAE procedures per year that training centers should perform, experts agree that DAE endoscopists should be undertaking approximately 75 procedures per year. This suggested caseload would ensure that the DAE endoscopists are keeping their skills up to date, with adequate volume and complexity. DAE endoscopists should regularly audit their detection and complication rates individually and as part of the whole service.

Minor performance measure	Small-bowel multidisciplinary team (MDT)
Description	Percentage of DAE patients where management plans are discussed at a dedicated small-bowel MDT meeting
Domain	Training and competency
Category	Process
Rationale	Discussion of patient management at a small-bowel MDT meeting ensures the best management is provided for patients and provides a good training experience for trainees in small-bowel endoscopy
Construct	**Denominator**: All DAEs performed **Numerator**: DAEs where the management of a patient's small-bowel pathology is discussed during an MDT meeting **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service level and individual level Frequency: Yearly and/or for a sample of at least 50 DAEs
Standards	Minimum standard: ≥ 50 % Target standard: ≥ 80 %
Consensus agreement	90.4 %
PICO number	9.3
Evidence grading	Very low quality evidence

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

- DAE training centers should have a small-bowel multidisciplinary team (MDT) meeting with input from an experienced radiologist, where patients with small-bowel pathologies can be discussed. This will serve as a learning experience for trainees in DAE and provide the best management plan for such patients. (Statement number 9.3) Agreement 90.4 %

In DAE training centers, the complex cases of patients with small-bowel pathology should ideally be discussed in an MDT setting where radiology findings, the results of SBCEs, and findings during DAEs are reviewed among a team of small-bowel experts and small-bowel radiologists to ensure the best management plan for these patients [47]. A small-bowel MDT meeting may provide trainees with appropriate exposure to patients with varied pathologies and allow them to manage such patients correctly.

13 Domain: Patient experience

Key performance measure	Patient comfort
Description	Percentage of DAE procedures where patient comfort levels are adequate
Domain	Patient experience
Category	Process
Rationale	DAE-related patient comfort is associated with better patient satisfaction, better diagnostic and therapeutic yield, and compliance with further endoscopies if required
Construct	**Denominator**: Patients undergoing DAE **Numerator**: Patients in the denominator with a recorded and reported comfort score **Exclusions**: None Calculation: Proportion (%) Level of analysis: Service level and individual level Frequency: Yearly and/or for a sample of at least 50 DAEs
Standards	Minimum standard: ≥ 90 % Target standard: ≥ 90 % If the minimum standard level of comfort is not reached, analysis of the type of sedation used, route of insertion, type of insufflation, and previous endoscopist experience should be performed at a service level and for each DAE-performing endoscopist After evaluation and adjustment, close monitoring should be performed with a further audit within 12 months and/or for a sample of 100 DAEs
Consensus agreement	90.4 %
PICO number	9.2
Evidence grading	Low quality evidence

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

- Patient comfort should be audited for all DAE procedures. Inadequate comfort levels should be audited against the route of insertion, sedation, insufflation methods, and endoscopist experience. (Statement number 9.2) Agreement: 90.4 %

It is standard practice to monitor patient comfort during routine endoscopies [67]. The same should be encouraged for DAEs, as patient comfort is a quality indicator in endoscopy [1]. Patient comfort during endoscopy is associated with patient satisfaction and a higher likelihood of procedural success, and is likely to improve compliance with further endoscopies if required [49]. Although there is no standard method to assess patient comfort in endoscopy, several scores exist, such as the La Crosse intra-endoscopy sedation comfort score [67] and the nurse-assessed patient comfort score (NAPCOMS) [68].

Evidence shows that carbon dioxide insufflation, as compared with air insufflation, improves patient comfort scores during DAE [69–71]. Patient tolerance is poor with conscious sedation in prolonged procedures [49, 72], and it improves with deeper sedation [49, 73, 74]. Endoscopist experience can also positively impact patient comfort [75].

Summary of statements for DAE

The final agreed statements relating to DAE are shown in ▶ **Table 2**, with those that are new or have been updated displayed in bold text.

Future research

Several unanswered questions remain regarding SBCE and DAE. Despite numerous publications and meta-analyses, there is no clear consensus on the optimal bowel preparation that can improve diagnostic yield and completion rates for SBCE. Further research in this area is still warranted.

The diagnostic yield in SBCE is the accepted terminology for most publications relating to lesion detection at SBCE; however, this continues to receive criticism as there is no gold standard to compare with, apart from DAE, which is done mainly based on need only. Lesion detection relies on the correct indication for SBCE, good visualization, and the SBCE reader's expertise and concentration. Arguably, follow-up of patients post-SBCE helps to clarify the diagnoses made based on capsule endoscopy findings, with subsequent radiology, enteroscopy, or surgery. In this guidance, we have advised that AI can be used as an adjunct to help readers and reduce reading time. A considerable amount of research is being done in AI and SBCE, which will no doubt better inform the small-bowel community about the role of AI in SBCE. The responsibility of the final report still lies with the SBCE reader, hence the need to ensure performance measures continue to be kept up to date. We need more centers to monitor and benchmark their performance against these ESGE standards to refine specific quality measures further.

With DAE, we have seen the withdrawal of spiral enteroscopy, highlighting the importance of monitoring complication rates. The training requirements for trainees to adhere to and for training centers to abide by before offering training may be challenging to follow in smaller centers. The previous guidance in 2019 [1] suggested that centers should undertake 50–100 DAEs annually before offering training. In this document, we have followed the ESGE curricula, which sets an approximate number of 75 procedures per annum, which is not dissimilar but ensures the delivery of high quality endoscopy and training. The formal DAE certification pathway has recently been launched in the UK by the Joint Advisory Group [76], paving the way for other European centers to formalize training in DAE and publish their learning curves. The role of AI within the field of DAE still requires defining with real-world studies.

We have included a recommendation for good practice regarding the provision of small-bowel MDT meetings. While the evidence for this is low, SBCE and DAE centers should adopt this

▶ **Table 2** List of statements for small-bowel device-assisted enteroscopy (DAE).

Domains	Statements
Pre-procedure	DAE examinations should be performed for recognized indications, as published in international guidelines A "straight to DAE" approach should be reserved for emergencies, including active small-bowel bleeding, using the antegrade route first unless a distal lesion is known to be present All patients undergoing DAE should receive adequate pre-procedure preparation, including fasting for antegrade DAE and approved bowel preparation for retrograde DAE All patients referred for antegrade DAE should be fasting for solids for at least 6 hours prior to the procedure All patients referred for retrograde DAE should follow the same regimen for preparation as recommended by ESGE guidelines for colonoscopy
Completeness of procedure	The maximal depth of insertion should be measured and marked with a submucosal tattoo of sterile carbon particles in at least 80 % of cases when clinically indicated
Identification of pathology	**The procedure intent and diagnostic yield of DAE should be ≥ 70 % if DAE is used as a second-line diagnostic method after SBCE or magnetic resonance/computed tomography enterography, according to ESGE indications** **Although the use of AI has shown promising results in helping with the delineation of lesions in DAE, there is not enough evidence to suggest its routine use** It is recommended to use photodocumentation as a record of findings in all cases
Management of pathology	It is recommended practice to mark a lesion/tumor that may later be a target for therapeutic intervention
Complications	The rate of severe complications (overall, including perforation, bleeding, and pancreatitis) resulting from diagnostic DAE should not exceed 1 % in an unselected population The rate of severe adverse events (overall, including perforation, bleeding, and pancreatitis) resulting from therapeutic DAE should not exceed 5 % in an unselected population Adverse event rates by operator and indication should be audited for all DAE procedures against known rates of adverse events. Reasons for variations from these rates should be examined
Training and competency	**Training in DAE should be structured according to the ESGE curriculum, with a minimum of 75 procedures, including 35 retrograde DAEs, with therapeutic procedures undertaken in at least 50 % of the DAEs performed** **DAE endoscopists should monitor their KPIs and ensure they maintain competency in accordance with the ESGE curricula guidance** **DAE training centers should have a small-bowel MDT meeting with input from an experienced radiologist, where patients with small-bowel pathologies can be discussed. This will serve as a learning experience for trainees in DAE and provide the best management plan for such patients**
Patient experience	Patient comfort should be audited for all DAE procedures. Inadequate comfort levels should be audited against the route of insertion, sedation, insufflation methods, and endoscopist's experience

AI, artificial intelligence; KPI, key performance indicator; MDT, multidisciplinary team; SBCE, small-bowel capsule endoscopy.

approach to ensure a multifaceted delivery of care to patients with small-bowel pathology.

Conflict of interest

E.J. Despott has received educational grants, plus speaker's and consultancy fees from Fujifilm (2017 to present), educational grants and consultancy fees from Boston Scientific (2017 to present), educational grants from Olympus Medical (2017 to present) and Pentax Medical (2017–2019), consultancy fees from Ambu (2017–2018), and educational grants and speaker's fees from Norgine (2017 to present). X. Dray is a co-founder and shareholder in Augmented Endoscopy (2019 to present) and was the inaugural (and now past) president of the international CApsule endoscopy Research (iCARE) group (2021 to present); his department has received support for lectures and continuing medical education from Medtronic (2023); and the following patents are held: Automatic quality classification of wireless capsule endoscopy images from small bowel according a computer-based score (EP18305275.2. 2019); Methods and devices for calculating a level of "clinical relevance" for abnormal small bowel findings captured by capsule endoscopy video (US20220039639A1. 2022); Device and method for producing a numerical classifier of images, so as to determine the viewing quality of the endoscopic videocapsule images of a segment of the digestive tube. (WO2019175248A1. 2019); Device and method for producing a digital video classifier (US 2022/0101525 A1). M. Ferlitsch has received speaker's fees from Ferring, Olympus, and Norgine. M. Keuchel has received speaker's fees from Medtronic (2002 to present), speaker's fees and study support from Jinshan (2023 to present), study support from AnX Robotics (2019 to present) and Norgine (2020–2023), and is a consultant for Medtronic (2002 to present) and CapsoVision (2023 to present); he is also a co-editor of the Springer book *Video Capsule Endoscopy*. A. Koulaouzidis has provided consultancy to Jinshan Group Ltd. (2021 to present), he is a co-founder and stakeholder in AJM Medicaps Ltd. (2017 to present) and a stakeholder in iCERV Ltd. (2021 to present); the following patent is held: Intestinal diagnostic screening device and method for targeted gastrointestinal therapy (WO2021038464A1). D. McNamara has received speaker's fee and meeting sponsorship from Medtronic (2022, 2023), and sponsored access to a cloud reading platform (2021 to present). E. Rondonotti has received speaker's fees from Fujifilm (2020 to present) and has provided consultancy to Medtronic Co. (2022 to present). J. Sabino has received speaker's fees from Pfizer, Abbvie, Ferring, Falk, Takeda, Janssen, Fresenius, and Galapagos; consultancy fees from Pfizer, Janssen, Ferring, Fresenius, Abbvie, Galapagos, Celltrion, Pharmacosmos, and Pharmanovia; and research support from Galapagos and Viatris;

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